ANNUAL REPORT 2022/23

SAHPRA

South African
Health Products
Regulatory Authority

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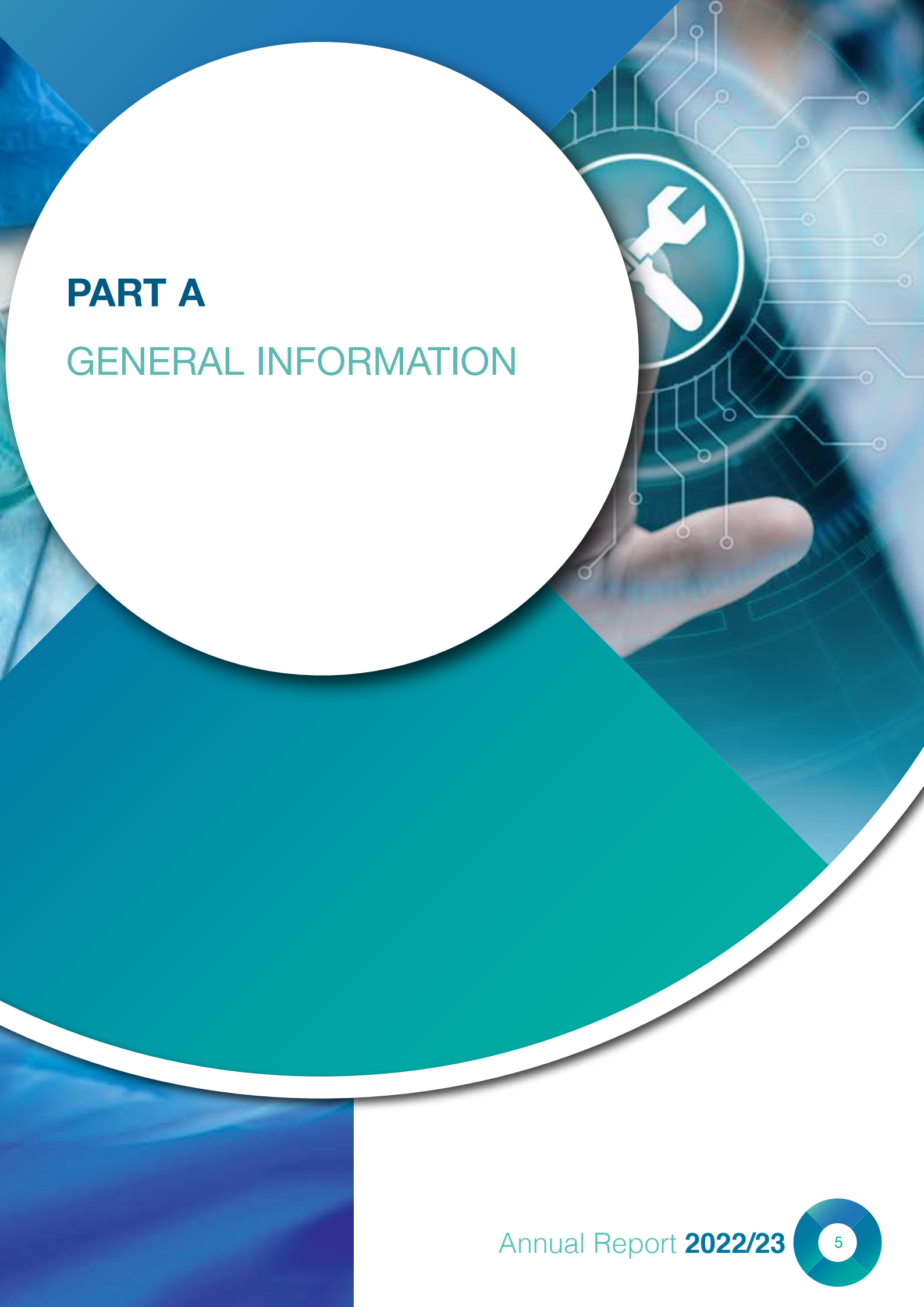


PART A

GENERAL INFORMATION

1. PUBLIC ENTITY'S GENERAL INFORMATION

Registered Name:	South African Health Products Regulatory Authority (SAHPRA)
Registration Number (If applicable):	Not applicable
Physical Address:	Building A Loftus Park 402 Kirkness Street Arcadia Pretoria 0083
Postal Address:	Private Bag X828 Pretoria 0001
Telephone Number/s:	(012) 501 0300
Email Address:	enquiries@sahpra.org.za
Website Address:	www.sahpra.org.za
External Auditors:	Auditor-General of South Africa
Bankers:	ABSA
Board Secretary (Acting):	Ms Letjubana Chokoe

2. LIST OF ABBREVIATIONS/ACRONYMS

ABBREVIATION	EXPLANATION
AFS	Annual Financial Statements
AEFI	Adverse Events Following Immunisation
AGSA	Auditor-General of South Africa
AUDA	African Union Development Agency
B-BBEE	Broad-Based Black Economic Empowerment
BMGF	Bill and Melinda Gates Foundation
CDC	Centres for Disease Control and Prevention
CHAI	Clinton Health Access Initiative
COVID-19	Coronavirus (SARS COV-2)
CPD	Corporation for Public Deposits
CSIR	Council for Scientific and Industrial Research
DPSA	Department of Public Service and Administration
GMP	Good Manufacturing Practice
GRAP	Standards of Generally Recognised Accounting Practice
GWP	Good Warehouse Practice
GxP	Good Manufacturing Practice, Good Warehouse Practice, Good Clinical Practice, Good Distribution Practice and Good Vigilance Practice
HR	Human Resources
HRReemco	Human Resource and Remuneration Committee
ICT	Information Technology and Communication
INCB	International Narcotics Control Board
N/A	Not applicable
NCE	New Chemical Entity
NCL	National Control Laboratory
NDoH	National Department of Health
NEPAD	New Partnership for Africa's Development
OHS	Occupational Health and Safety
PERSAL	Personnel and Salary System
PFMA	Public Finance Management Act
PMDS	Performance Management Dispensation System
QMS	Quality Management System
RAG	Risk Audit and Governance Committee
SAHPRA	South African Health Products Regulatory Authority
SAPC	South African Pharmacy Council
TORS	Technical Oversight and Regulatory Strategy Committee
VEC	Ventilator Evaluation Committee
WHO	World Health Organization

3. FOREWORD BY THE CHAIRPERSON

The last three years of the COVID-19 pandemic have demonstrated why an effective and agile medicines regulatory authority is an essential pillar of a country's health system. The primary role of the South African Health Products Regulatory Authority (SAHPRA) is to ensure that all health products are safe, effective and of high quality, and that the regulator is sensitive and responsive to changing societal needs and new technology developments. In 1998, I was appointed as the chair of the Medicines Control Council (MCC) which was SAHPRA's predecessor. The MCC's regulatory requirements at that time were more limited in scope and more straightforward than those required by modern day drug regulatory authorities. SAHPRA was established in law in 2017 and became functional in 2018. The products that SAHPRA has to oversee include all medicines, medical devices, biologics, diagnostics, radionuclides and veterinary products. The development, production and manufacturing of these products have produced new and more complex requirements for regulatory oversight.

Whether it is new vaccine platforms, monoclonal antibodies or gene therapies, SAHPRA is tasked with overseeing an unprecedented and rapid change in technologies and applications. In addition, SAHPRA has a key role in supporting the development of products that have local relevance both in their use and in their impact for local communities, such as cannabis.

The enthusiasm for local development and production of health products expanded enormously during the COVID-19 pandemic. The African Union committed to the ambitious goal of manufacturing 60% of all vaccines used in the region by 2040. Furthermore, the COVID-19 pandemic clearly demonstrated that access to essential health products in a public health emergency is massively enhanced by the advancement of regional research and development and of manufacturing. Integral to South Africa's progress in developing its pharmaceutical manufacturing capacity, is the existence of an effective drug regulatory authority. South Africa's recent success in being awarded by the World Health Organization (WHO) an mRNA vaccine manufacturing hub, depended not only on the manufacturing and scientific skills of the applicants, but also on the demonstrated effectiveness of SAHPRA as a competent regulator.

To give a sense of the complexity of a regulator's responsibilities, the WHO lists the following key functions: "licensing, inspection of manufacturing facilities and distribution channels, product assessment and registration, adverse drug reaction monitoring, quality control, control of drug promotion and advertising, and control of clinical drug trials." SAHPRA was established in 2018 to deliver on all these areas with a mandate considerably wider than that of the MCC. Not only did the Authority have to set itself up as a functioning organisation that could deliver on this extensive portfolio for all stakeholders, but the Authority also had to assume the new role of employer and as an effective manager of its finances.

On the technical side, SAHPRA inherited a backlog of 16 000 products awaiting registration. This backlog had to be urgently cleared if SAHPRA was to achieve its ambition of becoming a world class regulator. SAHPRA secured funding from the Bill and Melinda Gates Foundation to both address the backlog and to build new systems and capacity within the authority. In 2022 after three years of dedicated work, the backlog was cleared and new systems for the registration of products had been introduced. This includes shifting towards a risk-based approach to regulation. The underpinning of this approach is to allocate regulatory efforts more proportionately, so that greater resources and time are dedicated to higher risk products than are allocated to lower risk products. In addition, SAHPRA is developing 'reliance' arrangements with other trusted regulatory authorities, including many African regulators. This approach allows regulatory authorities in different countries to take into account work products of other authorities such as inspection reports, clinical or pharmaceutical assessment reports, and joint assessment reports produced together with another regulator.

While regulatory oversight is core to a drug regulator's role, an often neglected component of its activities is that of communication. SAHPRA has many stakeholders including manufacturers, health professionals, civil society organisations, patients and the general public. To enhance public health and safety, the regulator must communicate relevant information to all these sectors. In the past year, SAHPRA has put considerable effort into the implementation of a communications strategy that uses social media, webinars and traditional media to disseminate messages tailored for different audiences. In these days of misinformation and disinformation, the regulator's role in rapidly communicating accurate and relevant information is critical.

Noting the many and varied challenges that confronted SAHPRA in 2018, compounded by the regulatory demands placed on the authority during the COVID-19 pandemic, SAHPRA has performed extraordinarily well in 2022-23. In July 2022 the SAHPRA CEO and the SAHPRA team were awarded a Management Award from the National Science and Technology Forum (NSTF) that recognises outstanding contributions to science, engineering and technology and innovation. In addition, the Auditor-General gave SAHPRA an unqualified audit for the first time since its inception. In 2022 the WHO conferred on SAHPRA the status of 'Maturity level 3/4', a score which signifies very good regulatory performance, and more, the WHO recognition as a mature regulatory authority is still anticipated. All of these achievements signify a highly effective national regulatory authority which is not only a critical pillar to the health of all South Africans but is an essential institution if South Africa's ambitions to expand innovation and manufacturing in the pharmaceutical sector are to be achieved.

But going forward, there is more work still to be done. An offshoot of the COVID-19 pandemic was the strengthening of pharmacovigilance for health products used in response to the pandemic. The lessons learnt are being expanded to strengthen SAHPRA's pharmacovigilance activities for all health products. There are other new portfolios that fall under SAHPRA's mandate which require more attention in 2023-24. These include medical devices, cannabis, complementary medicines, and the regulation of radionuclides as part of SAHPRA's nuclear oversight responsibilities. As part of the cannabis portfolio, SAHPRA is contributing to the Presidential Cannabis Commission's deliberations on the commercial development of cannabis products. In the field of nuclear safety, SAHPRA is partnering with the National Nuclear Regulator to ensure the safe use and disposal of a range of health products including radionuclides.

To address this expanding and increasingly complex portfolio of work, SAHPRA will need to pay more attention to the development of skilled human resources. While 2022 has been a successful year, the combination of SAHPRA's many new portfolios together with the COVID-19 pandemic, has put enormous strain

on the staff. Part of SAHPRA's ambition for 2023-24 is to ensure that there are sufficient staff to address SAHPRA's new responsibilities and to offer training and upskilling of its staff. Like many other citizens, SAHPRA's staff have taken strain because of the COVID-19 pandemic, but they are also feeling the pressures of load shedding and of the global financial climate. In the year ahead, the SAHPRA Board and Executive have discussed ways in which its staff can be supported, so that SAHPRA remains a caring and progressive organisation for all its employees.

Professor Helen Rees
Chairperson: SAHPRA Board
31 August 2023

Finally, I would like to thank SAHPRA's exceptional and dynamic CEO, the executive team and all of SAHPRA's staff for their outstanding performance in the past year. Many SAHPRA staff have gone well beyond the call of duty in their diverse portfolios, and for this the Board is truly grateful. And I would like to extend my appreciation to my fellow Board members, who have performed their roles on committees and on the Board with astonishing dedication and insight. The 'Authority' as defined in the Medicines Act, is a combination of staff and Board, and this Authority is being driven by an exceptional team who deserve the country's gratitude.

4. CHIEF EXECUTIVE OFFICER'S OVERVIEW

Accolades and Systematic Progression

The 2022-23 Financial Year is best characterised as a year when SAHPRA encountered burgeoning accolades and recognition as an entity that was able to achieve vast strides.

In order to get a better understanding of our stakeholders, SAHPRA initiated a Customer Relationship Management (CRM) system to track enquiries, complaints and feedback to serve the needs of SAHPRA stakeholders better. SAHPRA employees were trained on the new Quantum System to track customer feedback in July 2022. This will no doubt set the trend for the upcoming Stakeholder Perception Survey in the next financial year.

SAHPRA embarked on a Corporate Social Responsibility programme where SAHPRA partnered with a Non-Government Organisation (NGO), Gift of the Givers, to donate food to victims of the floods in KwaZulu-Natal. Furthermore, SAHPRA staff visited the Leamogetswe Safety Home in Atteridgeville as part of our Nelson Mandela Day programme.

SAHPRA staff members spent 67 minutes where they read to the children and played games with them as part of the activities. SAHPRA also donated food, books, board games and toys. SAHPRA intends on nurturing stronger relationships with communities, especially those from impoverished backgrounds.

As part of its engagement with its various publics, SAHPRA held 12 successful webinars on burning issues. SAHPRA was opportunistic in selecting topics at the most appropriate times. The organisation also visited three schools of Pharmacy at three universities: University of KwaZulu-Natal, Wits University and Nelson Mandela University. The objective of these visits was to raise awareness of SAHPRA's *modus operandi* and to also demonstrate possible career opportunities at SAHPRA.

A Women's Month Coffee session following the CEO receiving the National Science and Technology Forum (NSTF) award in the Management category was held. The CEO joined the NSTF Executive Director, Ms Jansie Niehaus, in sharing their experiences.

Following the Clearance of the Backlog Project, the Communication Unit planned and executed a celebratory event at the SAHPRA Head Office on 2 December. The keynote speaker was Dr Nicholas Crisp, Deputy Director-General: National Health Insurance. The CEO and Board Chair of SAHPRA as well as the Backlog Clearance Project Manager, Lorraine Danks, also addressed the audience.

The Cape Town Office moved to new premises. The Communication Unit assisted with signage and an official launch of the new premises.

The Communications Unit provided front-end designing to IT for the newly launched Lot release search as well as the Registered Health Products database.

The Unit continues to provide design support for changing technical scopes and visual improvements.

The document library continues to be updated weekly as Units send documents to be uploaded on the website. Since its launch, 86 documents have been published, replacing previous outdated versions. The Communications Unit continues to have monthly meetings with all Technical Units to improve the document library.

A Chatbot has been developed to assist stakeholders who seek information and documents on the SAHPRA website. The Chatbot is currently running on the website development site and will be published upon EXCO approval.

SAHPRA's newly revamped website was presented at the South African Association of Pharmacists in Industry (SAAPI) in Sandton. The new navigation and additional features were presented. Furthermore, a demonstration of SAHPRA's Over the Counter (OTC) directory was also presented.

SAHPRA received an accolade from the National Press Club (NPC) on 3 November 2022 at a gala dinner event. The COVID-19 pandemic restricted the National Press Club's activities, and the NPC recognised the support of SAHPRA and the webinars that the NPC hosted. SAHPRA was presented with a statuette.

SAHPRA hosted a radio campaign on three mainline radio stations- SAFM, RSG and Ukhozi FM – on medicine and vaccine safety. The purpose of this campaign was to raise awareness on pharmacovigilance matters to the public at large. A total of nine interviews were held over November and December and these interviews were posted on SAHPRA's website as podcasts.

The Communication Unit facilitated media training focusing on public understanding of science during 16-17 March 2023. During the year under review SAHPRA conducted 29 interviews and responded to 40 media queries.

SAHPRA's social media platforms were also abuzz to debunk myths and to present credible scientific evidence. Apart from many media appearances, SAHPRA also created videos and infographics to convey information in a palatable format. SAHPRA media spokespersons were trained on engaging the media and the public on various media and social media platforms to disseminate vital information optimally. Partnerships with entities such as PATH, the National Press Club, Government Communication and Information System (GCIS), Daily Maverick and Bhekisisa proved to be most favourable.

During the 2022/23 financial year, SAHPRA realised a significant year on year increase in fee income generated which amounted to R197 million from R169 million in 2021/22. The increase in revenue generation was mainly due to the impact of the revised Fee Gazette issued in December 2020 as well as an increase in application reviews finalised. An accounting surplus amounting to R22.5 million was realised for the 2022/23 financial year compared to an adjusted surplus of R22 million in the prior year resulting in an increase in our net asset position. Management's assessment is that SAHPRA will be continuing as a going concern for the foreseeable future due to the strong cash position held at year end and the material liabilities reported relate to revenue received in advance which will be recognized as revenue in future financial periods.

A strong focus was placed on strengthening governance and internal control processes which enabled SAHPRA to retain an unqualified audit for the 2022/23 financial year which resulted in a significant decrease in irregular expenditure reported.

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

Dr Boitumelo Semete-Makokotlela
Chief Executive Officer
31 August 2023

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

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

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

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

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 E) have been prepared in accordance with the standards of generally recognised accounting practice (GRAP) applicable to the public entity.

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

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

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

In our opinion, the annual report fairly reflects the operations, the performance information, the human resources information and the financial affairs of the entity for the financial year ended 31 March 2023.

Yours faithfully

Dr Boitumelo Semete-Makokotlela
Chief Executive Officer
31 August 2023

Prof. Helen Rees
Chairperson of the Board
31 August 2023

6. STRATEGIC OVERVIEW

VISION

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

MISSION

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

VALUES

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

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 with regard to healthcare, food, water and social security:

- Everyone has the right to have access to healthcare services, including reproductive healthcare, sufficient food and water and social security as well as appropriate social assistance if they are unable to support themselves and their dependants.

- The state must take reasonable legislative and other measures within the ambit of its available resources to achieve the progressive realisation of each of these rights, and no one may be refused emergency medical treatment.

7.2 Legislative Mandate

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

- Since its establishment in February 2018, as a schedule 3A entity of the National Department of Health (NDoH), there has been no updates to its legislative and policy mandates. The cornerstone legislative mandates of SAHPRA are derived from the national Constitution, the National Health Act, 2003 (Act No. 61 of 2003) and the Medicines and Related Substances Act, 1965 (Act No. 101 of 1965), as amended (herein after referred to as "the Medicines Act").

- Pursuant to the expansion of SAHPRA's mandate which, inter alia, includes the regulation and control of radiation emitting devices and radioactive materials, it is important to consider that the following pieces of legislation define the legislative framework within which SAHPRA executes its mandate.

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

This Act provides a framework for a structured uniform health system within the Republic, taking into account the obligations imposed by the Constitution and other laws of national, provincial and local government with regard to health services. The objectives of the National Health Act, as understood alongside other laws and policies that relate to health, are to:

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

7.2.2 The Medicines and Related Substances

Act, 1965 (Act No. 101 of 1965) as amended

Amended by the Amendment Act, 2008 (Act No. 72 of 2008) and Amendment Act, 2015 (Act No. 14 of 2015) and enacted in May 2017, the Act enabled, among others, the establishment of SAHPRA, the licensing of manufacturers and importers of active pharmaceutical ingredients and the regulation of medical devices.

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

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

As per section 2b (1) of the Medicines Act, the Authority must, 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 of medicines, medical devices, radiation emitting devices and radioactive nuclides is transparent, fair, objective and concluded timeously;
- The periodic re-evaluation or re-assessment and ongoing monitoring of medicines, medical devices, radiation-emitting devices and radionuclides;
- The investigation, monitoring and analysis of evidence of existing and new adverse events as well as reactions, interactions and signals emerging from post-marketing surveillance and vigilance activities, while ensuring that these are acted upon;
- That compliance with existing legislation is promoted and achieved through a process of active inspection and investigation; and
- That clinical trial or clinical performance study protocols are assessed according to prescribed scientific, ethical and professional criteria and defined standards.

In executing its functions, the Authority may:

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

7.2.3 Hazardous Substances Act, 1973 (Act No. 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 ionising or non-ionising radiation). SAHPRA is only responsible for the regulation of Group III and Group IV hazardous substances.

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

7.2.4 Other Related Legislations

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

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

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

- **Animal Diseases Act, 1984 (Act No. 35 of 1984)**

Provides for the control of animal diseases and parasites, for measures to promote animal health and for related matters.

- **Veterinary and Para-Veterinary Professions Act, 1982 (Act No. 19 of 1982)**

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

- **Drugs and Drug Trafficking Act, 1992 (Act No. 140 of 1992)**

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

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

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

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

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

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

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

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

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

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

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

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

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

The South African Pharmacy Council (SAPC) in terms of section 35A of the Pharmacy Act (Act No. 53 of

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

of the Pharmacy Act include investigation of complaints received alleging misconduct or unprofessional conduct.

- **Customs and Excise Act, 1964 (Act No. 91 of 1964)**

Provides for the prohibition and control of the importation, export or manufacture of certain goods and related matters. A favourable legislative environment is fundamental to the operations of a regulator such as SAHPRA when it comes to supporting an effective execution of its mandate. There have been notable developments in SAHPRA's operating environment that have necessitated a review of its legislative and policy framework.

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

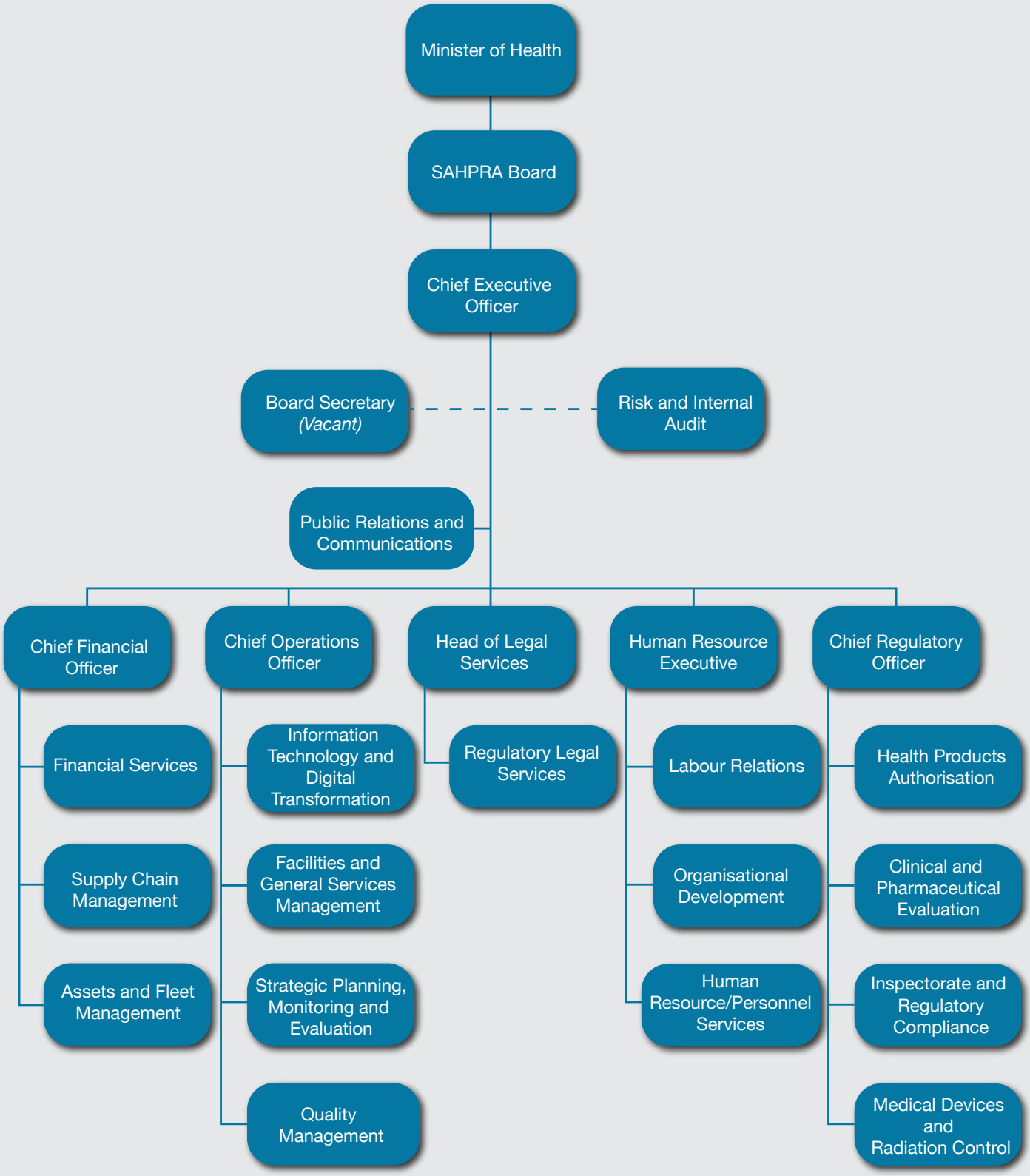
One of the key new responsibilities emanating from SAHPRA's extended mandate relates to radiation control, which has crucial elements within the ambit of the jurisdiction of the Department of Mineral Resources and Energy. Another responsibility is cannabis regulation, which involves multiple ministries such as the Department of Justice and Correctional Services and the Department of Agriculture, Land Reform and Rural Development, to affect the country's enhancement of access to this medicinal product. As SAHPRA continues to mature into its role, it is becoming increasingly evident that there is a critical need to harmonise roles and responsibilities to avert

the risk of an internal leadership vacuum or duplication of efforts and subsequent potential "conflict."

7.3 Policy Mandate

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

8. ORGANISATIONAL STRUCTURE



9. MEMBERS OF THE BOARD

Prof. Helen Rees
(Chairperson)

Dr Obakeng Khaole
(Vice Chairperson)

Mr Itani Mashau

Ms Ditaba Maraka

Prof. Patrick Demana

Adv. Hasina Cassim

Mr Tinyiko Norman Baloyi

Dr Xolani Ngobese

Ms Lerato Mothae

Prof. Joyce Tsoka-Gwegweni

Dr Alfred Kgasi

Prof. Johanna C Meyer

Ms Mandisa Skhosana

Prof. Yahya Choonara

Dr Zinhle Makatini

10. EXECUTIVE MANAGEMENT

Dr Boitumelo Semete-Makokotlela
Chief Executive Officer

Mr Regardt Gouws
Chief Financial Officer

Ms Portia Nkambule
Chief Regulatory Officer

Ms Christelna Reynecke
Chief Operations Officer

Mr Gordon Mtakati
Human Resource Executive

Ms Letjubana Chokoe
Acting Board Secretary

PART B

PERFORMANCE INFORMATION

1. AUDITOR'S REPORT: PREDETERMINED OBJECTIVES

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

Refer to page 121 of the Report of the Auditor-General, published as Part E: Financial Information.

2. OVERVIEW OF PERFORMANCE

2.1 Service Delivery Environment

In this financial year, Programme 3 continued to recruit and capacitate the technical levels of the unit, in an effort to improve service delivery. Talent attraction and retention is a challenge for the unit to recruit and retain inspectors.

In 2022/2023, Medical Device unit saw the first renewals of Medical Device Establishments for Manufacturers, Distributors and Wholesalers. This was the first license renewal since their first issuing. SAHPRA announced the requirements for review and approval of self-test kits and have to date approved four (4) self-test kits for COVID-19.

SAHPRA has continued to build the organisational culture as an entity that had to infuse cultures from employee diverse backgrounds to the SAHPRA culture to be lived. The values of the Authority are communicated in all engagement sessions with employees so that they can be practiced and applied as required. The Authority has sustained the best practice to develop policies and Standard Operating Procedures (SOPs) to guide and lead employees in the alignment of human resources practices with the achievement of organisational objectives and goals. The organisational ability to attract and retain the best talent especially in the technical field has become a challenge due to competition for best talent in the health, regulatory and pharmaceutical market.

In the financial year 2022/3, the worst of the peak of the COVID-19 pandemic receded and allowed us to refocus long-term regulatory mandates that were also competing for attention. All the lessons learnt through operational efficiency and service delivery under pressure were implemented for timely registration of strategic public health products in the HIV, TB, Malaria, and Oncology disease areas. The handling of these products intersected with the established Priority Review Framework of SAHPRA. The evidence-based decision to de-escalate the importance of ivermectin in COVID-19 disease treatment reduced the pressure on the compassionate use Section 21 programme to focus on other unmet medical need access areas, such as medical cannabis, where literature evidence of therapeutic effectiveness could be proven by applicants. The quick turn-around times were maintained for non-COVID-19 clinical trial protocol assessments with a regulatory decision. A hybrid model (physical and remote clinical trial monitoring) is still in place from the lessons of the COVID-19 pandemic and has proven to be just as effective currently in monitoring participant safety and well-being according to international Good Clinical Practice standards.

The public uptake of the MedSafety App, a convenient mobile tool for safety reporting of adverse drug reactions to medicines, and AEFIs for vaccines, continues to grow and there are plans in place to extend its use and integrate the App into Programmatic HIV and TB pharmacovigilance. Following a WHO benchmarking exercise between 2021 to 2022 a need was identified to better integrate vigilance work in the country between regulatory (SAHPRA) and programmatic (NDoH) pharmacovigilance. In terms of the Medicines and Related Substances Act (Act 101 of 1965, as amended), SAHPRA is legally mandated to

continuously monitor the safety of all health products in the Republic. To this end, important discussions were held between SAHPRA and the NDoH to put in place measure to integrate pharmacovigilance into the public health system, from the point of care up to SAHPRA, the ultimate custodian of vigilance in the Republic. This integrated framework is at an advanced stage and should be largely in place by end financial year 2023/4. The national pharmacovigilance integration efforts go hand-in-hand with an aggressive vigilance awareness campaign through face-to-face training engagements and webinars at provincial health departments and health facilities, as well as at tertiary educational institutions to socialise pharmacovigilance among future healthcare workers.

2.2 Organisational Environment

Capacitating the organisation with the right skills is significant in achieving the objectives of the Authority. SAHPRA focused on providing support and ensuring speedy approval of the medicines and health products to continue in the fight against the COVID-19 pandemic. During the 2022/23 financial year, SAHPRA was able to recruit externally while providing opportunities to internal employees to capacitate the organisation with the right skills and retain key talent. Digitisation of the Authority remained a priority to ensure good service delivery and high performance.

2.3 Key Policy Developments and Legislative Changes

There were litigations cases brought against SAHPRA during the year under review. These cases were primarily about challenging the mandate and powers of SAHPRA, and decisions to approve COVID-19 vaccines. These cases are still pending.

SAHPRA Gazetted the regulations on compounding and the Regulations on Medical Devices were published for public comments.

2.4 Progress Towards Achievement of Institutional Impacts and Outcomes

SAHPRA's revised 2020/21 – 2024/25 Strategic Plan was approved in January 2023. The revisions were made to the to ensure alignment with revisions in the Annual Performance Plan based on the recommendations from the audit by Internal Audit, Outcome indicators, 5-year targets and method of calculation in the Technical Indicator Descriptions.

2.4.1 Impact Statement

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

2.4.2 Progress on Outcomes

MEDIUM TERM STRATEGIC FRAMEWORK PRIORITY 3: EDUCATION, SKILLS AND HEALTH			
OUTCOMES	**OUTCOME INDICATORS**	**FIVE-YEAR TARGET**	**PROGRESS**
Effective financial management (1)	1.1 Unqualified audit opinion obtained on the annual financial statements	Clean audit opinion obtained for the 2023/24 financial year	Unqualified audit opinion obtained for 2021/22 financial year
Financial sustainability achieved through revenue generated and enhanced operational efficiencies (2)	1.2 Total revenue generated from fees in the financial year	Annual revenue of R185 million generated from fees	Revenue of R197million generated
Continuously respond to the needs and expectations of SAHPRA stakeholders (3)	1.3 Percentage of accepted recommendations from the stakeholder perception survey implemented	100% accepted recommendations from the stakeholder perception survey implemented	Recommendations from the 2020/21 stakeholder perception survey implemented, *3 out of 5 accepted recommendations from the 2020/21 were implemented*
A positive and enabling working culture created (4)	1.4 Percentage of recommendations from the staff satisfaction survey implemented	Review of the change management intervention conducted	80% of the change management intervention implemented *Change Management plan was approved by EXCO*.
Attract and retain superior talent (5)	1.5 Percentage of positions in the staff establishment filled	80% of core business positions in the staff establishment filled	65% budgeted positions filled, *48 budgeted positions and 26 positions funded through Global Fund which 18 have been filled, (65%) was achieved.*
Strengthened Information and Communication Technology and digitisation (6) **(6)**	1.6 Enterprise Architecture developed	Phase 2 of the roadmap on the Enterprise Architecture implemented	The Enterprise Architecture has not been approved by the Board. *To be tabled to the Board in April 2023.*

MEDIUM TERM STRATEGIC FRAMEWORK PRIORITY 3: EDUCATION, SKILLS AND HEALTH			
OUTCOMES	**OUTCOME INDICATORS**	**FIVE-YEAR TARGET**	**PROGRESS**
High levels of organisational operational efficiency and effectiveness in the regulatory function maintained (7)	1.7 Percentage of medicine registrations in the backlog cleared	100% medicine registrations backlog cleared	100% of applications cleared *Backlog project concluded*
	1.8 Percentage of medicine variation applications in the backlog cleared	100% medicine variation applications backlog cleared	100% of applications cleared *Backlog project concluded*
	1.9 Percentage of New Chemical Entities finalised within 360 working days	80% New Chemical Entities finalised within 360 working days	100 % New Chemical Entities finalised within 490 working days and exceeded achievement Out of 342 applications received, 0 (0 %) were due for finalisation Although no applications were due for finalisation, 89 (100%) were finalised within 490 workings days
	1.10 WHO maturity level obtained	WHO maturity level 4 obtained	WHO Maturity level 3 obtained for vaccines Maturity Level 4 achieved for lot release.
	1.11 Percentage of new Good Manufacturing Practice (GMP) and Good Warehouse Practice (GWP) related licenses finalised within 125 working days	80% new GMP and GWP related licenses finalised within 125 working days	22% new GMP and GWP related licenses finalised within 125 working days *Out of 54 due for finalisation, 28 (51%) were finalised, of which 12 (22%) were finalised within 125 workings days*
	1.12 Percentage of human clinical trial applications finalised within 90 working days	80% human clinical trial applications finalised within 90 working days	104% human clinical trial applications finalised within 90 working days *Out of 163 due for finalisation, 184 (113%) were finalised, of which 169 (104%) were finalised within 90 workings days*
	1.13 Medical Device registration regulations implemented	Call up of Class D (high risk)	Guidelines have been placed on hold until the regulations are finalised from NDoH

3. INSTITUTIONAL PROGRAMME PERFORMANCE INFORMATION

3.1 Programme 1: Leadership and Support

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

Sub-programmes:

Sub-Programme	Purpose
Financial and Supply Chain Management	To serve all business units in SAHPRA, the senior management team and the Board by maintaining an efficient, effective and transparent system of financial, and risk management that complies with the applicable legislation
Governance and Compliance	To provide support services and ensure compliance with relevant legislation; and achieve an unqualified audit outcome by ensuring continuous management practices through compliance with standards operating procedures and systems within SAHPRA. Further, to review existing operational processes and recommend new or changed processes and work methods to ensure optimal organisational effectiveness and, measure and monitor the Authority's performance
Information Technology and Communication (ICT)	to develop and implement ICT integrated governance framework by focusing on the business continuity plan and support the needs and requirements of the end users. Further, to manage public relations, information and communication services to ensure proper management and dissemination of information to internal and external stakeholders, to ensure a seamless harmonious operational platform by building strong and sustainable relationships with all its stakeholders
Human Resource Management	To provide human resources and organisational development systems and solutions that meet the needs of the organisation and support the achievement of the Authority's strategic objectives

Outcomes:

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

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

PROGRAMME 1: ADMINISTRATION								
Outcome	**Output**	**Output Indicator**	**Audited Actual Performance 2020/2021**	**Audited Actual Performance 2021/2022**	**Planned Annual Target 2022/2023**	**Actual Achievement 2022/2023**	**Deviation from Planned Target to Actual Achievement 2022/2023**	**Reasons for Deviations**
Effective financial management (1)	Attain and maintain an unqualified overall AG Audit outcome on previous year's performance	Unqualified audit opinion obtained on the annual financial statements	Qualified audit opinion obtained for the 2020/21 financial year	Qualified audit opinion obtained (2020/21 financial year)	**Unqualified audit opinion obtained for 2021/22 financial year**	**Unqualified audit opinion obtained for 2021/22 financial year**	None	none
Financial sustainability achieved through revenue generated and enhanced operational efficiencies (2)	Total revenue generated from fees	Total revenue generated from fees in the financial year	R102 million	Revenue of R169 million generated from fees	**Annual revenue of R170 million generated from fees**	Revenue of R197 million generated	Target exceeded by R27m	Higher than expected overall revenue vs budget due to impact of 2020 Gazetted fees and number of applications
	Break-even of expenses and revenue by 31 March	Break-even of expenses and revenue by 31 March 2023	-R24.7 million	R28 million The breakeven point was exceeded by R28 million, which is an accounting surplus reported	**≥ zero amount on the budget versus income and expenditure report**	R22.5 million surplus	Target achieved	Higher than expected revenues generated resulting in an accounting surplus

PROGRAMME 1: ADMINISTRATION								
Outcome	**Output**	**Output Indicator**	**Audited Actual Performance 2020/2021**	**Audited Actual Performance 2021/2022**	**Planned Annual Target 2022/2023**	**Actual Achievement 2022/2023**	**Deviation from Planned Target to Actual Achievement 2022/2023**	**Reasons for Deviations**
Continuously respond to the needs and expectations of SAHPRA stakeholders (3)	Recommendations implemented	Percentage of accepted recommendations from the 2022/23 stakeholder perception survey implemented	SAHPRA obtained a 68% positive rating for its effectiveness and efficiency as rated by private and public direct users of SAHPRA's services	67% prioritised recommendations from the survey implemented Out of 3 prioritised recommendations from the survey, the following 2 (67%) were implemented: • *A web query system. Out of the 1 103 queries received, 623 (56%) were responded to* • *Out of a staff establishment of 395, 266 (67%) posts were occupied which included positions that were filled by employees who were placed on higher grades during the administrative placement exercise*	**60% accepted recommendations from the 2022/23 stakeholder perception survey implemented**	60% accepted recommendations from the 2020/21 stakeholder perception survey implemented Out of 5 accepted recommendations from the 2020/21 stakeholder perception survey, the following 3 (60%) were implemented: • *Document management system* • *Online application system was tested* • *Online medicines register is live*	Target achieved	Executive Committee took a decision that a stakeholder survey will not be conducted during the 2022/23 financial year as outstanding recommendations from the 2020/21 survey needed to be prioritised Online medicine register was implemented earlier than planned due to the demand by industry

PROGRAMME 1: ADMINISTRATION								
Outcome	**Output**	**Output Indicator**	**Audited Actual Performance 2020/2021**	**Audited Actual Performance 2021/2022**	**Planned Annual Target 2022/2023**	**Actual Achievement 2022/2023**	**Deviation from Planned Target to Actual Achievement 2022/2023**	**Reasons for Deviations**
A positive and enabling working culture created (4)	Change management intervention implemented	Percentage of change management interventions implemented	-	92% of the change management interventions implemented *Out of 13 change management interventions identified, 12 (92%) were implemented*	**80% of the change management intervention implemented**	80% of the change management intervention implemented *Change Management plan was approved by EXCO*	Target was achieved with change management intervention getting implemented	Target was based on EXCO's approval which ensured outcome is implemented .Outcome implemented was through change engagements with staff employees
	Workplace Skills Plan implemented	Percentage of the Workplace Skills Plan implemented	-	39% of the Workplace Skills Plan implemented Out of 23 planned training interventions in the Workplace Skills Plan, 9 (39%) were implemented	**50% of the Workplace Skills Plan implemented**	Out of 459 training initiatives planned, 68 (15%) were implemented	Target was missed by 35%	The workplace skills place did not include the relevant training that was included in the IDPS
Attract and retain superior talent (5)	Budgeted positions filled	Percentage of budgeted positions filled	Out of the 375 positions in the approved staff establishment, 265 (71%) were filled	96% budgeted positions filled *Out of 55 budgeted positions, 53 (96%) were filled*	**95% budgeted positions filled**	65% budgeted positions filled, 48 budgeted positions and 26 positions funded through Global Fund which 18 have been filled, (65%) was achieved.	Target missed by 30%	SAHPRA offers are rejected by the top candidates.

PROGRAMME 1: ADMINISTRATION								
Outcome	**Output**	**Output Indicator**	**Audited Actual Performance 2020/2021**	**Audited Actual Performance 2021/2022**	**Planned Annual Target 2022/2023**	**Actual Achievement 2022/2023**	**Deviation from Planned Target to Actual Achievement 2022/2023**	**Reasons for Deviations**
Strengthened Information and Communication Technology and digitisation (6)	Enterprise Architecture	Enterprise Architecture developed	10% of processes digitised. The User Requirements Specification for the Regulatory Information Management Systems was developed and submitted for approval in March 2021	Section 21 business process was digitised in June 2021 Development of an online application submission system was in progress Leave application process was digitalised	**Enterprise Architecture approved by the Board**	The Enterprise Architecture has not been approved by the Board.	The ICT documents including the recommended "To Be" Architecture report we deferred at the RAG committee meeting due to inadequate IT representation on the committee. A representative will be added to the next RAG session meeting to adequately review and provide input.	The document was deferred at previous RAG

Finance and Supply Chain Management

SAHPRA's total revenue amounted to R396 million against a budget of R349 million. The variance of R47 million was mainly due to additional funding support received during the year and additional fee revenue derived. SAHPRA spent R374 million against the initial approved budget of R349 million. The additional expenditure was allowed due to unbudgeted for external financial support received as well as above budgeted for fee income generated during the year. The overall result was an accounting surplus amounting to R22.5 million. The accounting surplus resulted in an increase of accumulated surpluses from R47 million to R70 million.

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

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

Human Resource Management

During this reporting period, a total of 93 vacancies were filled, which include 18 positions funded by the Global Fund in assisting SAHPRA will human resources to achieve its mandate.

The development and implementation of the Hybrid Policy on the regulation of working hours is enabling SAHPRA to create a work environment that is conducive and has levels of flexibility for employees to create a work-life balance. It must be noted that the work demands at the Authority make it very hard to achieve true work-life balance. The organisation strives for a working environment that can be established within which employees can flourish and be developed through learning opportunities – within the regulatory environment and amongst each other's experiences.

The three- year Employment Equity Plan from the 2022/23 financial year, the equity targets focused on areas where representation of a certain race or gender is minimal across all the employment levels, especially in core business. The plan intended to further address challenges with establishing an employment Equity Committee and to minimise salary disparities throughout the organisation.

- Professionally qualified and experienced specialists and mid-management, the Authority targeted to appoint five (5) Indian males, two (2) coloured females and three (3) white females. This included people with disabilities.

- Skilled technical and academically qualified workers, junior management, supervisors, foremen, and superintendents, three (3) males targeted for who are Coloured, Indian and White.

- People with disabilities, target as per plan was to appoint one (1) male Indian and one (1) female Coloured within the professionally qualified and experienced specialists and mid-management.

Six (6) African males and one (1) Coloured male were recruited on a fixed-term contract.

Eleven (11) African females and two (2) Indian females were recruited on a fixed-term contract.

Mitigations and measures were put in place to achieve the above.

Communication and PR

SAHPRA initiated a Customer Relationship Management (CRM) system to track enquiries, complaints and feedback to serve the needs of SAHPRA stakeholders better. SAHPRA employees were trained on the new Quantum System to track customer feedback in July 2022. The SAHPRA Communication unit together with the Office of the CEO began tracking queries, complaints and feedback.

As part of its awareness drive, SAHPRA held webinars.:

- One was held on 21 June (abuse of codeine-containing medicines). SAHPRA detected the burgeoning abuse of codeine-containing medicines, especially among the youth. There is also a concern about the unethical conduct of pharmacies and pharmacists in this regard. Participants included the Pharmacy Council, the HAWKS, Pharmaceutical Society of South Africa (PSSA), SAHPRA and South African Network of People who Use Drugs (SANPUD).
- On 30 June (Launch of the Over the counter (OTC) medicines Directory. The online mobile friendly medicines' directory was developed to assist the public and healthcare professionals with information on how to use these OTC products safely.
- On 4 August 2022, SAHPRA hosted a webinar with the Minister of Health on the first fatality linked to the Guillain-Barré syndrome following vaccination with COVID-19 Vaccine Janssen. This was an important development as part of SAHPRA's role of tracking AEFIs.
- SAHPRA hosted a webinar in commemoration of the "World Patient Safety Day" and "World Pharmacist Day" (observed annually on 17 and 25 September, respectively). It was a conversation on medicine safety to increase awareness and reporting of adverse events. The WHO's theme for the 2022 World Patient Safety Day was "Medication Safety", with the slogan "Medication without Harm".
- SAHPRA's Radiation Control (RadCon) X-Ray unit hosted a targeted workshop on regulatory compliance (1 December), and a webinar on engaging Inspection Bodies (7 December). The Communications unit supported RadCon in terms of drafting emails to prospective attendees, setting up Teams registration pages, to the overall management on the day of the event.
- On 26 October, PATH hosted SAHPRA in a webinar that focused on the regulator achieving Maturity Level 3 (ML3) from the WH On with regard to vaccine registration. The webinar was designed to unpack what ML3 entails and what this accolade means for SAHPRA. The webinar was attended by 224 delegates.
- On 22 November, the South African Medical Association (SAMA) hosted a webinar where the SAHPRA CEO, COO, and the Office of the CRO delivered presentations during the session. The purpose of the webinar was to demystify SAHPRA's mandate and procedures for this fraternity.
- The RadCon unit hosted a webinar on the Interpretation of calibration certificates for radiation monitoring instruments on 10 November. The Communications unit supported RadCon in terms of drafting emails to prospective attendees, setting up a Teams registration page, formatting of programme, to overall management on the day of the event.
- The Communications unit also supported two webinars – one for the Pharmacovigilance Team (23 February 2023) and one for Radiation Control (24 February 2023).

SAHPRA developed revised infographics on Cannabis to communicate key developments around cannabis and the legislation and control to the public and stakeholders. SAHPRA published a thought leadership article based on Management coinciding with the CEO's nomination for the Management award at the National Science and Technology Forum (NSTF) Awards. In order to disseminate articles far and wide, SAHPRA partnered with GCIS, SAPC and HPCSA to disseminate and promote SAHPRA content.

As part of its outreach programme, SAHPRA visited the School of Pharmacy at the University of KwaZulu-Natal. SAHPRA presented their core business to approximately 500 students. The Communication Unit assisted in planning and attending two events at Schools of Pharmacy at Wits University on 4 October and Nelson Mandela University on 14 October. This is an outreach programme led by HR and the Communication unit provided support and ensured that the SAHPRA brand featured prominently. SAHPRA presented their core business to approximately 200 students.

A Women's Month Coffee session following the CEO receiving the National Science and Technology Forum (NSTF) award in the Management category was held. The CEO joined the NSTF Executive Director, Ms. Jansie Niehaus, in sharing their experiences.

Following the Clearance of the Backlog Project, the Communication Unit planned and executed a celebratory event at the SAHPRA Head Office on 2 December. The keynote speaker was Dr Nicholas Crisp, Deputy Director-General: National Health Insurance. The CEO and Board Chair of SAHPRA as well as the Backlog Clearance Project Manager, Lorraine Danks, also addressed the audience.

Pharmacovigilance (PV) participated in two conferences – one was the South African Association of Hospital and Institutional Pharmacists (SAAHIP) Conference in the Drakensberg and the Pharmacy Show at the Sandton Convention Centre. Material in terms of pamphlets, videos, and corporate gifts were made available.

The Cape Town Office moved to new premises. The Communication Unit assisted with signage and an official launch of the new premises.

The Communications Unit provided front-end designing to IT for the newly launched Lot release search as well as the Registered Health Products database. The Unit continues to provide design support for changing technical scopes and visual improvements.

The document library continues to be updated weekly as Units send documents to be uploaded on the website. Since its launch, 86 documents have been published, replacing previous outdated versions. The Communications Unit continues to have monthly meetings with all Technical Units to improve the document library.

A Chatbot has been developed to assist stakeholders who seek information and documents on the SAHPRA website. The Chatbot is currently running on the website development site and will be published upon EXCO approval.

SAHPRA's newly-revamped website was presented at the South African Association of Pharmacists in Industry (SAAPI) in Sandton. The new navigation and additional features were presented. Furthermore, a demonstration of SAHPRA's Over the Counter (OTC) directory was presented.

SAHPRA hosted a Heritage Day celebration at the SAHPRA offices. The Cape Town office also held their own event at their offices. The Durban office staff completed a video, expressing their culture, dress, and tradition and this was posted on the SAHPRA intranet. Staff members dressed in traditional outfits and enjoyed tasting various traditional foods. The Head Office was addressed on the significance of the day by the CEO of Freedom Park, Ms. Jane Mufamadi. Excess food was donated to the Leamogetswe Safety Home.

SAHPRA celebrated World AIDS Day on 1 December at SAHPRA offices (Head Office and Cape Town). Mr Deon Poovan and Adv Nazreen Shaik-Peremanov addressed staff members at Head Office. Staff members were handed out lapel pins and condoms provided by NDoH. Staff were also informed about the event through an intranet article with accompanying photos that was disseminated via email.

On 14 December, SAHPRA held a Year-End Debrief Session with staff members and SAHPRA Board representatives. EXCO members delivered informative talks to staff members and the event was also streamed to the Durban and Cape Town office staff members. A total of 116 staff members from Head Office attended the event.

On 27 October, the Communication and PR Unit provided support to the HR team who hosted an Employee Wellness Day at SAHPRA. The event was a resounding success, and it was well attended. The unit provided photographic services and an intranet article was written to create an awareness of the event, visually represented through a photo gallery, and distributed via email.

SAHPRA received an accolade from the National Press Club (NPC) on 3 November 2022 at a gala dinner event. The COVID-19 pandemic restricted the National Press Club's activities, and the NPC recognised the support of SAHPRA and the webinars that the NPC hosted. SAHPRA was presented with a statuette.

SAHPRA hosted a radio campaign on three mainline radio stations- SAFM, RSG and Ukhozi FM – on medicine and vaccine safety. The purpose of this campaign was to raise awareness on pharmacovigilance matters to the public at large. A total of nine interviews were held over November and December and interviews were posted on SAHPRA's website as podcasts.

The Unit facilitated media training focusing on public understanding of science during 16-17 March 2023. During the year under review, SAHPRA conducted 29 interviews and responded to 40 media queries.

The Unit facilitated media training focusing on public understanding of science during 16-17 March 2023. During the year under review, SAHPRA conducted 29 interviews and responded to 40 media queries.

3.1.2 Linking Performance with Budgets

2022/2023				2021/2022		
Programme	**Budget R'000**	**Actual Expenditure R'000**	**(Over)/Under Expenditure R'000**	**Budget R'000**	**Actual Expenditure R'000**	**(Over)/Under Expenditure R'000**
Programme 1	127 736	139 060	(11 324)	116 510	115 586	924
TOTAL	**127 736**	**139 060**	**(11 324)**	**116 510**	**115 586**	**924**

3.1.3 Strategy to overcome Areas of under Performance

To accelerate the digitisation of business processes, the automation of SCM and Claims processes under way through appointment of service providers to develop such systems. The externally funded Quantum System was implemented that cater for all SAHPRA's business processes.

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

Programme	Intervention	Geographic Location (Province/ District/ Local municipality) (Where Possible)	No. of Beneficiaries (Where Possible)	Disaggregation of Beneficiaries (Where Possible)	Total Budget Allocation per Intervention (R'000)	Budget Spent per Intervention	Contribution to the Outputs in the APP (Where Applicable)	Immediate Outcomes
Programme 1	Issued PPE, refill sanitisers bottles, issue masks to new employees as and when requested	Pretoria (Head Office) and Cape Town Regional Office	+/- 319	Not applicable (N/A)	Operational budget	Operational budget	N/A	N/A

3.2. Programme 2: Health Products Authorisation

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

Sub-programmes

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

Outcomes:

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

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

PROGRAMME 2: HEALTH PRODUCT AUTHORISATION								
Outcome	**Output**	**Output Indicator**	**Audited Actual Performance 2020/2021**	**Audited Actual Performance 2021/2022**	**Planned Annual Target 2022/2023**	**Actual Achievement 2022/2023**	**Deviation from Planned Target to Actual Achievement 2022/2023**	**Reasons for Deviations**
High levels of organisational operational efficiency and effectiveness in the regulatory function maintained (7)	Backlog in medicine registration cleared	Percentage of medicine registrations on backlog cleared	Out of 5 320* backlog applications for medicine registrations, 2 819 (53%) were cleared	75% medicine registrations backlog cleared *Out of 3 395* backlog applications for medicine registrations received, 2 557 (75%) were cleared* *Denominator revised to refer only to applications received after Go-Live. Non-resubmissions excluded (1 925 applications were not resubmitted). Thus % clearance of the 3 395 new registration applications received*	**100% medicine registrations backlog cleared**	Out of 3 566* backlog applications for medicine registrations received, 3 566 (100%) were cleared, i.e., 3126 registrations, 137 rejections & non-acceptances and 303 official withdrawals **Denominator revised from initial denominator of 5320 to refer only to applications received after Go-Live of the project, non-resubmissions excluded (1 754 applications were not resubmitted). The number of applications received (3 395) was a shifting target as some applications were missed due to the initial manual uploading process (changed from 3 395 to 3 566) – 171 additional applications.*	0%	Improved coordination and execution of the business process. In addition implementation of Risk-Based Review.

PROGRAMME 2: HEALTH PRODUCT AUTHORISATION								
Outcome	**Output**	**Output Indicator**	**Audited Actual Performance 2020/2021**	**Audited Actual Performance 2021/2022**	**Planned Annual Target 2022/2023**	**Actual Achievement 2022/2023**	**Deviation from Planned Target to Actual Achievement 2022/2023**	**Reasons for Deviations**
	Backlog in medicine variation applications cleared	Percentage of medicine variation applications backlog cleared	Out of the 7 440* backlog applications for variations, 7 165 (96%) were cleared	95% medicine variation applications backlog cleared *Out of 2569* backlog applications for medicine variations received, 2455 (95%) were cleared* *Denominator revised to refer only to applications received after Go-Live. Prior clearance initiatives and non-resubmissions excluded. Thus % clearance of the 2569 variation applications received*	**100% medicine variation applications backlog cleared**	Out of the 2569* backlog applications for variations, 2569 (100%) were cleared **Denominator revised from initial denominator of 7440 to refer only to applications received after Go-Live of the project, non-resubmissions excluded (1 002 variation codes were not resubmitted). The number of applications received (2569) was a shifting target as some applications were missed due to the initial manual uploading process*	0%	Improved coordination and execution of the business process. In addition implementation of Risk-Based Review.

PROGRAMME 2: HEALTH PRODUCT AUTHORISATION								
Outcome	**Output**	**Output Indicator**	**Audited Actual Performance 2020/2021**	**Audited Actual Performance 2021/2022**	**Planned Annual Target 2022/2023**	**Actual Achievement 2022/2023**	**Deviation from Planned Target to Actual Achievement 2022/2023**	**Reasons for Deviations**
	New Chemical Entities applications finalised	Percentage of New Chemical Entities finalised within 490 working days	Out of the 72 New Chemical Entities registered, all 72 (100%) were finalised within 590 days	100% New Chemical Entities finalised within 590 working days *Out of 246 New Chemical Entities applications received, 44 (18%) were finalised. Out of the 44 finalised, all 44 (100%) were finalised within 590 working days*	**80% New Chemical Entities finalised within 490 working days**	100 % New Chemical Entities finalised within 490 working days *Out of 342 applications received, 0 (0 %) were due for finalisation* *Although no applications were due for finalisation, 89 (100%) were finalised within 490 workings days*	Target exceeded by 20%	Applications that are novel treatments, for unmet medical needs were Finalised **Applications not due for finalisation were finalised earlier than anticipated**
	Generic medicines applications finalised	Percentage of generic medicines finalised within 250 working days	Out of the 240 generic medicines registered, 131 (55%) were finalised within 250 days	80% generic medicines finalised within 250 working days *Out of 2 075 generic medicine applications received, 184 (9%) were finalised. Out of the 184 finalised, 148 (80%) were finalised within 250 working days*	**75% generic medicines finalised within 250 working days**	57 % generic medicines finalised within 250 working days Out of 2 832 applications received, 520 (18 %) were due for finalisation Out of 520 due for finalisation, 514 (99 %) were finalised, of which 295 (57 %) were finalised within 250 workings days	Target missed by 18%	Limited human resource capacity. Need to implement re-engineered business processes

PROGRAMME 2: HEALTH PRODUCT AUTHORISATION								
Outcome	**Output**	**Output Indicator**	**Audited Actual Performance 2020/2021**	**Audited Actual Performance 2021/2022**	**Planned Annual Target 2022/2023**	**Actual Achievement 2022/2023**	**Deviation from Planned Target to Actual Achievement 2022/2023**	**Reasons for Deviations**
	International Organization for Standardization 9001: 2015 certified	International Organization for Standardization 9001: 2015 certification obtained	The implementation roadmap for the Quality Management System was developed and approved in October 2020 The Quality Management System is being implemented on an ongoing basis	73% Quality Management System requirements implemented	**International Organization for Standardization 9001: 2015 certified**	All planned activities in the Implementation roadmap have been concluded.	Target not met	ISO 9001:2015 certification was deprioritised and deferred to the 2023/24 financial year to focus on maturity level 3(ML3) project
Global best practices maintained (8)	WHO global benchmarking conducted	WHO global benchmarking conducted	Commenced with preparations to conduct the survey and engagements were held with WHO to provide support to SAHPRA	Based on the WHO provisional assessment report received in November 2021, an Institutional Development Plan was developed to address the recommenda-tions	**WHO maturity level 3 obtained**	WHO Maturity level 3 obtained	Target achieved	Institutional Development Plan implemented

3.2.3 Backlog Clearance Programme

In 2018, SAHPRA inherited a backlog of over 16 000 medicine applications (new registrations and variations, i.e., changes to registered products) from its predecessor, the Medicines Control Council.

To address this backlog, SAHPRA set up a dedicated Backlog Clearance Programme, with dedicated, contracted staff, to clear these applications. The clearance initiatives prior to the Go-Live of the project, included applicant opt-outs, Project Starburst, certification variations, as well as non-resubmissions of applications. The Backlog Clearance Programme was tasked with optimising processes and implementing efficiencies, using totally re-engineered approaches for medicines assessment and registration. This included the introduction of reliance procedures that allowed SAHPRA to exchange information with recognised regional and international regulatory authorities. A further mandate was to establish the feasibility of risk-based assessment of certain aspects of generic applications (SAHPRA in the main receives >90% generic (Multi-Source Medicine) applications).

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

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

Medicine registration backlog

The initial denominator for the new medicine registration applications has been amended three times since reporting for the Backlog Clearance Programme commenced, viz. for the 2019/2020 period, a denominator of 8 220 was used, as this reflected all new registration applications expected in line with the industry survey. During the 2020/2021 reporting period, the denominator was revised to 5 320, i.e., all new registration applications that SAHPRA expected for resubmission at the Go-Live of the project. This figure took into account opt-outs by applicants. Upon the Go-Live, it initially appeared that only 3 395 new registration applications were resubmitted by applicants and received by the Backlog Clearance Programme (i.e., 1 925 applications were not resubmitted into the Programme). This was the reported denominator for 2021-2022. With the final consolidation of new registration finalisations in the Programme, the denominator was yet again amended, as some applications were initially missed due to the manual ICT uploading process at the start of the COVID-19 pandemic (all have subsequently been finalised). The final denominator for new registration applications is 3 566, with 1 754 line items not resubmitted in the Backlog Clearance Programme. All 3 566 new registration applications have been finalised (3126 registrations, 137 rejections & non-acceptances and 303 official withdrawals).

Both reliance practices and risk-based assessment played a pivotal role in clearing especially the new medicine registration applications, while the re-engineered processes also contributed.

Medicines variation applications backlog

As with new medicine registration applications, the initial calculation method for variation applications (and consequently the denominator) was amended between the 2020/2021 and 2021/2022 reporting period. Initially, a denominator of 7 740 was used, i.e., the variation applications expected in the project after opt-outs by applicants. The performance reported for 2020/2021, therefore, included results from clearance initiatives prior to the Go-Live of the project, as well as subsequent non-resubmissions. During the 2021/2022 reporting period, the denominator was revised to 2569, namely all variation applications that SAHPRA received upon the Go-Live of the project. This included both Type I and II variations. The reason for the amendment is similar to that for new registration applications, in that the manual ICT uploading process led to missed variation applications. In conclusion, 2569 variation applications have been finalised since Go-Live of the Backlog Clearance Programme.

The resubmitted applications were processed through various mechanisms that included official withdrawals by applicants, non-accepting/rejecting non-compliant applications and registering/approving compliant applications. As of 31 March 2023, the backlog applications were 100% cleared.

3.2.4 New Registration Applications

New Chemical Entities

There were 342 NCE applications received. These include applications carried over from the previous financial year and applications received up until March 2023. Out of the 342 NCE applications received, 89 (26%) NCEs were finalised. Out of the 89 NCEs finalised, 70 (79%) NCEs were finalised within 490 working days from date of receipt and all 89 (100%) NCEs were finalised within 490 working days from the date of completion of technical screening.

Generic applications

There were 2 832 generic applications received. These include applications carried over from the previous financial year and applications received up until March 2023. Out of the 2 832 generic applications received, 514 (18 %) generics were finalised. Out of the 514 generics finalised, 66 (13%) generics were finalised within 250 working days from date of receipt and 295 (57%) generics were finalised within 250 working days from the date of completion of technical screening. Generic medicines applications from April 2020 onwards are already in a backlog. Various strategies are currently being implemented to reduce and clear this backlog. These strategies include the implementation of different forms of reliance including participating in ZAZIBONA, which is a collaborative process for the evaluation of new medicine applications and making use of assessment reports from Recognised Regulatory Authorities and SAHPRA. The registrations encompassed the therapeutic areas such as antigens (Covid-19), tuberculostatics, anti-convulsants, anti-inflammatory, anti-depressants, anti-coagulants, anti-acids, anti-infectives, oncology and antiviral. This enhanced access of medicines in the mentioned therapeutic areas.

HPA

To comply with the legal provisions, as set out in the Medicines and Related Substances Act (Act 101 of 1965), as amended, SAHPRA will be implementing a process to renew the validity of human and veterinary medicine registrations. Implementing this process will ensure that SAHPRA complies with the legal provisions, but it will also enable the regulator to comply with the requirements as set out by the WHO in the Global Benchmarking Tool.

The relevant legal provisions that may be referenced can be found in the Medicines and Related Substance Act No. 101 of 1965, as amended.

- Section 2B(1)(c) provides for the periodic reevaluation or reassessment and monitoring of medicines, medical devices and IVDs.
- Section 15(6)(a)(b) provides for the registration of medicines, medical devices or IVDs. It further states that any registration under this section may be made subject to such conditions as may be determined by the Authority and shall in the case of medicines, be valid for a period of five years.

SAHPRA embarked on a renewal pilot in September 2022 to establish a robust and effective renewal process. The purpose of the renewal pilot was:

- to provide a model for future renewal processes, with clear guidelines and best practices that can be applied to other medicines as well
- to streamline the renewal templates and Standard Operating Procedures
- to identify gaps and risks in the renewal process

Guidelines, SOPs and reporting templates were prepared for the renewals pilot. The renewal pilot is envisaged to be concluded at the end of the first quarter of the 2023/24 cycle.

Quality Management System

Implementation of Quality Management System (QMS) has reached the final stage. Activities planned in the implementation roadmap have been successfully completed and the Quality Management System (QMS) unit was actively engaging in follow up activities and effectiveness checks of the implemented requirements. QMS committee was established to provide support to the QMS team, committee members were tasked with driving QMS awareness and perform documentation review in their respective units in order to prepare for the certification journey that will commence in the new financial year.

SAHPRA successfully managed to attain the Maturity Level 3(ML3) status from WHO indicating that SAHPRA is confirms a stable, well-functioning and integrated regulatory system is in place.

3.2.3 Linking Performance with Budgets

2022/2023				2021/2022		
Programme	**Budget R'000**	**Actual Expenditure R'000**	**(Over)/Under Expenditure R'000**	**Budget R'000**	**Actual Expenditure R'000**	**(Over)/Under Expenditure R'000**
Programme 2	51 615	50 689	926	72 534	73 660	(1 126)
TOTAL	**51 615**	**50 689**	**926**	**72 534**	**73 660**	**(1 126)**

3.2.4 Strategy to overcome Areas of under Performance

To improve the number of applications for medicine registrations cleared, a risk-based assessment pilot study was initiated in 2022. This has resulted in shortened review and applicant response timeframes. The implementation of the second phase is scheduled during the 2023/24 financial year. This will further assist in mitigating the long extension requests from applicants to respond to quality and bioequivalence queries. The pre-submission Pilot was initiated to offer and opportunity to applicants to understand the requirements and timeframes. The Priority Review Policy was implemented to accelerate registration of medicines for public health access. QMS Committee established.

The public entity must provide the strategies to address under performance.

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

Programme	Intervention	Geographic Location (Province/ District/ Local municipa-lity) (Where Possible)	No. of Benefi-ciaries (Where Possible)	Disaggre-gation of Benefi-ciaries (Where Possible)	Total Budget Allocation per Interven-tion (R'000)	Budget Spent per Interven-tion	Contri-bution to the Outputs in the APP (Where Applicable)	Immediate Outcomes
Not applicable								

3.3 Programme 3: Inspectorate and Regulatory Compliance

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

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

Sub-programmes

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

Outcomes:

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

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

PROGRAMME 3: INSPECTORATE AND REGULATORY COMPLIANCE								
Outcome	**Output**	**Output Indicator**	**Audited Actual Performance 2020/2021**	**Audited Actual Performance 2021/2022**	**Planned Annual Target 2022/2023**	**Actual Achievement 2022/2023**	**Deviation from Planned Target to Actual Achievement 2022/2023**	**Reasons for Deviations**
High levels of organisational operational efficiency and effectiveness in the regulatory function maintained (7)	New GMP and GWP related licences finalised	Percentage of new GMP and GWP related licenses finalised within 125 working days	Out of the 39 new GMP licence applications received, 29 (74%) new GMP licences were issued Out of the 29 new GMP licences issued, 17 (59%) were issued within 125 working days	42% new GMP and GWP related licenses finalised within 125 working days *Out of 64 new GMP and GWP related licences applications received, 31 (48%) were finalised. Out of the 31 finalised, 13 (42%), were finalised within 125 working days*	**60% new GMP and GWP related licenses finalised within 125 working days**	22% new GMP and GWP related licenses finalised within 125 working days. Out of 73 applications received, 54 (74%) were due for finalisation. Out of 54 due for finalisation, 28 (51%) were finalised, of which 12 (22%) were finalised within 125 workings days	Target missed by 38%	Limited human resources to conduct inspections timeously
	Permits finalised	Percentage of permits finalised within 20 working days		71% permits finalised within 20 working days *Out of 4 553 permit applications received, 4 474 (98%) were finalised. Out of the 4 474 finalised, 3 186 (71%) were finalised within 20 working days*	**70% permits finalised within 20 working days**	79% permits finalised within 20 working days. Out of 4 305 applications received, 4 285 (99.5%) were finalised, of which 3 406 (79%) were finalised within 20 working days	Target exceeded by +9%	Improved coordination and execution of the business process.

PROGRAMME 3: INSPECTORATE AND REGULATORY COMPLIANCE								
Outcome	**Output**	**Output Indicator**	**Audited Actual Performance 2020/2021**	**Audited Actual Performance 2021/2022**	**Planned Annual Target 2022/2023**	**Actual Achievement 2022/2023**	**Deviation from Planned Target to Actual Achievement 2022/2023**	**Reasons for Deviations**
	Regulatory compliance investigation reports	Percentage of regulatory compliance investigation reports produced within 30 working days	Out of the 101 health product quality complaints received, 84 (83%) were investigated and reports produced	72% health product quality complaints reports produced within 30 working days *Out of 130 health product quality complaints received, 93 (72%) reports were produced within 30 working days*	**70% regulatory compliance investigation reports produced within 30 working days**	72% regulatory compliance investigation reports produced within 30 working days 297 complaints received, 290 (97%) reports were produced, of which 215 (72%) were produced within 30 working days	Target exceeded by 2%	Improved coordination and execution of the business process.

Licencing

The Licensing unit showed continued improvement throughout the financial year. Issued Licence data are now publicly available on the SAHPRA website and are continuously updated. As a result of the WHO GBT benchmarking of SAHPRA, the Licensing unit has made progress towards ML4 indicator achievement with the maintenance of database for revoked, suspended, and cancelled licences. The unit also published a new guideline for the amendment of licences as well as a revision of all guidelines and forms previously published. The addition of technical resources at the beginning 2022 added to the efficiency of the unit and the ability for it to address the backlog of licence renewals and amendments in the 2022/2023 financial year. In an effort to improve the achievement of percentage of new GMP and GWP licences, the unit has conducted analyses of the business process, which has resulted in an improved application referral process to the Inspectorate for inspection of new licence applicants as well as the identification of resource constraints in the Inspectorate. In the latter half of the year, the Licensing unit was further capacitated with a seconded portfolio coordinator from the Health Products Authorisation programme. The additional resources have led to improved reporting timeline adherence, accuracy of portfolio of evidence and improved QMS. In the last quarter of the financial year, the Licensing unit issued its first Licence to Distribute Scheduled Substances. This licence enables wholesaler who import to import scheduled substances and sell to persons who may lawfully possess these substances. As a result of this, there will be better compliance to SAHPRA requirements at the ports of entry. The roll-out of this licensing framework is still in pilot stage with full implementation expected in the coming financial year.

Inspectorate

The start of the financial year saw the Inspectorate unit resume routine physical international inspections as a result of the lifting of global travel restriction. The Inspectorate, with the Pharmacovigilance unit, conducted the first pilot Good Pharmacovigilance Practice (GVP) inspections with reports issued to inspected sites in the second quarter of the year. The GVP inspections led to the publishing of SAHPRA's first Guidelines for Pharmacovigilance Systems and Pharmacovigilance Inspections. These new guidelines require Holders of Certificates of Registration to implement and maintain pharmacovigilance systems for the management of safety data and reporting to SAHPRA. The unit will continue to capacitate this area in the coming financial year.

The Inspectorate rate of review of new dossier applications remained constant through the financial year, with need identified for additional capacity in order to reduce the age of applications in the system from one year to six (6) months. It was identified that unit be capacitated as well to improve the percentage of new GMP and GWP-related licences issued within 120 working days. The lifting of travel restrictions has benefitted the unit in terms of making training opportunities available, especially for newly appointed inspectors. The Inspectorate unit was able to attend the 2023 Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme (PIC/S) Committee meeting held in Ireland, which also coincided with the celebration of the 50th Anniversary of PIC/S. The meeting also included a seminar on the implementation of ICH Q12. A SAHPRA delegation was also in attendance at a PIC/S Seminar on Risk Management, held in Brazil and two (2) inspectors were able to attend GMP training in Tanzania in February 2023. SAHPRA was also able to attend a workshop on the manufacturing of vaccines hosted by the United States Pharmacopeial Convention Promoting the Quality of Medicines Plus (USP PQM+) in Cape Town. Towards the end of the year, under the facilitation and aid of the USP's Promoting Quality of Medicines Plus programme, funded by the US Agency for International Development (USAID), the Good Wholesaling Practice inspectors and Inspectorate Manager, were trained in WHO-aligned Good Storage and Distribution Practices

in a five-day workshop. The workshop also included the demonstration and use of an electronic inspection tool which automates site risk determination and inspection report writing. The tool will be a considered for adoption and implementation through the proper SAHPRA channels. The tool represents an efficiency improvement to relieve administrative burden on inspectors.

Regulatory Compliance

During this financial year, several guidelines, systems and processes related to post-market surveillances were implemented in the Regulatory Compliance unit. The unit recruited and deployed 4 border medicines control technicians to oversee five (5) out of the seven (7) ports of entry for medicines in South Africa. In the second half of the year, an additional resource was recruited to cover the last two (2) remaining ports. The implementation of the presence of SAHPRA technicians at the port has been effective in highlighting import noncompliance, thus being an effective mechanism for the detection and prevention of substandard, falsified or unauthorised product.

SAHPRA developed and implemented a post market surveillance plan and, with the appointed of additional technical resource, was able to conduct sampling and testing of product sampled from the supply chain. The Regulatory Compliance unit revised and published its Guideline for Recalls and Withdrawals which included the communication of rapid alerts for product quality defects. SAHPRA initiated and communicated its first rapid alert under this framework, which included communication to global regulatory authorities. Furthermore, as the first implementation of SAHPRA's post-market surveillance plan related to the monitoring of marketing and promotional material, SAHPRA actively sampled and reviewed marketing and promotional material from the market.

SAHPRA has developed a better working relationship with its third party laboratory for testing of small molecules, as it increased sampling and testing as part of its implementation of the risk-based post-market surveillance sampling and testing plan. The above measures continue to assist SAHPRA's efforts to detect, prevent and remove substandard and falsified medicines, further strengthened by the addition of SAHPRA to the authorities in the WHO Rapid Alert Network in 2022. The lifting of travel restrictions facilitated an in-person workshop hosted by WHO in Johannesburg. The workshop dealt with substandard and falsified medicines and was attended by WHO-AFRO countries, thus allowing SAHPRA delegates to network and learn from other African regulators on the prevention, detection and response to substandard and falsified medicines.

Through the USP PQM+ programme, SAHPRA participated in a workshop in the third quarter of the year with USP PQM+ colleagues on improving the Post-Market Surveillance Plan. In the fourth quarter, SAHPRA established and held its first Post Market Surveillance Working Group meeting, with facilitation and aid from USP's Promoting Quality of Medicines Plus programme, funded by the US Agency for International Development (USAID). As part of the facilitation, a workshop was held with the members of the PMS WG around the adoption and implementation of an electronic risk-based PMS programme which would generate a risk based PMS Sampling Plan and Protocol for the year 2023/2024. This plan and protocol is an improvement on the plan and protocol developed in 2022/2023 year.

With respect to Cannabis, SAHPRA continued to be a major stakeholder in the interim measures identified by the Project Management office of the Presidency, with a focus on the medicines schedule inscriptions for limits for THC in industrial hemp. SAHPRA achieved a milestone in the fourth quarter in review of THC levels following engagements with stakeholders such as civil society, business, DALRRD and the Agricultural Research Council. SAHPRA is in the process of discussing possible changes to the schedules. In the fourth quarter, SAHPRA conducted various information

sharing sessions regarding cannabis and related substances. The Regulatory Compliance unit also participated at the 66th Session of the Commission on Narcotic Drugs and cemented the commitment of the country in terms of control of narcotic and psychotropic substances with various presentations that SAHPRA made during the session in Vienna.

3.3.2 Linking Performance with Budgets

2022/2023				2021/2022		
Programme	**Budget R'000**	**Actual Expenditure R'000**	**(Over)/Under Expenditure R'000**	**Budget R'000**	**Actual Expenditure R'000**	**(Over)/Under Expenditure R'000**
Programme 3	37 314	42 399	(5 085)	35 827	35 370	457
TOTAL	**37 314**	**42 399**	**(5 085)**	**35 827**	**35 370**	**457**

3.3.3 Strategy to overcome Areas of under Performance

To improve the operations at Ports of entries, measures have been put in place and prioritised appointment of personnel to be stationed at major Ports of entries. To ensure improved coordination at Ports of entries, SAHPRA has been engaging with relevant stakeholders such as The South African Revenue Services (SARS) and National Department of Health (Port Health).

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

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

3.4 Programme 4: Clinical and Pharmaceutical Evaluation

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

Sub-programmes

Sub-Programme	Purpose
Clinical Evaluation	To evaluate the safety and efficacy of orthodox medicines
Clinical Trials	To evaluate clinical trial applications of orthodox medicines, complementary medicines and medical devices to ensure that the trial to be conducted is scientifically sound in accordance with the South African Good Clinical Practice guidelines and to ensure safety and protection of rights of patients
Pharmaceutical Evaluations	To perform pharmaceutical and analytical evaluations of new and registered medicines inclusive of clinical aspects of veterinary medicines and biological
Authorisation of the Sale of Unregistered Medicines	To conduct an abbreviated evaluation of applications to authorise the sale of unregistered medicines based on 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 safety, quality and efficacy and to register and/or regulate them for use where applicable
Veterinary Medicines	To evaluate the safety, efficacy and quality of veterinary medicines.

Outcomes:

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

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

PROGRAMME 4: MEDICINE EVALUATION AND REGISTRATION								
Outcome	**Output**	**Output Indicator**	**Audited Actual Performance 2020/2021**	**Audited Actual Performance 2021/2022**	**Planned Annual Target 2022/2023**	**Actual Achievement 2022/2023**	**Deviation from Planned Target to Actual Achievement 2022/2023**	**Reasons for Deviations**
High levels of organisational operational efficiency and effectiveness in the regulatory function maintained (7)	Applications for the sale of unregistered Category A (human) medicines finalised	Percentage applications for the sale of unregistered Category A (human) medicines finalised within 3 working days	Out of the 19 346 applications for the sale of unregistered Category A (human) medicines – Section 21 received, 17 658 (91%) were finalised Out of the 17 658 applications finalised, 16 182 (92%) were finalised within 24 working hours	63% applications for the sale of unregistered Category A (human) medicines finalised within 24 working hours *Out of the 16 435 applications received, 14 780 (90%) were finalised, of which 9 385 (57%) were finalised 24 working hours*	**85% applications for the sale of unregistered Category A (human) medicines finalised within 3 working days**	87% of applications finalised within 3 working days. *Out of 169409 received and responded to, 15 918 were finalised with 14 784 (87%) applications finalised within 3 working days*	Target exceeded by 2%	Due to reviewed Business process that have shown efficiencies and additional resources.

PROGRAMME 4: MEDICINE EVALUATION AND REGISTRATION								
Outcome	**Output**	**Output Indicator**	**Audited Actual Performance 2020/2021**	**Audited Actual Performance 2021/2022**	**Planned Annual Target 2022/2023**	**Actual Achievement 2022/2023**	**Deviation from Planned Target to Actual Achievement 2022/2023**	**Reasons for Deviations**
	Human clinical trial applications finalised	Percentage of human clinical trial applications finalised within 90 working days	Out of the 233 human clinical trial applications received, 203 (87%) were finalised Out of the 203 applications finalised, 194 (96%) were finalised within 120 working days	95% human clinical trial applications finalised within 90 working days *Out of 274 human clinical trial applications received, 248 (91%) were finalised. Out of the 248 finalised, 235 (95%) were finalised within 90 working days*	**80% human clinical trial applications finalised within 90 working days**	104% human clinical trial applications finalised within 90 working days *Out of 239 applications received, 163 (68%) were due for finalisation* *Out of 163 due for finalisation, 184 (113%) were finalised, of which 169 (104%) were finalised within 90 workings days*	Target exceeded by 24%	Due to reviewed Business process that have shown efficiencies

PROGRAMME 4: MEDICINE EVALUATION AND REGISTRATION								
Outcome	**Output**	**Output Indicator**	**Audited Actual Performance 2020/2021**	**Audited Actual Performance 2021/2022**	**Planned Annual Target 2022/2023**	**Actual Achievement 2022/2023**	**Deviation from Planned Target to Actual Achievement 2022/2023**	**Reasons for Deviations**
	Health product safety signals issued	Percentage of reports on health product safety signals issued within 40 working days	Out of the 86 health product safety signals identified, all 86 (100%) were actioned (investigated and finalised) Out of the 86 health product safety signals actioned, 37 (43 %) were actioned within 20 working days	69% reports on health product safety signals issued within 40 working days *Out of the 235 applications received, 95 (40%) reports were issued, of which 66 (28%) were issued within 40 working days*	**70% reports on health product safety signals issued within 40 working days**	Out of 298 signals received, 251 (84.2%) signals were due for finalisation. Out of 251 signals due for finalisation, 169 (67.3%) reports were issued, of which 101 (40.2%) were issued within 40 working days	Target missed by 30%	Insufficient human resource
	Safety awareness webinars held	Number of safety awareness webinars held	-	13 safety awareness webinars held	**4 safety awareness webinars held**	Six safety webinars on medication errors was held in 2023)	Target exceeded	The unit is currently promoting pharmacovigilance awareness as per the WHO benchmarking.

PROGRAMME 4: MEDICINE EVALUATION AND REGISTRATION								
Outcome	**Output**	**Output Indicator**	**Audited Actual Performance 2020/2021**	**Audited Actual Performance 2021/2022**	**Planned Annual Target 2022/2023**	**Actual Achievement 2022/2023**	**Deviation from Planned Target to Actual Achievement 2022/2023**	**Reasons for Deviations**
	Lot release requests finalised	Percentage of lot release requests finalised within 30 working days	-	-	**95% of lot release requests finalised within 30 working days**	81%, From a total number of 226 lot release requests received since the commencement of the SAHPRA lot release process to the 31st of March 2023, 182 (81%) were due for finalisation. Out of 182 due for finalisation, 192 (105.50%) were finalised – including 20 that were not due for finalisation, of which 147/192 (76.5%) were finalised within 30 working days. Although it appears that 147 were finalised on time, only 127 (75%) were finalised within 30 working days (note 20 were not due for finalisation). Hence, 147/182*100 = 80.76% rounded off to 81% is reported as performance.	Target missed by 14% (below target)	The products require longer testing periods.

Lot Release

Lot release is a process whereby a batch (lot) of registered or authorised vaccines in South Africa are subjected to testing to confirm their potency, sterility, identity and verification of compliance with regulatory requirements. The lot release was previously conducted by the South African National Control Laboratory (SANCL) as a contracted laboratory to SAHPRA. The process for lot release through SAHPRA was implemented with effect from 1 June 2022. The process as piloted in June 2022 was implemented fully in Q2.

In October 2022, WHO announced that SAHPRA has achieved ML3 for vaccines and ML4 for Lot release which demonstrates that for Lot Release activity SAHPRA with the SANCL is operating at an advanced level, is well-functioning and is continuously improving. In Q4, SAHPRA has achieved 81% of lot releases from an expected 95%, which is an improvement from Q3 (73%). It was realised that some vaccines have longer testing times which would require more than 30 working days for testing and hence affect the target. The target has been revised to suit the vaccine testing times for 2023-24. It is to be noted that during November 2022, a new submission approach using the Quantum system was introduced as a pilot process for Lot Release. The pilot is completed and has demonstrated improvement in tracking of applications and will be implemented from the next cycle.

3.4.2 Linking Performance with Budgets

2022/2023				2021/2022		
Programme	Budget R'000	Actual Expenditure R'000	(Over)/Under Expenditure R'000	Budget R'000	Actual Expenditure R'000	(Over)/Under Expenditure R'000
Programme 4	100 293	108 496	(8 203)	92 962	80 402	12 560
TOTAL	**100 293**	**108 496**	**(8 203)**	**92 962**	**80 402**	**12 560**

3.4.3 Strategy to overcome Areas of under Performance

In the case of Lot Release, there are cases of not meeting the 30-working day timeline which was predominantly as a result of testing times being longer for some vaccines, which may take up to 46 days, hence the new APP target has been changed to align with testing times.

The completion of the SAHRPA Service Desk pilot has shown improved traceability with the Lot Release applications, sharing of information with both SANCLBP simultaneously, thereby reducing time delays and hence improved performance target.

The processing of emerging health product safety signals is still underperforming. The 70% finalisation target within 40 working days was under-achieved by 30% (40.2%). The necessary technical human resources are being recruited and trained. To date two (2) technical staff have been recruited and trained and one (1) is being recruited. An increase in trained resources will greatly improve performance in this area.

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

Programme	Intervention	Geographic Location (Province/ District/ Local municipality) (Where Possible)	No. of Beneficiaries (Where Possible)	Disaggregation of Beneficiaries (Where Possible)	Total Budget Allocation per Intervention (R'000)	Budget Spent per Intervention	Contribution to the Outputs in the APP (Where Applicable)	Immediate Outcomes
Programme 4	COVID-19 update meetings with SAHPRA staff (vaccine safety)	Pretoria, Cape Town and Durban	+- 319	N/A	Operational Budget	Operational Budget	N/A	N/A
Programme 4 (CEM)	27 approvals for compassionate use of remdesivir were granted during the 4th quarter	National	27	N/A	Operational Budget	Operational Budget	N/A	N/A
Programme 4 (CEM)	90% of 30 Covid-19 clinical trial protocol applications were finalised within 90 working days	National	NA	N/A	Operational Budget	Operational Budget	N/A	N/A

Performance of PEM units with respect to vaccines and therapeutic agents are aligned with the Public Health Emergency (PHE) guideline developed as a result of the COVID-19 pandemic whereby all COVID -19 applications for registration, applications for variations and Lot release are treated with priority (where in case of Lot release the Lot release certification and testing performed by other National control Labs that SAHPRA aligns with are used as reliance or recognition of work done) hence using reliance mechanisms in reducing timelines.

Utilisation of rolling review and reliance on reports from agencies/organisations that SAHPRA aligns with enables shorter timelines. Engaging with other Regulators and signing MoUs with them to facilitate reliance and work sharing were some initiatives engaged in.

3.5 Programme 5: Medical Devices and Radiation Control

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

Sub-programmes

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

Outcomes:

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

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

PROGRAMME 5: MEDICAL DEVICE, DIAGNOSTICS AND RADIATION CONTROL								
Outcome	**Output**	**Output Indicator**	**Audited Actual Performance 2020/2021**	**Audited Actual Performance 2021/2022**	**Planned Annual Target 2022/2023**	**Actual Achievement 2022/2023**	**Deviation from Planned Target to Actual Achievement 2022/2023**	**Reasons for Deviations**
High levels of organisational operational efficiency and effectiveness in the regulatory function maintained (7)	Medical device establishment licence applications finalised	Percentage of medical device establishment licence applications finalised within 90 working days	Out of the 1 116 medical devices establishment licence applications received, 757 (68%) were finalised Out of the 757 applications finalised, 629 (83%) were finalised within 90 days	76% medical device establishment licence applications finalised within 90 days. *Out of 1 105 medical device establishment licence applications received, 804 (73%) were finalised. Out of the 804 finalised, 613 (76%) were finalised within 90 working days*	**70% medical device establishment license applications finalised within 90 working days**	136% medical device establishment licence applications finalised within 90 working days Out of 1 379 applications received, 692 (50%) were due for finalisation Out of the 692 due for finalisation, 1206 (174%) were finalised, of which 943 (136%) were finalised within 90 working days	**66% above target** 1. Worked on closing all applications and renewals within the time frame. 2. Closed all old applications. 3. Quality checks implemented on all applications received but not allocated. **Appointment of additional staff in the licensing unit**	Well established business processes resulted in efficiencies.

PROGRAMME 5: MEDICAL DEVICE, DIAGNOSTICS AND RADIATION CONTROL								
Outcome	**Output**	**Output Indicator**	**Audited Actual Performance 2020/2021**	**Audited Actual Performance 2021/2022**	**Planned Annual Target 2022/2023**	**Actual Achievement 2022/2023**	**Deviation from Planned Target to Actual Achievement 2022/2023**	**Reasons for Deviations**
	Medical device registration regulations implemented	Medical device registration regulations implemented	The draft regulations, which will form part of the medical registration framework were re-submitted to the State Law Adviser for review in September 2020	19 guidelines to support the medical device registration regulations were drafted	**7 guidelines to support the medical device registration regulations published**	Guidelines have been placed on hold until the regulations are finalised from NDOH	Target not achieved	While awaiting publication of regulations by NDOH. All guidelines due for comment are currently under review for preparation once the regulations are finalised

PROGRAMME 5: MEDICAL DEVICE, DIAGNOSTICS AND RADIATION CONTROL								
Outcome	**Output**	**Output Indicator**	**Audited Actual Performance 2020/2021**	**Audited Actual Performance 2021/2022**	**Planned Annual Target 2022/2023**	**Actual Achievement 2022/2023**	**Deviation from Planned Target to Actual Achievement 2022/2023**	**Reasons for Deviations**
	Radionuclide authorities finalised	Percentage of applications for radionuclide authorities finalised within 30 working days	Out of the 2 719 new application licences for ionizing radiation emitting devices and radioactive nuclides authorities received, 2 519 (92%) were issued	72% applications for radionuclide authorities finalised within 30 working days *Out of 4 740 applications for radionuclide authorities received, 3 803 (80%) were finalised. Out of the 3 803 finalised, 2 747 (72%) were finalised within 30 working days*	**50% applications for radionuclide authorities finalised within 30 working days**	83% applications for radionuclide authorities were finalised within 30 working days Out of the 2742 applications received 2380(86%) were due for finalisation. Out of 2380 due for finalisation 2384(100%) were finalised of which 1985(83%) were finalised within 30 working days.	Target exceeded by 33%	Well established business processes resulted in the efficient processing of the license applications and addition of team members (Technical) who assisted with review of application

PROGRAMME 5: MEDICAL DEVICE, DIAGNOSTICS AND RADIATION CONTROL								
Outcome	**Output**	**Output Indicator**	**Audited Actual Performance 2020/2021**	**Audited Actual Performance 2021/2022**	**Planned Annual Target 2022/2023**	**Actual Achievement 2022/2023**	**Deviation from Planned Target to Actual Achievement 2022/2023**	**Reasons for Deviations**
	Licence applications for listed-electronic products finalised	Percentage of licence applications for listed-electronic products finalised within 30 working days	Out of the 2 519 issued, 2 302 (91%) were issued within 30 working days	99% licence applications for listed-electronic products finalised within 30 working days *Out of 944 licence applications for listed-electronic products received, 934 (99%) were finalised. Out of the 934 finalised, 924 (99%) were finalised within 30 working days*	**70% license applications for listed-electronic products finalised within 30 working days**	169% licence applications for listed-electronic products were finalised within 30 working days Out of 1115 applications were received, of which 627 (56%) were due for finalisation. Out of 627 due for finalisation, 1115 (178%) were finalised of which 1057 (169%) were finalised within 30 working days	Target exceeded by 99%	Well established business processes resulted in the efficient processing of the license applications
	Co-Regulation Model	Approved Co-Regulation Model	-	Terms of Reference with the National Nuclear Regulator was signed. Draft Cooperate Governance and Co-Regulation Recommend-ation were developed	**Board approved Co-Regulation Model with the National Nuclear Regulator**	Co-regulation Model is submitted to the EXCO for review and approval	Target not achieved	Unavailability of resources to finalise the projects

Medical Devices and Radiation Control maintained its visibility through the formalising of strategic partnerships with stakeholders, such as SANAS, applying for the IMDRF affiliate membership.

Medical Devices

The unit managed to facilitate a number of workshops and webinars, as well as presenting at industry conferences, including but not limited to; the Conformity Assessment Bodies (CABs) workshop, the WHO 10th Annual meeting on collaborative registration processes (CRP), WHO Advocacy and sensitisation workshop on collaborative registration procedure (CRP) and emergency use listing (EUL) of WHO prequalified and listed in-vitro diagnostics in SADC held In Namibia. The unit also became more pro-active by making use of social media communication to broadcast new and/or updated information, addressing matters of concerns, and sending reminders, and presenting at the Health Technology Assessment Workshop.

An expert committee started reviewing COVID 19 self-test kits applications, with 4 test kits approved. The Medical Devices unit has recognised to date five (5) CABs following the workshop in October 2022.

The backlog on the application of establishment licences, which started during the COVID-pandemic, was cleared at the end of February 2023, because of the filling of vacant posts, re-focusing of functions to ensure efficiency in the unit and transfer of skills. SAHPRA continues to actively participate and contribute to various forum such as the Africa Medical Device Forum (AMDF) and Health Technology Assessment committee.

The adoption of digital solutions remains imperative to ensure the efficient functioning of the regulation of medical devices.

Radiation Control

Radiation control is continuing to implement business process that resulted in efficient processing of applications and issuing of licences. The achievements are an indication that regulatory framework for radionuclides and listed-electronic products licensing has been effective and ensure compliance monitoring of licence and authority holders across the entire country. Thirty-four (34) guidelines were published for the financial year. A Radiation Control expert committee has been put in place and support the Radiation control with Regulatory related matters.

The Radiation Control Unit underwent an intensive introductory training on the Regulatory Authority Information System (RAIS)+, which is an information system developed by the International Atomic Energy Agency (IAEA) to support Member States. SAHPRA is one of the regulatory bodies identified by IAEA to pilot the RAIS+ Project which aims to assist with the management of regulatory activities and functions. Furthermore, the unit hosted a successful webinar as part of stakeholder engagement with inspection bodies responsible for the inspection of diagnostic X-ray machines.

SAHPRA is actively participating in various regional workshops and the Radiation Control Manager was selected as the SADC region coordinator for the Forum of Nuclear Regulatory Bodies in Africa (FNRBA). The FNRBA‘s objective is to be catalysing the enhancement, strengthening and harmonisation of radiation and nuclear safety and security regulatory infrastructure in member states and serve as effective platform for the exchange of regulatory experiences and practices among the nuclear regulatory bodies in Africa. The Unit has also been participating in various trainings offered by the IAEA.

3.5.2 Linking Performance with Budgets

2022/2023				2021/2022		
Programme	Budget R'000	Actual Expenditure R'000	(Over)/Under Expenditure R'000	Budget R'000	Actual Expenditure R'000	(Over)/Under Expenditure R'000
Programme 5	32 399	33 144	(745)	39 717	34 290	5 427
TOTAL	**32 399**	**33 144**	**(745)**	**39 717**	**34 290**	**5 427**

3.5.3 Strategy to overcome Areas of under Performance

Medical device registration regulations, additional capacity was appointed to ensure the speedy finalisation of the regulations. The Regulations were submitted to the National Department of Health to be published in November of 2022 for the second round of public comment/s and Rigorous follow-will be done by the office of the CEO and CRO with the office of the Minister with proposed date towards publication by Q1. Policies, guidelines, and SOPs to manage the internal and external engagements were developed. The additional members to the technical expert committee will assist with the implementation of the policies, regulations, and guidelines. It is anticipated that the co-regulations between SAHPRA and the National Nuclear Regulator will be completed during the 2023/24 financial year. Feedback on progress will be requested from the working group on a regular basis.

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

Programme	Intervention	Geographic Location (Province/ District/ Local municipa-lity) (Where Possible)	No. of Beneficiaries (Where Possible)	Disaggregation of Beneficiaries (Where Possible)	Total Budget Allocation per Interven-tion (R'000)	Budget Spent per Interven-tion	Contribution to the Outputs in the APP (Where Applicable)	Immediate Outcomes
Programme 5	Employed a Covid 19 Evaluation committee to evaluate Covid 19 medical devices applications	National	7 CEC members	N/A	N/A	Operational budget	Maximum of 5applications reviews per month and at least one meeting is held once a week. The number of application has decreased for the financial year.	22 antigen test kits approved ;25 molecular test kits , 5 serological test kits and 7 self-test kits

4. REVENUE COLLECTION

2022/2023				2021/2022		
Sources of Revenue	Estimate R'000	Actual Amount Collected R'000	(Over)/Under Collection R'000	Estimate R'000	Actual Amount Collected R'000	(Over)/Under Collection R'000
Fee income	170 037	197 351	(27 314)	162 264	169 450	(7 186)
TOTAL	**170 037**	**197 351**	**(27 314)**	**162 264**	**169 450**	**(7 186)**

Better than anticipated revenue collection occurred due to new medicine registration percentage completion reached for certain applications. Revenue recognition will improve as SAHPRA fills funded vacancies in the 2023/24 financial year.

5. CAPITAL INVESTMENT

2022/2023				2021/2022		
Infrastructure Projects	Budget R'000	Actual Expenditure R'000	(Over)/Under Expenditure R'000	Budget R'000	Actual Expenditure R'000	(Over)/Under Expenditure R'000
None						
TOTAL						

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

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

A significant portion of SAHPRA's assets for the 2022/23 financial year comprises newly acquired assets. These acquisitions amounted to R8.1 million on 31 March 2023. The new acquisitions include other fixed assets (R119 689), computer equipment (R3 458 193), furniture (R1 294 519), motor vehicles (R2 317 812) and intangible assets (R626 750). The disposals for the year comprised old furniture and computer equipment which were transferred from NDoH and were no longer in use or had been replaced, which were either sold or donated. A significant portion of these assets was fully depreciated.

SAHPRA

PART C

GOVERNANCE

1. INTRODUCTION

The Board and its four (4) committees reviewed the systems and processes of the organisation timeously. They recognised the role of governance as critical to the efficient and effective functioning of the Regulator. The Board provided assurance to the Authority's stakeholders that strengthening the existing framework for governance and compliance remained high on SAHPRA's agenda.

2. PORTFOLIO COMMITTEES

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

- 20 April 2022 | Briefing by SAHPRA on the Annual Performance Plan and Budget for 2022/23 financial year
- 13 October 2022 | Briefing by SAHPRA on Annual Report for 2021/22 financial year
- 17 April 2023 | Briefing on SAHPRA's Annual Performance Plan and Budget for 2023/24 financial year

3. EXECUTIVE AUTHORITY

The Regulator submits quarterly reports on its performance and activities to the Executive Authority as mandated by the Medicines Act and Public Finance Management Act. In addition, the Executive Authority was briefed on these matters:

- SAHPRA's progress on the registration of COVID-19 vaccines. There were a few engagements that culminated in SAHPRA's participation in various COVID-19 structures.
- The clearing of backlog applications.
- WHO benchmark assessment conducted in September 2022.
- WHO announced vaccines regulatory system of South Africa achieved ML3, effective from 23 September 2022.
- Expert committee started reviewing COVID 19 self-test kits applications.
- The approval of X-ray inspection bodies list available on the website with effect from 7 September 2022. The majority of trials received were in the oncology area, followed by COVID-19 trials.
- The VigiFlow system has been integrated into the clinical trial safety data management system.
- SAHPRA and the National Control lab obtained ML4 for the lot release function.

4. THE ACCOUNTING AUTHORITY/ BOARD

The Board is the Accounting Authority in terms of the PFMA and is appointed for a renewable period of three years by the Minister of Health in terms of the Medicines Act. The Minister appointed the SAHPRA Board in October 2021 in compliance with Section 2C(a-f), however, in 2023 six (6) previous members were retained for continuity. The term of the board expires on 30 September 2024. The Regulator is governed and controlled in accordance with the Medicines Act No. 101 of 1965, as amended. The Board ensures compliance with the Medicines Act. During the period under review, a board evaluation will be conducted by LKA Advisory and Assurance Services (Pty) Ltd.

The role of the Board

The Board carries out and exercises general oversight over the performance of the Regulator's functions. The Board embraces the principles of good corporate governance and considers these as the underlying philosophy towards creating organisational excellence at all levels within the Regulator. The Board sets the tone in driving the ethics of good governance and members collectively, and individually acknowledging their responsibilities and duties in terms of governance, regulatory and legislative requirements.

Board Charter

The Board has approved its charter as an overall guiding tool for execution of its mandate. The charter sets out the responsibilities of members and procedures for meetings. The Board resolved to review the charter on an annual basis to ensure that it remains relevant and during the 2022/23 financial year, the charter was reviewed in May 2022.

Composition of the Board

Name	Designation (in terms of the Public Entity Board structure)	Date Appointed	Date Resigned	Qualifications	Area of Expertise	Board Directorships (List the Entities)	Other Committees or Task Teams	No. of Meetings Attended
Prof. Helen Rees	Chairperson	October 2021	N/A	Harvard Business School Senior Executive Programme Member of the Royal College of General Practitioners Doctor Instructor for Family Planning Diploma of Child Health Diploma of the Royal College of Obstetricians and Gynaecologists UK M.A Social and Political Sciences; MB BChir	Clinical trials	N/A	N/A	24
Dr Obakeng Masondo	Vice Chair	October 2021	N/A	MBCHB Bachelor of Surgery; Diploma in HIV Management Postgraduate in Occupational Medicine	Medical research and clinical trials	N/A	RAG HRRemco	22

Name	Designation (in terms of the Public Entity Board structure)	Date Appointed	Date Resigned	Qualifications	Area of Expertise	Board Directorships (List the Entities)	Other Committees or Task Teams	No. of Meetings Attended
Mr Norman Baloyi	Member	October 2021	N/A	Master of Science in Electronics (Information Security, Computer Networks) Master of Science in Electrical Engineering (Telecommunication) B.Sc. Honours in Computational and Applied Mathematics Higher Diploma in Computer Auditing Bachelor of Science (B.Sc.) in Computer Science and Information Systems; B.Sc. Mathematics and Computational & Applied Mathematics Diploma in Network Security Diploma in Datametrics (Computer Science) Certified Information Systems Auditor Certified Information Systems Security Professional Certified Information Security Manager	Information technology	N/A	Finance HRRemco Technical Oversight and Regulatory Strategy Committee (TORS)	22
Ms. Lerato Mothae	Member	October 2021	N/A	Bachelor of Accounting CTA (B.Compt Honours CA (SA)	Finance and Accounting	N/A	RAG Finance	17

Name	Designation (in terms of the Public Entity Board structure)	Date Appointed	Date Resigned	Qualifications	Area of Expertise	Board Directorships (List the Entities)	Other Committees or Task Teams	No. of Meetings Attended
Mr. Itani Mashau	Member	October 2021	N/A	B Pharm Diploma in Production Diploma in Q Management and Q Assurance Masters of Business Administration Diploma in Small Business Management	Good Manufacturing Practice	N/A	TORS HRRemco	20
Prof. Patrick Demana	Member	October 2021	N/A	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	20
Adv. Hasina Cassim	Member	October 2021	N/A	B Pharm LLB Certificate in Medicine Law Certificate in Pharmacoepidemiology Medical Mediation training	Law	N/A	RAG TORS	17
Ms Mandisa Skhosana	Member	October 2021	N/A	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	21

Name	Designation (in terms of the Public Entity Board structure)	Date Appointed	Date Resigned	Qualifications	Area of Expertise	Board Directorships (List the Entities)	Other Committees or Task Teams	No. of Meetings Attended
Prof. Joyce Tsoka-Gwegweni	Member	October 2021		B.A. Hons (Social Science & Psychology) B.Sc. Hons-Zoology & Microbiology Ph.D. in Public Health MPH in Public Health	Public health medicine	N/A	TORS	11
Dr Xolani Ngobese	Member	October 2021	N/A	Ph.D. in Business Administration Master's in Business Administration	Independent consultant	N/A	HRRemco Finance	22
Ms Lucy Ditaba Maraka	Member	October 2021	N/A	Bachelor of Arts Bachelor of Education Baccalaureus Atium Honores Master's Diploma in HR Training and Development Ethics Officer Certification Psychometrist Effective Audit Committees Effective Remuneration Committees Social & Ethics Committees	Independent Psychometrist	N/A	HRRemco	21
Dr Alfred Kgasi	Member	December 2021	N/A	Bachelor of Veterinary Medicine LLB Master's of Business Leadership	Veterinary	N/A	TORS	22

Name	Designation (in terms of the Public Entity Board structure)	Date Appointed	Date Resigned	Qualifications	Area of Expertise	Board Directorships (List the Entities)	Other Committees or Task Teams	No. of Meetings Attended
Dr Zinhle Makatini	Member	December 2021	N/A	BSc (Honours) Biochemistry Masters in Immunology of Infectious Diseases MBChB Ph.D. Virology Registrar in Virology Diploma in Travel Medicine Diploma in Tropical Medicine Diploma in HIV Management in the Workplace Diploma in HIV Management MMED in Biostatistics & Epidemiology (completed2/3) Ph.D. in Medical Virology	Virology	N/A	TORS	21
Prof. Yahya Choonara	Member	December 2021	N/A	BPharm MPharm Ph.D.	Medical devices	N/A	TORS	16
Prof. Johanna Meyer	Member	December 2021	N/A	BPharm MSc (Med) Ph.D. in Pharmacy	Pharmacovigilance Public Health	N/A	TORS	19

Committees

Committee	No. of Meetings Held	No. of Members	Name of Members
Finance Committee	6	3	Ms Lerato Mothae Mr Norman Baloyi Dr Xolani Ngobese
Technical Oversight and Regulatory Strategy Committee	5	9	Prof. Johanna Meyer Prof. Patrick Demana Adv. Hasina Cassim Mr. Itani Mashau Dr Alfred Kgasi Ms Mandisa Skhosana Dr Zinhle Makatini Prof. Yahya Choonara Prof. Joyce Tsoka-Gwegweni
Risk Audit and Governance Committee	6	9	Ms Lerato Mothae Adv. Hasina Cassim Ms Yongama Pamla (External member) Mr. Bruce Gordon (External member) Mr. Edward Okaro Omolo (External member)
Human Resources and Remuneration Committee	17	5	Mr. Itani Mashau Dr Xolani Ngobese Dr Obakeng Kaole Ms Lucy Ditaba Maraka Mr. Norman Baloyi

Remuneration of Board Members

Name	Remuneration	Other Allowance	Other Re-imbursements	Total
Prof. Helen Rees	190 992	-	-	190 992
Dr Obakeng Khaole	280 074	-	-	280 074
Mr. Norman Baloyi	209 150	-	-	209 150
Ms Lerato Mothae	268 541	-	-	268 541
Mr. Itani Mashau	228 429	-	-	228 429
Prof. Patrick Demana	96 025	-	-	96 025
Adv. Hasina Cassim	124 999	-	-	124 999
Ms Mandisa Skhosana	148 305	-	-	148 305
Prof. Joyce Tsoka-Gwegweni	79 091	-	-	79 091
Dr Alfred Kgasi	150 167	-	-	150 167
Dr Zinhle Makatini	-	-	-	-
Dr Xolani Ngobese	293 385	-	-	293 385
Ms Lucy Ditaba Maraka	226 654	-	-	226 654
Prof. Yahya Choonara	69 764	-	-	69 764
Prof. Johanna Meyer	96 950	-	-	96 950

5. RISK MANAGEMENT

- SAHPRA recently reviewed and approved the Risk Management Policy and Framework to ensure that both are still relevant in addressing the emerging risks and the trends.
- Risk assessments are conducted annually and reviewed quarterly across the Authority in their respective levels, i.e., strategic and operational. Risk assessments are not limited to being conducted annually. When the need arises or a significant change happens, risks will be reviewed, updated and communicated to the relevant governance structures.
- SAHPRA's Risk, Audit and Governance Committee (RAG) is an independent committee responsible for oversight of SAHPRA's control, governance, and risk management.
- The RAG provides an independent and objective view of SAHPRA's risk management effectiveness. The committee's role amongst others, entails setting an appropriate tone by supporting and monitoring effective risk management initiatives and system.
- Risk Management maturity within SAHPRA has improved since the last year, as the risk management activities are now embedded in the Authority's operations. Risk Management maturity will be assessed regularly to highlight improvement areas.

6. INTERNAL CONTROL ENVIRONMENT

- SAHPRA management is responsible for the implementation and maintenance of internal controls in their respective units and the entire Authority. SAHPRA continues to strengthen the internal control environment through the development and review of the governing documents, such as guidelines, policies and standard operating procedures, in line with the Quality Management System (QMS).
- In addition, the Internal Audit function also plays a role in the assessment of the adequacy and effectives of the existing internal controls. This work ensures the identification of gaps and the required interventions to improve the control environment.

7. INTERNAL AUDIT AND AUDIT COMMITTEES

Name	Qualifications	Internal or External	If Internal, Position in the Public Entity	Date Appointed	Date Resigned	No. of Meetings Attended
Ms Lerato Mothae	Bachelor of Accounting CTA B.Compt Honours CA	Internal	Board Member	01 October 2021	N/A	9
Adv. Hasina Cassim	B Pharm LLB. Certificate in Medicine Law Certificate in Pharmacoepidemiology Medical Mediation training	Internal	Board Member	01 October 2021	N/A	8

Name	Qualifications	Internal or External	If Internal, Position in the Public Entity	Date Appointed	Date Resigned	No. of Meetings Attended
Ms Yongama Pamla	BComm (Accounting) Postgraduate Diploma in Accounting (CTA) Postgraduate Diploma in Management (Financial Accounting)	External	N/A	01 April 2022	N/A	6
Mr. Edward Okaro Omolo	BComm MBA CPA CA	External	N/A	01 April 2022	09 September 2022	6
Mr. Bruce Gordon	B.Compt (Hons) CA	External	N/A	01 April 2023	N/A	7

- Internal Audit is expected to conduct amongst others, audits on operations of finance, ICT, performance information and any other special assignments and investigations on behalf of the CEO and the RAG.

- Performance of these assists function to provide the required independent assurance on the risk and control environment of SAHPRA. The internal audit function was previously within SAHPRA but has been outsourced for the 2022/23 financial year to implement the annual coverage internal audit plan as confirmed and approved by RAG, with the responsibility to provide assurance on work performed.

- The key activities for the function entailed scope of work conducted, as well as assessment of internal controls in operations, and support functions. A risk-based approach was used to select the focus areas requiring assurance.

- The development of a risk-based three-year rolling Internal Audit Plan together with the Annual Plan, where the plans also indicated the scope, cost and timelines of each planned audit assignment.

- The reporting on the performance and progress against the plan to allow effective monitoring and intervention, when necessary; and

- Co-ordination with both internal and external providers of assurance to ensure proper coverage and minimal duplication of effort.

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

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

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

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

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

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

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

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

During the 2022/23 financial year, RAG conducted the following activities but not limited to:

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

8. COMPLIANCE WITH LAWS AND REGULATIONS

Adherence and compliance to applicable laws and regulations remain a Board priority as the organisation finds its feet. As a Schedule 3A public entity, SAHPRA is governed by the PFMA, and National Treasury Regulations published under the PFMA and other legislative prescripts. Compliance is an ongoing activity within the organisation and monitoring of any non-compliance with legislative regulations resides with the office of the Board Secretary and the respective Executive Authority. Compliance is tracked regularly by the respective Executive and where non-compliance is noted, corrective actions are immediately developed.

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

9. FRAUD AND CORRUPTION

- SAHPRA has developed and implemented a robust fraud prevention strategy which assists the Authority to combat fraud and corruption through deterrence initiatives, multiple reporting channels, strengthening of controls and monitoring risks identified. Currently, the Authority has a fraud prevention policy and strategy which guides the initiatives, together with the operational platforms aimed at fighting misappropriations.
- SAHPRA launched its Whistleblowing hotline in September 2021 and is still maintaining it. The hotline was initiated as a managements' responsibility to protect anyone who wants to report misappropriation within SAHPRA, without disclosing their identity. As mentioned above, SAHPRA has other various reporting channels which can be used to report fraud, contraventions, and complaints. With all these

channels, reported cases are recorded and forwarded to the relevant units for further investigations and feedback.

- Feedback on all reported cases and their outcomes will be reported to RAG on a quarterly basis, or as required. The reports will be presented at a high level, however, where further details are required, these can be furnished. Management will report on all suspensions, disciplinary or criminal proceedings instituted, in cases of financial misconduct.

10. MINIMISING CONFLICT OF INTEREST

The Board has approved a Management of Conflict of Interest Policy and has procedures in place to manage issues of conflict of interest (perceived, potential or actual) to minimise if not prevent them. Board members, SAHPRA's Executive Committee and senior management are required to disclose financial interests on an annual basis. The disclosures are meant to ensure that there is no conflict of interest when decisions are made by anyone within SAHPRA's governance structures. Furthermore, at every Board meeting, members sign a declaration of interest form, and these are captured as standing agenda items for discussion to identify any conflict, while members recuse themselves from the meeting during the discussion of the item of conflict. SAHPRA employees also complete an annual declaration of any interest. This approach is also extended to the external evaluators and the Chief Executive Officer's committee's members.

11. CODE OF CONDUCT

SAHPRA is committed to an exemplary standard of business ethics and transparency in all its dealings with stakeholders. Board members and employees are bound by a code of conduct. Gifts received, if accepted, are declared in line with good corporate governance and the gift declaration policy.

12. HEALTH, SAFETY AND ENVIRONMENTAL ISSUES

During this reporting period, SAHPRA continued to implement planned OHS management activities. These activities entailed effectively identifying and mitigating Safety, Health and Environmental (SHE) risks through ensuring ongoing SHE compliance and training. OHS quarterly meetings were held, and all compliance measures are up to date. The OHS Audits were also conducted, and all audit reports were submitted to the COO and the CEO respectively. SAHPRA continues to demonstrate commitment to the health and safety of its employees through its occupational health and safety structures. This is to ensure that it creates a conducive environment for all staff members.

SAHPRA regards a proper working environment as key to service delivery. It, therefore, has an approved Occupational Health and Safety Policy that guides the organisation's management of health and safety matters.

SAHPRA has an OHS committee consisting of OHS representatives who are assigned duties of responsibility as outlined in Sections 17 and 18 of the OHS Act. SAHPRA complied with the provisions of the Occupational Health and Safety Act to ensure health and safety in the workplace. The organisation has appointed an OHS Committee and SHE Representatives from Regional Offices that form part of the OHS Committee. The committee is functional, and meetings are taking place on a quarterly basis. OHS representatives have also been appointed to identify hazards, monthly, within SAHPRA offices.

The new SHE representatives from the Cape Town Regional Office have been appointed and other members reappointed. The SAHPRA OHS Committee comprises of employee representatives, management representatives, and a union representative. Its function is to ensure continuous improvement to the health and safety system within SAHPRA. The Cape Town

Regional Office's SHE representatives has undergone accredited training on the evacuation and management procedure, to ensure the team is capacitated to assist in responding to emergencies to prevent or mitigate adverse consequences.

13. BOARD SECRETARY

SAHPRA is a Schedule 3A public entity with an appointed Board Secretary. With effect from January 2023, Ms. Letjubana Chokoe was appointed as the acting Board Secretary. She provides advice and supports the Board and is vital to its efficient functioning. As such, the position plays a central role in the governance and administration of the organisation's affairs. In the discharge of her duties, she makes members aware of any laws and regulations relevant to or affecting the Authority.

14. SOCIAL RESPONSIBILITY

SAHPRA embarked on a Corporate Social Responsibility programme where the organisation partnered with an NGO, Gift of the Givers, to donate food to victims of the floods in KwaZulu-Natal. Furthermore, SAHPRA staff visited the Leamogetswe Safety Home in Atteridgeville as part of the Nelson Mandela Day programme. SAHPRA staff members spent 67 minutes reading to the children and played games with them as part of the activity. SAHPRA also donated food, books, board games and toys to the home.

15. AUDIT COMMITTEE REPORT

Risk, Audit and Governance (RAG) Committee Report

Introduction

The RAG Committee is pleased to present its report for the financial year ended 31 March 2023.

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

Composition

The Committee composition is outlined on the below table.

The CEO is an ex officio member of the Committee. The Chief Operating Officer, Chief Financial Officer, Chief Regulatory Officer, Executive HR, Audit & Manager: Risk & Internal Audit, Manager: Strategic Business Planning, Monitoring and Evaluation, Legal Advisor are standing invitees to the RAG meetings.

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

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

Name	Qualifications	Board or External member	No. of meetings attended
Ms Lerato Mothae	B.Compt CTA CA	Board Member	9 out of 9
Adv. Hasina Cassim	B. Pharm LLB	Board Member	8 out of 9
Ms Yongama Pamla	B. Comm CA	External Member	6 out of 9
Mr. Bruce Gordon	B.Compt (Hons) CA	External Member	7 out of 9
Mr. Edward Okaro Omolo*	B.Comm MBA CPA CA	External Member	6 out of 9

**- resigned from the RAG Committee on 09 September 2022*

Audit Committee Responsibility

The Audit Committee reports that it has complied with its responsibilities arising from Section 51(1) (a)(ii) and Section 76(4)d of the Public Finance Management Act ("PFMA") and Treasury Regulation 3.1.13. The Audit Committee also reports that it has adopted appropriate formal terms of reference as its Audit Committee Charter, has regulated its affairs in compliance with this charter and has discharged all its responsibilities as contained therein, except where the committee has not reviewed changes in accounting policies and practices. These includes the requirements of the King IV Code of Corporate Governance:

- To assist the Board in its evaluation of the adequacy and effectiveness of the internal control systems, governance, accounting practices, information systems, risk management and auditing processes applied within SAHPRA's day-to-day management of its business;

- To facilitate and promote communication

between the Board, Management, the External Auditors and Internal Auditors on matters which fall within the responsibilities of the Committee;

- To ensure the risk and compliance areas of SAHPRA operations are covered in the scope of Internal and AGSA audits;
- To ensure the accounting and auditing concerns identified from the Internal and AGSA audits conducted during the period under review are addressed;
- To ensure SAHPRA's compliance with legal and regulatory provisions, the Medicines Act and the PFMA as well as the Treasury Regulations; and
- To ensure the independence and objectivity of the internal and external Auditors.

Whistleblowing

The Committee considered complaints received via the whistleblowing hotline.

Auditors' Report

The Committee has noted the audit outcome as issued by the Auditor-General, with the resultant unqualified audit opinion for the second consecutive year.

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

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

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

The Audit Committee concurs and accepts the conclusions of the external auditor on the annual financial statements and is of the opinion that the audited annual financial statements be accepted and read together with the report of the AGSA.

Effectiveness of Internal Control

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

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

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

- The key outcomes following the above assessment procedures include the internal financial controls and systems, although enhanced from the prior years, still have room for improvement.

Governance of Risk

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

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

Internal Audit

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

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

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 SAHPRA.

The Committee has:

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

Conclusion

The RAG Committee recommended the approval of the audited March 2023 annual financial statements and the audit opinion thereon at its meeting held on 26 July 2023. These annual financial statements and audit opinion were duly approved by the Board on 31 July 2023 to be included in the SAHPRA Annual Report for the financial year ended March 2023.

Chairperson of the RAG

16. 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 and Industry.

Has the Department / Public Entity applied any relevant Code of Good Practice (B-BBEE Certificate Levels 1 – 8) with regards to the following		
Criteria	**Response Yes / No**	**Discussion** (***Include a discussion on your response and indicate what measures have been taken to comply***)
Determining qualification criteria for the issuing of licences, concessions, or other authorisations in respect of economic activity in terms of any law?	No	Draft Policy for issuance of licences as per section 22c of the Medicines Act developed and pending approval. Implementation planned for financial year 20223/24
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	

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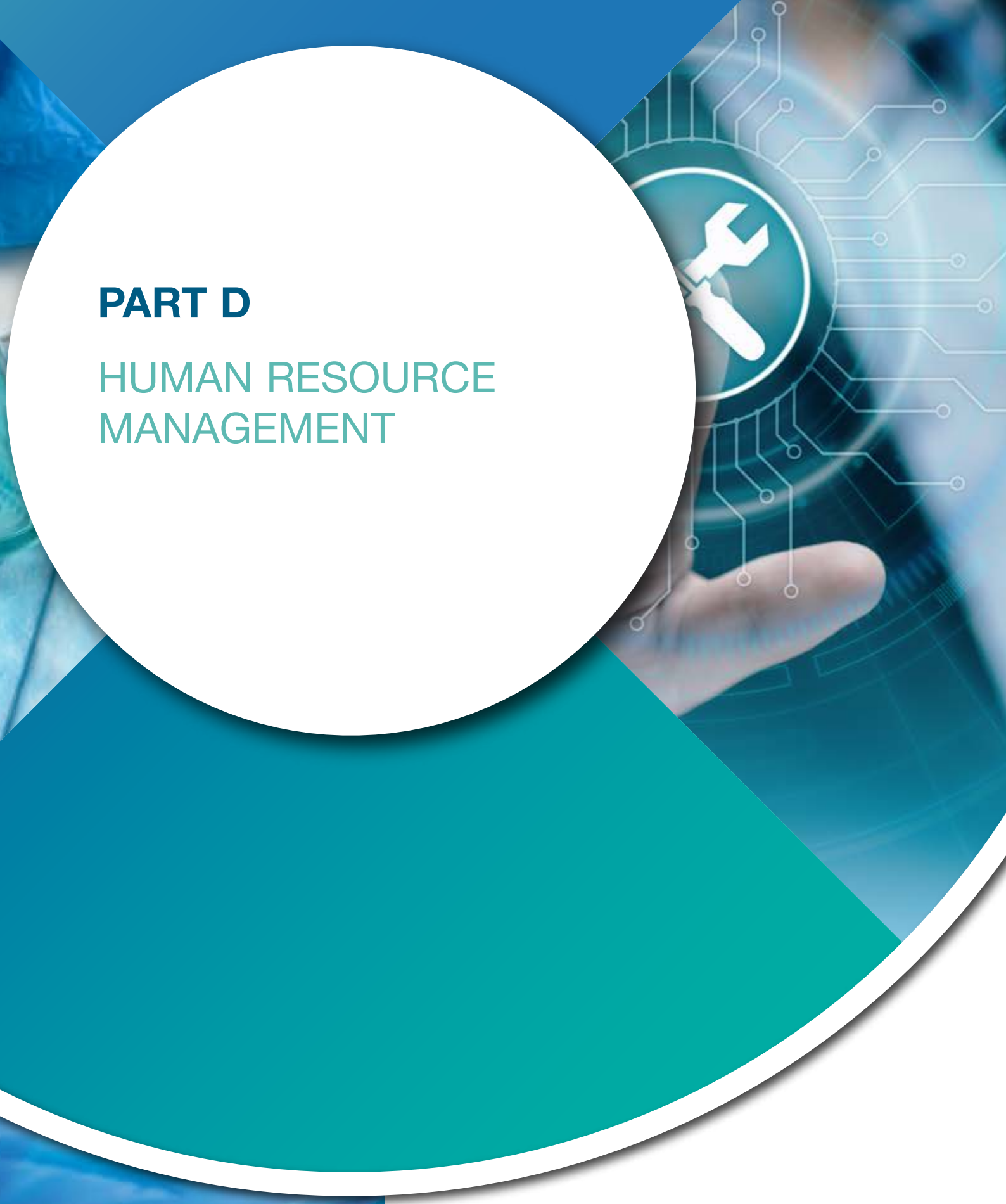
PART D

HUMAN RESOURCE MANAGEMENT



1. INTRODUCTION

SAHPRA has continued to build the organisational culture as an entity that had to infuse cultures from employees' diverse backgrounds to the SAHPRA culture to be lived. The values of the Authority are communicated in all engagement sessions with employees so that they can be practiced and applied as required.

The Authority has sustained the best practice to develop policies and SOPs to guide and lead employees in the alignment of human resource practices with the achievement of organisational objectives and goals.

The development and implementation of the Hybrid Policy on the regulation of working hours is enabling SAHPRA to create a work environment that is conducive and has levels of flexibility for employees to create a work-life balance. It must be noted that the work demands at the Authority make it very hard to achieve true work-life balance. The organisation strives for a working environment that can be established within which employees can flourish and be developed through learning opportunities – within the regulatory environment and amongst each other's experiences.

SAHPRA knows that performance management is a primary tool used to drive organisational performance through the alignment of individual objectives and the Authority's objectives and set targets. SAHPRA is committed to a comprehensive and well-implemented Performance Management and Development System (PMDS), which ensures that everyone in the Authority works towards the attainment of SAHPRA's strategic objectives, as defined in the Operational Plan and the Annual Performance Plans (APPs). Stricter education and training on the performance management system will be emphasised in the new fiscal year to employees for compliance.

The Authority engages all employees to create a shared understanding on technical, operational, cultural, strategic, and people issues. To provide a platform where SAHPRA employees discuss matters and build working relationships to ensure effective cross-functional efficiencies in the delivery of SAHPRA priorities. In financial year 2022/2023, there has been engagement sessions held with employees by the CEO; Executives; and the Human Resources team.

There is an Induction Program whereby new employees are introduced into SAHPRA. These Onboarding sessions take place every two months, with an all-inclusive program of introductions to the various programs within the Authority.

Again, it must be noted that the Authority needs to encourage employees to align with the set target dates in respect of employee performance contracting and mid-term reviews as directed by the Performance Management Policy.

The Human Resources Unit is in the process of reviewing the following policies and their corresponding their SOPs:

1. Performance Management System Policy
2. Leave Management Policy
3. Disciplinary Policy
4. Training and Development Policy

SAHPRA started with the implementation of the Bi-Annual Employee Awards during the 2022/2023 financial years, which has not been concluded. The intention is to complete this initiative in the new fiscal year of 2023/2024. This process included the opportunity to nominate best employees in the categories associated with the values of the Authority. This process will be conducted through an adjudication process during which all nominees will be announced. This will be the first Bi-Annual Employee Awards event.

The Authority is also in the process to review the Fit for Purpose Structure. The review of the organisational

structure will consist of filled and vacant positions, which will be made up of the total number of approved and budgeted positions.

SAHPRA has an Employee Health and Wellness Program, which provide services to all SAHPRA employees, with a mission to build and maintain a healthy workforce for increased productivity and excellent service delivery. The ICAS Health and Wellness Program is an external service provider, which facilitates and manages the wellness program. At the end of the day, the objective of the Employee Health and Wellness Program is to enhance the employees' value proposition by promoting a culture of individual health and organisational wellness. The wellness program focuses on the promotion of mental, physical, social, emotional, and occupational wellbeing, as well as individual finances. In addition, it enables employees to increase control over, and improve their own health. In this reporting fiscal year, there has been health talks, wellness campaigns and health information dissemination utilised to promote health. The ICAS employee wellness program ensures the availability of professional counselling support beyond office hours.

SAHPRA considers its relations with labour unions as a key interface to meet employee expectations in the workplace. In addition, the organisation considers employee discipline and adherence to the Disciplinary Policy, the Ethics and the Code of Conduct, as well as compliance to all the policies, procedures and regulations as serious matters. During the reporting period, no employee was dismissed for serious offences and transgressions. In addition, no cases were at the CCMA.

The Executives and Senior Managers participated in Leadership Coaching Program during this reporting period. With available funds, the HR unit intends to provide all the managers an opportunity to also participate in the Leadership Coaching Program in year 2023/2024.

2. HUMAN RESOURCE OVERSIGHT STATISTICS

2.1 Personnel Related Expenditure

Personnel Cost by Programme

Programme	Total Expenditure for the Entity (R'000)	Personnel Expenditure (R'000)	Personnel Expenditure as a % of Total Expenditure (R'000)	No. of Employees	Average Personnel Cost per employee (R'000)
Programme 1	139 060	52 435	38%	73	718.29
Programme 2	26 822	25 520	95%	54	472.59
Programme 3	42 399	34 723	82%	48	723.39
Programme 4	108 496	64 387	59%	84	766.51
Programme 5	33 144	30 943	93%	53	583.83
Contract (Backlog project and Global Fund)	23 867	16 234	68%	24	676.43
	373 788	**224 242**	**60%**	**336**	**667**

Personnel Cost by Salary Band completed

Level	Personnel Expenditure (R'000)	% of Personnel Expenditure to Total Personnel Cost (R'000)	No. of Employees	Average Personnel Cost per employee (R'000)
Top management	10 870.59	4.85%	6	1 811.77
Senior management	22 335.44	9.96%	18	1 240.86
Professional qualified	146 204.82	65.20%	194	753.63
Skilled	44 831.47	19.99%	118	379.93
Semi-skilled	-			
Unskilled	-			
TOTAL	**224 242**	**100%**	**336**	**667**

Performance Rewards

Level	Personnel Expenditure (R'000)	Number of staff - payment made	Number of staff did not qualify
Programme 1 to 5	4 728	116	147
TOTAL	**4 728**	**116**	**147**

Training Costs

Programme	Actual Training Expenditure (R'000)	% of Target Implemented	Average Training Cost per Employee (R'000)
Programme 1 to 5	1 601	15%	5
TOTAL	**1 601**	**15%**	**5**

Employment and Vacancies

Programme	2022/2023 No. of Employees	2022/2023 Approved Posts	2022/2023 No. of Employees	2022/2023 Vacancies	% of Vacancies
Programme 1	72	2	74	0	0%
Programme 2	41	8	45	4	18,18%
Programme 3	57	8	55	3	13,63%
Programme 4	87	10	80	7	31,81%
Programme 5	55	8	55	0	0%
Contract (Backlog project and Global Fund)	24	-	31	8	36.36%
TOTAL	**336**	**36**	**340**	**22**	**99,98%**

The recruitment of technical skills remains a challenge as it is a lengthy process (some positions had to be re-advertised) and costly as the required skill is expensive than what the organisation can afford. In addition, the recruitment of positions funded through Global Fund had to take priority to ensure the organisation does not forfeit the Global Fund donor funding received.

Employment Changes

Salary Band	Employment at the Beginning of Period	Appointments	Terminations	Employment at End of the Period
Top management	6	0	0	6
Senior management	18	0	3	15
Professional qualified	194	18	16	178
Skilled	118	38	14	104
Semi-skilled	0	0	0	0
Unskilled	0	0	0	0
TOTAL	**336**	**56**	**33**	**303**

Staff turnover was more prevalent in the technical skills areas and SAHPRA's recruitment efforts focused on this area. In future, the focus will be on ensuring the retention of technical skills as it is both expensive and time consuming to source. High employment changes in the professional levels are an operational risk to SAHPRA's deliverables, thus the need to ensure that this area is stabilised. Overall, SAHPRA's headcount increased from the previous financial year considering the inclusion of staff appointed through the Global Fund during the 2022/23 financial year.

Reasons for Staff Leaving

Reason	Number	% of Total No. of Staff Leaving
Death	1	0,29%
Resignation	19	5,65%
Dismissal	0	0.00%
Retirement	3	0,89%
Ill health	0	0.00%
Expiry of contract	9, including Backlog	2,67%
Other	1	0,29%
TOTAL	**33**	**9,79%**

In 2022/23, 19 staff members resigned, some of the reasons for resignations were due to personal reasons, better opportunities, employment contracts ending as well as employees getting higher salary offers compared to SAHPRA salaries. Human Resources has put measures in place in an attempt to address employees leaving SAHPRA.

In line with the Employee Health and Wellness Program, an anti-bullying workshop was conducted in the last financial year with all staff members in attendance. In the new financial year 2023/24, a survey that focuses on staff satisfaction is planned; it will assist to gather information on why employees leave the Authority.

In addition, exit interview forms that have been submitted to Human Resources indicate that most employees leave the organisation to join other companies in senior positions. The employer has also provided the services of ICAS to assist employees with Health and Wellness Program. There will be improved handling of grievance matters which will also assist in addressing these matters.

Labour Relations: Misconduct and Disciplinary Action

Nature of Disciplinary Action	Number
Verbal warning	4
Written warning	2
Final written warning	1
Dismissal	0

Equity Target and Employment Equity Status

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

The employment equity target was set for the 2022/23 financial year as the organisation has implemented the three-year Employment Equity Plan from the 2022/23 financial year. The equity targets focused on areas where representation of a certain race or gender is minimal across all the employment levels, especially in core business. There were no declared disabilities during the period under review.

Levels	MALE							
	African		Coloured		Indian		White	
	Current	Target	Current	Target	Current	Target	Current	Target
Top management	1						1	
Senior management	3		1		1			
Professional qualified	44		2				3	
Skilled	29							
Semi-skilled	33		3				1	
Unskilled	0							
TOTAL	110	0	7	0	1	0	5	0

Levels	FEMALE							
	African		Coloured		Indian		White	
	Current	Target	Current	Target	Current	Target	Current	Target
Top management	2						1	
Senior management	6				1		1	
Professional qualified	68		8		13		4	
Skilled	53		3		4		1	
Semi-skilled	37		4		2		5	
Unskilled	0							
TOTAL	166	0	15	0	20	0	12	0

PART E

PFMA COMPLIANCE REPORT

1. IRREGULAR, FRUITLESS AND WASTEFUL EXPENDITURE AND MATERIAL LOSSES

1.1 Irregular expenditure

a) Reconciliation of irregular expenditure

Description	2022/23	2021/22
	R'000	R'000
Opening balance	3 010	10 370
Add: Irregular expenditure confirmed	-	3 010
Less: Irregular expenditure condoned	(3 010)	(10 357)
Less: Irregular expenditure not condoned and removed	-	-
Less: Irregular expenditure recoverable	-	(13)
Less: Irregular expenditure not recovered and written off	-	-
Closing balance	-	3 010

Irregular expenditure condoned by the National Treasury

Reconciling notes

Description	2022/23	2021/22
	R'000	R'000
Irregular expenditure that was under assessment	-	-
Irregular expenditure that relates to 2021/22 and identified in 2022/23	-	-
Irregular expenditure for the current year	-	3 010
Total	-	3 010

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

Description[1]	2022/23	2021/22
	R'000	R'000
Irregular expenditure under assessment	-	-
Irregular expenditure under determination	-	-
Irregular expenditure under investigation	-	-
Total[2]	-	-

SAHPRA does not have any unconfirmed irregular expenditure

1 Group similar items

2 Total unconfirmed irregular expenditure (assessment), losses (determination), and criminal conduct (investigation)

c) Details of current and previous year irregular expenditure condoned

Description	2022/23	2021/22
	R'000	R'000
Irregular expenditure condoned	3 010	10 357
Total	**3 010**	**10 357**

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

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

Description	2022/23	2021/22
	R'000	R'000
Irregular expenditure NOT condoned and removed	-	-
Total	**-**	**-**

All irregular expenditure were condoned by the National Treasury

e) Details of current and previous year irregular expenditure recovered

Description	2022/23	2021/22
	R'000	R'000
Irregular expenditure recovered	-	13
Total	**-**	**13**

Additional charges not approved by SAHPRA recovered from the service provider

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

Description	2022/23	2021/22
	R'000	R'000
Irregular expenditure written off	-	-
Total	-	-

No irregular expenditure identified for recovery were written off

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

Disciplinary steps taken
2021/22 – 4 warnings issued to implicated staff following a determination process
2022/23 - 3 warnings issued to implicated staff following a determination process

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

1.2 Fruitless and wasteful expenditure

a) Reconciliation of fruitless and wasteful expenditure

Description	2022/23	2021/22
	R'000	R'000
Opening balance	**32**	**47**
Add: Fruitless and wasteful expenditure confirmed	342	32
Less: Fruitless and wasteful expenditure written off	-	(47)
Less: Fruitless and wasteful expenditure recoverable	(32)	-
Closing balance	**342**	**32**

Additional fruitless and wasteful expenditure identified during the 2022/23 financial year related to interest and penalties issued by SARS due to under payment of PAYE and is currently following a determination process to identify liable officials and corrective actions.

Reconciling notes

Description	2022/23	2021/22
	R'000	R'000
Fruitless and wasteful expenditure that was under assessment	-	-
Fruitless and wasteful expenditure that relates to 2021/22 and identified in 2022/23	-	-
Fruitless and wasteful expenditure for the current year	342	32
Total	**342**	**32**

d) Details of current and previous year fruitless and wasteful expenditure (under assessment, determination, and investigation)

Description[3]	2022/23	2021/22
	R'000	R'000
Fruitless and wasteful expenditure under assessment	-	-
Fruitless and wasteful expenditure under determination	-	-
Fruitless and wasteful expenditure under investigation	-	-
Total[4]	-	-

SAHPRA does not have any unconfirmed fruitless and wasteful expenditure

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

Description	2022/23	2021/22
	R'000	R'000
Fruitless and wasteful expenditure recovered	-	-
Total	-	-

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

Description	2022/23	2021/22
	R'000	R'000
Fruitless and wasteful expenditure written off	-	47
Total	-	47

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

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

Disciplinary steps taken
2021/22 – none
2022/23 – A determination has been initiated to determine cause of the transgression and liable officials

3 Group similar items

4 Total unconfirmed fruitless and wasteful expenditure (assessment), losses (determination), and criminal conduct (investigation)

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

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

Material losses through criminal conduct	2022/23	2021/22
	R'000	R'000
Theft	-	-
Other material losses	-	-
Less: Recovered	-	-
Less: Not recovered and written off	-	-
Total	-	-

No material losses identified

b) Details of other material losses

Nature of other material losses	2022/23	2021/22
	R'000	R'000
None	-	-
Total	-	-

2. LATE AND/OR NON-PAYMENT OF SUPPLIERS

Description	Number of invoices	Consolidated Value
	R'000	R'000
Valid invoices received	619	78 513
Invoices paid within 30 days or agreed period	581	77 154
Invoices paid after 30 days or agreed period	33	1 355
Invoices older than 30 days or agreed period *(unpaid and without dispute)*	-	-
Invoices older than 30 days or agreed period *(unpaid and in dispute)*	5	4

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

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

3. SUPPLY CHAIN MANAGEMENT

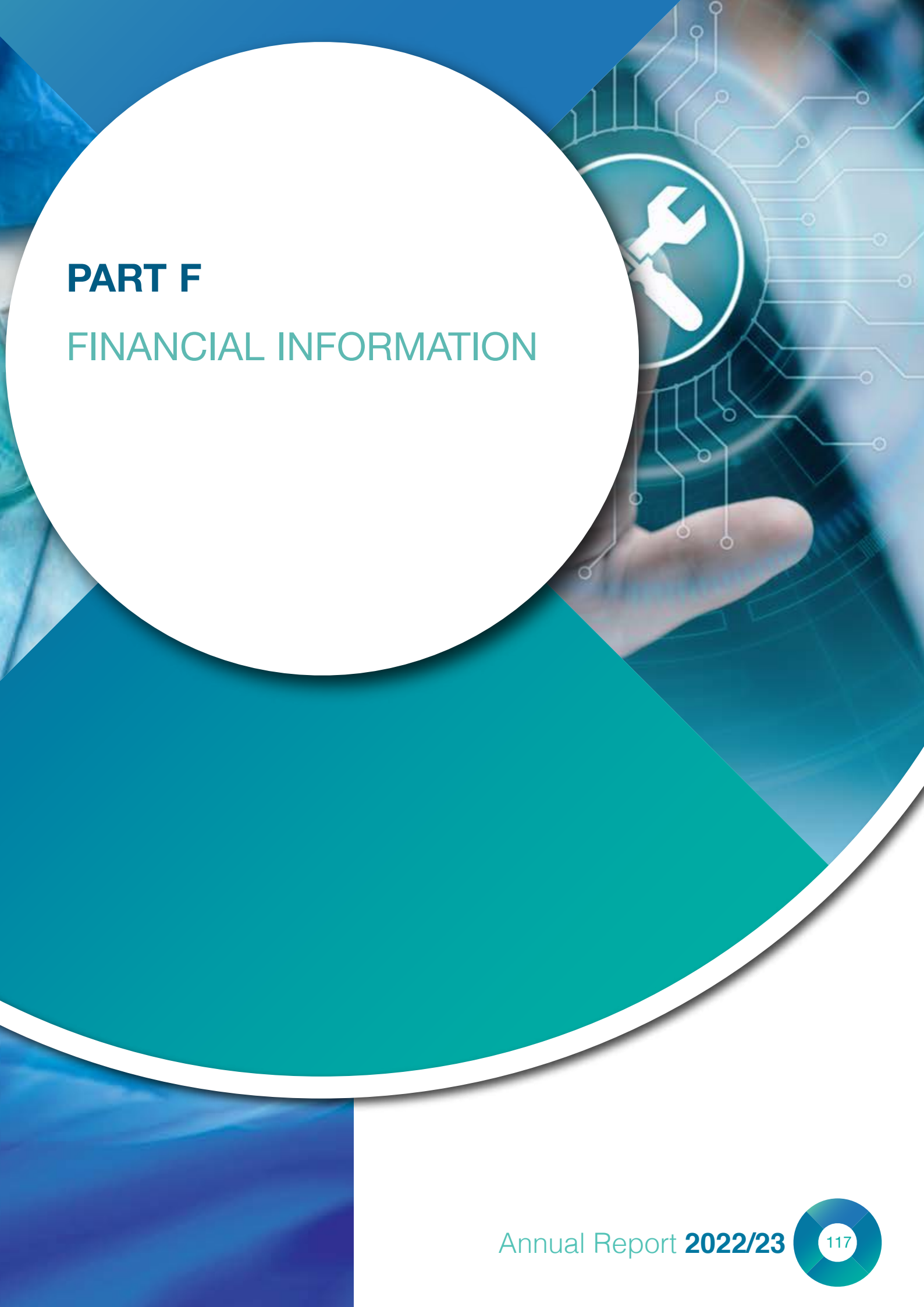
3.1 Procurement by other means

Project description	Name of supplier	Type of procurement by other means	Contract number	Value of contract R'000
Office space for border medicine control technicians	Airport Company South Africa - ACSA	Single source	PO0128	1 691
Procurement of vaccine lot release testing service from sole supplier	National Control Laboratory - NCLBP	Sole source	PO0052	22 698
EURS and EURS Next regulatory system	Extedo GmbH	Sole source	PO0118	975
Short term training on Pharmacoepidemiology and Pharmacovigilance	London School of Hygiene and Tropical Medicine	Single source	PO0180	48
Procurement of MIMS (Monthly Index of Medical Specialities) and MDR (Mims Desk Reference) subscriptions from sole source	Arena Holdings	Sole source	PO0123	15
Publication of Journal Article using Backlog Clearance Project Funding	Springer Nature Group	Single source	PO0242	60
Exhibition	South African Association of Hospital and Institutional Pharmacists - SAAHIP	Sole source	PO0250	23
Exhibition at the pharmacy show	Future publishing solutions	Sole source	PO0251	34
EURS and EURS Next Regulatory system	Extedo GmbH	Sole source	PO0281	1 846
Caseware financial statement software renewal	Adapt IT	Sole source	PO0260	115
Sage people 300 training	SAGE South Africa	Single source	PO0289	8
Total				**27 479**

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
Additional Adobe Electronic Signature Envelopes	Neo Technologies	Expansion	PO0001	379	56	268
Legal service to defend high court matter	Maenetja Attorneys	Expansion	N/A	500	1 000	1 500
Disaster recovery hosting service extension	Vodacom	Expansion	PO0015	338	-	26
Laptops rental	Innovent rental solutions	Expansion	PO0025	107	-	36
Payment of EURS services	Extedo	Variation	PO0060	1 317	-	165
Change management training	The integral Coaching Centre	Variation	PO0113	693	68	22
Additional Data SIM cards and SIM swaps	MTN	Expansion	PO0124	4 548	13	402
Additional work on repairs and renovations	Ntlheng Civil and Construction	Variation	PO0150	199	-	9
Protective clothing	Matena Trading	Expansion	PO0061	19	-	1
Strategy Planning	Travel With Flair	Variation	PO0156	35	-	8
Consultant–EMP – Tax Calculation	ICON Business Solutions	Variation	PO0169	288	-	144
Additional drywalling at Durban Regional Office	Bay Breeze	Expansion	PO0225	2 428	-	20
Public Liability Insurance	Lateral Unison (Pty) Ltd	Variation	PO0267	1 024	-	21
Total				**11 875**	**1 137**	**2 622**

South African
Health Products
Regulatory Authority
SAHPRA
South African
Health Products
Regulatory Authority
SUN PRIDE
Selati
SPRINKLE JOY
PURE WHITE
SUGAR
10 kg
Selati
SPRINKLE JOY
PURE WHITE
SUGAR
10 kg



PART F

FINANCIAL INFORMATION

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

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Accounting Authority's Responsibilities and Approval

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

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

The annual financial statements are based upon appropriate accounting policies consistently applied and supported by reasonable and prudent judgements and estimates.

The Accounting Authority acknowledge that they are ultimately responsible for the system of internal financial control established by SAHPRA and place considerable importance on maintaining a strong control environment. To enable the Accounting Authority to meet these responsibliities, 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 on identifying. The focus of risk management in SAHPRA is cin ide ntifying, 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 has reviewed SAHPRA's cash flow forecast for the year to 31 March 2024 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's 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 121.

The annual financial statements set out on page 129 to 193, which has been prepared on the going concern basis, was approved by the Accounting Authority on 31 July 2023 and were signed on its behalf by:

Dr Boitumelo Semete-Makokotlela
Chief Executive Officer

Prof. Helen Rees
Chairperson of the Board

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

Report on the audit of the financial statements

Opinion

1. I have audited the financial statements of the South African Health Products Regulatory Authority (SAHPRA) set out on pages 129 to 192, which comprise the statement of financial position as at 31 March 2023, 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 South African Health Products Regulatory Authority as at 31 March 2023 and its financial performance and cash flows for the year then ended in accordance with Generally Recognised Accounting Practice (GRAP) and the requirements of the Public Finance Management Act (PFMA).

Basis for opinion

3. I conducted my audit in accordance with the International Standards on Auditing (ISAs). My responsibilities under those standards are further described in the responsibilities of the auditor-general for the audit of the financial statements section of my report.

4. I am independent of the public entity in accordance with the International Ethics Standards Board for Accountants' *International code of ethics for professional accountants (including International Independence Standards)* (IESBA code) as well as other ethical requirements that are relevant to my audit in South Africa. I have fulfilled my other ethical responsibilities in accordance with these requirements and the IESBA code.

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

Emphasis of matter

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

Restatement of corresponding figures

7. As disclosed in note 33 to the financial statements, the corresponding figures for 31 March 2022 were restated as a result of an error in the financial statements of the public entity at, and for the year ended, 31 March 2023

Other matter

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

Irregular expenditure and fruitless and wasteful expenditure

9. On 23 December 2022, the National Treasury issued Instruction Note 4 of 2022-23, which came into effect on 3 January 2023, in terms of section 76(1)(b), (e) and (f), 2(e) and (4)(a) and (c) of the PFMA. The instruction note deals with the PFMA compliance and reporting framework and addresses, amongst others, the disclosure of unauthorised expenditure, irregular expenditure and fruitless and wasteful expenditure. Irregular expenditure and fruitless and wasteful expenditure incurred in prior financial years and not yet addressed no longer need to be disclosed

in either the annual report or the disclosure notes to the annual financial statements. Only the current year and prior year figures are disclosed in note 37 to the financial statements of the South African Health Products Regulatory Authority. Movements in respect of irregular expenditure and fruitless and wasteful expenditure also no longer need to be disclosed in the notes to the annual financial statements. The disclosure of these movements (e.g. condoned, recoverable, removed, written off, under assessment, under determination and under investigation) is now included as part of the other information in the annual report of the auditees.

10. I do not express an opinion on the disclosure of irregular expenditure and fruitless and wasteful expenditure in the annual report.

Responsibilities of the accounting authority for the financial statements

11. The accounting authority is responsible for the preparation and fair presentation of the financial statements in accordance with the GRAP and the requirements of the PFMA and for such internal control as the accounting authority determines is necessary to enable the preparation of financial statements that are free from material misstatement, whether due to fraud or error.

12. In preparing the financial statements, the accounting authorityis 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

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

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

Report on the annual performance report

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

16. I selected the following material performance indicators related to Programme 2: Health products authorisation, Programme 3: Inspectorate and regulatory compliance, Programme 4: Clinical and pharmaceutical evaluation and Programme 5: Medical devices and radiation control presented in the annual performance report for the year ended 31 March 2023. I selected those indicators that measure the entity's performance on its primary mandated

functions and that are of significant national, community or public interest.

- Percentage of medicine registrations backlog cleared
- Percentage of medicine variation applications in the backlog cleared
- Percentage of new chemical entities finalised within 490 working days
- Percentage of generic medicines finalised within 250 working days
- Percentage of new GMP and GWP related licenses finalised within 125 working days
- Percentage of permits finalised within 20 working days
- Percentage of regulatory compliance investigation reports produced within 30 working days
- Percentage applications for the sale of unregistered category A (human) medicines finalised within three (3) working days
- Percentage of human clinical trial applications finalised within 90 working days
- Percentage of reports on health product safety signals issued within 40 working days
- Percentage of lot release requests finalised within 30 working days
- Percentage of medical device establishment licence applications finalised within 90 working days
- Medical device registration regulations implemented
- Percentage of applications for radionuclide authorities finalised within 30 working days
- Percentage of licence applications for listed electronic products finalised within 30 working days

17. 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.

18. 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
    - 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 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 are adequate supporting evidence for the achievements reported and for the reasons provided for any over- or underachievement of targets.

19. I performed the procedures for the purpose of reporting material findings only.

20. The material findings on the performance information of the selected material performance indicators are as follows:

Percentage of medicine variation applications

in the backlog cleared

21. An achievement of 100% was reported against a target of 100%. I could not determine if the reported achievement was correct, as backlog variation applications on the system did not have unique identifier to the rest of the variation application on the system. Consequently, the achievement might be less than reported and was not reliable for determining if the target had been achieved.

Other matters

22. I draw attention to the matters below.

Achievement of planned targets

23. The annual performance report includes information on reported achievements against planned targets and provides explanations for over and underachievements. This information should be considered in the context of the material finding on the reported performance information.

Material misstatements

24. I identified material misstatement in the annual performance report submitted for auditing. This material misstatements was in the reported performance information for health products authorisation programme. Management did not correct all the misstatement and I reported the material finding in this report.

Report on compliance with legislation

25. In accordance with the PAA and the general notice issued in terms thereof, I must audit and report on compliance with applicable legislation relating to financial matters, financial management and other related matters. The accounting authority is responsible for the entity's compliance with legislation.

26. 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.

27. Through an established AGSA process, I selected requirements in key legislation for compliance testing that are relevant to the financial and performance management of the entity's, 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.

28. The material findings on compliance with the selected legislative requirements, presented per compliance theme, are as follows:

Annual financial statements, performance and annual report

29. The financial statements submitted for auditing were not fully prepared in accordance with the prescribed financial reporting framework and supported by full and proper records, as required by section 55(1)(b) of the PFMA. Material misstatements of financial instruments disclosure note and risk management note identified by the auditors in the submitted financial statement were corrected, resulting in the financial statements receiving an unqualified audit opinion.

Revenue management

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

Other information in the annual report

31. The accounting authority is responsible for the other information included in the annual report. The other information referred to does not include the financial statements, the auditor's report and those selected material indicators in the scoped-in programmes presented in the annual performance report that have been specifically reported on in this auditor's report.

32. My opinion on the financial statements, the report on the audit of the annual performance report and the report on compliance with legislation do not cover the other information included in the annual report and I do not express an audit opinion or any form of assurance conclusion on it.

33. 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 programmes presented in the annual performance report, or my knowledge obtained in the audit, or otherwise appears to be materially misstated.

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

Internal control deficiencies

35. 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.

36. The matters reported below are limited to the significant internal control deficiencies that resulted in the material findings on the annual performance report and the material findings on compliance with legislation included in this report.

37. Management did not establish and communicate policies and procedures to enable and support the understanding and execution of internal control objectives, processes and responsibilities for performance information.

38. Management did not prepare regular, accurate and complete financial and performance reports that are supported and evidenced by reliable information.

39. Management did not establish processes to ensure all monies owed are collected.

Auditor - General

Pretoria
31 July 2023

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 in order to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the 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 a 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 to communicate with them all relationships and other matters that may reasonably be thought to bear on my independence and, where applicable, actions taken to eliminate threats or safeguards applied.

Compliance with legislation – selected legislative requirements

The selected legislative requirements are as follows:

Legislation	Sections or regulations
Public Finance Management Act No.1 of 1999 (PFMA)	Section 51(1)(a)(iv); 51(1)(b)(i); 51(1)(b)(ii); 51(1)(e)(iii) Section 53(4) Section 54(2)(c'); 54(2)(d) Section 55(1)(a); 55(1)(b); 55(1)(c)(i) Section 56(1); 56(2) Section 57(b); Section 66(3)(c'); 66(5)
Treasury Regulations for departments, trading entities, constitutional institutions and public entities (TR)	Treasury Regulation 8.2.1; 8.2.2 Treasury Regulation ; 16A 6.1; 16A6.2(a) & (b); 16A6.2(e);16A 6.3(a); ; 16A 6.3(b); 16A 6.3(c); 16A 6.3(d); 16A 6.3(e); 16A 6.4; 16A 6.5; 16A 6.6; TR 16A.7.1; 16A.7.3; 16A.7.6; 16A.7.7; 16A 8.2(1); 16A 8.2(2); 16A 8.3; 16A 8.3(d); 16A 8.4; 16A9.1 16A9; 16A9.1(b)(ii); 16A9.1(c); 16A 9.1(d); 16A 9.1(e); 16A9.1(f); 16A 9.2; 16A 9.2(a)(ii); TR 16A 9.2(a)(iii) Treasury Regulation 30.1.1; 30.1.3(a); 30.1.3(b); 30.1.3(d); 30.2.1 Treasury Regulation 31.1.2(c') Treasury Regulation 31.2.1; 31.2.5; 31.2.7(a) Treasury Regulation 31.3.3 Treasury Regulation 32.1.1(a); 32.1.1(b); 32.1.1(c') Treasury Regulation 33.1.1; 33.1.3
Companies Act No.71 of 2008	Section 45(2); 45(3)(a)(ii); 45(3)(b)(i); 45(3)(b)(ii); 45(4) Section 46(1)(a); 46(1)(b); 46(1)(c') Section 112(2)(a); Section 129(7)
Public service regulation	Public service regulation ;18; 18 (1) and (2);
Prevention and Combating of Corrupt Activities Act No.12 of 2004 (PRECCA)	Section 34(1)
Construction Industry Development Board Act No.38 of 2000 (CIDB)	Section 18(1)
CIDB Regulations	CIDB regulation 17; ; & 25(7A)
PPPFA	Section ; 2.1(a); 2.1(b); 2.1(f)
PPR 2017	Paragraph 4.1; 4.2 Paragraph 5.1; 5.3; 5.6; 5.7 Paragraph 8.2; 8.5 Paragraph 9.1; 9.2 Paragraph 12.1 and 12.2

Legislation	Sections or regulations
PPR 2022	Paragraph 4.1; 4.2; 4.3; 4.4 Paragraph 5.1; 5.2; 5.3; 5.4
National Treasury Instruction No.1 of 2015/16	Paragraph 3.1; 4.1; 4.2
NT SCM Instruction Note 03 2021/22	Paragraph ; 4.3; 4.4; 4.4 (a); 4.4 (c) -(d);
NT SCM Instruction Note 11 2020/21	Paragraph 3.1; and (b); 3.9;
NT SCM Instruction note 2 of 2021/22	Paragraph 3.2.1; ; 3.2.4(a) ; 3.3.1;
NT instruction note 4 of 2015/16	Paragraph 3.4
Second amendment of NTI 05 of 2020/21	Paragraph 4.8; 4.9 ; 5.1 ; 5.3
Erratum NTI 5 of 202/21	Paragraph 1
Erratum NTI 5 of 202/21	Paragraph 2
Practice note 7 of 2009/10	Par agraph 4.1.2
NT instruction note 1 of 2021/22	Paragraph 4.1

Statement of Financial Position

As at 31 March 2023

	Note(s)	2023 R	2022 Restated* R
Assets			
Current Assets			
Receivables from exchange transactions	3	7 100 029	5 738 767
Receivables from non-exchange transactions	4	2 397 554	9 452 146
Prepayments		6 323 206	5 141 662
Cash and cash equivalents	5	329 603 895	244 373 304
		345 424 684	**264 705 879**
Non-Current Assets			
Property, plant and equipment	6	28 178 882	26 620 331
Intangible assets	7	2 885 878	2 818 059
		31 064 760	**29 438 390**
Total Assets		**376 489 444**	**294 144 269**
Liabilities			
Current Liabilities			
Operating lease liability	8	4 063 589	3 259 196
Payables from exchange transactions	9	11 519 758	15 656 404
Employee benefit obligation	10	993 930	1 147 605
Unspent conditional grants	11	4 317 696	3 383 259
Provisions	12	20 287 054	14 197 149
Income received in advance	13	256 776 351	191 526 908
Deferred income: Backlog reduction project	14	-	9 272 300
		297 958 378	**238 442 821**
Non-Current Liabilities			
Employee benefit obligation	10	8 559 108	8 236 727
Total Liabilities		**306 517 486**	**246 679 548**
Net Assets		**69 971 958**	**47 464 721**
Accumulated surplus		**69 971 958**	**47 464 721**
Total Net Assets		**69 971 958**	**47 464 721**

* See Note 33

Statement of Financial Performance

for the year ended 31 March 2023

	Note(s)	2023 R	2022 Restated* R
Revenue			
Revenue from exchange transactions			
Fee income	15	206 163 894	183 050 849
Sundry income	16	65 135	217 309
Interest received	17	20 661 972	9 557 126
Gain on foreign echange		-	127 249
Actuarial gains	10	1 930 448	-
Total revenue from exchange transactions		**228 821 449**	**192 952 533**
Revenue from non-exchange transactions			
Transfer payments received	18	149 965 000	146 287 000
Services in kind	19	3 599 397	15 348 507
Grant realised	20	9 990 493	5 389 733
Grant income	21	3 709 919	8 822 956
Assets donated		208 500	-
Total revenue from non-exchange transactions		**167 473 309**	**175 848 196**
Total revenue		**396 294 758**	**368 800 729**
Expenditure			
Employee related costs	22	(224 242 324)	(191 333 558)
Backlog reduction project	23	(20 157 015)	(52 275 755)
Depreciation	24	(6 286 082)	(7 016 149)
Impairment of assets	6	(6 952)	(404 044)
Lease rentals on operating lease		(20 474 650)	(19 518 295)
Bad debts written off		(1 530 189)	(4 231 329)
Global fund project expenditure	36	(3 709 919)	-
Laboratory services	25	(22 636 216)	(20 797 520)
Loss on disposal of assets	6	(136 414)	(412 627)
Loss on foreign exchange		(46 350)	-
Operating Expenses	26	(74 561 410)	(50 753 947)
Total expenditure		**(373 787 521)**	**(346 743 224)**
Surplus for the year		**22 507 237**	**22 057 505**

* See Note 33

Statement of Changes in Net Assets

for the year ended 31 March 2023

	Note(s)	Accumulated surplus R	Total net assets R
Balance at 01 April 2021		**25 407 216**	**25 407 216**
Surplus for the year		22 057 505	22 057 505
Total		**22 057 505**	**22 057 505**
Opening balance as previously reported		**53 644 553**	**53 644 553**
Adjustments:			
Correction of errors	33	(6 179 832)	(6 179 832)
Restated balance at 01 April 2022		47 464 721	47 464 721
Surplus for the period		22 507 237	22 507 237
Total		**22 507 237**	**22 507 237**
Balance at 31 March 2023		**69 971 958**	**69 971 958**

* See Note 33

Cash Flow Statement

for the year ended 31 March 2023

	Note(s)	2023	2022 Restated*
Cash flows from operating activities			
Receipts			
Fee and deferred income		272 761 089	261 125 028
Transfer payment received		149 965 000	146 287 000
Interest income		20 644 791	9 474 299
Grants received		14 574 523	8 772 992
		457 945 403	**425 659 319**
Payments			
Employee costs		(225 817 782)	(185 008 774)
Suppliers		(139 508 642)	(142 882 457)
		(365 326 424)	**(327 891 231)**
Net cash flows from operating activities	27	**92 618 979**	**97 768 088**
Cash flows from investing activities			
Purchase of property, plant and equipment	6	(7 429 028)	(3 307 623)
Proceeds from sale of property, plant and equipment	6	40 640	201 061
Purchase of other intangible assets	7	-	(1 052 518)
Net cash flows from investing activities		**(7 388 388)**	**(4 159 080)**
Net increase/(decrease) in cash and cash equivalents		**85 230 591**	**93 609 008**
Cash and cash equivalents at the beginning of the year		244 373 304	150 764 296
Cash and cash equivalents at the end of the year	5	**329 603 895**	**244 373 304**

* See Note 33

Statement of Comparison of Budget and Actual Amounts

for the year ended 31 March 2023

	Approved budget	Adjustments	Final Budget	Actual amounts on comparable basis	Difference between final budget and actual	Reference
Statement of Financial Performance						
Revenue						
Revenue from exchange transactions						
Fee income	170 036 654	-	**170 036 654**	197 350 794	**27 314 140**	39.1
Backlog fee income	20 203 800	-	**20 203 800**	8 813 100	**(11 390 700)**	39.1
Sundry income	-	-	**-**	65 135	**65 135**	39.1
Interest received	9 150 564	-	**9 150 564**	20 661 972	**11 511 408**	39.2
Total revenue from exchange transactions	**199 391 018**	**-**	**199 391 018**	**226 891 001**	**27 499 983**	
Revenue from non-exchange transactions						
Transfer revenue						
Transfer payment	149 965 000	-	**149 965 000**	149 965 000	**-**	
Service in-kind	-	-	**-**	3 599 397	**3 599 397**	39.8
Grants realised	-	-	**-**	9 990 493	**9 990 493**	39.8
Grants received	-	-	**-**	3 709 919	**3 709 919**	39.8
Assets transferred from landlord	-	-	**-**	208 500	**208 500**	
Total revenue from non-exchange transactions	**149 965 000**	**-**	**149 965 000**	**167 473 309**	**17 508 309**	
Total revenue	**349 356 018**	**-**	**349 356 018**	**394 364 310**	**45 008 292**	
Expenditure						
Employee cost	(210 548 706)	-	**(210 548 706)**	(224 242 324)	**(13 693 618)**	39.3
Backlog reduction project	(23 948 840)	-	**(23 948 840)**	(20 157 015)	**3 791 825**	39.6
Depreciation and amortisation	-	-	**-**	(6 286 082)	**(6 286 082)**	39.4
Impairment loss/ Reversal of- impairments	-	-	**-**	(6 952)	**(6 952)**	39.4
Lease rentals on operating lease	(19 263 600)	-	**(19 263 600)**	(20 474 650)	**(1 211 050)**	39.7
Bad debts written off	-	-	**-**	(1 530 189)	**(1 530 189)**	39.9
Global fund expenditure	-	-	**-**	(3 709 919)	**(3 709 919)**	
Laboratory services	(21 862 685)	-	**(21 862 685)**	(22 636 216)	**(773 531)**	
Operating Expenses	(73 732 187)	-	**(73 732 187)**	(74 561 410)	**(829 223)**	39.5
Total expenditure	**(349 356 018)**	**-**	**(349 356 018)**	**(373 604 757)**	**(24 248 739)**	
Operating surplus	-	-	**-**	**20 759 553**	**20 759 553**	
Loss on disposal of assets and liabilities	-	-	**-**	(136 414)	**(136 414)**	39.4
Loss on foreign exchange	-	-	**-**	(46 350)	**(46 350)**	
Actuarial gains/losses	-	-	**-**	1 930 448	**1 930 448**	
	-	**-**	**-**	**1 747 684**	**1 747 684**	
Surplus before taxation	**-**	**-**	**-**	**22 507 237**	**22 507 237**	
Actual Amount on Comparable - Basis as Presented in the Budget and Actual Comparative Statement	**-**	**-**	**-**	**22 507 237**	**22 507 237**	

Accounting Polices

for the year ended 31 March 2023

1. Significant accounting polices

The principal accounting policies applied in the preparation of these annual financial statements are set out below.

1.1 Basis of preparations

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

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. They are presented in South African Rand.

These accounting policies are consistent with the previous period, except for the changes set out in note Changes in accounting policy.

1.2 Presentation currency

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

1.3 Going concern assumption

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

1.4 Significant judgements and sources of estimation uncertainty

In preparing the annual financial statements, management is required to make estimates and assumptions that affect the amounts represented in the annual financial statements and related disclosures. Use of available information and the application of judgement is inherent in the formation of estimates. Actual results in the future could differ from these estimates which may be material to the annual financial statements. Uncertainties about these estimates and assumptions could result in outcomes that require a material adjustment to the carrying amount of the relevant asset or liability in future periods.

In the process of applying these accounting policies, management has made judgements that may have a significant effect on the amounts recognised in the financial statements.

Estimates are informed by historical experience, information currently available to management, assumptions, and other factors that are believed to be reasonable under the circumstances. The estimates shall be reviewed on a regular basis. Changes in estimates that are not due to errors are processed in the period of the review and applied prospectively.

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

Trade receivables

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

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

Impairment testing

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

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

Refer to note 6 for details regarding the impairment loss recognised in the current year.

Other provisions

Provisions shall be measured using the estimated future outflows required to settle the obligation. In the process of determining the best estimate of the amounts that will be required in future to settle the provision management considers the weighted average probability of the potential outcomes of the provisions raised.

This measurement entails determining what the different potential outcomes will be for a provision as well as the financial impact of each of those potential outcomes. Management then assigns a weighting factor to each of these outcomes based on the probability that the outcome will materialise in future.

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

Additional disclosure of these estimates of provisions are included in note 12 - Provisions.

Leave provision

Leave Provision shall be measured using the accumulated leave days on the assumption that all days will be taken within the stipulated timeframe per applicable leave policy.

Refer to note 12 for details regarding the leave provisions.

Depreciation and amortisation

Depreciation and amortisation recognised on property, plant and equipment and intangible assets shall be determined with reference to the useful lives and residual values of the underlying items.

The useful lives of assets are based on management's estimation of the asset's condition, expected condition at the end of the period of use, its current use, expected future use and the entity's expectations about the availability of finance to replace the asset at the end of its useful life. In evaluating the condition, the use of the asset informs the useful life. Management considers the impact of technology and minimum service requirements of the assets.

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

Contingencies

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

1.5 Property, plant and equipment

The cost of an item of property, plant and equipment is recognised as an asset when:

- it is probable that future economic benefits or service potential associated with the item will flow to the entity; and
- the cost of the item can be measured reliably.

Property, plant and equipment is initially measured at cost.

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

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

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

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

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

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

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

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

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

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

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

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

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

The residual values and the useful lives of the assets have been reviewed at least at each annual reporting date.

The gain or loss arising from the derecognition of an item of property, plant and equipment is included in surplus or deficit when the item is derecognised. The gain or loss arising from the derecognition of an item of property, plant and equipment is determined as the difference between the net disposal proceeds, if any, and the carrying amount of the item.

1.6 Intangible assets

An asset is identifiable if it either:

- is separable, i.e. is capable of being separated or divided from an entity and sold, transferred, licensed, rented or exchanged, either individually or together with a related contract, identifiable assets or liability, regardless of whether the entity intends to do so; or
- arises from binding arrangements (including rights from contracts), regardless of whether those rights are transferable or separable from the entity or from other rights and obligations.

A binding arrangement describes an arrangement that confers similar rights and obligations on the parties to it as if it were in the form of a contract.

An intangible asset is recognised when:

- it is probable that the expected future economic benefits or service potential that are attributable to the asset will flow to the entity; and
- the cost or fair value of the asset can be measured reliably.

The entity assesses the probability of expected future economic benefits or service potential using reasonable and supportable assumptions that represent management's best estimate of the set of economic conditions that will exist over the useful life of the asset.

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

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

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

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

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

Internally generated goodwill is not recognised as an intangible asset.

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

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

1.7 Financial instruments

Initial recognition

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

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

Initial measurement of financial assets and financial liabilities

When a financial instrument is recognised, SAHPRA measures it initially at its fair value plus, in the case of a financial asset or a financial liability not subsequently measured at fair value, transaction costs that are directly attributable to the acquisition or issue of the financial asset or financial liability.

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

Subsequent measurement of financial assets and financial liabilities

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

Gains and losses

For financial assets and financial liabilities measured at amortised cost or cost, a gain or loss is recognised in surplus or deficit when the financial asset or financial liability is derecognised or impaired, or through the amortisation process.

Impairment and uncollectibile financial assets

The entity assesses at the end of each reporting period whether there is any objective evidence that a financial asset or group of financial assets is impaired.

Financial assets measured at amortised cost:

If there is objective evidence that an impairment loss on financial assets measured at amortised cost has been incurred, the amount of the loss is measured as the difference between the asset's carrying amount and the present value of estimated future cash flows (excluding future credit losses that have not been incurred) discounted at the financial asset's original effective interest rate. The carrying amount of the asset is reduced directly. The amount of the loss is recognised in surplus or deficit.

If, in a subsequent period, the amount of the impairment loss decreases and the decrease can be related objectively to an event occurring after the impairment was recognised, the previously recognised impairment loss is reversed directly. The reversal does not result in a carrying amount of the financial asset that exceeds what the amortised cost would have been had the impairment not been recognised at the date the impairment is reversed. The amount of the reversal is recognised in surplus or deficit.

Derecognition

Financial assets

The entity derecognises financial assets using trade date accounting. The entity derecognises a financial asset only when:

- the contractual rights to the cash flows from the financial asset expire, are settled or waived;

Financial liabilities

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

An exchange between an existing borrower and lender of debt instruments with substantially different terms is accounted for as having extinguished the original financial liability and a new financial liability is recognised. Similarly, a substantial modification of the terms of an existing financial liability or a part of it is accounted for as having extinguished the original financial liability and having recognised a new financial liability.

1.8 Statutory receivables

Identification

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

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

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

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

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

Recognition

The entity recognises statutory receivables as follows:

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

Initial measurement

The entity initially measures statutory receivables at their transaction amount.

Subsequent measurement

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

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

Impairment losses

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

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

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

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

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

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

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

Derecognition

- The entity derecognises a statutory receivable, or a part thereof, when:
- the rights to the cash flows from the receivable are settled, expire or are waived;
- the entity transfers to another party substantially all of the risks and rewards of ownership of the receivable; or
- the entity, despite having retained some significant risks and rewards of ownership of the receivable, has transferred control of the receivable to another party and the other party has the practical ability to sell the receivable in its entirety to an unrelated third party, and is able to exercise that ability unilaterally and without needing to impose additional restrictions on the transfer. In this case, the entity:
  - derecognise the receivable; and
  - recognise separately any rights and obligations created or retained in the transfer.

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

1.9 Leases

A lease is classified as a finance lease if it transfers substantially all the risks and rewards incidental to ownership.

Leases are classified as finance leases where substantially all the risks and rewards associated with ownership of an asset are transferred to the entity through the lease agreement. Assets subject to finance leases are recognised in the Statement of Financial Position at the inception of the lease, as is the corresponding finance lease liability.

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

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

Assets subject to operating leases, i.e. those leases where substantially all of the risks and rewards of ownership are not transferred to the lessee through the lease, are not recognised in the Statement of Financial Position. The operating lease expense is recognised over the course of the lease arrangement.

The determination of whether an arrangement is, or contains, a lease is based on the substance of the arrangement at inception date; namely whether fulfillment of the arrangement is dependent on the use of a specific asset or assets or the arrangement conveys a right to use the asset.

Operating leases - lessee

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

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

1.10 Cash and cash equivalents

Cash comprises cash on hand and demand deposits.

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

Cash equivalents are held for the purpose of meeting short-term cash commitments rather than for investment or other purposes.

Cash and cash equivalents comprise bank balances, cash on hand, deposits held at call with banks and other short-term highly liquid investments with original maturities of three months or less which are available on demand.

1.11 Impairment of non-cash-generating assets

Recognition and measurement

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

An impairment loss is recognised immediately in surplus or deficit.

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

The entity assesses at each reporting date whether there is an indication that an asset may be impaired. Where the carrying amount of an asset exceeds its recoverable amount the asset is considered impaired and is written down to its recoverable amount. An assets recoverable amount is the higher of the fair value less costs to sell, and the value-in-use of the asset.

This recoverable amount is determined for individual assets, unless those individual assets are part of a larger cash-generating unit, in which case the recoverable amount is determined for the whole cash-generating unit.

An asset is part of a cash-generating unit where that asset does not generate cash inflows that are largely independent of those from other assets or group of assets.

In determining the recoverable amount of an asset the entity evaluates the assets to determine whether the assets are cash- generating assets or non-cash generating assets. For cash-generating assets the value in use is determined as a function of the discounted future cash flows from the asset.

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

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

2. Value-in-use for cash-generating assets – the estimated future cash flows are discounted to their present value using a discount rate that reflects current market assessments of the time value of money and the risks specific to the asset. In determining fair value less costs to sell, other fair value indicators are used.

Impairment losses of continuing operations are recognised in the Statement of Financial Performance in those expense categories consistent with the function of the impaired asset.

Reversal of an impairment loss

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

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

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

An assessment is made at each reporting date as to whether there is any indication that previously recognised impairment losses may no longer exist or may have decreased. If such indication exists, the entity makes an estimate of the assets or cash- generating unit's recoverable amount.

A previously recognised impairment loss is reversed only if there has been a change in the assumptions used to determine the asset's recoverable amount since the last impairment loss was recognised. The reversal is limited so that the carrying amount of the asset does not exceed its recoverable amount, nor exceed the carrying amount that would have been determined, net of depreciation, had no impairment loss been recognised for the asset in prior years. Such reversal is recognised in the Statement of Financial Performance.

1.12 Employee benefits

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

Short-term employee benefits

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

Short-term employee benefits include items such as:

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

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

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

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

Short term employee benefits encompasses all those benefits that become payable in the short term, i.e. within a financial year or within 12 months after the financial year. Therefore, short term employee benefits include remuneration, compensated absences and bonuses.

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

Post-employment benefits: defined contribution plans

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

Post-employment benefits: Defined benefit plans

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

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

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

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

Current service cost is the increase in the present value of the defined benefit obligation resulting from employee service in the current period.

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

Past service cost is the change in the present value of the defined benefit obligation for employee service in prior periods, resulting in the current period from the introduction of, or changes to, post-employment benefits or other long-term employee benefits. Past service cost may be either positive (when benefits are introduced or changed so that the present value of the defined benefit obligation increases) or negative (when existing benefits are changed so that the present value of the defined benefit obligation decreases). In measuring its defined benefit liability the entity recognises past service cost as an expense in the reporting period in which the plan is amended.

Plan assets comprise assets held by a long-term employee benefit fund and qualifying insurance policies.

The present value of a defined benefit obligation is the present value, without deducting any plan assets, of expected future payments required to settle the obligation resulting from employee service in the current and prior periods.

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

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

The amount recognised as a defined benefit liability is the net total of the following amounts:

- the present value of the defined benefit obligation at the reporting date;
- minus the fair value at the reporting date of plan assets (if any) out of which the obligations are to be settled directly;
- plus any liability that may arise as a result of a minimum funding requirement

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

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

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

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

The entity recognises the net total of the following amounts in surplus or deficit, except to the extent that another Standard requires or permits their inclusion in the cost of an asset:

- current service cost;
- interest cost;
- the expected return on any plan assets and on any reimbursement rights;
- actuarial gains and losses;
- past service cost;
- the effect of any curtailments or settlements; and
- the effect of applying the limit on a defined benefit asset (negative defined benefit liability).

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

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

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

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

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

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

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

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

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

Actuarial assumptions

Actuarial assumptions are unbiased and mutually compatible.

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

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

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

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

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

Other post retirement obligations

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

The entitlement to post-retirement health care benefits is based on the employee remaining in service up to retirement age and the completion of a minimum service period. The expected costs of these benefits are accrued over the period of employment. Independent qualified actuaries carry out valuations of these obligations. The municipality also provides a gratuity and housing subsidy on retirement to certain employees. An annual charge to income is made to cover both these liabilities.

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

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

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

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

1.13 Provisions and contingencies

Provisions are recognised when:

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

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

Provisions shall be measured as the present value of the estimated future outflows required to settle the obligation. Leave Provision shall be measured using the accumulated leave days and the cost of salaries.

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

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

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

Contingent assets and contingent liabilities are not recognised. Contingencies are disclosed in note 29.

1.14 Commitments

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

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

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

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

1.15 Revenue from exchange transactions

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

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

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

Measurement

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

Rendering of services

When the outcome of a transaction involving the rendering of services can be estimated reliably, revenue associated with the transaction is recognised by reference to the stage of completion of the transaction at the reporting date. The outcome of a transaction can be estimated reliably when all the following conditions are satisfied:

- The amount of revenue can be measured reliably;
- It is probable that the economic benefits or service potential associated with the transaction will flow to the entity;
- The stage of completion of the transaction at the reporting date can be measured reliably; and
- The costs incurred for the transaction and the costs to complete the transaction can be measured reliably.

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

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

New application for registration

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

Names and Scheduling Unit – 25%

Inspectorate – 25%

Clinical Trails – 25% PEM – 25%

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

Other fee types

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

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

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

Interest received

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

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

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

1.16 Revenue from non-exchange transactions

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

Non-exchange transactions are transactions that are not exchange transactions. In a non-exchange transaction, an entity either receives value from another entity without directly giving approximately equal value in exchange, or gives value to anotherentity without directly receiving approximately equal value in exchange.

Recognition

An inflow of resources from a non-exchange transaction recognised as an asset is recognised as revenue, except to the extent that a liability is also recognised in respect of the same inflow.

As the entity satisfies a present obligation recognised as a liability in respect of an inflow of resources from a non-exchange transaction recognised as an asset, it reduces the carrying amount of the liability recognised and recognises an amount of revenue equal to that reduction.

Measurement

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

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

Transfers

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

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

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

Services in-kind

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

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

1.17 Comparative figures

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

1.18 Fruitless and wasteful expenditure

Fruitless expenditure means expenditure which was made in vain and would have been avoided had reasonable care been exercised.

All expenditure relating to fruitless and wasteful expenditure is recognised as an expense in the statement of financial performance in the reporting period that the expenditure was incurred. The expenditure is classified in accordance with the nature of the expense, and where recovered, it is subsequently accounted for as revenue in the statement of financial performance.

Reporting and disclosure is done in line with National Treasury Instruction 4 of 2022-2023.

1.19 Irregular expenditure

Irregular expenditure as defined in section 1 of the PFMA is expenditure incurred in contravention of or that is not in accordance with a requirement of any applicable legislation, including PFMA

Confirmed irregular expenditure is investigated in-order to establish facts whether the transgression is related to fraudulent, corrupt and other criminal conduct. Irregular expenditure is recorded in the irregular expenditure register as soon as it is identified.

If losses were incurred and the entity did not achieve value for money and it can be demonstrated that it is impractical to determine total losses incurred, details and reasons as to why the amount cannot be quantified are disclosed.

Reporting and disclosure is done in line with National Treasury Instruction 4 of 2022-2023.

1.20 Segment information

A segment is an activity of an entity:

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

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

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

1.21 Budget information

Budget information in accordance with GRAP 1 and 24, shall be provided in a separate disclosure note to the annual financial statements.

The approved budget is prepared on a modified cash basis and presented by economic classification linked to performance outcome objectives.

The approved budget covers the fiscal period from 2022/04/01 to 2023/03/31.

The annual financial statements and the budget are not on the same basis of accounting therefore a reconciliation between the statement of financial performance and the budget have been included in the annual financial statements. Refer to note 39 & 40.

1.22 Related parties

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

1.23 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.

2. New standards and interpretations

2.1 Standards and interpretations issued, but not yet effective

The entity has not applied the following standards and interpretations, which have been published and are mandatory for the entity's accounting periods beginning on or after 01 April 2023 or later periods:

Standard/ Interpretation:	Effective date: Years beginning on or after	Expected impact:
• Guideline: Guideline on Accounting for Landfill Sites	01 April 2023	Unlikely there will be a material impact
• GRAP 103 (as revised): Heritage Assets	not yet determined	Unlikely there will be a material impact
• iGRAP 7 (as revised): Limit on defined benefit asset, minimum funding requirements and their interaction	01 April 2023	Impact is currently being assessed
• Guideline: Guideline on the Application of Materiality to Financial Statements	Not yet determined	Impact is currently being assessed
• GRAP 104 (as revised): Financial Instruments	01 April 2025	Impact is currently being assessed
• iGRAP 21: The Effect of Past Decisions on Materiality	01 April 2023	Unlikely there will be a material impact
• GRAP 1 (amended): Presentation of Financial Statements	01 April 2023	Unlikely there will be a material impact

Notes to the Annual Financial Statements

for the year ended 31 March 2023

	2023 R	2022 R
3. Receivables from exchange transactions		
Trade debtors	8 713 866	7 638 814
Provision for impairment	(5 155 309)	(4 691 161)
Rental deposit	3 541 472	2 791 114
	7 100 029	**5 738 767**
Statutory receivables included in receivables from exchange transactions above are as follows:		
Retention fees	6 651 703	6 876 900
Licence collection fees	1 231 260	303 060
Inspection fees	798 903	519 654
New registrations	32 000	-
	8 713 866	**7 699 614**
Provision for impairments	(5 155 309)	(4 691 161)
Financial asset receivables included in receivables from exchange transactions above	**3 541 472**	**2 730 314**
Total receivables from exchange transactions	7 100 029	5 738 767

3. Receivables from exchange transactions (continued)

Statutory receivables general information

Transaction(s) arising from statute

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

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

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

Determination of transaction amount

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

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

Interest or other charges levied/charged

There was no interest charged on the statutory receivable arising from exchange transactions at 31 March 2023 in line with SAHPRA's revenue policy

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

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

	2023 R	2022 R

3. Receivables from exchange transactions (continued)

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

Reconciliation of provision for impairment

Relating specifically to Statutory Receivables		
Opening balance	4 691 161	2 088 973
Provision for impairment	1 473 599	4 196 655
Amounts written off as uncollectable	(1 009 451)	(1 594 467)
	5 155 309	**4 691 161**

Receivables past due but not impaired

Relating specifically to Statutory Receivables

Statutory receivables which are less than 1 year past due are not considered to be impaired. At 31 March 2023, R830 903 (2022: R508 103) were past due but not impaired.

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

9 months past due	830 903	508 103

Factors the entity considered in assessing statutory receivables impaired

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

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

	2023 R	2022 R

3. Receivables from exchange transactions (continued)

Receivables impaired

Relating specifically to Statutory Receivables

As of 31 March 2023, statutory receivables of R7 882 963 (2022: R7 130 711) were impaired and provided for.

The amount of the provision was R5 155 309 31 March 2023 (2022: R4 691 161).

The ageing of these receivables are as follows:

3 to 6 months	427 200	207 400
6 - 12 months	3 969 093	2 883 061
Over 12 months	3 486 670	4 040 250
Total	**7 882 963**	**7 130 711**

Factors the entity considered in assessing statutory receivables impaired

The following is considered as objective evidence that a trade receivable is impaired:
- Debtors did not respond to follow request or indicate financial difficulty;
- Customer in liquidation;
- Judgment awarded in favor of the entity;
- Uneconomical to initiate or to continue with legal proceedings; and
- Official transfers, cancellations and licenced site that have closed down and liquidated.

Notes to the Annual Financial Statements

for the year ended 31 March 2023

	2023 R	2022 R
4. Receivables from non-exchange transactions		
Grant receivable	60 326	8 822 956
Staff debtors	2 337 228	629 190
	2 397 554	**9 452 146**

Grant receivables includes grant received from the Clinton Health Access Initiative (CHAI) and the Global Fund.

Staff debtors relate to section 197 transfer process of employees taken on from the NDOH where some employees were not removed from the NDOH persal system, two months medical aid contributions were not deducted from the employees salary during the transfer from persal to SAHPRA's payroll. During the 2022/23 period additional staff debt were raised relating to PAYE payments made on behalf of employees.

5. Cash and cash equivalents

Cash and cash equivalents consist of:		
Petty cash	5 650	8 031
Bank balances held at ABSA bank	1 692 549	2 370 048
Corporation for public deposits held at SA Reserve Bank	326 919 620	241 995 225
Call account - Global fund project	986 076	-
	329 603 895	**244 373 304**

No cash and cash equivalents balances are restricted except for unspent conditional grants as disclosed in note 11.

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 2023. The entity's maximum exposure to credit risk as a result of bank balances held is limited to the carrying value of these balances as detailed above.

6. Property, plant and equipment

	2023			2022		
	Cost / Valuation	Accumulated depreciation and accumulated impairment	Carrying value	Cost / Valuation	Accumulated depreciation and accumulated impairment	Carrying value
Furniture and fixtures	9 346 417	(2 277 132)	7 069 285	8 074 818	(1 413 901)	6 660 917
Motor vehicles	3 289 766	(291 475)	2 998 291	971 954	-	971 954
Computer equipment	23 482 454	(10 347 708)	13 134 746	21 467 037	(8 694 350)	12 772 687
Leasehold improvements[1]	6 989 440	(3 580 656)	3 408 784	6 750 625	(2 218 975)	4 531 650
Other fixed assets[2]	3 129 540	(1 561 764)	1 567 776	3 062 061	(1 378 938)	1 683 123
Total	**46 237 617**	**(18 058 735)**	**28 178 882**	**40 326 495**	**(13 706 164)**	**26 620 331**

Reconciliation of property, plant and equipment - 2023

	Opening balance	Additions	Disposals	Depreciation	Impairment loss	Total
Furniture and fixtures	6 660 917	1 294 519	(7 281)	(878 870)	-	7 069 285
Motor vehicles	971 954	2 317 812	-	(291 475)	-	2 998 291
Computer equipment	12 772 687	3 458 193	(126 245)	(2 962 950)	(6 939)	13 134 746
Leasehold improvements[1]	4 531 650	238 815	-	(1 361 681)	-	3 408 784
Other fixed assets [2]	1 683 123	119 689	(2 847)	(232 176)	(13)	1 567 776
	26 620 331	**7 429 028**	**(136 373)**	**(5 727 152)**	**(6 952)**	**28 178 882**

6. Property, plant and equipment (continued)

Reconciliation of property, plant and equipment - 2022

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

Other information

None of the property, plant and equipment for the current and prior year were pledged as security for any obligation.

No expenditure has been incurred relating to capital maintenance. Refer to note 26 for general repairs and maintenance expenditure.

[1]- Leasehold improvements include improvements made to leased office accommodation. Refer to notes 8 and 28.

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

7. Intangible assets

	2023			2022		
	Cost / Valuation	Accumulated depreciation and accumulated impairment	Carrying value	Cost / Valuation	Accumulated depreciation and accumulated impairment	Carrying value
Computer software	**3 969 884**	**(1 084 006)**	**2 885 878**	**3 343 134**	**(525 075)**	**2 818 059**

	2023 R	2022 R

7. Intangible assets (continued)

Reconciliation of intangible assets - 2023

Figures in Rand	Opening balance	Additions	Amortisation	Total
Computer software	2 818 059	626 750	(558 931)	2 885 878

Reconciliation of intangible assets - 2022

Figures in Rand	Opening balance	Additions	Amortisation	Total
Computer software	1 872 911	1 294 018	(348 870)	2 818 059

Other information

Intangible assets consist of acquired computer software and there are not internally generated computer software in use

8. Operating lease liability

Operating lease liability	**4 063 589**	**3 259 196**

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. Refer to note 28 for lease commitment disclosures.

9. Payables from exchange transactions

Trade payables	3 967 598	4 763 825
Salary accrual	1 320 175	1 584 383
Accrued thirteenth cheque	2 376 526	2 251 260
Accrued expenditure	3 210 797	6 673 294
Travel lodge card	644 662	383 642
	11 519 758	**15 656 404**

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

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

	2023 R	2022 R

10. Employee benefit obligations

Defined benefit plan

Post retirement medical aid 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 2023 the aggregate membership of the qualifying employees was 90 (2022:91). In-service employees were 90 (2022:91) retired employees, a total of 1 (2022:0) employee. Poneso Consulting conducted a valuation of the post-retirement liability as at 31 March 2023. Taking into consideration the current services cost, interest costs and benefits paid.

The amounts recognised in the statement of financial position are as follows:		
Carrying value		
Present value of the defined benefit obligation-wholly unfunded	(9 553 038)	(9 384 332)
Non-current liabilities	(8 559 108)	(8 236 727)
Current liabilities	(993 930)	(1 147 605)
	(9 553 038)	**(9 384 332)**

Changes in the present value of the defined benefit obligation are as follows:		
Opening balance	9 384 332	-
First time recognition	-	9 384 332
Net expense recognised in the statement of financial performance	168 706	-
	9 553 038	**9 384 332**

	2023 R	2022 R
10. Employee benefit obligations (continued)		
Net expense recognised in the statement of financial performance		
Current service cost	1 147 605	-
Interest cost	982 605	-
Actuarial (gains) losses	(1 930 448)	-
Benefits paid	(31 056)	-
	168 706	**-**
Calculation of actuarial gains and losses		
Actuarial (gains) losses – Obligation	(1 930 448)	-
Key assumptions used		
Assumptions used at the reporting date:		
Health care cost inflation	7,65 %	8,00 %
Discount rates used	10,48 %	11,31 %
Real discount rate	2,62 %	3,06 %
Continuation at retirement	75,00 %	75,00 %
Proportion married	80,00 %	80,00 %

Other assumptions

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:

	One percentage point increase	One percentage point decrease
Effect on the aggregate of the service cost	811 666	1 233 480
Effect on the aggregate of interest cost	893 939	1 319 987
Effect on defined benefit obligation	7 909 828	11 674 831

Amounts for the current and previous four years are as follows:

Amounts for the current and previous four years are as follows:

	2023	2022	2021	2020	2019
Defined benefit obligation	9 553 038	9 384 322	-	-	-

	2023 R	2022 R
11. Unspent conditional grants		
Unspent conditional grants and receipts comprises of:		
Unspent conditional grants and receipts		
Nepad Auda grant	651 570	297 630
BMGF grant	-	3 085 629
GiZ grant	3 626 236	-
SAMRC grant	39 890	-
	4 317 696	**3 383 259**
Movement during the year		
Balance at the beginning of the year	3 383 259	-
Additions during the year	14 574 523	8 772 992
Income recognition during the year	(13 640 086)	(5 389 733)
	4 317 696	**3 383 259**

These amounts are in a ring-fenced investment at the Corporation for Public Deposits as disclosed in Note 5 until utilised. Should the conditions not be met, a repayment to the grantor will include interest accrued at a rate of 6.00 percent.

12. Provisions		
Leave provision	13 311 676	8 838 633
PMDS provision	6 975 378	5 358 516
	20 287 054	**14 197 149**

Leave provision

SAHPRA does not have an unconditional right to defer settlement of its leave liabilities and its policies stipulate that leave is forfeited if not used within 6 months after the start of a calendar year, except for capped leave. A significant part of the leave provision balance relates to take on balance for employees who were transferred from the National Department of Health to the entity.

12. Provisions (continued)

Performance management and development system provision (PMDS)

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

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

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

- Actual scores for the 2021/22 assessment
- That more staff will strive to comply and achieve with evidence available based on understanding and experiences of the 2021/22 assessment
- The inability to retain staff or failed recruitment due to inadequate package offering

	Current Cycle Leave	Previous Cycle Leave	Capped Leave	PMDS	Notch Increase	Total
As at 1 April 2022	2 518 091	5 536 899	783 643	5 358 516	-	14 197 149
Additions for the year	4 459 538	8 350 835	-	6 378 439	-	19 188 812
Reversal during the year	(2 518 091)	(5 536 899)	(282 341)	(4 761 576)	-	(13 098 907)
As at 31 March 2023	**4 459 538**	**8 350 835**	**501 302**	**6 975 379**	**-**	**20 287 054**

	Current Cycle Leave	Previous Cycle Leave	Capped Leave	PMDS	Notch Increase	Total
As at 1 April 2021	2 635 350	7 293 766	658 969	2 110 938	1 489 373	14 188 395
Additions for the year	2 518 093	5 536 899	261 933	5 358 516	-	13 675 438
Reversal during the year	(2 635 350)	(7 293 766)	(137 259)	(2 110 938)	(1 489 373)	(13 666 686)
As at 31 March 2022	**2 518 093**	**5 536 899**	**783 643**	**5 358 516**	**-**	**14 197 149**

	2023 R	2022 R
13. Income received in advance		
Reconciliation		
Unallocated deposits received	125 675 804	72 348 162
Revenue received in advance	131 100 547	119 178 746
	256 776 351	**191 526 908**

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

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

14. Deferred income : Backlog reduction project		
Deferred income	-	9 272 300

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

Notes to the Annual Financial Statements

for the year ended 31 March 2023

15. Fee Income

	2023 R	2022 R
Amendments	25 802 430	28 895 360
Backlog reduction project	8 813 100	15 549 797
Biological medicine	3 857 600	5 012 700
Cannabis inspection	723 200	857 839
Cannabis licences	1 097 640	740 890
Certificates	781 199	751 800
Clinincal trials	13 463 300	13 344 180
Evaluations	36 675 400	18 317 125
Inspection fees	8 176 399	6 344 579
Licence fee	2 683 240	1 968 780
Licence retention fees	8 067 600	7 941 199
MD clinical trials	282 100	-
MD licence fees	16 533 040	9 772 960
Permits	6 199 775	5 553 390
Registration fee	1 146 400	423 960
Retention fees	67 704 900	63 684 662
Screening	-	193 600
Section 21	4 012 021	3 517 338
Section 21 CMS	7 700	11 370
Section 21 Veterinary	136 850	169 320
	206 163 894	**183 050 849**
Fees received per function		
Medicines evaluation, registration and product lifecycle	156 473 230	145 421 385
Inspections, permits and licences issued	45 534 093	33 931 436
The use of unregistered medicines	4 156 571	3 698 028
Total	**206 163 894**	**183 050 849**

Notes to the Annual Financial Statements

for the year ended 31 March 2023

	2023 R	2022 R
16. Sundry income		
Proceeds from sale of assets and insurance	65 135	217 309
17. Investment revenue		
Investment Income	20 661 972	9 557 126

Included in interest revenue is total interest earned from cash held at ABSA bank based on the average interest rate of 5% (2022: 3%) and cash held at SA Reserve Bank Corporation for Public Deposits bank based on the average interest rate of 6.04% (2022: 3.77%) per annum. Accrued interest on the rental deposit held by the lessor in a interest bearing call account at an average rate of 5.00% (2022: 3%) per annum.

18. Transfer payments		
Operating grants		
Transfer payment from the National Department of Health	149 965 000	146 287 000
19. Services in-kind		
The nature and type of major classes of services in-kind received, are as follows:		
Services in-kind that are significant to the entities operations and/or service delivery objectives		
Backlog reduction project	-	15 348 507
SAHPRA received an in-kind benefit as services from international evaluators were paid directly by a 3rd party - Wits Health Consortium. Other costs were incurred to render the services including bank charges and management fees.		
Customer relations system	2 252 735	-
SAHPRA received an in-kind benefit as services for intangible assets and other costs were paid directly by a 3rd party - FDCO.		
Quality management system	1 346 662	-
SAHPRA received an in-kind benefit as a quality management system was paid directly by a 3rd party - Clinton Health Access Initiative.		
	3 599 397	**15 348 507**
Services in-kind not significant to the entity's operations and/or service delivery objectives and/or do not satisfy the criteria for recognition		
CHAI CSIR project	-	2 236 152
CSIR incurred cost on behalf of SAHPRA through the CHAI grant whereby CSIR assists SAHPRA with Data anlaytics and analyse Healthcare professionals' COVID-19 vaccination data.		
	-	**2 236 152**

Notes to the Annual Financial Statements

for the year ended 31 March 2023

	2023 R	2022 R
20. Grant realised		
BMGF grant	9 398 629	3 954 011
Nepad Auda grant	108 774	1 435 722
SAMRC grant	483 090	-
	9 990 493	**5 389 733**
Reconciliation of conditional contributions		
Current-year receipts	14 308 189	8 772 992
Conditions met - transferred to revenue	(9 990 493)	(5 389 733)
Conditions not met - balance of conditional grant	(4 317 696)	(3 383 259)
	-	-

Refer to note 11 for the remaining balance of funds where conditions are still to be met.

21. Grant income		
Grant income - global fund	3 709 919	7 889 314
Clinton Health Access Initiative (CHAI) grant	-	933 642
	3 709 919	**8 822 956**

	2023 R	2022 R
22. Employee related costs		
Basic and pensionable salaries	169 894 363	151 184 083
Bargaining council	7 708	3 470
Cellphone allowances	1 443 558	947 726
Housing benefits and allowances	2 109 704	2 241 772
Leave accrued	5 797 619	(571 803)
Medical aid	8 635 128	3 257 193
Post retirement medical aid adjustment	168 000	9 384 332
Overtime payments	93 891	-
PAYE	-	108 000
Pension fund	20 877 644	9 991 270
SARS penalty	348 656	-
SDL and UIF	2 949 653	1 756 899
Standby allowances	97 504	42 421
Thirteenth cheque and performance bonus	11 579 367	12 922 352
Travel, subsistence and other allowances	239 529	65 843
	224 242 324	**191 333 558**

	2023 R	2022 R
23. Backlog reduction project		
Bank charges	103 612	101 811
Foreign evaluators	6 083 364	7 000 996
Local evaluators	2 064 581	7 490 649
Services in kind	-	15 348 507
Share of communication	-	95 000
Catering	70 675	-
Extedo System	1 498 955	1 282 909
Publication of journal	58 851	-
Share of rental	-	779 120
Training	-	11 843
Compensation of employees	10 276 978	20 164 920
	20 157 016	**52 275 755**

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

24. Depreciation and amortisation		
Property, plant and equipment	5 727 152	6 667 279
Intangible assets	558 930	348 870
	6 286 082	**7 016 149**

25. Laboratory services		
Outsourced services		
NCL Laboratory	**22 636 216**	**20 797 520**

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

Notes to the Annual Financial Statements

for the year ended 31 March 2023

	2023 R	2022 R
26. Operating expenses		
Advertising	207 188	180 624
Auda Nepad expenses	108 774	1 228 733
Bank charges	197 953	133 344
Board costs	2 623 563	1 733 687
Bursaries	8 810	72 069
Catering	357 757	135 383
Cleaning	655 785	535 441
Communication	1 644 012	2 407 161
Computer expenses	945 665	1 779 241
Conferences	138 344	73 489
Consulting and professional fees [1]	3 067 794	1 439 892
Consumables	8 277	-
Electricity and utilities	297 748	(89 532)
External audit fees [2]	4 278 390	2 933 119
Foreign evaluators	6 213 263	-
General expenses	6 881	910
Insurance	388 664	295 234
Internal audit fees [2]	2 703 785	418 550
Legal fees	5 531 380	7 516 893
Licences	7 384 426	3 380 027
Local evaluators and expert committees	16 605 955	17 075 693
Marketing, printing and publication	2 112 909	348 785
Medicine testing	401 145	155 616

	2023 R	2022 R
26. Operating expenses (continued)		
Membership fees	507 452	328 169
Minor assets	140 389	44 182
Motor vehicle expenses	3 492 370	1 711 586
Postage and courier	14 474	13 222
Printing and stationery	246 380	501 253
Protective clothing	118 524	17 038
Refreshments	-	40 974
Relocation of SAHPRA	947 822	753 190
Repairs and maintenance	300 195	212 115
Security	222 284	278 712
Services in kind	2 972 646	-
Staff training and welfare	1 827 695	1 072 912
Travel - local	5 250 268	4 026 235
Travel - non-employees	281 808	-
Travel - overseas	2 189 923	-
Venue and facilities	160 712	-
	74 561 410	**50 753 947**

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

[2] Audit fees were separated into external audit fees and internal audit fees. The convention was applied retrospectively for 2022 with no change to the overall amount.

Notes to the Annual Financial Statements

for the year ended 31 March 2023

	2023 R	2022 R
27. Cash generated from operations		
Surplus	22 507 237	22 057 505
Adjustments for:		
Depreciation and amortisation	6 286 082	7 016 149
Loss on sale of assets and liabilities	136 414	412 627
Impairment deficit	6 952	404 044
Bad debts written off	1 530 189	-
Movements in operating lease assets and accruals	804 393	1 658 681
Movements in retirement benefit assets and liabilities	168 706	9 384 332
Movements in provisions	6 089 905	8 754
Accrued interest on rental deposit and debtors	176 553	-
Gain on foreign exchange	142 407	-
Assets donated	208 500	-
Proceeds from disposal of assets	(40 640)	(201 062)
Changes in working capital:		
Receivables from exchange transactions	(3 338 091)	4 698 198
Other receivables from non-exchange transactions	7 054 592	(9 417 472)
Prepayments	(1 181 544)	(2 031 352)
Investing in payables	(850 060)	(1 213 454)
Payables from exchange transactions	(3 994 196)	(16 409 387)
Unspent conditional grant	934 437	3 383 259
Income received in advance	65 249 443	93 765 664
Deferred income - backlog reduction project	(9 272 300)	(15 748 398)
	92 618 979	**97 768 088**

	2023 R	2022 R
28. Commitments		
Authorised expenditure		
Already contracted for but not provided for		
National Control Laboratory contract	5 742 094	3 495 905
Supply of facilities services	1 956 506	2 408 338
Supply of IT equipment and related IT expenditure	3 128 670	5 044 548
Supply of finance services	3 353 112	-
Open purchase orders	18 645 545	8 424 632
Supply of communication services	-	571 869
Office accommodation	67 785 247	68 834 418
Supply of legal services	8 223 971	4 841 843
Supply of secretarial services	471 019	-
Supply of risk management	741 495	2 574 904
Supply of HR services	898 730	1 878 446
	110 946 389	**98 074 903**
Total commitments		
Already contracted for but not provided for	110 946 389	98 074 903

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

Operating leases - as lessee (expense)		
Minimum lease payments due		
- within one year	20 400 838	18 575 725
- in second to fifth year inclusive	34 643 946	52 948 510
	55 044 784	**71 524 235**

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

29 Contingencies

Contingent assets

Cost order

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

Vaccines being made available to children of the age of 12 to 17. The matter was ruled in favour of SAHPRA with costs during the 2021/22 financial year.

The registration and sale of a certain vaccine. The application was dismissed by the court and the applicant's application for leave to appeal was also dismissed in April 2023 with costs in favour of SAHPRA.

Interdicting government on the roll out of Covid-19 vaccines and to provide detailed information. The applicants filed the matter in two courts of which one has already dismissed the applications with costs in favour of SAHPRA in February 2023.

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

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

Claim against SAHPRA for services rendered

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

The matter went through an arbitration process which ruled in favour of SAHPRA and dismissing the claimants claim

The contingent asset amounts to R96 337.78 which based on a settlement estimated agreed between the parties which is still to be finalized by the Tax Master.

Notes to the Annual Financial Statements

for the year ended 31 March 2023

	2023 R	2022 R

30. Related parties

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

Related party balances

National Department of Health

Creditors balance - owing to NDOH	-	(1 073 324)

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

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

Related party transactions

National Department of Health

Government grant received	149 965 000	146 287 000

Remuneration of Executive Authority and Management

	2023	
Board fees[1]	**Board Fees**	**Total**
Prof H.V. Rees - Chairperson	190 992	190 992
Adv H. Cassim - Member	124 999	124 999
Mr T.N. Baloyi - Member	209 150	209 150
Prof H. P. Demana - Member	96 025	96 025
Mr I. Mashau - Member	228 429	228 429
Ms L. Mothae - Member	268 541	268 541
Dr O. Khaole - Vice Chair	280 074	280 074
Dr J. Tsoka-Gwegweni - Member	79 091	79 091
Dr X Ngobese - Member	293 385	293 385
Ms D Maraka - Member	226 654	226 654
Prof Y Choonara - Member	69 764	69 764
Prof J Meyer - Member	96 950	96 950
Ms M Skhosana - Member	148 305	148 305
Dr A Kgasi - Member	150 167	150 167
Dr Z Makatini - Member[2]	-	-
	2 462 526	**2 462 526**

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

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

30. Related parties (continued)

Executive management 2023

	Basic salary	Pension	Other benefits received	Total
Name				
Dr B Semete-Makokotlela - Chief Executive Officer	3 005 567	-	56 421	3 061 988
Ms. P Nkambule - Chief Regulatory Officer	1 459 917	142 826	36 505	1 639 248
Ms. C Reyneke - Chief Operating Officer	2 247 800	-	36 505	2 284 305
Mr RB Gouws - Chief Financial Officer	1 898 253	-	41 712	1 939 965
Mr G Mtakati - HR Executive	1 394 373	-	36 673	1 431 046
	10 005 910	**142 826**	**207 816**	**10 356 552**

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

30. Related parties (continued)

	2022	
Board fees	**Board Fees**	**Total**
Prof H.V. Rees - Chairperson [3] [4]	227 569	227 569
Ms M. Hela - Deputy Chairperson [3]	56 607	56 607
Prof M.S. Banoo - Member [1] [3]	-	-
Dr E.N. Madela-Mntla - Member [3]	45 527	45 527
Dr T.M. Motshudi - Member [3]	51 861	51 861
Prof A. Dhai - Member [3]	57 152	57 152
Prof M.J. Mphahlele - Member [3]	12 462	12 462
Dr U. Mehta - Member [3]	37 294	37 294
Dr M.S.M. Molefe - Member [2]	-	-
Adv H. Cassim - Member [3] [4]	192 521	192 521
Mr T.N. Baloyi - Member [3] [4]	172 500	172 500
Prof K.C. Househam - Member [3]	10 731	10 731
Prof H.P. Demana - Member [3] [4]	49 408	49 408
Mr I. Mashau - Member [3] [4]	118 909	118 909
Ms L Mothae - Member [3] [4]	95 059	95 059
Dr O. Khaole - Vice Chair [4]	79 184	79 184
Dr J. Tsoka-Gwegweni - Member [4]	25 348	25 348
Dr X Ngobese - Member [4]	63 224	63 224
Ms D Maraka - Member [4]	34 630	34 630
Prof Y Choonara - Members [5]	29 570	29 570
Prof J Meyer - Member [5]	21 836	21 836
Ms M Skhosana - Member [5]	27 749	27 749
Dr A Kgasi - Member [5]	20 955	20 955
Dr Z Makatini - Member [5]	26 830	26 830
	1 456 926	**1 456 926**

[1] The board fees 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
[3] 1st Board term expired 30 September 2021
[4] 2nd board term commenced 1 October 2021
[5] Appointed December 2021

	2023 R	2022 R

30. Related parties (continued)

Executive management

2022	Basic salary	Pension	Other benefits received	Total
Name				
Dr B Semete-Makokotlela - Chief Executive Officer	2 892 750	-	77 157	2 969 907
Ms P Nkambule - Chief Regulatory Officer	1 536 809	140 542	53 437	1 730 788
Ms C. Reynecke - Chief Operating Officer	2 163 426	-	64 737	2 228 163
Mr G. Mtakati - HR Executive	1 327 974	-	35 982	1 363 956
Mr R.B. Gouws - Chief Financial Officer	1 827 000	-	61 372	1 888 372
	9 747 959	**140 542**	**292 685**	**10 181 186**

31. Independent audit committee members remuneration

Independent audit committee members - fee for attending meetings

Mr E.O. Omolo [1]	28 875	41 413
Ms Y. Pamla [2]	91 526	30 741
Mr B Gordon [3]	-	-
	120 401	**72 154**

[1] Appointed 2 May 2020 - Resigned September 2022

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

[3] Appointed 1 April 2021 - Member appointed in the public sector - no fees claimed.

32. Financial instruments disclosure

Categories of financial instruments

Financial assets

2023	At amortised cost	Total
Receivables from non-exchange transactions	2 397 554	2 397 554
Cash and cash equivalents	329 603 895	329 603 895
	332 001 449	**332 001 449**

Financial liabilities

2023	At amortised cost	Total
Trade payables	3 967 598	3 967 598
Accrued expenditure	3 210 797	3 210 797
Travel lodge card	644 662	644 662
Income received in advance	256 776 351	256 776 351
	264 599 408	**264 599 408**

Financial assets

2022	At amortised cost	Total
Receivables from non-exchange transactions	9 452 146	9 452 146
Cash and cash equivalents	244 373 304	244 373 304
	253 825 450	**253 825 450**

Financial liabilities

2022	At amortised cost	Total
Trade payables	4 763 825	4 763 825
Accrued expenditure	7 446 712	7 446 712
Travel lodge card	383 642	383 642
Income received in advance	191 526 908	191 526 908
Deferred income - Backlog reduction project	9 272 300	9 272 300
	213 393 387	**213 393 387**

	2023 R	2022 R

32. Prior period errors

a) During the finalisation of the Backlog Clearance projected during 2022/23 a final reconciliation was performed on the remaining deferred revenue and identified withdrawn applications not yet removed. This was mainly due to the official application withdrawal only indicating masters and not the duplicates matched to the master resulting in a remaining balance after the project was completed. Revenue should have been recognised for the withdrawn duplicates in the prior year.

b) A correction in the treatment of post-retirement medical aid subsidy resulted in recognition of a medical aid obligation in the prior year.

c) Some retention fees were incorrectly raised as debtors in the prior years' resulting in a duplication of revenue. Management reversed the debtor raised and the revenue recognised as revenue and debtors were overstated by R1 948 538. Furthermore, the provision for impairment was also reduced by R1 948 538 which has resulted in a net effect of R0 on trade and other receivables.

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

Statement of financial position

Deferred income: Backlog reduction project	-	(3 204 501)
Employee benefit obligation: current liability	-	1 147 605
Employee benefit obligation: non-current liability	-	8 236 727
Trade debtors	-	(1 948 538)
Provision for impairments	-	1 948 538

Statement of financial performance

Fee income	-	1 255 962
Employee related cost	-	9 384 332
Bad debts wriiten off	-	(1 948 538)

33.1 Prior-year adjustments

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

Statement of financial position

2022	Note	As previously reported	Correction of error	Restated
Deferred income: Backlog reduction project		(12 476 800)	3 204 500	(9 272 300)
Employee benefit obligation: current liability		-	(1 147 605)	(1 147 605)
Employee benefit obligation: non-current liability		-	(8 236 727)	(8 236 727)
Receivables from exchange transactions		5 738 767	-	5 738 767
		(6 738 033)	**(6 179 832)**	**(12 917 865)**

Statement of financial performance

2022	Note	As previously reported	Correction of error	Restated
Fee income		(181 794 887)	(1 255 962)	(183 050 849)
Employee related cost		181 949 226	9 384 332	191 333 558
Bad debts written off		6 179 867	(1 948 538)	4 231 329
Surplus for the year		**6 334 206**	**6 179 832**	**12 514 038**

34. Risk management

Financial risk management

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

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

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

Liquidity risk

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

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

Maturity groupings

	Later than one month	Later than one month and no later than three months	Later than three months and no later than one year	Later than one year and no later than five years	Total
Trade payables from exchange transactions	-	3 911 728	55 840	-	3 967 598
Income received in advance	-	-	256 776 351	-	256 776 351
Accrued expenditure	-	846 451	2 364 346	-	3 210 797
Travel lodge card	644 662	-	-	-	644 662
	644 662	**4 758 179**	**259 196 537**	**-**	**264 599 408**

	2023 R	2022 R

34. Risk management (continued)

Concentration of risk

	Neither past due nor impaired	Past due but not impaired less than two months	Past due but not impaired more than two months	Carrying amount
Revenue received in advance	256 776 351	-	-	256 776 351
Receivables from non-exchange transactions	-	-	2 397 554	2 397 554
	256 776 351	**-**	**2 397 554**	**259 173 905**

Credit risk

Credit limits were exceeded during the reporting period, and appropriate provisions were raised to mitigate this risk.

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

Cash and cash equivalents	329 603 895	244 373 304
Receivables from non-exchange transactions	2 429 554	9 452 146

Market risk

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

Interest rate risk

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

35. Going concern

The annual financial statements have been prepared on the basis of accounting policies applicable to a going concern. This basis presumes that funds will be available to finance future operations and that the realisation of assets and settlement of liabilities, contingent obligations and commitments will occur in the ordinary course of business.

36. Grant funding

36.1 Bill and Melinda Gates Foundation

During the 2020/21 financial year, SAHPRA received an in-kind donation from the Bill and Melinda Gates Foundation (BMGF). There is an in principle agreement in place between SAHPRA and the BMGF to financially support the "Backlog Reduction Project". The support is specifically for:

- Provide ongoing backlog clearance project management support in the development to the official launch of the project and harmonization of 'business as usual' with backlog processes
- Recruitment, management and payment of foreign evaluators to support backlog clearance programme
- Development of guidelines and procedures.

The maximum benefit for the period under review amounts to R0 (2022: R15,3 million).

Refer to note 20 for more information regarding the Backlog reduction project expenditure and note 19 for the services in-kind note

36.2 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.

36.3 Clinton Health Access Initiative (CHAI)

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

Refer to Note 4 for amount invoiced for the project.

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

Refer to note 19 for the services in-kind showing benefit received.

	2023 R	2022 R

36. Grant funding (continued)

36.4 Global fund

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

Refer to note 21 for breakdown of grant received.

37. Irregular and Fruitless and Wasteful Expenditure [1]

Irregular expenditure	-	3 009 867
Fruitless and wasteful expenditure	342 385	32 000
Closing balance	**342 385**	**3 041 867**

[1]-Refer to the reconciling notes under section E in the annual report

Notes to the Annual Financial Statements

for the year ended 31 March 2023

	2023 R	2022 R
38. 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	22 507 237	22 057 505
Adjusted for:		
(Under) / over expenditure on backlog reduction project	(3 791 825)	4 797 228
Prior year adjustment	-	(1 542 161)
Increase / decrease in backlog reduction project - grant received	11 390 700	28 855 396
Increases / decreases in services in kind	(3 599 397)	(15 348 507)
Grant realised	(9 990 493)	(1 435 722)
Backlog reduction project - grant received	-	(7 889 314)
Over expenditure on impairment of assets	6 952	404 044
(Increase) / decrease in fee income	(27 314 140)	(6 744 464)
(Increase) / decrease in interest received	(11 511 408)	(5 558 112)
Over / (under) expenditure in employee related costs	13 693 618	3 594 271
Over expenditure on operating leases	1 211 050	(3 212 275)
Under expenditure on operating expenses	829 223	(28 702 061)
Over expenditure on depreciation	6 286 082	7 016 149
Over expenditure on contracted services	773 531	2 480
Over expenditure on loss of disposal of assets	136 414	376 028
Over expenditure on bad debts	1 530 189	3 669 823
Increase in gain on foreign exchange	46 350	(127 249)
Increase in sundry income	(65 135)	(213 059)
Increase in asset transferred	(208 500)	-
Increase in actuarial gain	(1 930 448)	-
Net surplus per approved budget	**-**	**-**

39. Budgeted differences

Material differences between budget and actual amounts

39.1 Fee and Sundry Income

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

39.2 Interest Received

Interest received is higher than the budget due to a higher interest rate received on invested cash at the Corporation for Public Deposits and a higher than expected cash balance maintained during the year.

39.3 Employee Related Costs

Employee related costs are higher than the budget due to impact of non-cash items such as provisions raised.

39.4 Asset related expenditure

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

39.5 Operating Expenses

Operating expenses are higher than budget due to increased cost on foreign and local external evaluators and expert committees.

39.6 Backlog reduction project

Expenditure is less than budget due to reduction in cost of employment and the project finalised as anticipated.

39.7 Lease rentals on operating lease

Expenditure is higher due to new leases entered into for CPT and DBN as well as in year levies, rates and tax increases.

39.8 Grant revenue

Grant revenue not budgeted for

38.9 Non-cash expenditure

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

PHYSICAL ADDRESS:
Building A
Loftus Park
402 Kirkness Street
Arcadia
Pretoria

POSTAL ADDRESS:
South African Health Products
Regulatory Authority
Private Bag X828
Pretoria
0001

CONTACT

012 501 0300

enquiries@sahpra.org.za

www.sahpra.org.za