SAHPRA
South African
Health Products
Regulatory Authority

ANNUAL REPORT 2020|21

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SAHPRA
South African Health Products Regulatory Authority

PART A
GENERAL INFORMATION

1. PUBLIC ENTITY'S GENERAL INFORMATION

REGISTERED NAME	South African Health Products Regulatory Authority (SAHPRA)
REGISTRATION NUMBER	Not applicable
PHYSICAL ADDRESS	Building A Loftus Park 402 Kirkness Street Arcadia Pretoria 0083
POSTAL ADDRESS	Private Bag X828 Pretoria 0001
TELEPHONE NUMBER	012 501 0300
E-MAIL ADDRESS	enquiries@sahpra.org.za
WEBSITE ADDRESS	www.sahpra.org.za
EXTERNAL AUDITORS	Auditor-General of South Africa
BANKERS	ABSA
COMPANY/ BOARD SECRETARY	Advocate Teboho Peter Nthotso

2. LIST OF ABBREVIATIONS/ACRONYMS

ADR	Adverse Drug Reactions
AE	Adverse Event
AGSA	Auditor-General of South Africa
APIs	Active Pharmaceutical Ingredients
AVAREF	African Vaccine Regulatory Forum
B-BBEE	Broad-Based Black Economic Empowerment
CBD	Cannabidiol
COVID-19	Coronavirus Disease
FTP	File Transfers Protocol
GL	General Ledger
GMP	Good Manufacturing Practice
GRAP	Standards of Generally Recognised Accounting Practice
HR	Human Resources
ICT	Information and Communication Technology
IESBA	Ethics Standards Board for Accountants
ISA	International Standards on Auditing
IVD	*In Vitro* Diagnostic
MCC	Medicines Control Council
NCE	New Chemical Entity
NDoH	National Department of Health
NEDLAC	National Economic Development and Labour Council
NHA	National Health Act
OTC	Over-the-counter
PFMA	Public Finance Management Act
PMDS	Performance Management and Development System
PPA	Public Audit Act
PPE	Personal Protective Equipment
PQ	Prequalification
QMS	Quality Management System
RAG	Risk Audit and Governance Committee
RMC	Risk Management Committee
SAHPRA	South African Health Products Regulatory Authority
SAPC	South African Pharmacy Council
SHE	Safety, Health and Environment
THC	Trandselta-9-tetrahydrocannabinol
WHO	World Health Organization

3. FOREWORD BY THE CHAIRPERSON

PROF. HELEN REES
Chairperson

Writing the Board Chair's forward to the SAHPRA Annual Report always requires thought and reflection, but even more so than for the year in question. At the beginning of 2020, SAHPRA was just finding its feet as a new regulatory authority when the coronavirus disease (COVID-19) pandemic hit. For the past year the World Health Organisation continued to declare the COVID-19 pandemic as a Public Health Emergency of International Concern, and we are far from being out of the woods yet. The health and economic impacts on South Africa are unprecedented, and the pandemic has challenged SAHPRA in a way that no-one could have anticipated. SAHPRA was required to address new and urgent issues outside its usual scope of work. This included the urgent approval of laboratory and point of care SARS-CoV-2 diagnostic tests, approval of locally manufactured ventilators and approval of the hospital end of personal protective equipment. The newly appointed Chief Executive Officer (CEO), Dr Boitumelo Semete, who commenced in this role in February 2020, immediately appointed experts to assist in the review of diagnostics, ventilators and personal protective equipment (PPE), to undertake emergency review COVID-19 clinical trials and Section 21 requests, and to assist in reviews for the emergency licensure of therapeutics and vaccines. The Board similarly rolled up its sleeves to offer additional technical and governance support to the CEO and her team.

But SAHPRA's core business needed to continue in parallel to its work on COVID-19. As part of her new role as CEO, Dr Semete was tasked with continuing to lead the transition from the Medicines Control Council (MCC) towards SAHPRA as an effective, independent statutory body. Everything has required fresh eyes and, in some instances, a complete overhaul. The MCC had functioned as an entity dependent on the National Department of Health for its human resource, finance management and accommodation and SAHPRA had to take over responsibility for all these core functions. This included the completion of staff transfer from the MCC into new roles in SAHPRA, establishing independent financial processes and moving into new fit for purpose accommodation. In many instances the way of undertaking the core work of SAHPRA had to be comprehensively re-engineered. Under the revised legislation, SAHPRA was also taking on new responsibilities in the fields of medical devices and *in vitro* diagnostics, as well as in Radiation Control. A Senior

"SAHPRA was required to address new and urgent issues outside its usual scope of work. This included the urgent approval of laboratory and point of care SARS-CoV-2 diagnostic tests, approval of locally manufactured ventilators and approval of the hospital end of personal protective equipment."

Manager for Medical Devices Radiation Control was appointed, and engagements to define the responsibilities of SAHPRA and that of the National Nuclear Regulator were initiated and are now at an advanced stage. This is work in progress and more needs to be done over the next year to ensure that this very important portfolio has proper oversight and management.

All this was happening as a new executive team was being appointed which included the Chief Operations Officer, Chief Financial Officer, and Human Resource Executive. The CEO introduced a new organisational structure and appointments continue to be made to support the new staff organogram. There is an ongoing process of transferring staff from the National Department of Health (NDoH) and the old MCC into their new positions in SAHPRA is ongoing. In parallel to staff changes, SAHPRA has continued to work on improving core outputs required for regulatory excellence and organisational efficiencies. Key to the establishment of SAHPRA as an effective regulator has been the 'Backlog Project'. In February 2018 the newly appointed SAHPRA Board and its acting CEO recognised that unless SAHPRA addressed the backlog of products awaiting licensure, it would never get out of the starting blocks. A point not often appreciated is that a functioning and efficient regulator is a key pillar of an effective health sector and is central to the health and wellbeing of citizens. In addition, a well-functioning regulatory authority is essential for the growth of the South African pharmaceutical industry which government has recognised as a key role-player in the country's economic growth. The subsequent priority that the SAHPRA Board and Executive has placed on rebuilding the regulatory authority in the context of changed legislation, has started to pay dividends. The partnership with industry in formulating the approach to the backlog has been critical to its success to date. This flagship programme is supported by the Bill and Melinda Gates Foundation whose insight into the importance of SAHPRA's re-engineering project and confidence in SAHPRA's ability to transform has been unstinting.

In addition, the lessons being learnt from the Backlog Project are now being applied to the 'Business as Usual' component of SAHPRA's work, transforming traditional paper based and exhaustive homegrown reviews of applications, into electronic submissions that incorporate reliance on the work of other recognised regulatory authorities. Efficiencies and revised time frames for registration are being introduced, and a new Information Technology and Communications Strategy has been approved and introduced. We recognise that more needs to be done in the field of communication to the public, and this continues to be a prioritised work in progress.

We also recognise that we are not yet where we want to be, as the outcome of the audit for the year under review remains qualified. However, the number of findings has been reduced from 88 in the previous year to 23 in the year under review, and with only one finding leading to a qualification. Management have started working on these findings with intention of attaining clean audit for the next year.

On behalf of the SAHPRA Board I want to take this opportunity to offer our wholehearted appreciation for the work being done by the SAHPRA CEO, her staff and the academics who serve on expert technical committees advising the CEO. I also wish to thank members of SAHPRA Board who have made outstanding contributions throughout this challenging period both in their support for SAHPRA senior management but also in their willingness to use their respective skills and wisdom to support the development of SAHPRA. The term of the current Board comes to the end in September 2021. We leave this important entity in a much more satisfactory and sound space both financially and in terms of reporting and performance.

Professor Helen Rees
Chairperson: SAHPRA Board
Date: 31 August 2021

4. CHIEF EXECUTIVE OFFICER'S OVERVIEW

DR BOITUMELO SEMETE-MAKOKOTLELA
Chief Executive Officer

As the world at large was facing and grappled with the pandemic, for SAHPRA, the 2020/21 financial year was characterised by uncertainty and SAHPRA needed to be responsive in an agile and flexible manner. SAHPRA, as the National Health Products Regulator, was at the heart of the South African national response strategy to the COVID-19 pandemic.

At the beginning of the 2020/21 financial year, the country was in its initial stages of the level 5 lockdown. The positive COVID-19 cases were on the increase, and the health system, both private and public, were implementing their emergency response interventions. Whilst hospital capacity was being increased, pharmaceutical companies were preparing for possible medicine shortages. Companies of medical devices and *in vitro* diagnostic (IVDs) tests were ramping up efforts to develop COVID-19 test kits. Every institution in the country had its hands on deck, implementing various business continuity strategies to maintain operations.

Although still in its infancy as a Schedule 3 public entity, with several manual operations, the SAHPRA team took on the challenge and implemented its business continuity plan. All the application processes were digitised, staff were provided with the required trade tools which enabled a large portion of the organisation to work remotely. The balance of the staff that did not have the tools for working remotely was supported with relevant PPE and tools at the office to ensure their safety. SAHPRA's role, while important in the health system, became ever so critical for the national response.

The framework and guidelines in the Medical Devices and IVDs Unit had to be amended to ensure that SAHPRA provides adequate oversight of the COVID-19 molecular and serology tests. This also resulted in a strengthened partnership with the National Health Laboratory Services (NHLS) that served as a reference lab for validation testing. Furthermore, partnership with the South African Bureau of Standards and the National Regulatory for Compulsory Specifications enabled the implementation of the regulatory oversight of PPE. While this had its own challenges, wherein substandard products were found in the country, mitigating interventions were put in place to curb the sale of these substandard products.

"The national scientific community must be applauded for championing several COVID-19 clinical trials, ranging from therapeutic to vaccine trials."

With the anticipation of the possible medicine shortages as various countries went into lockdown, SAHPRA worked together with the industry to ensure that it is informed of these possible shortages in time. The unit responsible for the assessment of any variations made to the original registered products had to ensure the timeous finalisation of variation applications. While repurposed drugs were being explored, the Section 21 Unit put in place an application mechanism to ensure that all these products follow a proper approval process and are monitored along the value chain.

The national scientific community must be applauded for championing several COVID-19 clinical trials, ranging from therapeutic to vaccine trials. In total, 55 therapeutic trials were approved in 2020/21 and ten (10) vaccine trials. These approvals were finalised in record time, due to the extended hours that both the internal team and external evaluators worked.

Typically, it takes SAHPRA 20 months to review, assess and make a final decision for vaccines authorisation. In response to the pandemic, and due to strong partnership with regulators such as the United States Food and Drug Administration, Medicines and Healthcare Product Regulatory Agency (UK) and European Medicines Agency as well as participation in global harmonisation programmes and associations such as the International Coalition of Medicines Regulatory Authorities, World Health Organisation (WHO) and African Vaccine Regulatory Forum (AVAREF), SAHPRA was able to reduce this timeframe to 90 days. Furthermore, SAHPRA internal and external experts participated in collaborative review processes with the WHO and AVAREF for a number of the vaccines. Communicating to the public and various other stakeholders on these achievements as well as on the role of the regulator became ever so critical. All media platforms had to be effectively leveraged to send out factual messages to counter any fake news.

While the core functions of SAHPRA progressed well, the strides achieved would not have been attained without the exceptional backing provided by SAHPRA's support teams. Appointment of new staff continued even under remote working conditions. This included the appointment of the new Chief Financial Officer and Chief Operations Officer as well as the filling of critical vacant positions such as Senior Manager: Health Products Authorisation, Legal Regulatory Advisor, Manager for Strategic Planning, Monitoring and Evaluation, Manager for Quality Management Systems and the Manager for Risk and Internal Audit. Furthermore, the placement of close to 90 admin staff under the Labour Relations Act section 197 transfer process was completed.

The support team worked closely with the core functional units to ensure that the required internal controls and portfolio of evidence was in place for the audit. The new fees were gazetted and implemented from December of 2020. These revised fees will go a long way in ensuring the financial sustainability of the organisation. The Finance team buckled down to ensure that the annual financial statements are adequately put together to support an efficient audit process. This hard work was demonstrated by the audit outcome, wherein for the 2020/21 financial year SAHPRA had a 75% reduction in the audit findings with only one (1) being material finding that led to the basis for the audit outcome.

Once again, the SAHPRA team demonstrated resilience and agility. I would like to thank every single SAHPRA employee as well as our exceptional external experts for their commitment and support. A key stakeholder that ensures SAHPRA functions under strong governing frameworks, policies, and practices, is the SAHPRA Board. Their support to the SAHPRA CEO was unwavering.

Thank you to the entire SAHPRA team.

Dr Boitumelo Semete-Makokotlela
Chief Executive Officer
Date: 31 August 2021

5. STATEMENT OF RESPONSIBILITY

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 that 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 2021.

Yours faithfully

Dr Boitumelo Semete-Makokotlela
Chief Executive Officer
31 August 2021

Prof. Helen Rees
Chairperson of the Board
31 August 2021

6. STRATEGIC OVERVIEW

6.1 VISION

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

6.2 MISSION

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

6.3 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

The South African Health Products Authority'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, 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 (NHA), 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 (APIs) 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 ionizing or non-ionizing radiation).

SAHPRA is only responsible for the regulation of Group III and Group IV hazardous substances.

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

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 (OTC) 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 para-veterinary 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 the Concourt 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 co-operative governance and procedures for coordinating environmental functions exercised by organs of state and related matters.

HEALTH PROFESSIONS ACT, 1974 (ACT NO. 56 OF 1974)

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

NURSING ACT, 1978 (ACT NO. 50 OF 1978)

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

PHARMACY ACT, 1974 (ACT NO. 53 OF 1974)

The South African Pharmacy Council (SAPC) in terms of section 35A of the Pharmacy Act (Act No. 53 of 1974) regulates the practice of pharmacy within South Africa. SAPC ensures that all responsible pharmacists, pharmacy support personnel and pharmacy owners provide pharmaceutical services that comply with good pharmacy practice standards prescribed in the Pharmacy Act and relevant provisions of the Medicines and Related Substances Act. The Medicines Act, in section 16(d), provides for possession of medicines or scheduled substances for sale by the pharmacists or

a person licenced to own a pharmacy in terms of the Pharmacy Act, 1974 or a person who is the holder of a license as completed in section 22C of the Medicines Act. The SAPC has, in terms of section 38A of the Pharmacy Act, appointed inspection officers with a view to monitoring pharmacies for compliance. The provisions of the Pharmacy Act include investigation of complaints received alleging misconduct or unprofessional conduct.

CUSTOMS AND EXCISE ACT, 1964 (ACT NO. 91 OF 1964)

Provides for the prohibition and control of the importation, export or manufacture of certain goods and related matters.

A favourable legislative environment is fundamental to the operations of a regulator such as SAHPRA when it comes to supporting an effective execution of its mandate. There have been notable developments in SAHPRA's operating environment that have necessitated a review of its legislative and policy framework.

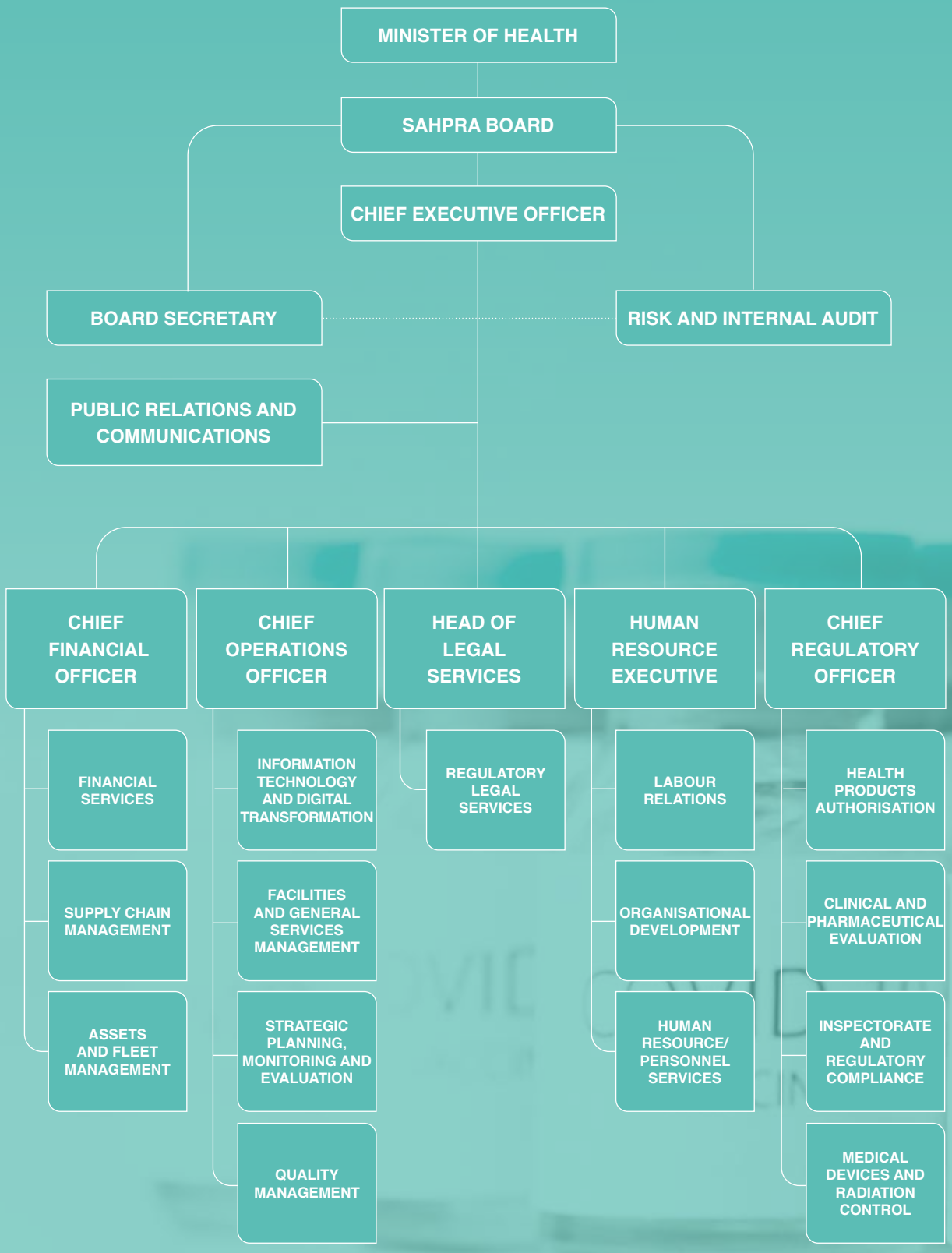
In the first instance, SAHPRA enacts its role within an extremely complex legislative context where a series of other players are involved and where SAHPRA has only a limited yet important regulatory role. A case in point is a role SAHPRA should be fulfilling through its representation at key ports of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

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

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



MEMBERS OF THE BOARD

Prof. Helen Rees
Chairperson

Ms Mandisa Hela
Vice-Chairperson

Prof. Shabir Banoo
Member

Prof. Graig Household
Member

Ms Lerato Mothae
Member

Prof. Jeffrey Mphahlele
Member

Mr Norman Baloyi
Member

Dr Ushma Mehta
Member

Adv. Hasina Cassim
Member

Prof. Ames Dhai
Member

Dr Edith Madela-Mntla
Member

Dr Mphane Molefe
Member

Dr Thapelo Motshudi
Member

Prof. Patrick Demana
Member

Mr Itani Mashau
Member

Dr Boitumelo Semete-Makokotlela
Chief Executive Officer
(*ex-officio* member)

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

Adv. Peter Nthotso
Company Secretary

SENIOR MANAGEMENT

SENIOR MANAGER: HEALTH PRODUCT AUTHORISATION

SENIOR MANAGER: INSPECTORATE AND REGULATORY COMPLIANCE

SENIOR MANAGER: CLINICAL EVALUATION MANAGEMENT

SENIOR MANAGER: PHARMACEUTICAL EVALUATION MANAGEMENT

SENIOR MANAGER: MEDICAL DEVICES AND RADIATION CONTROL

SAHPRA
South African Health Products Regulatory Authority

PART B
PERFORMANCE INFORMATION

1. AUDITOR'S REPORT: PREDETERMINED OBJECTIVES

The Auditor-General of South Africa (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 68 of the Report of the Auditor-General, published as Part E: Financial Information.

2. SITUATIONAL ANALYSIS

2.1 SERVICE DELIVERY ENVIRONMENT

The COVID-19 pandemic impacted on the routine business processes of SAHPRA. Consequently, SAHPRA transitioned to digital platforms, which resulted in the implementation of a file transfers protocol (FTP) uploading system. This reduced the administration burden caused by handling physical applications, thereby improving turnaround times for receipt and allocation of dossiers.

In contrast, COVID-19 negatively impacted the progress of the backlog clearance programme significantly. The beginning of the 2020/21 financial year coincided with the global hard lockdown, which saw many industries grind to a halt. Within the backlog unit, all further re-submission windows had to be to be extended to accommodate applicants' requests. Staff members had to adapt to working remotely before the Backlog Clearance Programme could increase its productivity. The negative effect of the global lockdown was that international manufacturing sites were operating with minimal staff and numerous requests for extensions to respond to evaluation queries were received. These delays significantly impacted the backlog time frames.

Resource constraints experienced by the inspectorate and law enforcement programme impacted its ability to speedily respond to reports of non-compliance by the industry. Since the beginning of COVID-19, the inspectorate unit was limited to conducting local inspections. At the end of the financial year, international inspections were still hampered by the COVID-19 lockdown and international country restrictions on South African travellers. Options such as remote inspections and desktop reviews were implemented for international inspections, entailing the possibility of a shorter period for approval of remotely inspected sites.

SAHPRA employs a unit responsible for the review of clinical trial protocol applications and ensures that the approved trials are scientifically sound, in accordance with South African good clinical practice to ensure that the safety and rights of participants are protected. Even as it is faced by limited capacity, the unit receives approximately 130 clinical trial applications per year with the approval timeline for review of clinical trial application averaging 90 working days from receipt. In response to the pandemic, the unit dedicated its resources to expediting the review of COVID-19 applications. This saw the team working overtime, including external assessors who equally worked overtime to finalise the applications.

The vigilance unit is responsible for monitoring the safety, efficacy and quality of medicines available in the South African market following their approval by SAHPRA. Vigilance is aimed at monitoring the risk-to-benefit ratio of health products, improving patient safety and quality of life. Adverse event (AE) reporting involves the receipt, triage, assessment, data capturing and committing of adverse drug reactions (ADR) reports, archiving of AE data and documentation. The source of AE reports includes spontaneous reports from healthcare professionals, patients and pharmaceutical companies. Currently, reports are processed on the VigiFlow® Case Management System. Furthermore, a COVI-Vig application was in place to ensure that all COVID-19 repurposed drugs accessed through section 21 for off-label use were reported timeously. This enabled reports on drugs such as hydroxychloriquine, remdesivir and ivermectin. The capacity to assess the cause of medicine safety events and concerns from the public, pharmaceutical industry and healthcare workers was strengthened by the work of external experts recruited into SAHPRA's advisory pharmacovigilance Expert Committee. The VigiFlow® System is not customised and does not fully accommodate the South African environment. As a result, SAHPRA launched the Med Safety App, an international mobile tool for drug safety designed to simplify and promote the reporting of ADRs and AEs following immunisation. The App is a simple and convenient medicine safety reporting tool that stores and saves uncompleted and un-submitted reports in the user's device for later completion. The App generates and sends an e-mail to the user to acknowledge the submitted report and is readily available from the most recent version of the Apple App Store (iOS compatible) and Google Play (Android compatible).

Spontaneous reporting is the only method used by the Authority to acquire adverse event reports. Active surveillance is not yet implemented by the Regulator due to the lack of human resources, skills, financial resources and partnerships with relevant stakeholders, such as universities. The Programmatic Pharmacovigilance based at the National Department of Health conducts targeted spontaneous reporting by means of sentinel-site surveillance.

"In contrast, COVID-19 negatively impacted the progress of the backlog clearance programme significantly. The beginning of the 2020/21 financial year coincided with the global hard lockdown, which saw many industries grind to a halt."

For reports to have a meaningful impact, they must be clinically assessed so that signals can be identified. This requires medical experts who assist the understanding of cases in terms of finer details. In order to promote vigilance awareness within the country for healthcare professionals and the public, a National Vigilance Framework was developed for implementation in the 1st quarter of the 2021/22 financial year. Also, vigilance awareness is performed by means of presentations at universities, conferences and workshops, upon invitation. More human and financial resources are required to promote pharmacovigilance among the public, healthcare professionals and medical students in universities.

To further enhance the safety monitoring of registered medicines, medicines safety reporting guidelines were amended and published for comment. A dedicated submission e-mail address was created to streamline receipt of medicine safety concerns from the public, pharmaceutical industry and healthcare workers. The National Vigilance Framework in South Africa is being reviewed.

The Authority was presented with legal challenges pertaining to regulatory decisions made regarding COVID-19 products. A number of these involved section 24 appeals for decisions made regarding medical devices and *in vitro* diagnostics, which the Authority subsequently completed. A number of these were resolved without applicants having had to appeal to the Minister. There was, however, a court challenge around the ivermectin compassionate-access programme that the Authority had to get legal counsel to support this matter. This matter is currently under appeal in the courts.

2.2 ORGANISATIONAL ENVIRONMENT

SAHPRA's organisational environment remained resilient amidst the organisation's transition. The appointment of the Chief Executive Officer in the last quarter of the 2019/20 financial year provided stability and guidance in relation to the transfer of employees from the National Department of Health, finalising the SAHPRA organisational structure and prioritising critical positions necessary to achieve the organisational goals. The Chief Financial Officer resigned and key executive and critical appointments, such as the appointment of a new Chief Financial Officer, were finalised in the financial year, which strengthened leadership and the operational team.

2.3 KEY POLICY DEVELOPMENTS AND LEGISLATIVE CHANGES

There were no major changes to the relevant policies or legislation that may have affected SAHPRA's operations during the period under review or future financial periods.

2.4 PROGRESS TOWARDS ACHIEVEMENT OF INSTITUTIONAL IMPACT AND OUTCOMES

The progress made towards the achievement of the 5-year targets in relation to the outcome indicators are reflected in the section below under each programme.

3. INSTITUTIONAL PROGRAMME PERFORMANCE INFORMATION

3.1 PROGRAMME 1: ADMINISTRATION

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

SUB-PROGRAMMES

- Financial and Supply Chain Management
- Governance and Compliance
- Information Technology and Communication
- Human Resource Management.

OUTCOMES

- Ensure effective financial management and alignment of budget allocation with strategic priorities;
- Achieve and maintain financial sustainability through revenue generated and enhanced operational efficiencies;
- Consistently meet the needs and expectations of all SAHPRA's stakeholders;
- Valuing our people;
- Achieve and maintain high levels of organisational operational efficiency and effectiveness in the regulatory function;
- Strengthened information and communication technology capacity;
- Attract and retain superior talent;
- To promote the work of SAHPRA as a means of advancing the business objectives and organisational reputation; and
- To ensure that SAHPRA attains and maintains global best practices.

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

PROGRAMME 1: ADMINISTRATION								
OUTCOME	OUTPUT	OUTPUT INDICATOR	AUDITED ACTUAL PERFORMANCE 2018/2019	AUDITED ACTUAL PERFORMANCE 2019/2020	PLANNED ANNUAL TARGET 2020/2021	ACTUAL ACHIEVEMENT 2020/2021	DEVIATION FROM PLANNED TARGET TO ACTUAL ACHIEVEMENT 2020/2021	REASONS FOR DEVIATIONS
Ensure effective financial management and alignment of budget allocation with strategic priorities (1)	Attain and maintain an unqualified overall Auditor-General audit outcome on previous year's performance	An unqualified opinion issued by the Auditor-General on the annual financial statements by 31 July each year	Qualified audit opinion obtained for the 2018/19 financial year	Qualified audit opinion obtained for the 2019/20 financial year	**Unqualified audit opinion**	Qualified audit opinion obtained for the 2020/21 financial year		
Achieve and maintain financial sustainability through revenue generated and enhanced operational efficiencies (2)	Total revenue generated in financial year	Total revenue generated in financial year	-	-	**Total revenue generated in financial year (R387 million)**	R268 million	-R119 million	Less applications received than anticipated thus impacting the revenue from fees
	Total revenue generated from fees in financial year	Total revenue generated from fees in financial year	-	-	**Total revenue generated from fees in financial year (R196.7million)**	R102 million	-R94.7 million	Less applications received than anticipated
	Break-even of expenses and revenue by 31 March each year	Break-even of expenses and revenue by 31 March each year	-	-	**Break-even of expenses and revenue by 31 March each year (Zero-based balance)**	-R24.7 million	-R24.7 million	Revenue received in advance not recognised by financial year end due to applications still at the evaluation stage
Consistently meet the needs and expectations of all SAHPRA's stakeholders (3)	SAHPRA effectiveness and efficiency by industry rated by public and private sector players aligned to aspects of mandate	Percentage positive ratings of SAHPRA's effectiveness and efficiency as rated by private and public direct users of SAHPRA's services	-	Material developed and disseminated. Responses and report to be reviewed in Q1 2020	**60% positive ratings of SAHPRA's effectiveness and efficiency as rated by private and public direct users of SAHPRA's services**	SAHPRA obtained a 68% positive rating for its effectiveness and efficiency as rated by private and public direct users of SAHPRA's services	+13%	As a new entity, SAHPRA received a higher posting rating than anticipated
	Appraise public* perceptions of SAHPRA's effectiveness **Public includes end users of health products*	Percentage of public sampled, accurately engaging with SAHPRA	-	-	**50% positive rating of SAHPRA services and offerings**	SAHPRA obtained a 68% positive rating for its services and offerings	+36%	As a new entity, SAHPRA received a higher posting rating than anticipated

OUTCOME	OUTPUT	OUTPUT INDICATOR	AUDITED ACTUAL PERFORMANCE 2018/2019	AUDITED ACTUAL PERFORMANCE 2019/2020	PLANNED ANNUAL TARGET 2020/2021	ACTUAL ACHIEVEMENT 2020/2021	DEVIATION FROM PLANNED TARGET TO ACTUAL ACHIEVEMENT 2020/2021	REASONS FOR DEVIATIONS
Valuing our people (4)	Annual staff engagement/climate surveys conducted	Assess and action recommendations of staff climate survey	-	-	**50% positive responses in all surveyed dimensions**	Out of all the 12 surveyed dimensions, 10 (83%) received 50% positive responses	2 surveyed dimensions received less than 50% positive responses	The lower responses were received due to low staff morale. A change management programme has been implemented
Achieve and maintain high levels of organisational operational efficiency and effectiveness in the regulatory function (5)	SAHPRA regulatory processes and practices are standardised with standardised policies, procedures and frameworks	Percentage implementation of Medicines Regulatory Quality Management System	-	-	**Medicines Regulatory Quality Management System developed and implemented**	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	Not applicable	Not applicable
Strengthened information and communication technology capacity (6)	Digital transformation of SAHPRA's process	Percentage of SAHPRA business processes digitised	-	-	**60% digitisation of SAHPRA processes**	10% of processes digitised. The User Requirements Specification for the Regulatory Information Management Systems was developed and submitted for approval in March 2021	The target was not achieved	The User Requirements Specifications needed to be finalised before the number of business processes could be digitalised. A number of processes were digitised including the FTP portal, albeit that they continue to remain desperate. Furthermore, the Chief Operations Officer was appointed during the last quarter of the financial year

OUTCOME	OUTPUT	OUTPUT INDICATOR	AUDITED ACTUAL PERFORMANCE 2018/2019	AUDITED ACTUAL PERFORMANCE 2019/2020	PLANNED ANNUAL TARGET 2020/2021	ACTUAL ACHIEVEMENT 2020/2021	DEVIATION FROM PLANNED TARGET TO ACTUAL ACHIEVEMENT 2020/2021	REASONS FOR DEVIATIONS
Attract and retain superior talent (7)	Vacant positioned prioritised in annual staffing plan and budgeted for filled	Percentage of prioritised positions filled	-	-	**100% of prioritised positions filled**	Out of the 30 prioritised positions, 24 (80%) were filled	-20%	Due to the reduced income received, positions had to be re-prioritised. Thus, some positions were not filled. The Human Resource Executive was appointed in the middle of the financial year
	Total staff complement reflected as filled positions in staff establishments	Percentage of staff establishment positions filled	91%	76%	**70% of positions in staff establishment filled in current year**	Out of the 375 positions in the approved staff establishment, 265 (71%) were filled	+1%	Recruitment efforts focused on filling the prioritised positions
	Staff in key core business functions earmarked for capacity building	Percentage staff trained in key core business functions	0%	-	**25% of staff in core business trained**	All 125 (100%) staff in key core functions were trained during the 3rd quarter	+567%	All staff were required to participate in the compulsory training on Quality Management System
To promote the work of SAHPRA as a means of advancing the business objectives and organisational reputation (8)	Disseminate thought leadership and regulatory science pieces in magazines, websites, journals and media	Percentage increase of sector thought leadership and regulatory science pieces in magazines, websites, journals and media sources	-	-	**Determine baseline sector thought and regulatory science pieces disseminated**	23 thought and regulatory science pieces were disseminated	Not applicable	Not applicable
To ensure that SAHPRA attains and maintains global best practices (9)	World Health Organization Global benchmarking conducted	Determine WHO maturity level	-	-	**Maturity level 3**	Commenced with preparations to conduct the survey and engagements were held with WHO to provide support to SAHPRA	The target was not achieved	The WHO-assisted assessment could not take place due to the lockdown restrictions of the COVID-19 pandemic

FINANCE AND SUPPLY CHAIN

SAHPRA's total revenue amounted to R268 million against a budget of R385 million. The variance of R117 million was mainly due to the lower number of expected applications received and late implementation of newly revised fee structures. SAHPRA spent R291 million against the initial approved budget of R388 million. The result was an accounting deficit amounting to R25 million, as total expenditure exceeded total revenue due to SAHPRA's inability to recognise revenue in the statement of financial performance as the services were not rendered by financial year end. Accumulated surpluses of prior years were able to absorb the accounting deficit and SAHPRA ended in a net asset position of R20 million.

The sub-programme focused on improving previous audit outcomes as well as positioning the Authority for financial sustainability.

The entity has:

- enforced finance and supply chain policies and standards;
- implemented the General Ledger (GL) accounts per services;
- implemented revenue allocation triggers as an aid to improve revenue allocation;
- revised service fees structures to align to global trends; and
- generated significant year on year revenue growth.

HUMAN RESOURCES

During the financial year, SAHPRA staff numbers increased by 71 positions of which 24 were prioritised vacancies. Recruitment efforts, mostly performed remotely, intensified even during the COVID-19 lockdown periods to ensure that critical positions, primarily those in support functions, could be filled. The framework of transfer and placement to give effect to the Labour Relations Act section 197 process was adopted. This framework guided the 1st phase of placement for administration staff. All 95 administration staff members were placed in positions within SAHPRA's organisational structure.

In the last quarter of the year, SAHPRA conducted its 1st employee engagement survey, which received positive participation of over 60% employees. The survey encouraged feedback and input in different dimensions of the organisation. Survey results were shared with the organisation and a change management action plan was developed in response to suggestions and recommendations received.

Employee engagement and information sessions remain key elements of building a unifying SAHPRA culture that will close the gap between the old and the new ways of doing things. In addition, human resource policies are currently under development and will be workshopped as soon as consultations and approvals have been finalised.

SAHPRA is encouraged by open communication that occurred during the employee engagement sessions held throughout the year, where staff propose solutions to challenges. As part of the change management programme, employees volunteered to be change agents and accepting the role with enthusiasm of delivering the vision of the Authority. These change agents observed developments in their work areas and proposed interventions.

Employees received training on the performance management system, including individual development plans, and these allowed employees to be proactive around ensuring that they had performance contracts in place.

COMMUNICATIONS

Despite challenging times during the COVID-19 pandemic, SAHPRA managed to create greater visibility and build on its brand equity by participating in various webinars, Southern African Development Community engagements and the African Vaccine Regulatory Forum vaccine review committee, while supporting the Ministerial Advisory Committee in addition to the many radio and television campaigns hosted around COVID-19 products. SAHPRA management also strengthened the relationship with pharmaceutical and industry task group representatives and continues to work on cementing a good foundation to this end.

As part of ensuring that its stakeholders are kept abreast of the latest information, SAHPRA re-designed its website. Furthermore, to gain a deeper understanding of its stakeholders needs, SAHPRA conducted a survey with industry and the public. The findings from the survey will assist SAHPRA in identifying what can be improved to continuously meet its stakeholders' needs.

SAHPRA's 2020 overall benchmark service satisfaction score was 68%, while industry had an average score of 77%. The outcome is considered acceptable in view of the challenges SAHPRA faced, such as the backlog in applications and the relocation of its offices. To improve, SAHPRA developed initiatives planned for implementation in the 2021/22 financial year.

Following the re-scheduling of transdelta-9-tetrahydrocannabinol (THC) and cannabidiol (CBD), a dedicated page was created that included infographics and videos to demystify this topic. All related topics and documents were posted on this portal. Furthermore, SAHPRA hosted a webinar to educate stakeholders on the amended schedules as well as licensing and permit processes.

SAHPRA created a mechanism on its website to communicate the latest web posts to subscribers. A mechanism was created for media to register on SAHPRA's media database. Furthermore, all SAHPRA-related podcasts and videos were migrated to a dedicated portal on the website. A mechanism for feedback to SAHPRA via the website was also created. Continuous engagement with the public on COVID-19 matters was performed by means of radio interviews and webinars on COVID-19 diagnostic tests, repurposed drugs and vaccines. These platforms were extremely beneficial.

INFORMATION TECHNOLOGY

A number of digital initiatives were implemented during this period, given the disruption brought about by the COVID-19 pandemic, which required a swift transition from the traditional way of doing things to a digitally driven approach. New infrastructure, systems and processes had to be activated quickly to enable remote working, remote application receival and review to support the operations of SAHPRA under lockdown conditions.

With the rapid implementation of a number of information technology solutions and initiatives in face of the COVID-19 pandemic, and having to continuously embrace the new normal, the next concern for SAHPRA became cybersecurity and data privacy. This brought about various changes to SAHPRA's information technology security infrastructure, policies and services, such as the

introduction of multi-factor authentication, encryption and secure document backups. The information technology policies and disaster recovery plan were approved and are being implemented.

In terms of SAHPRA's long-term digitisation goals, a considerable effort was spent on developing a 5-year information and communication technology (ICT) strategy and roadmap to guide the transformation and budgeting processes. A focus area for the last quarter in the year was the crafting of a business blue-print for user requirement specification – which was also approved and signed off by business process owners and executive management team.

QUALITY MANAGEMENT SYSTEMS

Detailing the implementation roadmap has provided direction around identifying and describing tasks required to make quality management systems (QMS) fully compliant with the standard. The roadmap is specific and details the following:

- Documentation to be developed
- The relevant International Organization for Standardisation 9001 standard section
- Person or team responsible
- Approvals, training and resources required
- Estimated completion date.

Part of creating a quality assurance culture and ensuring that all staff members are involved in QMS, is a QMS awareness training, which was conducted. A document control system was developed that manages the creation, approval, distribution, revision and storage of all quality documentation.

The World Health Organisation Benchmarking programme is a method deployed by WHO to assess the maturity levels of national regulatory authorities. SAHPRA aims to obtain a WHO maturity level 3, where 8 core regulatory functions will be assessed against the criteria and standards set. The Authority will conduct the WHO Global Benchmarking self-assessment and develop an institutional development plan to address identified gaps and interventions. It is expected that the WHO assessment will take place in November of 2021.

3.1.2 STRATEGY TO OVERCOME AREAS OF UNDER PERFORMANCE

The following strategies will be implemented in the 2021/22 financial year to improve financial performance:

- Reworking of current revenue stream standard operating procedures to reduce the income received in advance balance;
- Development of a temporary electronic system to track applications and link these to proof of service rendered and payments received;
- Implementation of a new budgeting process to enable calculation of prudent revenue and expenditure expectations;
- Implementation of weekly reporting on revenue by various units; and
- Reviewing of deferred revenue opening balances to compile accurate listings to consider for revenue recognition.

The recruitment of prioritised positions (30) was mixed with the recruitment of other vacant positions, which delayed the pace of this. By the end of the financial year, all the prioritised positions were in the recruitment pipeline, but not all were finalised. In the 2020/21 financial year, a total of 73 new appointments were finalised. In future, SAHPRA will ensure that reporting focuses on the entire recruitment basket to minimise underreporting.

To achieve the correct performance results and create the desired performance-driven culture, the following must be in place:

- Job descriptions – defining the purpose of the job, the deliverables that the job is responsible for, the expected standard of work performance and how performance will be monitored/tracked as well as the frequency of monitoring;
- Clear Standard Operating Procedures – providing adequate guiding details for each employee on how to carry out the tasks that they are responsible for and ensuring a common understanding around which role is responsible for which action;
- Conducting the required training with personnel – ensuring that employees are deemed competent in performing the task assigned to them and monitoring deviations to identify areas requiring re-training;

- Ensuring that the frontline management team is adequately equipped with a toolkit to identify and manage poor performance in a timely and effective manner;
- Creating consistency around rewarding good results and performance and progressively managing poor performance and poor results. Providing a clear framework for the organisation within which to do this;
- Deriving activity targets for each operator that will feed into the management dashboard and which will be updated through to the functional area senior manager's key performance indicators;
- Linking with the key performance areas that the executive managers can track as they relate to strategic objectives;
- Creating reporting transparency and auditability; and
- Centralising management and follow-up of projects/initiatives to ensure all decisions taken/resolutions are seen through to their successful implementation and tracking initiatives to confirm resulting performance improvement/stabilisation achieved.

An organisational culture shift is required. The aspects mentioned above will assist in driving performance centric behaviours. A cultural change campaign championed by the human resources department will further support the shift.

The senior management team will tackle Newton's first law -- it is critical that management challenges the inertia and apply adequate directional force to change the movement and momentum of the organisation to align with the vision SAHPRA has.

Initiatives are underway to create clear organisational charts and informative job descriptions that will create clarity of purpose, and detail responsibilities. This will be supported by the process of performance-contracting with each staff member and by ensuring that regular performance feedback is provided to all staff members.

Additional training efforts of the 2020/21 financial year will focus on improving the skills levels of managerial layers towards steering difficult conversations and driving performance discussions as well as correct handling of progressive performance management.

A skills matrix for the organisation will be developed and a skills gap assessment completed so that a training plan for the organisation can be developed in line with SAHPRA's strategic priorities.

To further support SAHPRA staff, the implementation process of the Quality Management System remains a key initiative. Standardised work procedures on which all staff members are trained and must comply with offer repeatable and consistent results.

A process-mapping project which was completed with assistance from the Department of International Trade in the United Kingdom under auspices of the Better Health Programme South Africa have further highlighted process-based inefficiencies/bottlenecks that have a detrimental impact on the efficiency of dealing with applications.

It further elevates the challenge around management's ability to make swift data-driven decisions on interventions that are required to course-correct any deviation in performance, consequently eroding SAHPRA's brand equity from an external stakeholder's perspective.

SAHPRA is challenged by a "paper processing environment" and needs to swiftly move to a an analytical and data-driven environment where the information is of a real-time nature and accessible on various levels of detail to all interested parties, while it must be easily auditable.

The implementation of an information/workflow management system will provide process transparency that will support and enhance the management efforts that are taken to eliminate/minimise any opportunity for irregular transactions. It is envisaged that implementing such a system could yield 65% or more process-efficiency improvement if considering related resources and cost-optimisation.

3.1.3 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
1	Personal protective equipment, Sanitisers, fumigation practices post-exposure incidents	Pretoria and Cape Town facilities	+/-279 staff	Not applicable	Operational budget	Operational budget	Not applicable	Not applicable

From a perspective informed by centralised COVID-19 response, SAHPRA's appointed COVID-19 Officer assisted the health and safety team to compile a risk register that guided the organisation's response to mitigating risk to SAHPRA staff members who worked in offices.

In quarter 4 - under adjusted Lockdown Level 3, a plan was devised to introduce a phased return to the workplace to re-introduce and re-integrate members back into working from site. This was implemented to support efforts that were deployed by the Human Resources department towards cultural change as well as the training/induction for new team members that joined SAHPRA in February and March 2021.

3.1.4 LINKING PERFORMANCE WITH BUDGETS

PROGRAMME	2020/21			2019/20		
	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	137 985	110 727	27 258	81 076	79 842	1 234
TOTAL	**137 985**	**110 727**	**27 258**	**81 076**	**79 842**	**1 234**

3.2 PROGRAMME 2: HEALTH PRODUCT 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, and to manage and maintain SAHPRA's main registry.

SUB-PROGRAMMES

- Document Reception and Helpdesk
- Records Management
- Project Office – Regulatory Decision for Medicines
- Project Office – Clinical Trials, Section 21 Portfolio Management
- Licensing, Permits and Certificates Portfolio Management.

OUTCOMES

- Achieve and maintain high levels of organisational operational efficiency and effectiveness in the regulatory function.

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

PROGRAMME 2: HEALTH PRODUCT AUTHORISATION								
OUTCOME	OUTPUT	OUTPUT INDICATOR	AUDITED ACTUAL PERFORMANCE 2018/2019	AUDITED ACTUAL PERFORMANCE 2019/2020	PLANNED ANNUAL TARGET 2020/2021	ACTUAL ACHIEVEMENT 2020/2021	DEVIATION FROM PLANNED TARGET TO ACTUAL ACHIEVEMENT 2020/2021	REASONS FOR DEVIATIONS
Achieve and maintain high levels of organisational operational efficiency and effectiveness in the regulatory function (5)	Elimination of backlog in medicine registration and variation applications	Percentage of medicines registrations backlog eradicated	Not applicable for 2018/19	58%	**40% applications for medicines registration in backlog cleared**	Out of 5 320 backlog applications for medicine registrations, 2 819 (53%) were cleared	+33%	The Abridged Pilot Study led to an increase in registrations. Furthermore, there was a higher rate of non-resubmissions than anticipated
		Percentage of medicines registrations backlog eradicated	-	-	**90% variation applications cleared**	Out of the 7 440 backlog applications for variations, 7 165 (96%) were cleared	+7%	There was a higher rate of non-re-submissions than anticipated and the implementa-tion of Go-Live the certification project
	Finalisation of new licences for local manufacturers, importers and exporters for all health products within timelines predefined	Percentage of new Good Manufacturing Practice (GMP) licences of local applications finalised within 125 working days	-	77%	**50% licences issued for new applications within predetermined timeline**	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	+18%	Some of the licences issued were handrub applications, which required a desktop review therefore shortening the timeframe required for finalisation

BACKLOG

SAHPRA inherited a backlog of around 16 170 medicine applications (new registrations and variations, that is, changes to registered products). To address this backlog, SAHPRA introduced several optimisational processes and efficiencies using totally re-engineered approaches for medicines registration. This included digitalisation, reliance procedures that allowed SAHPRA to exchange information with recognised regional and international regulatory authorities and standardisation of evaluation processes allowing applicants and regulators to know what was expected of them and how long it would take. To this end, SAHPRA developed and implemented the re-engineered framework to eradicate the backlog of health product registrations. Additional resources, including international expert evaluators, were brought on board to support this.

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
- 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 application conforms to reference authorisation and provide required information.

As of 31 March 2021, the backlog was cleared by 78% through various mechanisms that included opt-out by applicants, clearing the variations applications, rejecting non-compliant applications and approving re-submitted applications.

Out of 5 320 backlog applications for medicine registrations, 2 819 (53%) were cleared. Denominator (total applications for registration – 8 220 minus opt-out 2 900) = 5 320. Numerator = total of 2 819 applications cleared (152 Starburst + 1 825 withdrawn* + 818 registered + 6 rejected + 18 non-acceptances) 2 819/5 320x100 = 53%. *Includes 16 withdrawn Zazibona applications, 99 formal withdrawals and 1 710 new registrations not re-submitted during windows 1-12.

Out of the 7 440 backlog applications for variations, 7 165 (96%) were cleared. Denominator (total number of

variations – 7 950 minus opt-out 510) = 7 440. Numerator = total of 7 165 variations cleared (2 800 variation certification + 93 (18) formal withdrawals + 1 139 non-resubmissions + 2 838 approved + 295 (179) Type I rejected/not accepted). 7 165/7 440x100 = 96%.

LICENSING

During the 2020/21 financial year, 29 GMP-related licences were issued to first-time applicants. Licences issued included manufacturers of alcohol-based hand-rubs/sanitisers who were prioritised in response to COVID-19. Over the period, 68 new licences related to all good manufacturing, clinical and wholesale practice standards were issued. Furthermore, 17 licence amendments and 44 licence renewals were processed.

3.2.2 STRATEGY TO OVERCOME AREAS OF UNDER PERFORMANCE

Not applicable as all the targets were achieved.

3.2.3 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
2	Change to entry point of licence applications, from physical receipt of applications to eletronic	Gauteng	Not applicable	Not applicable	Operational budget	Operational budget	Applications could be received and processed	Improved licensing process

The change in process for the receipt of licences during COVID-19 lockdown resulted in an improvement of the licensing process, while reducing the risk of exposure by removing the requirement for physical application receipt. The process allows for improved control over evidence for entry points and document traceability.

3.2.4 LINKING PERFORMANCE WITH BUDGETS

PROGRAMME	2020/21			2019/20		
	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	69 098	34 223	34 875	68 663	28 883	39 780
TOTAL	**69 098**	**34 223**	**34 875**	**68 663**	**28 883**	**39 780**

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; Good Clinical Practice; Good Warehouse Practice; Good Distribution Practice; Good Laboratory Practice; Good Vigilance Practice.

SUB-PROGRAMMES

- Inspections
- Regulatory Compliance.

OUTCOMES

- Achieve and maintain high levels of organisational operational efficiency and effectiveness in the regulatory function.

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

PROGRAMME 3: INSPECTORATE AND REGULATORY COMPLIANCE								
OUTCOME	OUTPUT	OUTPUT INDICATOR	AUDITED ACTUAL PERFORMANCE 2018/2019	AUDITED ACTUAL PERFORMANCE 2019/2020	PLANNED ANNUAL TARGET 2020/2021	ACTUAL ACHIEVEMENT 2020/2021	DEVIATION FROM PLANNED TARGET TO ACTUAL ACHIEVEMENT 2020/2021	REASONS FOR DEVIATIONS
Achieve and maintain high levels of organisational operational efficiency and effectiveness in the regulatory function (5)	Ensure regulatory compliance through a process of active inspections and investigations	Percentage of health product premises/ sites inspections finalised with an inspection report submitted to the applicant within 30 working days of conducting a GMP inspection	37%	70%	**60% of GMP inspection completed with report submitted to applicant**	Out of 97 planned inspections, 86 (88%) were completed Out of the 86 inspections completed, 35 (41%) reports were submitted to the applicants within 30 working days	-19%	Reports could not be timeously completed due to capacity constraints as the focus was on completing inspections that were delayed due to the COVID-19 lockdown
		Percentage of investigations completed with decisions in line with predefined standards and timelines of all health product quality complaints reported to the Regulator	-	-	**70% of health product quality complaints investigated**	Out of the 101 health product quality complaints received, 84 (83%) were investigated and reports produced	+13%	COVID-19 investigations were prioritised. Resources also focused on obtaining quick turnaround times for cases related to ivermectin

SAHPRA South African Health Products Regulatory Authority

INSPECTIONS

This programme supports backlog and business-as-usual registrations in terms of evaluation and/or inspection requirements for GMP to support registration of products. Despite the COVID-19 lockdown that halted onsite inspections during the 1st quarter of the 2020/21 financial year, SAHPRA introduced guidelines and training in order to commence virtual inspections during the 2nd quarter. With the ease of lockdown restrictions and the implementation of a guideline for onsite inspections, SAHPRA initiated and conducted more complex inspections. These complex inspections were more time consuming. In total, 158 good manufacturing, clinical and wholesale practice inspections were conducted of 191 inspections planned.

CANNABIS

The programme continues to prioritise cannabis advocacy and SAHPRA is a critical stakeholder in the establishment of the cannabis master plan, an initiative led by the Department of Agriculture. During the 2020/21 financial year, 30 cannabis cultivation inspections were completed leading to the issuing of 28 licences to cultivate cannabis for the purposes of producing scheduled substances. SAHPRA has experienced two protest actions in the 2021/22 financial year by cannabis interest groups in relation to the provision of pre-licences to applicants who applied for the licence to cultivate cannabis for the purposes of producing scheduled substances. The concerns of this group were escalated to the Minister of Health and the Director-General in the Department of Health as the demands made were policy related. In response to the public outcry and concerns raised by this interest group on matters within SAHPRA's mandate, a pre-licence status letter mechanism has been implemented. This measure was accepted by many stakeholders in the cannabis industry.

The cannabis industry continues to grow and evolve which requires capacitation of the regulatory compliance unit in terms of providing frameworks to be reviewed and amended to allow the industry to grow within compliance. Eighty four (84) product quality-related investigations were conducted.

3.3.2 STRATEGY TO OVERCOME AREAS OF UNDER PERFORMANCE

The process of good manufacturing, clinical and wholesale practice inspections consists of a number of steps, that is, planning, inspecting, report writing, response by site, review of response and the issuing of good manufacturing, clinical and wholesale practice status resolution letters. The process is to be analysed for root causes of inefficiencies and corrective action is to be implemented in terms of procedures and training. The effectiveness of the implementation of corrective actions is to be monitored.

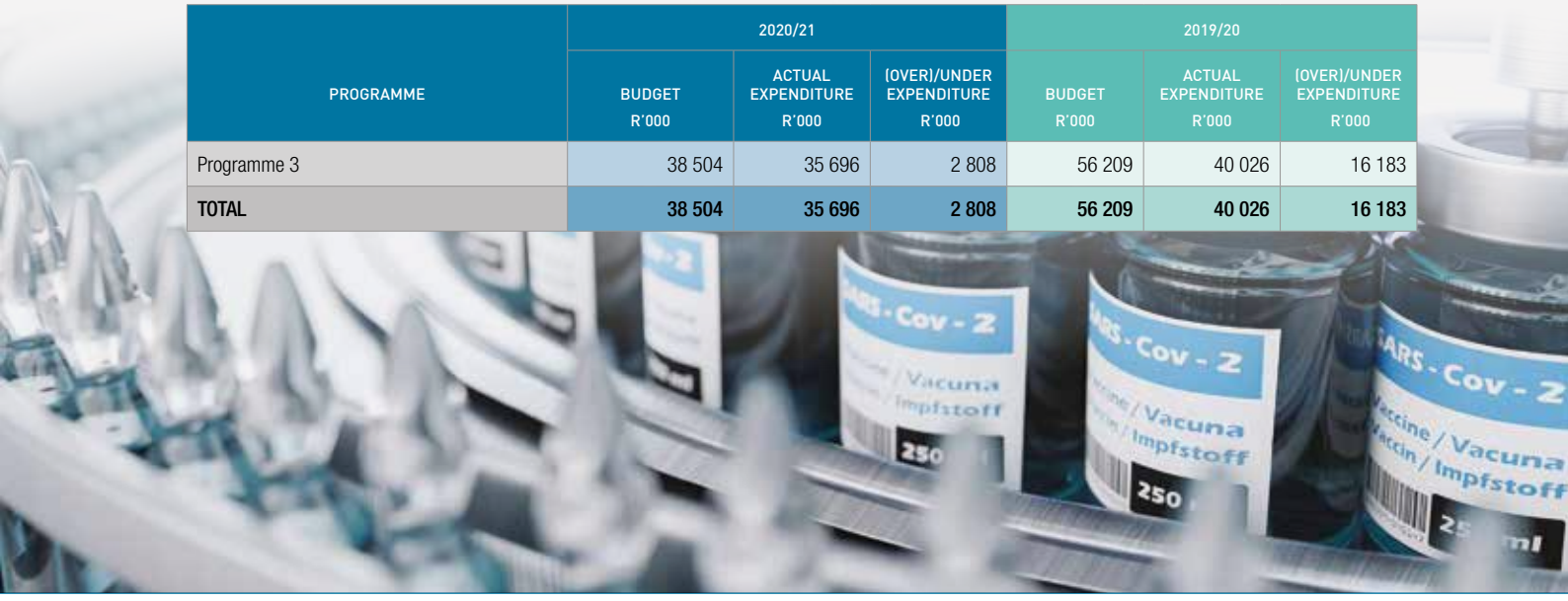
3.3.3 REPORTING ON THE INSTITUTIONAL RESPONSE TO THE COVID-19 PANDEMIC

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
3	Guidelines for remote inspections	Gauteng	Not applicable	Not applicable	Operational budget	Operational budget	Guidelines for remote inspections required development to commence inspections under lockdown	Inspections could be completed
3	Guidelines for onsite inspections	Gauteng	Not applicable	Not applicable	Operational budget	Operational budget	Guidelines for onsite inspections during the pandemic provided for assessment of risk to inspectors being onsite. Guideline allowed for a hybrid approach that is, combining onsite and remote approaches in one inspection	Onsite inspections could be recommenced during Level 3 lockdown

The lockdown necessitated revising processes to enable remote inspections. Implementation of remote inspections allowed inspectors to implement a hybrid approach where an inspection can be conducted as a combination of remote work as well as onsite work.

3.3.4 LINKING PERFORMANCE WITH BUDGETS

PROGRAMME	2020/21			2019/20		
	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	38 504	35 696	2 808	56 209	40 026	16 183
TOTAL	**38 504**	**35 696**	**2 808**	**56 209**	**40 026**	**16 183**



3.4 PROGRAMME 4: MEDICINE EVALUATION AND REGISTRATION

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

- Clinical Evaluation
- Clinical Trials
- Pharmaceutical Evaluations
- Authorisation of the Sale of Unregistered Medicines
- Vigilance and Post-Marketing Surveillance
- Complementary and Alternative Medicines
- Veterinary Medicines.

OUTCOMES

- Achieve and maintain high levels of organisational operational efficiency and effectiveness in the regulatory function.

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

PROGRAMME 4: MEDICINE EVALUATION AND REGISTRATION								
OUTCOME	OUTPUT	OUTPUT INDICATOR	AUDITED ACTUAL PERFORMANCE 2018/2019	AUDITED ACTUAL PERFORMANCE 2019/2020	PLANNED ANNUAL TARGET 2020/2021	ACTUAL ACHIEVEMENT 2020/2021	DEVIATION FROM PLANNED TARGET TO ACTUAL ACHIEVEMENT 2020/2021	REASONS FOR DEVIATIONS
Achieve and maintain high levels of organisational operational efficiency and effectiveness in the regulatory function (5)	Improved turnaround times of medicine registration and regulatory activities	Percentage registrations of New Chemical Entities (NCEs) finalised within predefined timelines	0%	100%	**Percentage registrations of New Chemical Entities finalised within predefined timelines (60% in 590 days)**	Out of the 72 New Chemical Entities registered, all 72 (100%) were finalised within 590 days	+67%	All applications were prioritised due to the COVID-19 pandemic
		Percentage registration of generic medicines finalised within predefined timelines	3%	-	**Percentage registration of generic medicines finalised within predefined timelines (60% in 250 days)**	Out of the 240 generic medicines registered, 131 (55%) were finalised within 250 days	-8%	Insufficient human resources and capacity constraints. Furthermore, selected applicants took longer to provide feedback due to the COVID-19 lockdown restrictions
		Percentage applications for the sale of unregistered Category A (human) medicines finalised within 24 working hours counting from the time (stamp) when the application was received	80%	96%	**85% applications for the sale of unregistered Category A (human) medicines finalised within 24 working hours**	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	+8 %	Additional resources were allocated when the Ivermectin Compassionate Access Programme was introduced

OUTCOME	OUTPUT	OUTPUT INDICATOR	AUDITED ACTUAL PERFORMANCE 2018/2019	AUDITED ACTUAL PERFORMANCE 2019/2020	PLANNED ANNUAL TARGET 2020/2021	ACTUAL ACHIEVEMENT 2020/2021	DEVIATION FROM PLANNED TARGET TO ACTUAL ACHIEVEMENT 2020/2021	REASONS FOR DEVIATIONS
Achieve and maintain high levels of organisational operational efficiency and effectiveness in the regulatory function (5)	Improved turnaround times of medicine registration and regulatory activities	Percentage of human clinical trial applications finalised within 120 working days, counting from the date the application was received	95%	100%	**80% human clinical trial applications finalised within 120 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	+20 %	The majority of clinical trial applications received were for COVID-19 interventions with dedicated resources working overtime
		Percentage of reports on health product safety signals actioned within 20 working days after receipt	Quarterly reports to the public for 3 quarters	4 quarterly reports	**70% reports on health product safety signals actioned within 20 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	-39 %	The finalisation is dependent on external experts who did not have sufficient capacity to assist SAHPRA




NEW CHEMICAL ENTITY REGISTRATION

All 72 NCEs registered were done within the target period of 590 days for the accumulative period 1 April 2020 to 31 March 2021. This achievement is attributable to the request to prioritise applications that are novel treatments, for unmet medical needs and oncology treatments. The number registered includes biological medicines and veterinary medicine NCEs.

The impact of COVID-19 on new registrations includes ongoing delays in applicant responses to queries as access to the data from their principles are subject to availability based on curfews in other countries. The delays have in some cases been around 6 months. The number of variations received increased around priority review requests due to changes and access of treatments for the management of COVID-19 patients, which resulted in priority applications receiving attention and other products being processed later.

GENERIC MEDICINE REGISTRATION

A total of 131 out of 240 generic medicine were registered within the 250-day target timeline. The underachievement is attributable among others to the following:

- prioritisation of NCEs and prioritising agents that were required for the management of COVID-19. COVID-19 Vaccine Janssen (NCE) was registered and prioritised;
- numerous requests for extensions to timelines for submission of responses which in many cases exceeded three months due to delays around applicants' ability to obtain data from principals due to COVID-19 restrictions. These timeline extensions in some instances exceeded 6 months; and
- inadequate human resource capacity.

To ensure improved turnaround times, lessons learnt from the backlog project such as the establishment of evaluator coordinators and the implementation of the reliance approaches will be replicated in the business-as-usual stream.

CLINICAL EVALUATION MANAGEMENT

In order to enhance the safety monitoring of registered medicines, medicines safety reporting guidelines were amended and published for comment. A dedicated submission e-mail address was created to streamline receipt of medicine safety concerns from the public, pharmaceutical industry and healthcare workers. Furthermore, a dedicated pharmacovigilance project to closely monitor treatment outcomes of medicines used off-label for COVID-19 was implemented. The capacity to assess the cause of medicine safety events and concerns from the public, pharmaceutical industry and healthcare workers was strengthened by using external experts recruited into SAHPRA's advisory pharmacovigilance expert committee. The National Vigilance Framework in South Africa is in the process of being reviewed. The MedSafety App for reporting of adverse drug reactions was acquired.

Explanatory notes for fees for clinical variations were developed to address challenges raised by industry. The prioritisation of medical research protocols related to COVID-19 ensured that effective medicines and vaccines would be available as soon as possible to help in the effort against the pandemic.

3.4.2 STRATEGY TO OVERCOME AREAS OF UNDER PERFORMANCE

A key challenge resulting in underperformance was limited human capacity and filling vacant posts, which will be prioritised. Training for staff members will also be prioritised.

To ensure that health safety signals are timeously attended to, SAHPRA will re-engineer the processes by increasing its own technical capacity when it comes to relying on external experts for areas that are more complex.

The proposed regulatory information management system will optimise and enable digital tracking and a stop-clock system that will improve efficiency of accessing information and accuracy in calculating the time queries are with the applicant. This will also ensure strict adherence to rejecting applications that exceed the timelines for responses and exceed the number of review rounds permitted.

3.4.3 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
4	Prioritisation and timely handling of all regulatory matters related to COVID-19	National	All citizens of the Republic of South Africa	Not applicable	Not applicable	Not applicable	The prioritisation of all regulatory matters related to COVID-19 resulted in an improvement in performance timelines for the regulation of clinical trials	Reduced timelines for the regulation of clinical trials

To promote the conduct of clinical trials related to the COVID-19 pandemic, SAHPRA's clinical trial protocol submission guidelines were amended and implemented with immediate effect. This was done to further strengthen the regulatory response effort to the emergency conditions of clinical research in the COVID-19 space. The review of COVID-19 clinical trial applications was expedited to enhance the country's COVID-19 emergency response and the approval turnaround times were between 7 – 10 working days. In terms of this expedited review process, the Sisonke Phase 3B open label clinical trial using the Ad26.COV2.S COVID-19 vaccine (Janssen vaccine) in healthcare workers was approved. During the period under review, 64 COVID-19 clinical trial applications were finalised. SAHPRA expedited the approval of COVID-19 vaccine trials applications and COVID-19 vaccine registration applications by applying due diligence in the evaluation processes, while matching the timeframe taken by other global regulatory agencies to finalise decisions on applications.

As part of enhancing the country's COVID-19 regulatory response, SAHPRA approved the majority of unregistered medicines that were used off-label to treat COVID-19 infections within 24 working hours.

The use of ivermectin in the treatment and prevention of COVID-19 infections received avid interest due to its antiviral and anti-inflammatory properties *in vitro*. Available data to date, as obtained mostly from small under-powered studies, show a trend towards some benefit in the management of COVID-19. National and international bodies have reviewed the data and have concluded that unclear evidence existed as to benefit

and harm in the treatment and prevention of COVID-19. After consideration of the impact of the second wave as well as the clinical equipoise that was presented through the various studies reviewed, SAHPRA implemented an ivermectin controlled compassionate use programme for approved unregistered ivermectin products to be accessed via a three-tier programme for section 22C(1)(b) permit holders, healthcare facilities and named-patient applications. On 16 March 2021, SAHPRA registered Soolantra 10mg/g cream formulation, which contains ivermectin. Soolantra Cream is indicated for the topical treatment of moderate to severe inflammatory lesions of papulopustular rosacea in adult patients and not for the prevention or treatment of COVID-19. The registration of this product enabled the compounding of ivermectin on a prescription basis for specific patients as well as off-label use of ivermectin under the section 21 controlled compassionate-use programme.

SAHPRA approved 277 bulk applications of remdesivir and 328 named-patient applications for remdesivir for use in COVID-19 treatment. Furthermore, it authorised two COVID-19 vaccines (Covishield by the Serum Institute of India Pvt Ltd and Comirnaty by Pfizer Laboratories Pty Ltd). SAHPRA registered the COVID-19 Vaccine Janssen by Janssen Pharmaceutica Pty Ltd on 31 March 2021, with conditions. The registration was done in terms of section 15(6a) of the Medicines and Related Substance Act, Act No. 101 of 1965. The registration signalled a significant step in the fight against the COVID-19 pandemic.

In addition, SAHPRA's experts are participating in the World Health Organisation prequalification (PQ) global joint review of COVID-19 vaccines and in the African Vaccine Regulatory Forum. Their participation is beneficial in expediting reviews of the vaccine applications submitted to SAHPRA, as the same review reports would be considered and relied upon for the same vaccine applications. WHO PQ/AVAREF support national regulatory authorities for reviewing COVID-19 vaccine applications in terms of the recommendation of the WHO PQ emergency-use listing by using reliance principles.

A medicines-safety reporting system to monitor the safety and efficacy of all new and repurposed therapies for COVID-19 is in place to further obtain safety and efficacy data on repurposed registered medicines and novel unregistered medicines used to treat or prevent COVID-19 and its complications.

3.4.4 LINKING PERFORMANCE WITH BUDGETS

PROGRAMME	2020/21			2019/20		
	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	88 217	73 666	14 551	65 440	59 435	6 005
TOTAL	**88 217**	**73 666**	**14 551**	**65 440**	**59 435**	**6 005**

3.5 PROGRAMME 5: MEDICAL DEVICE, DIAGNOSTICS AND RADIATION CONTROL

Purpose: To develop and maintain regulations and guidelines pertaining to the regulatory oversight of medical devices, ionizing and non-ionizing radiation emitting devices; and radioactive nuclides.

SUB-PROGRAMMES

- Medical Devices
- Radiation Control.

OUTCOMES

- Achieve and maintain high levels of organisational operational efficiency and effectiveness in the regulatory function.

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 2018/2019	AUDITED ACTUAL PERFORMANCE 2019/2020	PLANNED ANNUAL TARGET 2020/2021	ACTUAL ACHIEVEMENT 2020/2021	DEVIATION FROM PLANNED TARGET TO ACTUAL ACHIEVEMENT 2020/2021	REASONS FOR DEVIATIONS
Achieve and maintain high levels of organisational operational efficiency and effectiveness in the regulatory function (5)	Finalisation licences for medical device and radiation control related activities and sites within predefined number of working days (spent at the Regulator) counting from the date the application was received	Percentage of medical device establishment licence applications finalised within 90 days	70%	99%	**70% medical device establishment licence applications finalised within 90 days**	Out of the 1 116 medical device establishment licence applications received, 757 (68%) were finalised Out of the 757 applications finalised, 629 (83%) were finalised within 90 days	+19%	All COVID-19 related products applications were prioritised due to the COVID-19 pandemic
		Develop and implement Medical Device registration Framework	73%	The medical device system has not been implemented. Regulations, fees schedule, guidelines and Standard Operating Procedures to be implemented	**Medical device registration framework developed and 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	The target was not achieved	Delays were encountered with the State Law Adviser finalising the submission and the subsequent publication
		Percentage of new application licences for ionizing radiation-emitting devices and radioactive nuclides issued within 30 working days	An approved system to register medical devices has been implemented	99%	**70% of new application licences for ionizing radiation-emitting devices and radioactive nuclides issued 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 Out of the 2 519 issued, 2 302 (91%) were issued within 30 working days	+30%	Well established business processes resulted in the efficient processing of applications

MEDICAL DEVICES

A phased approach is used to implement the regulatory framework for medical devices. The medical device regulations were amended to, among others, enforce mandatory compliance to quality management systems for the medical device establishment. The draft medical device regulations are anticipated to be published for public comment during the 1st quarter of the 2021/22 financial year. The adoption of digital solutions remained a priority around ensuring efficient functioning for the regulation of medical devices. SAHPRA adapted processes for registering medical device establishments during the COVID-19 pandemic. As a result, in response to the COVID-19 pandemic, SAHPRA seamlessly transitioned to adopting a process that allowed for the submission of applications manually or electronically.

SAHPRA received 1 116 applications for medical device licences specifically related to the listing of COVID-19-related test kits, masks, ventilators, thermometers, pulse oximeters and auxiliary consumables. Of the applications received, SAHPRA finalised 757. A stringent approval process for COVID-19 tests was developed and deployed over this period, which resulted in the fact that SAHPRA only approved products that met the required product profile which, in turn, resulted in no product recalls.

RADIATION CONTROL

Working on an ageing but stable ORACLE database platform, radiation control continued to process applications timeously for ionizing radiation-emitting devices and radioactive nuclides. Despite the COVID-19 pandemic, SAHPRA was able to maintain a steady flow of licenced products throughout the year. Based on SAHPRA's information technology roadmap, gradual steps are being taken to fully digitise this function.

3.5.2 STRATEGY TO OVERCOME AREAS OF UNDER PERFORMANCE

- Reallocate technical resources to focus on the regulatory framework with the assistance of various committees;
- Increase human resources in the medical device and radiation control areas;
- Finalise regulatory pathways for the sub-programme on medical devices, define and develop policies, guidelines and Standard Operating Procedures to manage the processes (internal and external engagement);
- Update the regulatory framework and publish for comments and implement by the 2021/22 financial year;
- Ensure availability of resources (finance, human resource, and infrastructure) that are vital in safeguarding the success of implementing a robust, efficient and continuous regulatory roadmap;
- Increase the departmental technical capacity by hiring skilled, capable and qualified personnel;
- Recognise that information technologies (digitalisation) play a crucial role in implementing the said regulatory framework, while the use of digital solution is imperative for the effective functioning of the programme;
- Use the source of the technical expert committee to assist with implementation of policies, regulations and guidelines; and
- Use a phased approach for sub-programme radiation control to implement a regulatory framework to align to the International Atomic Energy Agency and Integrated Regulatory Review Service regulatory international recognised standards.

3.5.3 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
Not applicable								

Various actions were implemented to ensure efficiency and effectiveness of the programme during the wake of COVID-19. These are summarised below.

- Applications are now processed online and the approach is assisted by traceability and record keeping of all applications and queries received;
- Expedited pathways were crafted for the review and approval of licences and section 21 authorisations without compromising the quality of the devices authorised;
- Alternative pathways and additional conditions of licences were implemented for respirator mask manufacturers, distributors and wholesalers to mitigate the influx of falsified and substandard masks entering the South African market;
- Interim expert committees were established to review and evaluate diagnostic tests for COVID-19 and rapidly manufactured ventilators;
- Industry engagement was increased by using various platforms, that is, guidelines, workshops and meetings;
- Internal resource allocation was used to addresses the resurgence of COVID-19 without compromising other processes of the programme;
- Further assistance was received to manage the overflooding of applications;
- The NHLS assisted with validations for antibody, antigen and molecular tests;
    - 49 antigen tests authorised for validations of which 17 were completed
    - 96 antibody tests authorised for validation of which 70 were completed
    - 40 molecular tests were authorised for validation of which 24 were completed
- Interim expert committees that assisted with reviews and recommendations for various applications were implemented: COVID-19 committee which looked at test kits, and ventilators and breathing apparatus committees; and
- Wits B. Pharm. 4th year students were recruited to assist in the call centre to manage the influx of queries during the period April - August 2020.

3.5.4 LINKING PERFORMANCE WITH BUDGETS

PROGRAMME	2020/21			2019/20		
	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	53 959	38 128	15 831	36 886	22 231	14 655
TOTAL	**53 959**	**38 128**	**15 831**	**36 886**	**22 231**	**14 655**

4. REVENUE COLLECTION

SOURCES OF REVENUE	2020/21			2019/20		
	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	196 771	101 734	95 037	122 000	54 179	67 821
TOTAL	**196 771**	**101 734**	**95 037**	**122 000**	**54 179**	**67 821**

5. CAPITAL INVESTMENT

INFRASTRUCTURE PROJECTS	2020/21			2019/20		
	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						

SAHPRA is a Public Finance Management Act Schedule 3A Public Entity under the National Department of Health. 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 entered into a new lease agreement for its head office 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 2020/21 financial year comprises newly acquired assets. These acquisitions amounted to R23.4 million on 31 March 2021. The new acquisitions include other fixed assets (R645 287), computer equipment (R6 685 458), furniture (R7 620 967), leasehold improvements (R6 659 775) and intangible assets (R1 767 133). 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 has an asset management unit within its finance department that is responsible for updating the asset register including all asset transactions such as receipts, movements, disposals, useful life assessments and other changes. The unit conducts asset verifications at least twice a year in terms of the approved asset management policy.

SAHPRA
South African Health Products Regulatory Authority

PART C
GOVERNANCE

1. INTRODUCTION

The Board and its 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:

- Portfolio Committee on Health
  - 3 February 2021 - updating the Portfolio Committee on Ivermectin.
  - 17 March 2021 - tabling of the 2019/20 annual report.
- Portfolio Committee on Defence and Military Veterans
  - 17 February 2021 - appeared before the Portfolio Committee discuss procurement of the medicine called Heberon Alfa R.
  - 24 February 2021 - follow-up meeting with the Portfolio Committee to discuss procurement of the medicine called Heberon Alfa R.

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 three critical 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.
- SAHPRA's position on Ivermectin. This matter led to litigation against the Minister and the Regulator and reports in this regard were submitted to the Executive Authority.
- SAHPRA's position on cannabis. Various reports were submitted to the Executive Authority on the activities of SAHPRA together with its narrow mandate on medicinal cannabis.

4. THE ACCOUNTING AUTHORITY/BOARD

INTRODUCTION

The Board is the Accounting Authority in terms of the Public Finance Management Act and is appointed for a renewable period of three years by the Minister of Health in terms of the Medicines Act. The Minister extended the term of the Board by a further 12 months. The term of the current board expires on 30 September 2021. The Regulator is governed and controlled in accordance with the Medicines Act (Act No. 101 of 1965), as amended. The Board ensures that the objects of the Act are achieved. During the period under review, SAHPRA appointed the Institute of Directors Southern Africa to conduct Board assessments.

THE ROLE OF THE BOARD IS AS FOLLOWS

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.

COMPOSITION OF THE BOARD

NAME	DESIGNATION	DATE APPOINTED	DATE RESIGNED	QUALIFICATIONS	AREA OF EXPERTISE	BOARD DIRECTORSHIPS	OTHER COMMITTEES OR TASK TEAMS	NO. OF MEETINGS ATTENDED
Prof. Helen Rees	Chairperson	17 November 2017	Not applicable	MB BChir M.A. Social and Political Sciences Doctor Instructor for Family Planning	Clinical Trials	Not applicable	Not applicable	24
Ms Mandisa Hela	Vice Chairperson	17 November 2017	Not applicable	B Pharm BSC MPH	Public Health	Not applicable	RAG and HRRemCo	21
Mr Norman Baloyi	Member and Chairperson (ICT)	17 November 2017	Not applicable	MBA BSC Masters in Science	Information Technology	Not applicable	RAG, Finance and TORS	23
Prof. Shabir Banoo	Member and Chairperson (TORS)	17 November 2017	Not applicable	B.Pharm PHD	Medicine Regulation	Not applicable	RAG, TORS and Stakeholder Communications	24
Prof. Jeffrey Mphahlele	Member and Chairperson (HR&Remco)	17 November 2017	Not applicable	BSc (Biological Sciences) BSc Med Honours PhD (Medical Virology)	Epidemiology and Virology	Not applicable	HRRemCo and Finance	22
Dr Ushma Mehta	Member and Chairperson (Stakeholder Communications)	17 November 2017	Not applicable	B.Pharm Pharm.D DrPH	Pharmacovigilance	Not applicable	Stakeholder Communications, TORS and IT	21
Prof. Craig Household	Member and Chairperson (RAG)	17 November 2017	Not applicable	MBCHB MD	Human Resources	Not applicable	RAG, HRRemCo and Finance	23
Ms Lerato Mothae	Member and Chairperson (Finance)	20 May 2020	Not applicable	B. Compt CTA	Finance and Accounting	Not applicable	Finance and RAG	20
Prof. Ames Dhai	Member	17 November 2017	Not applicable	MBCHB FCOG LLM	Bio-Ethics	Not applicable	RAG, TORS and Stakeholder Communications	23
Mr Itani Mashau	Member	25 April 2019	Not applicable	B.Pharm Diploma In Production D in Q Management and Q Assurance MBA	Good Manufacturing Practice	Not applicable	None	24
Prof. Patrick Demana	Member	25 April 2019	Not applicable		Virologist	Not applicable	TORS	20
Adv Hasina Cassim	Member	17 November 2017	Not applicable	Pharm LLB	Law	Not applicable	RAG, TORS, and Stakeholder Communications	22
Dr Thapelo Motshudi	Member	17 November 2017	Not applicable	MBCHB FC Rad Diag	Radiology	Not applicable	RAG	22
Dr Edith Madela-Mntla	Member	17 November 2017	Not applicable	D Cur M Cur B. Cur	Clinical Trails	Not applicable	TORS, HRRemCo, Stakeholder Communications and ICT	21
Dr Mphane Molefe	Member	17 November 2017	Not applicable	Bachelor of Veterinary Medicine and Surgery	Veterinary Public Health	Not applicable	TORS and RAG	19

COMMITTEES

COMMITTEE	NO. OF MEETINGS HELD	NO. OF MEMBERS	NAME OF MEMBERS
Finance Committee	11	4	Ms Lerato Mothae Prof. Craig Household Prof. Jeffrey Mphahlele Mr Norman Baloyi
Risk Audit and Governance Committee (RAG)	7	9	Prof. Craig Household Prof. Ames Dhai Mr Norman Baloyi Prof. Shabir Banoo Adv. Hasina Cassim Dr Mphane Molefe Ms Lerato Mothae Dr Thapelo Motshudi Mr Edward Okaro (external member)
Technical Oversight and Regulatory Strategy Committee	8	7	Prof. Shabir Banoo Prof. Ames Dhai Dr Ushma Mehta Adv. Hasina Cassim Ms Mandisa Hela Dr Mphane Molefe Prof. Patrick Demana Dr Edith Madela Mntla
Human Resource and Remuneration Committee	2	4	Prof. Jeffrey Mphahlele Dr Edith Madela-Mntla Prof. Craig Household Ms Mandisa Hela
Information Communication and Technology Committee	1	4	Mr Norman Baloyi Dr Edith Madela-Mntla Dr Ushma Mehta Dr Thapelo Motshudi
Stakeholder Engagement and Communication Committee	2	5	Dr Ushma Mehta Adv Hasina Cassim Prof. Ames Dhai Prof. Shabir Banoo Dr Edith Madela-Mntla

REMUNERATION OF BOARD MEMBERS

NAME	REMUNERATION	OTHER ALLOWANCE	OTHER RE-IMBURSEMENTS	TOTAL
Prof. Helen Rees	193,024	-	-	193,024
Ms Mandisa Hela	136,357	-	-	136,357
Prof. Shabir Banoo	-	-	-	-
Dr Edith Madela - Mntla	102,548	-	-	102,548
Dr Thapelo Motshudi	86,595	-	-	86,595
Prof Ames Dhai	133,569	-	-	133,569
Prof. Jeffrey Mphahlele**	-	-	-	-
Dr Ushma Mehta	61,965	-	-	61,965
Dr Mphane Molefe**	-	-	-	-
Adv. Hasina Cassim	160,527	-	-	160,527
Mr Norman Baloyi	166,388	-	-	166,388
Prof. Craig Household	184,269	-	-	184,269
Prof. Patrick Demana	60,818	-	-	60,818
Mr Itani Mashau	72,811	-	-	72,811
Ms Lerato Mothae	245,149	-	-	245,149

**Members were not remunerated as they are employed in the Public Service

5. RISK MANAGEMENT

Following the appointment of a risk management service provider during 2020 for the establishment of a risk management function, SAHPRA approved the risk management policy and facilitated the development of a risk management framework.

During the period, the entity developed a strategic risk register and operational risk registers with the relevant executives and managers. The registers were developed in alignment with strategic objectives to capture risks facing the SAHPRA, and devised mitigation plans to minimise risk exposure.

The Risk Management Committee (RMC) was established as a committee of the executive committee with approved terms of reference. The RMC was established to assist the Chief Executive Officer to fulfil its risk management and control responsibilities in accordance with King IV and the Public Sector Risk Management Framework. The RMC is tasked with reviewing the effectiveness of SAHPRA's risk management, internal control systems practices and procedures through the evaluation of the effectiveness of action plans implemented to address identified risks, while providing recommendations for improvement and reporting to the executive committee and the Risk Audit and Governance Committee (RAG).

The Board of SAHPRA has ultimate responsibility for risk management and, through the RAG, provides guidance and direction in the management of risk. Quarterly, RAG committee reviews the risk management report with the objective to assess the risks identified, the effectiveness of mitigation plans and monitoring of the risk management activities against the annual risk management implementation plan.

Activities for the risk management function has recently stabilised with the appointment of the Risk and Internal Audit Manager during the 3rd quarter of the 2020/21 financial year. The period saw the review of risk registers since their development, setting up of risk management structures and appointment of risk champions to embed risk management within the SAHPRA. Training and awareness on risk management principles must continue for staff to ensure embedment and the maturity of risk within the entity.

6. INTERNAL CONTROL ENVIRONMENT

While SAHPRA is at its infancy, management has worked extremely hard to improve the internal control environment by developing Standard Operating Procedures for critical processes across the business together with a quality management function.

Policies within the business such as those in finance and ICT areas were approved. In view of this achievement, management anticipates an improved internal control system within SAHPRA, which will significantly reduce internal control deficiencies during planned audits.

7. INTERNAL AUDIT AND AUDIT COMMITTEES

RISK AUDIT AND GOVERNANCE COMMITTEE

NAME	QUALIFICATIONS	INTERNAL OR EXTERNAL	IF INTERNAL, POSITION IN THE PUBLIC ENTITY	DATE APPOINTED	DATE RESIGNED	NO. OF MEETINGS ATTENDED
Prof. Craig Household	MBCHB MD	Internal	Board member	17 November 2017	Not applicable	7
Prof. Ames Dhai	MBCHB FCOG LLM	Internal	Board member	17 November 2017	Not applicable	6
Mr Norman Baloyi	MBA BSC Masters in Science	Internal	Board member	17 November 2017	Not applicable	7
Prof. Shabir Banoo	B.Pharm PhD	Internal	Board member	17 November 2017	Not applicable	7
Adv. Hasina Cassim	B.Pharm LLB	Internal	Board member	17 November 2017	Not applicable	6
Dr Mphane Molefe	Bachelor of Veterinary Medicine and Surgery	Internal	Board member	17 November 2017	Not applicable	6
Ms Lerato Mothae	B. Compt CTA CA	Internal	Board member	24 April 2020	Not applicable	5
Dr Thapelo Motshudi	MBCHB FC Rad Diag	Internal	Board member	17 November 2017	Not applicable	7
Mr Edward Okaro	B.Comm MBA CPA CA	External	Not applicable	02 May 2020	Not applicable	6

The internal audit function was outsourced for the 2020/21 financial year with the annual coverage plan approved by RAG Committee. The key activities for the function entailed the following:

- The development of a risk-based three-year rolling Internal Audit Plan concomitant with the annual plan, where the plans also indicate the scope, cost and timelines of each planned audit assignment;
- Reporting on the performance and progress against the plan to allow effective monitoring and intervention when necessary; and
- Co-ordination between internal and external providers of assurance to ensure proper coverage and minimal duplication of effort.

Based on prescripts and best practice, the internal audit function assisted SAHPRA to accomplish its objectives by adopting 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 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 Committee in the annual audit plan, including but not limited to:

- Performance of audit assignments across the business;
- Verification of internal and external audit action plans with the objective of providing assurance on the corrective actions implemented as based on previous findings; and

- Assessment of 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 when it comes to maintaining effective controls through assessment and evaluation of internal controls and, thereafter, developing recommendations for enhancement or improvement of the inefficiencies identified.

During the 2020/21 financial year, RAG conducted the following activities, though not limited to these:

- Reviewing effectiveness and approval of internal audit activities, internal controls, risk management, fraud prevention and compliance management; and
- Reviewing 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 Public Finance Management Act (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

In a continuous effort to combat fraud and corruption within the public sector, SAHPRA strengthens its internal controls and risk management by embarking on a process of developing fraud prevention governance documents that should guide the behaviour of staff, management, executives, the Board and its stakeholders.

The Fraud Prevention Policy was approved with the development of the Fraud Prevention Plan as well as a Whistle-blowing Policy and plan, which is underway in the 2021/22 financial period.

In pursuit of SAHPRA managed fraud and corruption reporting tools, management is in the process of procuring services that will be tailor-made for effective and efficient responses to reported cases. However, in absence of the entity-owned tool, staff and stakeholders are encouraged to use the national anti-corruption hotline until the establishment of its own such tool. In the new year, management will actively communicate and train staff on identification, management and reporting of actual or suspected fraud and corruption activities against SAHPRA.

Currently different mechanisms such as telephone calls and the NDoH whistle-blowing facility have been used to report actual or alleged fraud and corruption cases. To date, reported cases with sufficient information, have undergone internal investigation and disciplinary processes. SAHPRA is in the process of building its own infrastructure to deal with fraud and corruption.

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 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

Safety, health and environment (SHE) is a general phrase used to refer to laws, rules, regulations, professions, programs, and workplace efforts to protect the health and safety of employees and the public as well as safeguarding the environment from hazards associated with the workplace.

SHE in the workplace is vital, as it ensures the general welfare of employees and supports them when carrying out specific tasks. This includes providing a risk-free working environment to employees, providing face masks, sanitisers, first aid kits, fire extinguishers, purified water, *et cetera*. There are various mechanisms in place to support employees, employers and the general public on implementing health and safety procedures at work, including the Occupational Health and Safety Act, (Act No. 85 of 1993), SAHPRA's Occupational Health and Safety Policy, the COVID-19 Cleaning Protocol and the COVID-19 Suspected Infection Response Protocol. During the financial year, the Chief Executive Officer (16.1 Appointee) appointed the Chief Operations Officer (16.2 Appointee) for SAHPRA – the appointment letter was displayed in reception areas. SAHPRA trained SHE representatives, established SAHPRA's Occupational Health and Safety Committee which held monthly meetings, conducted quarterly SHE workplace inspections, ensured and complied with COVID-19 Regulations as published by the Department of Employment and Labour and the Department of Cooperative Governance and Traditional Affairs, et cetera.

But regardless of the regulations, everyone is responsible for workplace health and safety and should always raise concerns and act responsibly.

13. COMPANY/BOARD SECRETARY

SAHPRA is a Schedule 3A public entity with an appointed Board Secretary. Advocate Peter Nthotso was appointed by SAHPRA as the Board Secretary in 2019. He 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 his duties, he makes members aware of any laws and regulations relevant to or affecting the Authority.

14. SOCIAL RESPONSIBILITY

Not applicable.

15. RISK AUDIT AND GOVERNANCE (RAG) COMMITTEE REPORT

As required by the Treasury Regulation 27.1.10, the Risk Audit and Governance Committee submits the report of the Risk Audit and Governance Committee.

FUNCTIONS OF THE RAG COMMITTEE

The Committee adopted its formal terms reference in an Audit Committee Charter, as required by Treasury Regulations 27.1.6 and 27.1.7. The Charter was last reviewed by the Committee in January 2021 in line with the approved workplan. The Committee hereby confirms that it has discharged functions limited to those embodied in its charter and ascribed to it in terms of the Treasury Regulations 27.1.8 and 27.1.10.

INTERNAL CONTROLS, SYSTEMS, AND PROCESSES

The Risk Audit and Governance Committee undertook the following activities during the past financial year:

- The Committee approved its workplan which provided an opportunity for the committee to discuss all significant matters that fall within the purview of its mandate.
- 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.
- Reviewed the accounting and auditing concerns identified by the Auditor-General in the prior year, which included the tabling and discussion of 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 Committee has noted the significant weaknesses that have been identified by the Auditor-General, with the resultant qualified opinion.

QUALIFICATION

The Auditor-General has qualified the entity for the year under review. The basis of the qualification relates to the opening balances which will be addressed during the 2021/22 financial year. However, the Committee noted significant improvement of the audit overall primarily for the following reasons;

- The audit was completed on time and within budget, and
- The number of audit findings was reduced from 88 to 23 with only one finding leading to a qualification.

ATTENDANCE

In order to address the finding in the audit of the previous financial year relating to the required composition of the Risk Audit and Governance Committee, the Board resolved to reconfigure the committee. The committee is now comprised of 4 independent board members and 3 external members all with expertise in financial and audit matters. The CEO is an *ex officio* member of the committee.

The audit committee meetings were attended by both management and board members, with the relevant senior managers always reporting at the meeting as per standing invitation.

CONFIDENTIAL MEETINGS

The nature of these meetings and the agendas provided for confidential deliberations between committee members related to issues of risk, audit and governance within SAHPRA.

INDEPENDENCE AND THE OPINION OF THE EXTERNAL AUDITOR

The Audit Committee is satisfied that the the Auditor-General has fulfilled its role as an independent auditor of the public entity. The Committee has considered findings of the Auditor-General and the conclusions related to the Annual Financial Statements. The Committee is of the opinion that the audited Annual Financial Statements read together with the Report of the Auditor-General are a true reflection

of the financial state of SAHPRA. In addition, the committee has reviewed the performance information as reflected in the Annual Report as well as the results of the audit of this information. The committee was pleased to note an improvement in this regard compared to the audit of the previous financial year.

During the past financial year, the Risk Audit and Governance Committee met on:

- 13 May 2020
- 20 July 2020
- 11 August 2020
- 22 October 2020
- 18 November 2020
- 21 January 2021
- 26 February 2021

I would like to thank the committee members, both board and external members, together with management for their contributions that in my opinion contributed to the improved audit results in the financial year under review.

Professor Craig Household
Chairperson: Risk Audit and Governance Committee
Date: 31 August 2021

16. B-BBEE COMPLIANCE PERFORMANCE INFORMATION

SAHPRA was engaging the Minister of Health and the Broad-Based Black Economic Empowerment (B-BBEE) Commission to try to address compliance.

SAHPRA
South African Health Products Regulatory Authority

PART D

HUMAN RESOURCE MANAGEMENT

1. INTRODUCTION

The year 2020/21 has been challenging for SAHPRA as it was not business as usual. The year was made up by telecommuting of employees and more than 50% of staff worked from home. There were lockdowns caused by the COVID-19 pandemic. The Human Resources (HR) Unit recruited an HR Manager and Human Resources Officer on contract to keep this part of the Authority going under these unprecedented, tough times. The HR Department evolved and adapted its approach in doing business for SAHPRA, to meet ongoing business requirements and demands.

Under these conditions, the Human Resources Department was able to achieve the following:

- Reduce the vacancy rate by recruiting core, critical and scarce skills. It is critical for the human resources department to ensure a capacitated SAHPRA for the fulfilment of the Authority's mandate. The appointment of candidates, especially externally, directly influences the vacancy rate which must be kept lower than 10% to achieve SAHPRA goals.
- Performance management assessments were lagging due to the transferring of employees from NDoH to SAHPRA and the fact that employees were outside the Civitas Building. Approximately 80% of employees were performance assessed for the 2019/20 financial year.
- Policy development and review, which entail guidelines to promote fairness and consistency, known as "rules of the game," as well as diversity and transformation in the Authority were developed to prepare for approval, since SAHPRA has been reliant on NDoH policies. The following HR Policies were developed and submitted for approval: Recruitment and Selection, Performance Management System, Training and Development, and Disciplinary Policy and Procedures. In the next two years, these policies will be reviewed.
- The Human Resources Department achieved the appointment of the Executive Manager: Human Resources, the Chief Operations Officer and the Chief Financial Officer after the unfortunate resignation by the previous Chief Financial Officer. These appointments finalised the composition of the executive committee to complement the Chief Executive Officer and the Chief Regulatory Officer.
- The HR Department, working with organised labour, were able to conclude a Placement Framework for administration staff of 95 employees and was able to appoint and place 100% of administrative employees by the end of the fiscal year – as per the requirements of the Labour Relations Act, Section 197.
- An employees engagement survey was conducted and concluded with more than 60% participation. SAHPRA is in the process of implementing some of the recommendations made from the Survey.

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	NO. OF EMPLOYEES	AVERAGE PERSONNEL COST PER EMPLOYEE (R'000)
Programme 1	64 368	37 487	58%	57	658
Programme 2	34 223	13 460	39%	45	299
Programme 3	35 696	26 460	74%	38	696
Programme 4	73 666	52 638	71%	72	731
Programme 5	38 128	16 129	42%	34	474
Project (Backlog reduction)	46 359	18 252	39%	31	589
TOTAL	**292 440**	**164 426**		**277**	

PERSONNEL COST BY SALARY BAND

LEVEL	PERSONNEL EXPENDITURE (R'000)	% OF PERSONNEL EXPENDITURE TO TOTAL PERSONNEL COST	NO. OF EMPLOYEES	AVERAGE PERSONNEL COST PER EMPLOYEE (R'000)
Top management	10 189	6%	5	2 038
Senior management	8 256	5%	5	1 651
Professional qualified	98 205	60%	122	805
Skilled	25 466	15%	59	432
Semi-skilled	18 210	11%	70	260
Unskilled	0	0%	0	0
Community service	4 100	2%	16	260
TOTAL	**164 426**	**100%**	**277**	**594**

In collaboration with the NDoH, SAHPRA hosts community-service pharmacists and medical doctors for a practical year towards their qualification. The recruitment of the community-service category is managed by the National Department of Health and the numbers allocated to SAHPRA is based on its business needs.

PERFORMANCE REWARDS

LEVEL	PERFORMANCE REWARDS (R'000)	PERSONNEL EXPENDITURE (R'000)	% OF PERFORMANCE REWARDS TO TOTAL PERSONNEL COST (R'000)
Top management	0	0	0
Senior management	0	0	0
Professional qualified	0	0	0
Skilled	0	0	0
Semi-skilled	0	0	0
Unskilled	0	0	0
TOTAL	**0**	**0**	**0**

The moderation phase for the 2019/2020 performance management process was not concluded by the end of the period. The delays are attributed to the employee transfer and placement process as guided by Section 197 of the Labour Relations Act. Core to the placement process are changes related to internal employment movements, new responsibilities and reporting lines.

The related performance incentives will be processed once the due diligence process is finalised.

TRAINING COSTS

PROGRAMME	PERSONNEL EXPENDITURE (R'000)	TRAINING EXPENDITURE (R'000)	TRAINING EXPENDITURE AS A % OF PERSONNEL COST (R'000)	NO. OF EMPLOYEES TRAINED	AVERAGE TRAINING COST PER EMPLOYEE (R'000)
All programmes	164 426	758	0%	118	7
TOTAL	**164 426**	**758**	**0%**	**118**	**7**

The training attended was enhanced by a high number of virtual training programmes made available to employees due to the COVID-19 pandemic.

EMPLOYMENT AND VACANCIES

PROGRAMME	2020/2021 NO. OF EMPLOYEES (AS AT 1 APRIL 2020)	2020/2021 APPROVED POSTS	2020/2021 NO. OF EMPLOYEES (AS AT 31 MARCH 2021)	2020/2021 VACANCIES	% OF VACANCIES
Programme 1	25	59	57	2	5%
Programme 2	26	48	45	3	7%
Programme 3	40	47	38	9	22%
Programme 4	92	82	72	10	25%
Programme 5	27	51	34	17	41%
Backlog Project	20	31	31	0	0%

Employees were reallocated to different programmes with the transfer and placement process as reflected by the changes in numbers.

LEVEL	2020/2021 NO. OF EMPLOYEES (AS AT 1 APRIL 2020)	2020/2021 APPROVED POSTS	2020/2021 NO. OF EMPLOYEES (AS AT 31 MARCH 2021)	2020/2021 VACANCIES	% OF VACANCIES
Top management	3	5	5	0	0%
Senior management	1	6	5	1	2%
Professional qualified	105	157	122	35	85%
Skilled	51	64	59	5	12%
Semi-skilled	71	70	70	0	0%
Comm Serves	10	16	16	0	0%
TOTAL	**241**	**318**	**277**	**41**	

SAHPRA was successful in recruiting for the executive and the senior management levels. Recruitment challenges were experienced in the professionally qualified technical-skills level. The job market in this level is very competitive with higher salary ranges. Benchmarking processes and targeted recruitment are some of the strategies SAHPRA has undertaken to manage these challenges.

EMPLOYMENT CHANGES

SALARY BAND	EMPLOYMENT AT THE BEGINNING OF PERIOD	APPOINTMENTS	TERMINATIONS	EMPLOYMENT AT END OF THE PERIOD
Top management	3	3	1	5
Senior management	1	5	1	5
Professional qualified	105	21	7	122
Skilled	51	12	3	59
Semi-skilled	71	2	3	70
Unskilled	0	0	0	0
Community Service	10	16	1	16
TOTAL	**241**	**59**	**16**	**277**

The executive and the senior management teams were fully appointed in the period.

REASONS FOR STAFF LEAVING

REASON	NUMBER	% OF TOTAL NO. OF STAFF LEAVING
Death	1	7%
Resignation	9	60%
Dismissal	1	7%
Retirement	3	20%
Ill health	0	0%
Expiry of contract	1	7%
Other (Transfer)	1	7%
TOTAL	**16**	

The majority of employees resigned due to better salaries offered to them. SAHPRA is in the process of conducting a salary benchmarking exercise to determine the gaps in the medical, health and regulatory environment. The benchmarking exercise assisted SAHPRA in developing its retention strategies.

LABOUR RELATIONS: MISCONDUCT AND DISCIPLINARY ACTION

NATURE OF DISCIPLINARY ACTION	NUMBER
Verbal warning	2
Written warning	2
Final written warning	0
Dismissal	1

EQUITY TARGET AND EMPLOYMENT EQUITY STATUS

	MALE							
	AFRICAN		COLOURED		INDIAN		WHITE	
LEVELS	CURRENT	TARGET	CURRENT	TARGET	CURRENT	TARGET	CURRENT	TARGET
Top management	1	0	0	0	0	0	1	0
Senior management	3	0	0	0	0	0	0	0
Professional qualified	37	0	3	0	1	0	4	0
Skilled	15	0	1	0	1	0	1	0
Semi-skilled	25	0	2	0	0	0	0	0
Community Service	3	0	0	0	0	0	2	0
TOTAL	**84**	**0**	**6**	**0**	**2**	**0**	**8**	**0**

	FEMALE							
	AFRICAN		COLOURED		INDIAN		WHITE	
LEVELS	CURRENT	TARGET	CURRENT	TARGET	CURRENT	TARGET	CURRENT	TARGET
Top management	2	0	0	0	0	0	1	0
Senior management	0	0	0	0	1	0	1	0
Professional qualified	63	0	2	0	7	0	8	0
Skilled	26	0	4	0	5	0	2	0
Semi-skilled	34	0	7	0	0	0	3	0
Community Service	5	0	1	0	4	0	1	0
TOTAL	**130**	**0**	**14**	**0**	**17**	**0**	**16**	**0**

The Employment Equity Plan will be developed in the 2021/22 financial year. No targets have been determined to date.

SAHPRA
South African Health Products Regulatory Authority

PART E

FINANCIAL INFORMATION

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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 the entity as at the end of the financial year and the results of its operations and cash flows for the period then ended. The external auditors are engaged to express an independent opinion on the annual financial statements and were given unrestricted access to all financial records and related data.

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

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

The accounting authority acknowledge that they are ultimately responsible for the system of internal financial control established by the entity and place considerable importance on maintaining a strong control environment. To enable the accounting authority to meet these responsibilities, the accounting authority sets standards for internal control aimed at reducing the risk of error or deficit in a cost effective manner. The standards include the proper delegation of responsibilities within a clearly defined framework, effective accounting procedures and adequate segregation of duties to ensure an acceptable level of risk. These controls are monitored throughout the entity and all employees are required to maintain the highest ethical standards in ensuring the entity's business is conducted in a manner that in all reasonable circumstances is above reproach. The focus of risk management in the entity is on identifying, assessing, managing and monitoring all known forms of risk across the entity. While operating risk cannot be fully eliminated, the entity endeavours to minimise it by ensuring that appropriate infrastructure, controls, systems and ethical behaviour are applied and managed within predetermined procedures and constraints.

The accounting authority are of the opinion, based on the information and explanations given by management, that the system of internal control provides reasonable assurance that the financial records may be relied on for the preparation of the annual financial statements. However, any system of internal financial control can provide only reasonable, and not absolute, assurance against material misstatement or deficit.

The accounting authority have reviewed the entity's cash flow forecast for the year to 31 March 2022 and, in the light of this review and the current financial position, they are satisfied that the entity has or has access to adequate resources to continue in operational existence for the foreseeable future.

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

Although the accounting authority are primarily responsible for the financial affairs of the entity, they are supported by the entity's external auditors.

The external auditors are responsible for independently reviewing and reporting on the entity's annual financial statements. The annual financial statements have been examined by the entity's external auditors and their report is presented from page 68 to 72.

The annual financial statements set out from pages 73 to 118, which have been prepared on the going concern basis, were approved by the accounting authority on 28 July 2021 and were signed on its behalf by:

Dr B. Semete-Makokotlela
Chief Executive Officer

Prof. H.V. Rees
Chairperson

REPORT OF THE AUDITOR-GENERAL

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

REPORT ON THE AUDIT OF THE FINANCIAL STATEMENTS

QUALIFIED

1. I have audited the financial statements of the South Africa Health Products Regulatory Authority (SAHPRA) set out on pages 73 to 118, which comprise the statement of financial position as at 31 March 2021, the statement of financial performance, statement of changes in net assets and cash flow statement and statement of comparison of budget information with actual information for the year then ended, as well as notes to the financial statements, including a summary of significant accounting policies.

2. In my opinion, except for the possible effects on the corresponding amounts of the matter described in the basis for qualified opinion section of this report, the financial position of Sahpra as at 31 March 2021 and its financial performance and cash flows for the year then ended in accordance with the Standards of Generally Recognised Accounting Practice and the requirements of the Public Finance Management Act 1 of 1999.

BASIS FOR QUALIFIED OPINION

INCOME RECEIVED IN ADVANCE AND FEE INCOME

3. During 2020, I was unable to obtain sufficient appropriate audit evidence for income received in advance (deferred income) and fee income due to the status of the records. I was unable to confirm the revenue received in advance (deferred income) and fee income by alternative means. Consequently, I was unable to determine whether any adjustment was necessary to the corresponding figure of revenue received in advance (deferred income), stated at R76 136 236 in note 10 to the financial statements, and fee income, stated R54 178 520 in note 11 to the financial statements. My audit opinion on the financial statements for the period ended 31 March 2020 was modified accordingly. My opinion on the current year financial statements was also modified because of the possible effects of this matter on the comparability of the income received in advance and fee income for the current period.

CONTEXT FOR THE OPINION

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

5. I am independent of the 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.

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

RESPONSIBILITIES OF THE ACCOUNTING AUTHORITY FOR THE FINANCIAL STATEMENTS

7. The board of directors, which constitutes the accounting authority, is responsible for the preparation and fair presentation of the financial statements in accordance with the Standards of 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.

8. In preparing the financial statements, the accounting authority is responsible for assessing the 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 entity or to cease operations, or has no realistic alternative but to do so.

AUDITOR-GENERAL'S RESPONSIBILITIES FOR THE AUDIT OF THE FINANCIAL STATEMENTS

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

10. A further description of my responsibilities for the audit of the [consolidated and separate] financial statements is included in the annexure to this auditor's report.

REPORT ON THE AUDIT OF THE ANNUAL PERFORMANCE REPORT

INTRODUCTION AND SCOPE

11. In accordance with the Public Audit Act 25 of 2004 (PAA) and the general notice issued in terms thereof, I have a responsibility to report on the usefulness and reliability of the reported performance information against predetermined objectives for selected programmes presented in the annual performance report. I performed procedures to identify material findings but not to gather evidence to express assurance.

12. My procedures address the usefulness and reliability of the reported performance information, which must be based on the entity's approved performance planning documents. I have not evaluated the completeness and appropriateness of the performance indicators included in the planning documents. My procedures do not examine whether the actions taken by the entity enabled service delivery. My procedures do not extend to any disclosures or assertions relating to the extent of achievements in the current year or planned performance strategies and information in respect of future periods that may be included as part of the reported performance information. Accordingly, my findings do not extend to these matters.

13. I evaluated the usefulness and reliability of the reported performance information in accordance with the criteria developed from the performance management and reporting framework, as defined in the general notice, for the following selected programmes presented in the entity's annual performance report for the year ended 31 March 2021:

PROGRAMMES	PAGES IN THE ANNUAL PERFORMANCE REPORT
Programme 4 – Medicine Evaluation and Registration	38 – 43

14. I performed procedures to determine whether the reported performance information was properly presented and whether performance was consistent with the approved performance planning documents. I performed further procedures to determine whether the indicators and related targets were measurable and relevant, and assessed the reliability of the reported performance information to determine whether it was valid, accurate and complete.

15. I did not identify any material findings on the usefulness and reliability of the reported performance information for this programme:

    - Programme 4 – Medicine Evaluation and Registration.

OTHER MATTER

16. I draw attention to the matter below.

ACHIEVEMENT OF PLANNED TARGETS

17. Refer to the annual performance report on page(s) 21 to 47 for information on the achievement of planned targets for the year and management's explanations provided for the under-/over-achievement of targets.

REPORT ON THE AUDIT OF COMPLIANCE WITH LEGISLATION

INTRODUCTION AND SCOPE

18. In accordance with the PAA and the general notice issued in terms thereof, I have a responsibility to report material findings on the entity's compliance with specific matters in key legislation. I performed procedures to identify findings but not to gather evidence to express assurance.

19. The material findings on compliance with specific matters in key legislation are as follows:

ANNUAL FINANCIAL STATEMENTS, PERFORMANCE AND ANNUAL REPORTS

20. The financial statements submitted for auditing were not prepared in accordance with the prescribed financial reporting framework and supported by full and proper records, as required by section 55(1)(a) and (b) of the PFMA.

21. Material misstatements of fee income identified by the auditors in the submitted financial statements were corrected, but the uncorrected material misstatements of income received in advance (deferred income) and fee income identified in the prior year resulted in the financial statements receiving a qualified opinion.

EXPENDITURE MANAGEMENT

22. Effective and appropriate steps were not taken to prevent irregular expenditure amounting to R6 268 808, as disclosed in note 31 to the annual financial statements, as required by section 51(1)(b)(ii) of the PFMA. The majority of the irregular expenditure was caused by variations to a contract that was not approved by the relevant authority.

PROCUREMENT AND CONTRACT MANAGEMENT

23. Some of the goods and services with a transaction value below R500 000 were procured without obtaining the required price quotations, as required by treasury regulation 16A6.1 and paragraph 3.3.1 of National Treasury Practice Note 8 of 2007-08. Similar non-compliance was also reported in the prior year.

OTHER INFORMATION

24. The accounting authority is responsible for the other information. The other information comprises the information included in the annual report, which includes the audit committee's report. The other information does not include the financial statements, the auditor's report and those selected programmes presented in the annual performance report that have been specifically reported in this auditor's report.

25. My opinion on the financial statements and findings on the reported performance information and compliance with legislation do not cover the other information and I do not express an audit opinion or any form of assurance conclusion on it.

26. In connection with my audit, my responsibility is to read the other information and, in doing so, consider whether the other information is materially inconsistent with the financial statements and the selected programmes presented in the annual performance report, or my knowledge obtained in the audit, or otherwise appears to be materially misstated.

27. 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 re-issue an amended report as appropriate. However, if it is corrected this will not be necessary.

INTERNAL CONTROL DEFICIENCIES

28. I considered internal control relevant to my audit of the financial statements, reported performance information and compliance with applicable legislation; however, my objective was not to express any form of assurance on it. The matters reported below are limited to the significant internal control deficiencies that resulted in the basis for the qualified opinion, the findings on the annual performance report and the findings on compliance with legislation included in this report.

29. The entity did not implement proper record keeping in the prior year to ensure that complete, relevant and accurate information is accessible and available to support financial and reporting.

30. The entity did not implement controls over the monthly processing and reconciling of transactions.

31. The entity did not review and monitor compliance with applicable legislation.

Auditor - General

Pretoria
30 July 2021

AUDITOR-GENERAL
SOUTH AFRICA

Auditing to build public confidence

ANNEXURE – AUDITOR-GENERAL'S RESPONSIBILITY FOR THE AUDIT

1. As part of an audit in accordance with the ISAs, I exercise professional judgement and maintain professional scepticism throughout my audit of the financial statements and the procedures performed on reported performance information for selected programmes and on the entity's compliance with respect to the selected subject matters.

FINANCIAL STATEMENTS

2. In addition to my responsibility for the audit of the financial statements as described in this auditor's report, I also:

    - identify and assess the risks of material misstatement of the financial statements, whether due to fraud or error; design and perform audit procedures responsive to those risks; and obtain audit evidence that is sufficient and appropriate to provide a basis for my opinion. The risk of not detecting a material misstatement resulting from fraud is higher than for one resulting from error, as fraud may involve collusion, forgery, intentional omissions, misrepresentations or the override of internal control
    - obtain an understanding of internal control relevant to the audit in order to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the entity's internal control
    - evaluate the appropriateness of accounting policies used and the reasonableness of accounting estimates and related disclosures made by the board of directors, which constitutes the accounting authority
    - conclude on the appropriateness of the accounting authority entity's 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 Sahpra to continue as a going concern. If I conclude that a material uncertainty exists, I am required to draw attention in my auditor's report to the related disclosures in the financial statements about the material uncertainty or, if such disclosures are inadequate, to modify my opinion on the financial statements. My conclusions are based on the information available to me at the date of this auditor's report. However, future events or conditions may cause an entity to cease operating as a going concern
    - evaluate the overall presentation, structure and content of the financial statements, including the disclosures, and determine whether the financial statements represent the underlying transactions and events in a manner that achieves fair presentation.

COMMUNICATION WITH THOSE CHARGED WITH GOVERNANCE

3. 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.

4. I also provide the accounting authority with a statement that I have complied with relevant ethical requirements regarding independence, and communicate with them all relationships and other matters that may reasonably be thought to bear on my independence and, where applicable, actions taken to eliminate threats or safeguards applied.

STATEMENT OF FINANCIAL POSITION

as at the 31 March 2021

	NOTES	2021 R	2020 R
ASSETS			
CURRENT ASSETS			
Receivables from exchange transactions	3	11 252 061	2 696 835
Receivables from non-exchange transactions	4	34 674	14 634 131
Prepayments		3 110 306	451 580
Cash and cash equivalents	5	150 764 296	121 957 555
		165 161 337	**139 740 101**
NON-CURRENT ASSETS			
Property, plant and equipment	6	29 824 703	14 671 465
Intangible assets	7	1 872 911	267 380
		31 697 614	**14 938 845**
Total Assets		**196 858 951**	**154 678 946**
LIABILITIES			
CURRENT LIABILITIES			
Operating lease liability (smoothing)		1 600 515	-
Payables from exchange transactions	8	31 671 920	21 369 850
Provisions	9	14 188 396	12 108 776
Income received in advance	10	107 223 891	40 546 636
Deferred income - Backlog reduction project	10	21 868 100	35 589 600
Total Liabilities		**176 552 822**	**109 614 862**
Net Assets		**20 306 129**	**45 064 084**
Accumulated surplus		**20 306 129**	**45 064 084**

STATEMENT OF **FINANCIAL PERFORMANCE**

for the year ended 31 March 2021

	NOTES	2021 R	2020 R
REVENUE			
REVENUE FROM EXCHANGE TRANSACTIONS			
Fee income	11	101 733 589	54 178 520
Sundry income	12	2 325 801	-
Interest received	13	4 006 563	8 094 788
Gain on foreign exchange		171 284	-
Total revenue from exchange transactions		**108 237 237**	**62 273 308**
REVENUE FROM NON-EXCHANGE TRANSACTIONS			
Transfer payment received	14	156 572 000	183 274 000
Transfer of assets received from National Department of Health		767 922	-
Backlog reduction project - grant received	15	2 104 925	16 075 301
Total revenue from non-exchange transactions		**159 444 847**	**199 349 301**
Total revenue		**267 682 084**	**261 622 609**
EXPENDITURE			
Employee related costs	16	(147 089 885)	(131 598 533)
Backlog reduction project	17	(46 359 007)	(17 409 082)
Depreciation	18	(5 558 241)	(2 203 533)
Impairment of assets		(624 618)	(46 733)
Lease rentals on operating lease		(15 502 556)	(6 543 404)
Bad debts written off		(2 795 929)	-
Contracted service	19	(19 922 033)	(19 992 200)
Loss on disposal of assets		(1 228 163)	(66 635)
Loss on foreign exchange		-	(59 360)
Operating Expenses	20	(53 359 607)	(52 497 838)
Total expenditure		**(292 440 039)**	**(230 417 318)**
(Deficit) surplus for the year		**(24 757 955)**	**31 205 291**

STATEMENT OF CHANGES IN NET ASSETS

for the year ended 31 March 2021

	ACCUMULATED SURPLUS R	TOTAL NET ASSETS R
Balance at 01 April 2019	**13 749 308**	**13 749 308**
Changes in net assets		
Assets and liabilities transferred from NDOH	109 485	109 485
Net income (losses) recognised directly in net assets	**109 485**	**109 485**
Surplus for the period	31 205 291	31 205 291
Total recognised income and expenses for the year	**31 314 776**	**31 314 776**
Balance at 01 April 2020	**45 064 084**	**45 064 084**
Changes in net assets		
Surplus for the period	(24 757 955)	(24 757 955)
Balance at 31 March 2021	**20 306 129**	**20 306 129**

CASH FLOW STATEMENT

for the year ended 31 March 2021

	NOTES	2021 R	2020 R
CASH FLOWS FROM OPERATING ACTIVITIES			
RECEIPTS			
Fee and deferred income		146 895 718	71 874 849
Government grants		156 572 000	183 274 000
Interest received		3 962 298	8 125 225
CDC grant		16 704 382	-
		324 134 398	**263 274 074**
PAYMENTS			
Employee related costs		(171 886 679)	(131 942 136)
Suppliers		(102 364 911)	(102 962 077)
		(274 251 590)	**(234 904 213)**
Net cash flows from operating activities	21	**49 882 808**	**28 369 861**
CASH FLOWS FROM INVESTING ACTIVITIES			
Purchase of property, plant and equipment	6	(19 328 064)	(9 787 259)
Proceeds from disposal of assets	12&6	19 130	-
Purchase of other intangible assets	7	(1 767 133)	(281 983)
Net cash flows from investing activities		**(21 076 067)**	**(10 069 242)**
Net cash and cash equivalents		**28 806 741**	**18 300 619**
Cash and cash equivalents at the beginning of the year		121 957 555	103 656 936
Cash and cash equivalents at the end of the year	5	**150 764 296**	**121 957 555**

STATEMENT OF COMPARISON OF BUDGET AND ACTUAL AMOUNTS

for the year ended 31 March 2021

	APPROVED BUDGET R	ADJUSTMENTS R	FINAL BUDGET R	ACTUAL AMOUNTS ON COMPARABLE BASIS R	DIFFERENCE BETWEEN FINAL BUDGET AND ACTUAL R	REFERENCE
STATEMENT OF FINANCIAL PERFORMANCE REVENUE						
REVENUE FROM EXCHANGE TRANSACTIONS						
Fee income	196 771 015	-	196 771 015	101 733 589	(95 037 426)	33.1
Sundry income	-	-	-	2 325 801	2 325 801	33.1
Gain on foreign exchange	-	-	-	171 284	171 284	
Interest received	6 000 000	-	6 000 000	4 006 563	(1 993 437)	33.2
Total revenue from exchange transactions	**202 771 015**	**-**	**202 771 015**	**108 237 237**	**(94 533 778)**	
REVENUE FROM NON-EXCHANGE TRANSACTIONS						
TRANSFER REVENUE						
Government grants	159 152 000	(2 580 000)	156 572 000	156 572 000	-	
Transfer of assets from NDOH	-	-	-	767 922	767 922	
Backlog reduction project - grant received	25 840 000	-	25 840 000	2 104 925	(23 735 075)	33.7
Total revenue from non-exchange transactions	**184 992 000**	**(2 580 000)**	**182 412 000**	**159 444 847**	**(22 967 153)**	
Total revenue	**387 763 015**	**(2 580 000)**	**385 183 015**	**267 682 084**	**(117 500 931)**	
EXPENDITURE						
Employee Related Costs	(215 771 879)	-	(215 771 879)	(147 089 885)	68 681 994	33.3
Backlog reduction project	(26 000 000)	-	(26 000 000)	(46 359 007)	(20 359 007)	33.7
Depreciation	-	-	-	(5 558 241)	(5 558 241)	33.4
Impairment of assets	-	-	-	(624 618)	(624 618)	
Lease rentals on operating lease	(25 118 700)	-	(25 118 700)	(15 502 556)	9 616 144	33.8
Bad debts written off	-	-	-	(2 795 929)	(2 795 929)	
Contracted Services	(19 972 000)	-	(19 972 000)	(19 922 033)	49 967	33.5
Operating expenses	(100 900 436)	-	(100 900 436)	(53 359 607)	47 540 829	33.6
Total expenditure	**(387 763 015)**	**-**	**(387 763 015)**	**(291 211 876)**	**96 551 139**	
Operating deficit	-	(2 580 000)	(2 580 000)	(23 529 792)	(20 949 792)	
Loss on disposal of assets and liabilities	-	-	-	(1 228 163)	(1 228 163)	
Deficit before taxation	**-**	**(2 580 000)**	**(2 580 000)**	**(24 757 955)**	**(22 177 955)**	
Actual Amount on Comparable Basis as Presented in the Budget and Actual Comparative Statement	**-**	**(2 580 000)**	**(2 580 000)**	**(24 757 955)**	**(22 177 955)**	

ACCOUNTING POLICIES

1. PRESENTATION OF ANNUAL FINANCIAL STATEMENTS

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

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

In the absence of an issued and effective Standard of GRAP, accounting policies for material transactions, events or conditions were developed in accordance with paragraphs 8, 10 and 11 of GRAP 3 as read with Directive 5 issued by the Accounting Standards Board.

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

A summary of the significant accounting policies are disclosed below. These accounting policies have been consistently applied in the preparation of these annual financial statements, except for the change in the accounting policy related to revenue recognition. Refer to note 35 for details regarding the change in the accounting policy.

These accounting policies are consistent with the previous period, except for the changes set out in note 25 Changes in accounting policy.

When the presentation or classification of items in the Annual Financial Statement is amended, prior period comparative amounts are restated if material. The nature and reason for the reclassification is disclosed. Where the accounting errors have been identified in the current year, the correction is made retrospectively as far as is practicable, and prior year comparatives are restated accordingly. Where there has been a change in accounting policy in the current year, the adjustment is made retrospectively as far as practicable, and the prior year comparatives are restated accordingly.

1.1 PRESENTATION CURRENCY

These annual financial statements are presented in South African Rand.

1.2 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.

1.3 MATERIALITY

Material omissions or misstatements of items are material if they could, individually or collectively, influence the decisions or assessments of users made on the basis of the financial statements. Materiality depends on the nature or size of the omission or misstatement judged in the surrounding circumstances. The nature or size of the information item, or a combination of both, could be the determining factor.

Assessing whether an omission or misstatement could influence decisions of users, and so be material, requires consideration of the characteristics of those users. The Framework for the Preparation and Presentation of Financial

Statements states that users are assumed to have a reasonable knowledge of government, its activities, accounting and a willingness to study the information with reasonable diligence. Therefore, the assessment takes into account how users with such attributes could reasonably be expected to be influenced in making and evaluating decisions.

1.4 SIGNIFICANT JUDGEMENTS AND SOURCES OF ESTIMATION UNCERTAINTY

The use of judgment, estimates and assumptions is inherent to the process of preparing Annual Financial Statements. These judgements, estimates and assumptions affect the amounts presented in 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.

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 surplus 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.

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.

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 9 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.

1.5 PROPERTY, PLANT AND EQUIPMENT

Property, plant and equipment are tangible non-current assets that are held for use in the production or supply of goods or services, rental to others, or for administrative purposes, and are expected to be used during more than one period.

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.

The cost of an item of property, plant and equipment is the purchase price and other costs attributable to bring the asset to the location and condition necessary for it to be capable of operating in the manner intended by management. Trade discounts and rebates are deducted in arriving at the 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.

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 are depreciated on the straight line basis over their expected useful lives to their estimated residual value.

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	AVERAGE USEFUL LIFE
Furniture and fittings	Straight line	10 - 14 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. 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.

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.

An intangible asset arising from development (or from the development phase of an internal project) is recognised when:

- it is technically feasible to complete the asset so that it will be available for use or sale.
- there is an intention to complete and use or sell it.
- there is an ability to use or sell it.
- it will generate probable future economic benefits or service potential.
- there are available technical, financial and other resources to complete the development and to use or sell the asset.
- the expenditure attributable to the asset during its development can be measured reliably.

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 entity does not hold any intangible assets with indefinite useful lives.

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

Reassessing the useful life of an intangible asset with a finite useful life after it was classified as indefinite is an indicator that the asset may be impaired. As a result the asset is tested for impairment and the remaining carrying amount is amortised over its useful life.

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
Developed software	Straight line	7 Years
Acquired software	Straight line	7 Years

1.7 FINANCIAL INSTRUMENTS

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

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

Credit risk is the risk that one party to a financial instrument will cause a financial loss for the other party by failing to discharge an obligation.

Derecognition is the removal of a previously recognised financial asset or financial liability from an entity's statement of financial position.

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.

- a residual interest of another entity; or
- a contractual right to:
  - receive cash or another financial asset from another entity; or
  - exchange financial assets or financial liabilities with another entity under conditions that are potentially favourable to the entity.

A financial liability is any liability that is a contractual obligation to:

- deliver cash or another financial asset to another entity; or
- exchange financial assets or financial liabilities under conditions that are potentially unfavourable to the entity.

Interest rate risk is the risk that the fair value or future cash flows of a financial instrument will fluctuate because of changes in market interest rates.

Liquidity risk is the risk encountered by an entity in the event of difficulty in meeting obligations associated with financial liabilities that are settled by delivering cash or another financial asset.

A financial asset is past due when a counterparty has failed to make a payment when contractually due.

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 UNCOLLECTIBILITY OF 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;
- the entity transfers to another party substantially all of the risks and rewards of ownership of the financial asset; or
- the entity, despite having retained some significant risks and rewards of ownership of the financial asset, has transferred control of the asset to another party and the other party has the practical ability to sell the asset 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 asset; and
    - recognise separately any rights and obligations created or retained in the transfer.

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 LEASES

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

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 the amount substantially all of the fair value when it exceeds 95% of the fair value 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

The lease expense recognised for operating leases is charged to the Statement of Financial Performance on a straight-line basis over the term of the relevant lease. To the extent that the straight-lined lease payments differ from the actual lease payments the difference is recognised in the Statement of Financial Position as either lease payments in advance (operating lease asset) or lease payments payable (operating lease liability) as the case may be. This resulting asset and / or liability is measured as the undiscounted difference between the straight-line lease payments and the contractual lease payments.

The operating lease liability is derecognised when the entity's obligation to settle the liability is extinguished. The operating lease asset is derecognised when the entity no longer anticipates economic benefits to flow from the asset.

1.9 IMPAIRMENT OF CASH-GENERATING ASSETS

Cash-generating assets are assets used with the objective of generating a commercial return. Commercial return means that positive cash flows are expected to be significantly higher than the cost of the asset.

Impairment is a loss in the future economic benefits or service potential of an asset, over and above the systematic recognition of the loss of the asset's future economic benefits or service potential through depreciation (amortisation).

Carrying amount is the amount at which an asset is recognised in the statement of financial position after deducting any accumulated depreciation and accumulated impairment losses thereon.

A cash-generating unit is the smallest identifiable group of assets used with the objective of generating a commercial return that generates cash inflows from continuing use that are largely independent of the cash inflows from other assets or groups of assets.

Recoverable amount of an asset or a cash-generating unit is the higher its fair value less costs to sell and its value in use.

Fair value less costs to sell is the amount obtainable from the sale of an asset in an arm's length transaction between knowledgeable, willing parties, less the costs of disposal.

Costs of disposal are incremental costs directly attributable to the disposal of an asset, excluding finance costs and income tax expense.

IDENTIFICATION

When the carrying amount of a cash-generating asset exceeds its recoverable amount, it is impaired.

The entity assesses at each reporting date whether there is any indication that a cash-generating asset may be impaired. If any such indication exists, the entity estimates the recoverable amount of the asset.

Irrespective of whether there is any indication of impairment, the entity also tests a cash-generating intangible asset with an indefinite useful life or a cash-generating intangible asset not yet available for use for impairment annually by comparing its carrying amount with its recoverable amount. This impairment test is performed at the same time every year. If an intangible asset was initially recognised during the current reporting period, that intangible asset was tested for impairment before the end of the current reporting period. SAHPRA does not have cash-generating assets.

VALUE IN USE

Value in use of a cash-generating asset is the present value of the estimated future cash flows expected to be derived from the continuing use of an asset and from its disposal at the end of its useful life.

When estimating the value in use of an asset, the entity estimates the future cash inflows and outflows to be derived from continuing use of the asset and from its ultimate disposal and the entity applies the appropriate discount rate to those future cash flows.

1.10 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.

1.11 EMPLOYEE BENEFITS

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 recognise 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 recognise 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.

Short term employee benefits are recognised in the Statement of Financial Performance as services are rendered,. These short term employee benefits are measured at their undiscounted costs in the period the employee renders the related service or the specific event occurs.

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.

1.12 PROVISIONS AND CONTIGENCIES

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.

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 28.

1.13 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.

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.

Interest income, where is it 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, are recognized on a time proportion basis that takes into account the effective yield on the asset.

1.14 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 another entity 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 SAHPRA 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 SAHPRA.

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

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.

1.15 FRUITLESS AND WASTEFUL EXPENDITURE

Fruitless and wasteful 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.

A register of Fruitless and Wasteful Expenditure is maintained.

1.16 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.

If losses can be quantified and losses incurred are irrecoverable, amount of losses irrecoverable are disclosed in the irregular expenditure note.

If losses were not incurred and value for money was achieved and the transgression was free of fraudulent, corrupt or other criminal conduct; condonation of irregular expenditure is requested from the relevant authority and in line with the relevant guidelines issued by National Treasury;

If amounts of irregular expenditure are condoned by the relevant authority, amounts are disclosed in the irregular expenditure note as amounts condoned.

If irregular expenditure was not condoned by the relevant authority, amounts are disclosed as amounts of losses irrecoverable in the irregular expenditure note under “amounts not condoned and not recoverable”

If a liability for the irregular expenditure can be attributed to a person or company and is liable in law, a receivable should be raised for recovery from the irregular expenditure note.

If fraudulent, corrupt or other criminal conduct is alleged or confirmed Treasury Regulations 33 and the debt management policy of the SAHPRA is followed.

1.17 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 April to March annually.

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 29 & 30 & 34.

1.18 RELATED PARTIES

A related party is a person or an entity with the ability to control or jointly control the other party, or exercise significant influence over the other party, or vice versa, or an entity that is subject to common control, or joint control.

Control is the power to govern the financial and operating policies of an entity so as to obtain benefits from its activities.

Joint control is the agreed sharing of control over an activity by a binding arrangement, and exists only when the strategic financial and operating decisions relating to the activity require the unanimous consent of the parties sharing control (the ventures).

Related party transaction is a transfer of resources, services or obligations between the reporting entity and a related party, regardless of whether a price is charged.

Significant influence is the power to participate in the financial and operating policy decisions of an entity, but is not control over those policies.

Management are those persons responsible for planning, directing and controlling the activities of the entity, including those charged with the governance of the entity in accordance with legislation, in instances where they are required to perform such functions.

Close accounting authority of the family of a person are considered to be those family accounting authority who may be expected to influence, or be influenced by, that management in their dealings with the entity.

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.

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

1.19 EVENTS AFTER REPORTING DATE

Events after reporting date are those events, both favourable and unfavourable, that occur between the reporting date and the date when the financial statements are authorised for issue. Two types of events can be identified:

- those that provide evidence of conditions that existed at the reporting date (adjusting events after the reporting date); and
- those that are indicative of conditions that arose after the reporting date (non-adjusting events after the reporting date).

The entity will adjust the amount recognised in the financial statements to reflect adjusting events after the reporting date once the event occurred.

The entity will disclose the nature of the event and an estimate of its financial effect or a statement that such estimate cannot be made in respect of all material non-adjusting events, where non-disclosure could influence the economic decisions of users taken on the basis of the financial statements.

1.20 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 purposes of this Standard) 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 are 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.

1.21 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 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.

Commitments are recorded at cost in the notes to the financial statements.

1.22 TRANSLATION OF FOREIGN CURRENCIES FOREIGN CURRENCY TRANSACTIONS

A foreign currency transaction is recorded, on initial recognition in Rands, by applying to the foreign currency amount the spot exchange rate between the functional currency and the foreign currency at the date of the transaction.

At each reporting date:

- foreign currency monetary items are translated using the closing rate;
- non-monetary items that are measured in terms of historical cost in a foreign currency are translated using the exchange rate at the date of the transaction; and
- non-monetary items that are measured at fair value in a foreign currency are translated using the exchange rates at the date when the fair value was determined.

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.

When a gain or loss on a non-monetary item is recognised directly in net assets, any exchange component of that gain or loss is recognised directly in net assets. When a gain or loss on a non-monetary item is recognised in surplus or deficit, any exchange component of that gain or loss is recognised in surplus or deficit.

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.

1.23 COMPARATIVE FIGURES

Prior period comparative information has been presented in the current year's financial statements. Where necessary figures included in the prior period financial statements have been restated to ensure fair presentation in the current year's financial statements.

2. NEW STANDARDS AND INTERPRETATIONS

2.1 STANDARDS AND INTERPRETATIONS EFFECTIVE AND ADOPTED IN THE CURRENT YEAR

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

STANDARD/ INTERPRETATION:	EFFECTIVE DATE: YEARS BEGINNING ON OR AFTER	EXPECTED IMPACT:
GRAP 1 (amended): Presentation of Financial Statements	01 April 2020	The impact of this is disclosed in note 25 Changes in accounting policy.
GRAP 108: Statutory Receivables	01 April 2019	The impact of this is disclosed in note 25 Changes in accounting policy.

2.2 STANDARDS AND INTERPRETATIONS NOT YET EFFECTIVE OR RELEVANT

The following standards and interpretations have been published and are mandatory for the entity's accounting periods beginning on or after 01 April 2021 or later periods but are not relevant to its operations:

STANDARD/ INTERPRETATION:	EFFECTIVE DATE: YEARS BEGINNING ON OR AFTER	EXPECTED IMPACT:
GRAP 104 (amended): Financial Instruments	01 April 2021	Unlikely there will be a material impact
Guideline: Guideline on the Application of Materiality to Financial Statements	01 April 2021	Unlikely there will be a material impact
IGRAP 20: Accounting for Adjustments to Revenue	01 April 2020	Unlikely there will be a material impact
Directive 7 (revised): The Application of Deemed Cost	01 April 2020	Unlikely there will be a material impact

3. RECEIVABLES FROM EXCHANGE TRANSACTIONS

	2021 R	2020 R
Trade debtors	8 022 443	1 979 979
Rental deposit	3 229 618	716 856
	11 252 061	**2 696 835**

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

Retention fees	6 894 638	-
Licence collection fees	81 070	641 770
Inspection fees	1 046 731	1 338 209
	8 022 439	**1 979 979**
Financial asset receivables included in receivables from exchange transactions above	**3 229 622**	**716 856**
Total receivables from exchange transactions	**11 252 061**	**2 696 835**

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 of 1965 as amended.

The increase in statutory receivables increased due to the review of retention fee register.

Rental deposit increased due to occupation of new office accommodation. The 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 Substance 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 2021 in line with SAHPRA's revenue policy.

3. RECEIVABLES FROM EXCHANGE TRANSACTIONS (CONTINUED)	2021 R	2020 R

BASIS USED TO ASSESS AND TEST WHETHER A STATUTORY RECEIVABLE IS IMPAIRED

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.

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

Provision for impairment	2 088 973	-
Amounts written off as uncollectable	706 955	-
	2 795 928	**-**

RECEIVABLES PAST DUE BUT NOT IMPAIRED RELATING SPECIFICALLY TO STATUTORY RECEIVABLES

Statutory receivables which are less than 1 years past due are not considered to be impaired at 31 March 2021, R6 894 638 (2020: R1 979 979) were past due but not impaired.

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

2 months past due	-	1 530 727
9 months past due	6 894 638	449 252
	6 894 638	**1 979 979**

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 and licenced site that have closed down and liquidated.

RECEIVABLES IMPAIRED

RELATING SPECIFICALLY TO STATUTORY RECEIVABLES

As of 31 March 2021, statutory receivables of R2 795 929 (2020: R-) were impaired and provided for.

The amount of the provision was R2 088 973 31 March 2021 (2020: R-).

3. RECEIVABLES FROM EXCHANGE TRANSACTIONS (CONTINUED)

	2021 R	2020 R
THE AGEING OF THESE RECEIVABLES IS AS FOLLOWS:		
3 to 6 months	695 095	-
Over 6 months	2 100 234	-
	2 795 329	**-**

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 proceeding; and
- Official transfers, cancellations and licenced site that have closed down and liquidated.

The rental deposit is due to paid over to SAHPRA in the 2021-22 financial year after confirmation with the lessor.

TRADE AND OTHER RECEIVABLES PAST DUE BUT NOT IMPAIRED

Trade and other receivables which are less than 12 months past due are not considered to be impaired. At 31 March 2021, R 716 856 (2020: R 716 856) were past due but not impaired.

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

9 months past due	716 856	716 856

TRADE AND OTHER RECEIVABLES PLEDGED AS SECURITY

None of the trade and other receivables for current and prior year were pledged as security for any obligation.

4. RECEIVABLES FROM NON-EXCHANGE TRANSACTIONS

Grant receivable (Centre for Disease Control and Prevention – NDOH)	34 674	14 634 131

The balance of the CDC grant relates to the amount not paid by NDOH on the submitted invoice.

5. CASH AND CASH EQUIVALENTS

Cash and cash equivalents consist of:		
Bank balances held at ABSA bank	150 764 296	121 957 555

CREDIT QUALITY OF CASH AT BANK

The credit quality of cash at bank held at ABSA Bank that is neither past due nor impaired can be assessed by reference to external credit rating of Ba2 (long term) was ascribed by the Moody's rating agency as at 31 March 2021. The enity'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

	2021			2020		
	COST / VALUATION R	ACCUMULATED DEPRECIATION AND ACCUMULATED IMPAIRMENT R	CARRYING VALUE R	COST / VALUATION R	ACCUMULATED DEPRECIATION AND ACCUMULATED IMPAIRMENT R	CARRYING VALUE R
Furniture and fixtures	9 461 220	(1 915 252)	7 545 968	3 234 484	(837 368)	2 397 116
Computer equipment	19 224 842	(4 551 884)	14 672 958	12 385 674	(1 781 870)	10 603 804
Leasehold improvements	6 659 775	(878 853)	5 780 922	-	-	-
Other fixed assets *	2 799 822	(974 967)	1 824 855	2 236 270	(565 725)	1 670 545
Total	**38 145 659**	**(8 320 956)**	**29 824 703**	**17 856 428**	**(3 184 963)**	**14 671 465**

RECONCILIATION OF PROPERTY, PLANT AND EQUIPMENT - 2021

	OPENING BALANCE R	ADDITIONS R	DISPOSALS R	TRANSFERS RECEIVED R	DEPRECIATION R	IMPAIRMENT R	TOTAL R
Furniture and fixtures	2 397 116	7 622 383	(947 615)	16 875	(918 173)	(624 618)	7 545 968
Computer equipment	10 603 804	6 707 221	(222 535)	751 047	(3 166 579)	-	14 672 958
Leasehold improvements	-	6 659 775	-	-	(878 853)	-	5 780 922
Other fixed assets	1 670 545	645 356	(58 013)	-	(433 033)	-	1 824 855
	14 671 465	**21 634 735**	**(1 228 163)**	**767 922**	**(5 396 638)**	**(624 618)**	**29 824 703**

RECONCILIATION OF PROPERTY, PLANT AND EQUIPMENT - 2020

Furniture and fixtures	2 869 369	82 227	(40 108)	60 363	(551 558)	(23 177)	2 397 116
Computer equipment	2 708 271	9 153 096	(25 971)	49 122	(1 266 794)	(13 920)	10 603 804
Other fixed assets	1 502 871	551 936	-	-	(374 626)	(9 636)	1 670 545
	7 080 511	**9 787 259**	**(66 079)**	**109 485**	**(2 192 978)**	**(46 733)**	**14 671 465**

PLEDGED AS SECURITY

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

* Other assets relates to other office related equipments

7. INTANGIBLE ASSETS

	2021			2020		
	COST / VALUATION R	ACCUMULATED AMORTISATION AND ACCUMULATED IMPAIRMENT R	CARRYING VALUE R	COST / VALUATION R	ACCUMULATED AMORTISATION AND ACCUMULATED IMPAIRMENT R	CARRYING VALUE R
Computer software	2 049 116	(176 205)	1 872 911	281 983	(14 603)	267 380

RECONCILIATION OF INTANGIBLE ASSETS - 2021

	ADDITIONS R	ADDITIONS R	AMORTISATION R	TOTAL R
Computer software	267 380	1 767 133	(161 602)	1 872 911

RECONCILIATION OF PROPERTY, PLANT AND EQUIPMENT - 2020

Computer software	-	281 983	(14 603)	267 380

8. PAYABLES FROM EXCHANGE TRANSACTIONS

	2021 R	2020 R
Trade payables	13 242 087	18 896 314
Refunds due	-	141 049
Salary accrual	1 551 332	2 018 995
Accrued expenditure	16 878 501	313 492
	31 671 920	**21 369 850**

Overall trade payables from exchange transactions increased due to amounts due to to the National Department of Health for expenditure incurred on behalf of SAHPRA. SAHPRA considers that the carrying value of trade and other payables approximates the fair value.

Salary accruals relates to acting, travel and inconveniences allowances.

Refunds due are those payments received by SAHPRA in error, duplicate or for services not required from SAHPRA

9. PROVISIONS

Leave provision	10 588 084	7 141 575
Performance management and development system provision	2 110 939	4 967 201
Provision for notch increase	1 489 373	-
	14 188 396	**12 108 776**

9. PROVISIONS

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.

PERFORMANCE MANAGEMENT AND DEVELOPMENT SYSTEM PROVISION (PMDS)

SAHPRA has adopted the DPSA incentive policy framework which provides that the departements may not utilise more than a specific percentage of their annual remuneration budget as per circular no. 01 of 2019. This therefore means that the 2019-20 PMDS provision needs to revised to cater to the SAHPRA budget as in the previous years the NDOH budget. A decision was made that the PMDS for 2019-20 financial year will be processed by SAHPRA.

The decrease in the PMDS provision estimate will be noted due to the signaficant difference in the remuneration budget between SAHPRA and NDOH as the payout will be processed by SAHPRA.

The maximum percentage for a budgeted provision for performance rewards as per circular 01 of 2019 is as follows:

Provision for 2019-20 PMDS: 0.75% of the remuneration budget
Provision for 2020-21 PMDS: 0.50% of the remuneration budget

NOTCH INCREASE PROVISION

The 2020-21 PMDS assessments will be moderated starting June 2021. The delay is attributed to the COVID-19 Pandemic and extended lock down periods. Performance contracts were finalised later than normal for the majority of employees and those who did not contract are excluded from the Performance Management Cycle. The PMDS rewards for the 2020/2021 and the resultant notch-increase will be effected as per the PMDS policy after the moderation process.

	CURRENT CYCLE PRO-RATA R	PREVIOUS CYCLE R	CAPPED LEAVE R	PMDS R	NOTCH INCREASE R	TOTAL R
As at 1 April 2020	3 086 240	3 117 512	937 822	4 967 201	-	12 108 775
Additions for the year	2 635 350	7 293 766	-	1 078 859	1 489 373	12 497 348
Reversal for the year	(3 086 240)	(3 117 512)	(278 853)	(3 935 122)	-	(10 417 727)
As at 31 March 2021	**2 635 350**	**7 293 766**	**658 969**	**2 110 938**	**1 489 373**	**14 188 396**

	CURRENT CYCLE PRO-RATA R	PREVIOUS CYCLE R	CAPPED LEAVE R	PMDS R	TOTAL R
As at 1 April 2019	2 325 164	3 055 841	882 512	3 200 000	9 463 517
Additions for the year	761 076	61 671	55 311	1 767 201	2 645 259
As at 31 March 2020	**3 086 240**	**3 117 512**	**937 823**	**4 967 201**	**12 108 776**

10. INCOME RECEIVED IN ADVANCE

	2021 R	2020 R
RECONCILIATION		
Unallocated deposits received	38 179 274	-
Revenue received in advance	69 044 617	40 546 636
	107 223 891	**40 546 636**
Backlog reduction project - deferred income	21 868 100	35 589 600

The deferred income relates to revenue received in advance for services to be rendered in future financials periods.

Unallocated deposits refer to the those payments received by SAHPRA in the ABSA bank account that is not matched to an application for service rendered by SAHPRA. No comparatives are shown as in the prior year as the balance could not be assessed at year end.

11. FEE INCOME

Section 21	5 356 420	3 163 110
Section 21 Veterinary	133 990	156 940
Section 21 CMS	23 170	7 080
Screening	1 148 000	450 720
Clinincal trials	3 636 730	1 334 725
Pharma Licence fee	1 910 150	1 546 680
Licence retention fees	6 140 000	12 953 293
Cannabis	494 140	296 480
Post screening	8 736 190	2 682 600
Permits	5 482 613	2 928 033
Veterinary	-	172 750
Amendments	5 451 359	965 760
Inspection fees	2 932 347	1 748 769
Retention fees	29 191 600	14 425 940
Certificates	472 000	184 760
Registration fee	758 920	223 040
Backlog reduction project	13 721 500	198 600
MD Licence fees	12 416 560	7 989 240
Biological medicine	3 727 900	2 750 000
	101 733 589	**54 178 520**
FEES RECEIVED PER FUNCTION		
Medicines evaluation, registration and product lifecycle	66 372 199	23 388 895
Inspections, permits and licences issued	29 847 810	27 462 495
The use of unregistered medicines	5 513 580	3 327 130
	101 733 589	**54 178 520**

12. SUNDRY INCOME

	2021 R	2020 R
Discount received	2 306 671	-
Proceeds from sale of assets	19 130	-
	2 325 801	**-**

Discount received relates to athe lessor contribution on the leasehold improvements and furniture provided by the lessor as per the contract.

13. INTEREST RECEIVED

INTEREST REVENUE

Interest received	4 006 563	8 094 788

Included in interest received is total interest income earned from cash held at ABSA bank based on the average interest rate of 2.00% (2020: 4.91%) per annum and accrued interest on the rental deposit held by the lessor in a interest bearing call account at an average rate of 3.00% (2020: 0%) per annum.

14. TRANSFER PAYMENT

OPERATING GRANTS

Transfer payment from the NDOH	156 572 000	183 274 000

15. BACKLOG REDUCTION PROJECT - GRANT RECEIVED

Clinton Health Access Initiative (CHAI) grant	-	1 441 170
Center for Disease Control and Prevention (CDC) grant	2 104 925	14 634 131
	2 104 925	**16 075 301**

The CDC grant is a conditional grant facilitated through the National Department of Health. The agreement between SAHPRA and the CDC states that the grant will be received in advance, however the nature of the transactions resulted in the grant being received upon an invoice being issued. The CDC grant receivable is disclosed in note 4.

16. EMPLOYEE RELATED COSTS

Basic and non-pensionable salaries	113 984 081	100 773 102
Thirteenth cheque and performance bonus	4 550 898	7 745 876
Medical aid	3 563 753	3 405 285
UIF	132 832	38 592
SDL	283 012	384 204
Bargaining council	14 919	15 233
Pension fund	9 829 263	9 902 056
PAYE	8 359 202	4 921 339
Travel allowances	-	514 338
Housing benefits and allowances	2 646 222	2 391 479
Leave accrued	3 484 164	1 153 338
Cellphone allowances	144 048	-
Standby allowances	97 491	353 691
	147 089 885	**131 598 533**

17. BACKLOG REDUCTION PROJECT

	2021 R	2020 R
Backlog clearance project	3 812	-
Bank charges	65 743	-
Backlog foreign evaluators	11 764 046	-
Local evaluators	10 472 568	4 139 751
Catering	-	38 350
Share of communication	1 044 920	-
Conference	-	45 330
Extedo System	2 177 546	1 008 955
Newsletters	-	1 449
Overtime	2 489 022	-
PAYE	3 811 367	2 499 978
Portal Variations	83 029	394 673
Printing and stationery	-	1 306
Recruitment	-	1 604 701
Relocation cost	-	65 765
Share of rental	745 796	-
SDL	80 213	99 273
Salaries	11 757 520	7 349 676
Sundry HR	1 749 152	92 232
Travel	-	3 510
UIF	114 273	64 134
	46 359 007	**17 409 083**

Refer to note 29 for more information on the donor funding received to support this project.

18. DEPRECIATION

Property, plant and equipment	5 396 639	2 188 930
Intangible assets	161 602	14 603
	5 558 241	**2 203 533**

19. CONTRACTED SERVICE

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

OUTSOURCED SERVICE

NCL Laboratory	19 922 033	19 992 200

20. OPERATING EXPENSES	2021 R	2020 R
Administrative cost	114 052	57 002
Advertising	191 394	595 501
Minor assets	95 895	36 310
Auditors remuneration	4 925 961	6 261 301
Bank charges	66 009	114 770
Board Costs	1 645 841	865 855
Bursaries	10 140	5 158
Catering	21 498	247 744
Cleaning	534 593	31 589
Communication	5 189 433	1 167 994
Computer expenses	3 403 153	2 002 370
Conferences and seminars	34 160	202 059
Consulting and professional fees[1]	9 098 050	12 099 643
Expert committees	13 515 251	7 327 719
General expenses	42 741	64 146
Legal fees	2 091 262	567 036
Levies	553 918	-
Licences	1 888 853	2 160 189
Medical expenses	-	168 709
Membership fees	292 958	301 405
Motor vehicle expenses	2 535 672	3 478 299
Parking	35 534	60 508
Postage and courier	118 220	377 833
Printing and publication	206 115	504 699
Printing and stationery	1 009 452	1 503 365
Protective clothing	106 168	-
Refreshments	21 489	36 266
Relocation of SAHPRA	2 410 879	519 830
Repairs and maintenance	32 958	31 922
Research and development costs	256 210	45 281
Security	57 931	-
Staff training	729 124	218 517
Travel - local and overseas	1 819 636	10 964 361
Travel local and overseas- SAHPRA Board	-	53 463
Utilities	288 814	-
Venues and facilities	16 243	426 994
	53 359 607	**52 497 838**

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

21. CASH GENERATED FROM OPERATIONS

	2021 R	2020 R
(Deficit) surplus	(24 757 955)	31 205 291
Adjustments for:		
Depreciation and amortisation	5 558 241	2 203 533
Loss on disposal of assets and liabilities	1 228 163	66 637
Loss on foreign exchange	-	59 360
Impairment deficit	624 618	46 733
Movements in operating lease liabilities	1 600 515	-
Movements in provisions	2 079 620	2 645 260
Assets transferred from NDOH	(767 922)	-
Proceeds from disposal of assets	(19 130)	-
Discount received	(2 306 671)	-
Changes in working capital:		
Receivables from exchange transactions	(8 555 226)	670 466
Other receivables from non-exchange transactions	14 599 457	(14 634 131)
Prepayments	(2 658 727)	(181 653)
Payables from exchange transactions	10 302 070	(11 666 345)
Conditional grants	-	(1 441 170)
Fee and deferred income	52 955 755	19 395 880
	49 882 808	**28 369 861**

22. COMMITMENTS

AUTHORISED EXPENDITURE

Already contracted for but not provided for		
• National Control Laboratory contract	3 318 000	3 028 548
• Single supplier of eCTD software	-	1 448 712
• Supply of IT equipment and related IT expenditure	4 305 223	4 163 161
• Parking services	116 597	-
• Open purchase orders	5 929 468	2 725 698
• Supply of communication services	855 347	-
• Office accomodation	88 263 391	85 758 720
	102 788 026	**97 124 839**

TOTAL COMMITMENTS

Already contracted for but not provided for	102 788 026	97 124 839

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

22. COMMITMENTS (CONTINUED)	2021 R	2020 R
OPERATING LEASES - LESSEE (EXPENSE)		
Minimum lease payments due		
- within one year	15 493 062	9 833 981
- in second to fifth year inclusive	60 431 677	70 574 003
- later than five years	-	6 783 536
	75 924 739	**87 191 520**

Operating lease payments represent rental payable by SAHPRA for leased office space. No contingent rent is payable.

23. RISK MANAGEMENT

FINANCIAL RISK MANAGEMENT

SAHPRA manages its net assets to ensure that it will be able to continue as a going concern, while meeting its overall objectives. Funding is obtained primarily from grants and generation of fee income from a variety of services charged. The strategy is consistent with that applied in prior years.

The entity's activities expose it to a variety of financial risks: market risk, credit risk and liquidity risk.

This note presents information about SAHPRA's exposure to each of the above risks. Further quantitative disclosures are included throughout these financial statements. The Board has the overall responsibility for the establishment and oversight of SAHPRA's risk management framework. The Board has established the Audit and Risk Committee which is responsible for the oversight on the development and monitoring SAHPRA's risk management policies.

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 Audit and Risk Committee.

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.

23. RISK MANAGEMENT (CONTINUED)

LIQUIDITY RISK

Liquidity risk is the risk that SAHPRA will encounter difficulty in meeting obligations associated with financial liabilities that are settled by delivering cash or another financial asset. Liquidity risk is considered medium as the current assets does not exceeded current liabilities at 31 March 2021. The total current assets reported in the statement of Financial Position has already taken account of the provision for credit losses. Furthermore, all the open order commitments of SAHPRA at 31 March 2021 were fully funded. Management monitors rolling forecast of the SAHPRA's cash and cash equivalents on the basis of the expected cash flows.

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 R	LATER THAN ONE MONTH AND NO LATER THAN THREE MONTHS R	LATER THAN THREE MONTHS AND NO LATER THAN ONE YEAR R	LATER THAN ONE YEAR AND NO LATER THAN FIVE YEARS R	TOTAL R
Trade payables	-	13 242 087	-	-	13 242 087
Revenue received in advance	-	-	-	129 034 264	129 034 264
Provisions	-	-	14 188 396	-	14 188 396
Operating lease payable	-	-	-	1 600 515	1 600 515
Accrued expenditure	-	18 429 833	-	-	18 429 833
	-	**31 671 920**	**14 188 396**	**130 634 779**	**176 495 095**

CONCENTRATION OF RISK	NEITHER PAST DUE NOR IMPAIRED R	PAST DUE BUT NOT IMPAIRED LESS THAN TWO MONTHS R	PAST DUE BUT NOT IMPAIRED MORE THAN TWO MONTHS R	CARRYING AMOUNT R
Cash and cash equivalents	150 764 296	-	-	150 764 296
Receivables from exchange and non-exchange transactions	-	-	11 286 735	11 286 735
	150 764 296	**-**	**11 286 735**	**162 051 031**

CREDIT RISK

The entity's services are paid for in advance with exception of revenue from inspections. Revenue from inspection is done on request by the customer and is a regulatory requirement. Receivables balances are monitored on an ongoing basis with the result that the entity's exposure to bad debts is not significant. The maximum exposure is the carrying amounts as disclosed. There is no significant concentration of credit risk within the entity. With respect to credit risk arising from the other financial assets of the entity, which comprise cash and cash equivalents, the entity's exposure to credit risk arises from default of the counterparty, with a maximum exposure equal to the carrying amount of these instruments. The entity cash and cash equivalents are placed with high credit quality financial institutions therefore the credit risk with respect to cash and cash equivalents is low. Trade and other receivables are not rated.

23. RISK MANAGEMENT (CONTINUED)

FINANCIAL ASSETS

SAHPRA's principle financial assets are accounts receivables and cash and cash equivalents. At 31 March 2021, the carrying amount of financial assets are at amortised costs approximate their fair values, due to the short term maturities of these financial assets.

Management has assessed the impact of COVID-19 on outstanding balances and no further risks were identified. The available cash balances at year-end to meet future obligations were assessed and no material risks has been identified.

Financial assets at fair value are stated below:	2021 R	2020 R
Cash and cash equivalents	150 764 296	121 957 555
Receivables from exchange and non-exchange transactions	11 286 735	17 330 966

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, the entity's income and operating cash flows are substantially independent of changes in market interest rates.

CASH AND CASH EQUIVALENTS

SAHPRA only deposits cash with major banks with high quality credit standing. SAHPRA, therefore, does not consider to be any significant exposure to credit risk.

SAHPRA utilises ABSA bank for daily transactions which has a Ba2 rating.

24. 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.

The potential adverse impact of COVID-19 has been considered by the entity and is considered to have an insignificant impact on the ability to continue as a going concern.

25. CHANGES IN ACCOUNTING POLICY

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

The change in accounting policy is made in accordance with transitional provisions prescribed in Directive 2.

This change in accounting policy relates to the initial adoption of GRAP 108 Statutory receivables. SAHPRA's applies this Standard as its receivables from retention fees, inspections and licence issuing fees meet the recognition criteria for statutory receivables. All changes from the application of the Standard of GRAP on Statutory receivables shall be accounted for retrospectively in accordance with the requirements of GRAP 3. The transitional provisions for GRAP 108 requires that when an entity initially adopts a Standard of GRAP, GRAP 3 requires an enity to apply the requirements of the Standard being adopted restrospectively. The implication of adopting the Standard relate to additional disclosures relating to Statutory receivables and the implication did not result in the adjustment of financial figures.

26. RELATED PARTIES

RELATIONSHIPS	NATURE OF RELATED PARTY
Executive Authority	Dr Zweli Mkhize
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
Council for Scientific and Industrial Research	Public entity in National sphere
Provincial Department of Health – Gauteng	Provincial Department
Provincial Department of Health – Northern Cape	Provincial Department

RELATED PARTY BALANCES	2021 R	2020 R
NATIONAL DEPARTMENT OF HEALTH		
Creditors balance - owing to NDOH	(14 105 167)	(10 868 849)
Debtors balance - owing to SAHPRA	34 674	14 634 131
RELATED PARTY TRANSACTIONS		
NATIONAL DEPARTMENT OF HEALTH		
Government grant received	156 572 000	183 274 000
PROVINCIAL DEPART OF HEALTH - GAUTENG		
Inspection of depots	-	6 050
PROVINCIAL DEPART OF HEALTH - NORTHERN CAPE		
Inspection of depots	-	6 050
COUNCIL OF SCIENTIC AND INDUSTRIAL RESEARCH		
Rental expenditure	2 493 996	6 776 577

26. RELATED PARTIES (CONTINUED)

REMUNERATION OF EXECUTIVE AUTHORITY AND MANAGEMENT

BOARD FEES – 2021	BOARD FEES R	TOTAL R
Prof. H.V. Rees - Chairperson	193 024	193 024
Ms M. Hela - Deputy Chairperson	136 357	136 357
Prof. M.S. Banoo - Member[1]	-	-
Dr E.N. Madela-Mntla - Member	102 547	102 547
Dr T.M. Motshudi - Member	86 595	86 595
Prof. A. Dhai - Member	133 569	133 569
Prof. M.J. Mphahlele - Member[2]	-	-
Dr U. Mehta - Member	61 965	61 965
Adv. H. Cassim - Member	160 527	160 527
Dr M.S.M. Molefe - Member[2]	-	-
Mr T.N. Baloyi - Member	166 387	166 387
Prof. K.C. Household - Member	184 269	184 269
Prof. H. P. Demana - Member	60 818	60 818
Mr I. Mashau - Member	72 811	72 811
Ms L. Mothae - Member	245 149	245 149
	1 604 018	**1 604 018**

[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.

EXECUTIVE MANAGEMENT – 2021	BASIC SALARY R	POST-EMPLOYMENT BENEFITS R	OTHER BENEFITS RECEIVED R	TOTAL R
Dr B Semete-Makokotlela - Chief Executive Officer	2 850 000	-	44 945	2 894 945
P Nkambule - Chief Regulatory Officer	1 521 591	103 654	44 844	1 670 089
M.K. Kgauwe - Chief Financial Officer (former)[1]	1 205 620	-	22 539	1 228 160
C. Reynecke - Chief Operating Officer[2]	478 210	-	10 379	488 589
R.B. Gouws - Chief Financial Officer[3]	300 000	-	6 731	306 731
G. Mtakati - HR Executive[4]	654 173	-	12 585	666 758
	7 009 594	**103 654**	**142 023**	**7 255 272**

[1] Resigned - November 2020

[2] Appointed - January 2021

[3] Appointed - February 2021

[4] Apointed - October 2020

26. RELATED PARTIES (CONTINUED)

BOARD FEES – 2020[1]	BOARD FEES R	TRAVEL R	SALARY R	TOTAL R
Prof. H.V. Rees - Chairperson	33 625	-	-	33 625
Ms M. Hela - Deputy Chairperson[2]	86 075	10 870	589 186	686 131
Prof. M.S. Banoo - Member	25 064	2 243	-	27 307
Dr E.N. Madela-Mntla - Member	124 050	4 563	-	128 613
Dr T.M. Motshudi - Member	29 015	1 708	-	30 723
Prof. A. Dhai - Member	35 319	-	-	35 319
Prof. M.J. Mphahlele - Member[3]	-	-	-	-
Dr U. Mehta - Member	55 506	-	-	55 506
Dr M.S.M. Molefe - Member[3]	-	-	-	-
Adv. H. Cassim - Member	109 810	2 035	-	111 845
Ms L.J. Fosu - Member[4]	24 465	-	-	24 465
Mr T.N. Baloyi - Member	58 396	23 076	-	81 472
Prof. K.C. Household - Member	57 605	-	-	57 605
Prof. H.P. Demana - Member	32 707	794	-	33 501
Mr I. Mashau - Member	29 352	1 131	-	30 483
Ms L. Mothae - Member[5]	-	-	-	-
	700 989	**46 420**	**589 186**	**1 336 595**

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

[2] Ms Hela was seconded from the Board to support the Acting CEO to execute her duties from 1 February 2019

[3] Prof J Mphahlele and Dr MSM Molefe are employees in the public sector – no fees claimed

[4] Resigned August 2019

[5] Appointed 24 April 2020

EXECUTIVE MANAGEMENT – 2020	FEES FOR SERVICES AS A MEMBER OF MANAGEMENT R	POST-EMPLOYMENT BENEFITS R	OTHER BENEFITS RECEIVED R	TOTAL R
P. Nkambule - Acting Chief Executive Officer[1]	1 661 299	103 654	25 997	1 790 950
M.K. Kgauwe - Chief Financial Officer	1 819 674	-	-	1 819 674
Dr B. Semete-Makokotlela - Chief Executive Officer[2]	694 227	-	-	694 227
	4 175 200	**103 654**	**25 997**	**4 304 851**

[1] Appointed CRO - September 2019. Acting CEO to December 2019

[2] Appointed January 2020

27. AUDIT COMMITTEE MEMBERS REMUNERATION

INDEPENDENT AUDIT COMMITTEE MEMBERS - FEES FOR ATTENDING MEETINGS

E.O. Omolo[1]	35 113	-
M.A.E Amod[2]	3 572	-
	38 685	**-**

[1] Appointed 2 May 2020

[2] Appointed 2 May 2020, Resigned July 2020

28. CONTINGENT LIABILITIES

CLAIM AGAINST SAHPRA FOR SERVICES RENDERED

On the 13th of May a letter of demand for services rendered were received from a recruitment consultant claiming full services were rendered as per a contractual 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 letter of demand and intention to seek relief gives rise to a possible obligation, yet to be confirmed whether there is a present obligation that could lead to the payment of services in dispute.

Although SAHPRA still requires evidence and dispute that the services were rendered the possibility of a settlement is not remote. The maximum potential liability amounts to R1.3 million.

29. DONOR FUNDING

29.1 BILL AND MELINDA GATES FOUNDATION

During the year under review, 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 international evaluators to support backlog clearance programme
- Development of guidelines and procedures.

The maximum benefit for the period under review amounts to R19,9 million (2020: R45,4 million). Refer to note 17 for more information regarding the Backlog reduction project costs.

29.2 CENTERS FOR DISEASE CONTROL AND PREVENTION - (CENTERS FOR DISEASE CONTROL AND PREVENTION - NDOH)

During the year under review, SAHPRA received a grant from the NDoH-Centers for Disease Control and Prevention partnership (CDC). NDoH-CDC Cooperative Agreement will provide R27 million towards SAHPRA's Backlog Clearance Program for the specific purpose of clearing applications related to HIV and TB drugs including DTG and TLD as first priorities.

The benefit for the period under review amounts to R2,1 million (2020: R14,6 million).

30. TRANSFER OF FUNCTIONS BETWEEN ENTITIES UNDER COMMON CONTROL

NATURE OF TRANSFER

Entities involved in the transfer of functions were the NDoH (transferor) and SAHPRA (acquirer). The functions relating to the regulation of health products intended for human and animal use; the licensing of manufacturers, wholesalers and distributors of medicines, medical devices, radiation emitting devices and radioactive nucleides; and the conduct of clinical trials were transferred to SAHPRA. The transfer was in terms of the transitional provisions of the Medicines and Related Substances Act, (Act 14 of 2015), as amended. The transfer became effective following the 1st meeting of the SAHPRA Board on 1 February 2018.

VALUE OF THE ASSETS ACQUIRED AND LIABILITIES ASSUMED

ASSETS ACQUIRED	2021 R	2020 R
Property, plant and equipment	767 922	109 485

31. IRREGULAR EXPENDITURE

Opening balance	5 038 900	1 206 785
	5 038 900	**1 206 785**
Add: Irregular Expenditure - current year	6 268 808	3 876 396
Less: amount incorrectly classified as irregular expenditure	(6 335)	(44 281)
Less: amount condoned	(931 493)	-
Closing balance	**10 369 880**	**5 038 900**

The irregular expenditure relates to non-compliance with Supply Chain Management regulations.

Determinations were conducted for all previously reported irregular expenditure. Current year irregular expenditure are still under investigation.

Seven transgressions relating to the opening balances amounting to R931,493 were condoned by the National Treasury in May 2021.

The balance will be addressed in line with the Irregular Expenditure Framework issued by National Treasury.

32. FRUITLESS AND WASTEFUL EXPENDITURE

Add: Expenditure identified - current	47 232	-

Current year fruitless expenditure relates to interest charged on late payment to SARS. The transgression is currently under investigation.

33. BUDGET DIFFERENCES

Material differences between budget and actual amounts

33.1 FEE AND SUNDRY INCOME

Fee income is below budget due to fewer applications received than anticipated.

Sundry income is more than budget due to the discount received and proceeds, previously not budgeted for.

33.2 INTEREST RECEIVED

Interest received is lower than the budget due to the decrease in the repo rate and reduction in average cash balances during the year.

33.3 EMPLOYEE RELATED COSTS

Employee related costs are lower than the budget due to budget contrainst measures implemented.

33.4 DEPRECIATION

Depreciation is not budgeted for as SAHPRA utilises a cash basis for budgeting.

33.5 CONTRACTED SERVICES

Difference is immaterial.

33. BUDGET DIFFERENCES (CONTINUED)

33.6 OPERATING EXPENSES

Operating expenses are lower than budget due to under collection of planned revenue and as a result cost containment measures were implemented.

33.7 BACKLOG REDUCTION PROJECT

Expenditure is more than budget due to applications not finalised as anticipated.

33.8 LEASE RENTALS ON OPERATING LEASE

Expenditure is lower than budget due to delay in relocation of offices.

34. RECONCILIATION BETWEEN BUDGET AND STATEMENT OF FINANCIAL PERFORMANCE

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

	2021 R	2020 R
Net (deficit) surplus per the statement of financial performance	(24 757 955)	31 205 291
Adjusted for:		
(Under) / over expenditure on backlog reduction project	20 359 007	(32 590 918)
Over expenditure on impairment of assets	624 618	46 733
Increase / decrease in backlog reduction project - grant received	23 735 075	(16 075 301)
Decrease in fee income	95 037 426	67 821 480
(Increase) / decrease in interest received	1 993 437	(5 094 788)
Under expenditure on employee related costs	(68 681 994)	(6 012 020)
Over expenditure on operating lease	(9 616 144)	(12 639 596)
Under expenditure on operating expenses	(47 540 829)	(30 982 609)
Over expenditure on depreciation	5 558 241	2 203 533
Over expenditure on contracted services	(49 967)	1 992 200
Over expenditure on loss of disposal of assets	1 228 163	125 995
Over expenditure on bad debts	2 795 929	-
Increase in transfer of assets	(767 922)	-
Increase in gain on foreign exchange	(171 284)	-
Increase in sundry income	(2 325 801)	-
Decrease in grant received	2 580 000	-
	-	-

NOTES

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