SAHPRA
South African
Health Products
Regulatory Authority

2023/24

ANNUAL

PERFORMANCE PLAN

March 2023

SOUTH AFRICAN HEALTH PRODUCTS REGULATORY AUTHORITY'S (SAHPRA'S) GENERAL INFORMATION

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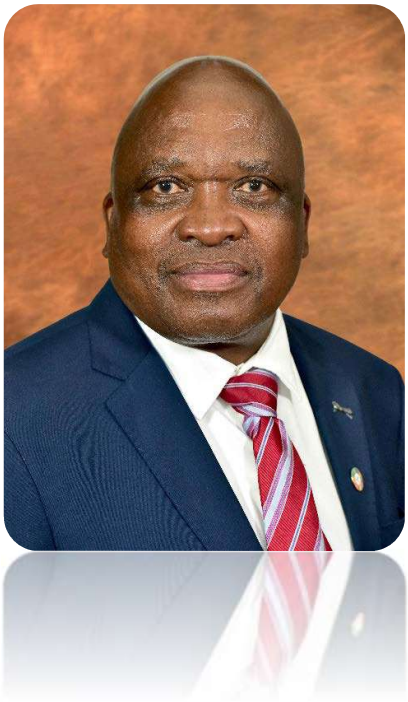
EXECUTIVE AUTHORITY STATEMENT



The Authority has focused on key areas to better its performance, bearing in mind safety, efficacy, and quality consonant with its mandate to deliver to the South African population at large. With the Authority's diverse mandate, socio-economic rights are critical for the country, as this constitutional and legal mandate is an ongoing focus area in keeping with the available resources doctrine. SAHPRA continues to work with its Board to meet the mandate requisites.

Having witnessed SAHPRA address the COVID-19 pandemic arduously, it is noteworthy that other critical focus areas now have the requisite dedicated time, energy, and resources. Indeed, it is good news to note that the combined work initiative of the Authority's Executive and its Board yielded an unqualified audit report in its four-year infancy. Also noteworthy is the Authority's ability to navigate the extreme demands, while also striving to balance its attention, which has been successfully demonstrated in the Auditor-General's findings.

Addressing good governance involves examining fundamental norms, as well as remaining cognisant of emerging needs. As such, the Authority's process of speaking to policies and guidelines across the spectrum seeks to meet the new demands that are essentially dynamic in nature.

While navigating this terrain, I recognise SAHPRA's diligence and commitment to clearing the backlog that came with the Medicines Control Council transition to SAHPRA. This position will now create room for the Authority to focus on its usual business. Recognising that this transition will take time, I am equally pleased to recognise the Authority's grading by the World Health Organization (WHO) at Maturity Level 3 on a scale of 1 to 4.

I also note SAHPRA's work in meeting its constitutional mandate to address cannabis regulation, for example. This area has been long coming, as evident the world over. In my opinion, the Authority will align cannabis regulation with the legal prescripts that haven been given to our nation, but simultaneously balance this with the needs of our society.

Undeniably, the Authority has been incredibly busy in discharging its mandate.

In supporting the Authority, I wish them well in executing their Annual Performance Plan.

DR MJ PHAAHLA, MP
MINISTER OF HEALTH

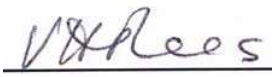
CHAIRPERSON OF THE BOARD STATEMENT

In the past year, the SAHPRA Board has worked in support of the SAHPRA Executive to implement best practice tools essential for good governance. This has included SAHPRA policies and guidelines, revised terms of reference (TORS) for the Board and its committees, revised standing operation procedures and new guidelines. The work of the Chief Financial Officer (CFO) and his team, supported by the Finance and Risk and Audit Committees of the Board, resulted in an unqualified audit report for the first time in SAHPRA's four-year history. The Board has spent considerable time with the executive to ensure that SAHPRA adheres to all good governance principles, including the attention now being given to social and ethical considerations.

The priorities that have received particular attention in the past year include the clearance of the considerable backlog inherited from the old Medicines Control Council, and aligned with this, a focus on re-engineering the processes required for the registration of health products. With the backlog now cleared, attention is being turned to the application of new evaluation processes by the "Business as Usual" (BAU) group. The new processes being introduced have shortened the time required for reviewing applications. The high standards being developed by SAHPRA have allowed the regulator to be recognised by the WHO as a Maturity Level 3 regulatory authority, with the highest recognition being Level 4, which SAHPRA also received for its quality evaluation of vaccines. A particular approach that is receiving significant global attention is that of reliance. This refers to the sharing of information between national regulatory authorities (NRAs) as they evaluate the same product. Information exchange has been further strengthened in the African region by the establishment of regional regulatory structures that jointly work together to evaluate new health products. In the future, the work of these platforms will be consolidated under the umbrella of the newly founded African Medicines Agency, and SAHPRA is heavily involved in all these initiatives.

While great strides have been made in governance and ways of doing business, there are many priorities ahead that will require renewed efforts by SAHPRA. These include the review of the framework for cannabis regulation, as part of the broader presidential initiative, a new approach to the regulation of medical devices and radiation control, and renewed efforts to strengthen the regulation of complementary medicines.

The staff and leadership of SAHPRA's executive and senior management team, with the support of a very committed Board, are both essential if we are to ensure that health products available in South Africa are safe, of good quality, efficacious, and contribute to the public health good.



PROFESSOR HELEN REES
CHAIRPERSON OF THE BOARD
SOUTH AFRICAN HEALTH PRODUCTS REGULATORY AUTHORITY

CHIEF EXECUTIVE OFFICER STATEMENT

As we move gradually to a state of near normality, we cannot help but reflect on the major strides made by SAHPRA in contributing to curbing COVID-19. SAHPRA Management, staff members, the SAHPRA Board, and all its associates and stakeholders must be acknowledged for playing their respective parts in this valiant conquest. However, as we move away from our cloistered interactions behind masks and shields, we need to remain cautious and observe the requisite health protocols. This pandemic may be under control, but it has not vanished yet.

Human contact and interactions are gradually becoming the norm, and we are now steering away from a virtual presence to a more personalised one. SAHPRA has also received accolades and recognition for its contribution as a health products regulator of note. SAHPRA received a Management Award at the National Science and Technology Forum (NSTF) Awards in July 2022, recognising outstanding contributions to science, engineering and technology (SET), and innovation.

SAHPRA was ranked at a functional level of Maturity (Level 3) according to the WHO's global classification system for national medical products regulatory authorities. This means that SAHPRA has a stable, well-functioning, and integrated regulatory system to ensure the quality, safety, and efficacy of vaccines registered by SAHPRA. The highest level is Maturity Level 4.

SAHPRA received an accolade from the National Press Club (NPC) on 3 December 2022 at a gala dinner event. During COVID-19, the NPC survived thanks to the support of a very special group of partners, SAHPRA being one of them.

SAHPRA had to forge and strengthen several partnerships and leverage the expertise of scientific experts to create systems and initiatives of world-class standards, while remaining locally relevant. SAHPRA was able to take two notable gigantic steps in creating such systems.

SAHPRA launched an online medicines directory for South African consumers and healthcare professionals. The online medicines directory will include, as phase one, all over-the-counter (OTC) Schedule 0, 1 and 2 registered SAHPRA-approved medicines. These medicines are all available for purchase from a pharmacy without a doctor's prescription.

Furthermore, SAHPRA launched an online medicines register. This will ensure that SAHPRA has a repository of all registered health products in real-time. Such initiatives are aimed at public safety and making the public active role players in ensuring that they are updated about health products so that they can make more informed decisions about their health. Public awareness and safety are important hallmarks for SAHPRA as it evolves exponentially.

As South Africa grapples with illicit products entering the market and dubious providers, the Inspectorate and Regulatory Compliance Unit has been working tirelessly with law enforcement agencies to curb such unethical practices. SAHPRA publishes regular alerts and updates to warn the public about such products and practices. The regulator also engages the public via the media in print, broadcast and online formats.

SAHPRA continues to monitor adverse reactions to vaccines and other health products. The organisation strives to encourage the public to use the Med Safety App. The Med Safety App works synergistically with the microsite that focuses on reporting adverse events following immunisation (AEFIs) as well as adverse events of special interest (AESIs) following vaccination.

SAHPRA partners with entities such as the Program for Appropriate Technology in Health (PATH), the NPC, the Government Communication and Information System (GCIS), *Daily Maverick*, Bhekisisa, the Solidarity Fund, and other such entities to package information for its various audiences in the form of webinars, media statements, infographics, videos, and podcasts as well as radio interviews. The SAHPRA website and its social media platforms are updated regularly to ensure regular feedback to the public and relevant stakeholders.

In raising awareness about SAHPRA as a brand and regulatory entity, we also partner with tertiary institutions to educate students within pharmacy faculties about our regulatory role in the country as well as the possibility of future work opportunities. Human Resources (HR), along with the Communications unit, have so far visited Nelson Mandela University, the University of KwaZulu-Natal as well as Wits University.

SAHPRA understands how critical it is to develop partnerships so that there is knowledge exchange to grow and develop continually as a responsive and agile regulator. We have had the opportunity to host many international organisations for knowledge sharing and creating relationships through robust engagements. We met with Germany's Federal Institute of Drugs and Medical Devices and discussed future collaboration in capacity building. There were also engagements with the French Embassy and French Trade Commission, Germany's BloodTrain programme, and the South African National Accreditation System.

As SAHPRA focuses on the three pillars of quality, safety and efficacy (QSE), we shall need to evolve constantly to ensure that we are an enabler and not a barrier in the health sector. The SAHPRA staff continuously play a critical role in ensuring the delivery of the objectives and mandate of the organisation. Furthermore, the newly appointed Board will support the organisation in ensuring the implementation of its strategic priorities, while maintaining strong governance standards.

SAHPRA is on the right trajectory as an agile, conscientious, socio-economically transformative, and globally positioned African health products regulator creating a sustainable, positive impact for the long and healthy lives of South Africans.

I am immensely pleased to present the Annual Performance Plan.

DR BOITUMELO SEMETE-MAKOKOTLELA
CHIEF EXECUTIVE OFFICER
SOUTH AFRICAN HEALTH PRODUCTS REGULATORY AUTHORITY

OFFICIAL SIGN-OFF

It is hereby certified that this Annual Performance Plan:

- was developed by the management of SAHPRA under the guidance of the Board;
- takes into account all the relevant policies, legislation, and other mandates for which SAHPRA is responsible; and
- accurately reflects the impact and outcomes which SAHPRA will endeavour to achieve during the 2023/24 financial year.

MS LETJUBANA CHOKOE
COMPANY SECRETARY (ACTING)

MR KUDA KAPFUMVUTI
SENIOR MANAGER: HEALTH PRODUCTS AUTHORISATION

MR DEON POOVAN
SENIOR MANAGER: INSPECTORATE AND REGULATORY COMPLIANCE

MS SILVERANI PADAYACHEE
SENIOR MANAGER: PHARMACEUTICAL EVALUATION MANAGEMENT

MR TOHLANG SEHLOHO
SENIOR MANAGER: CLINICAL EVALUATION MANAGEMENT

DR DIMAKATSO MATHIBE
SENIOR MANAGER: MEDICAL DEVICES AND RADIATION CONTROL

MS PORTIA NKAMBULE
CHIEF REGULATORY OFFICER

MR REGARDT GOUWS
CHIEF FINANCIAL OFFICER

MR GORDON MTAKATI
EXECUTIVE MANAGER: HUMAN RESOURCES

MS CHRISTELNA REYNECKE
CHIEF OPERATIONS OFFICER
HEAD OF PLANNING

DR BOITUMELO SEMETE-MAKOKOTLELA
CHIEF EXECUTIVE OFFICER
ACCOUNTING OFFICER

PROF. HELEN REES
CHAIRPERSON OF THE BOARD

APPROVED BY:

DR MJ PHAAHLA, MP
MINISTER OF HEALTH

LIST OF ABBREVIATIONS AND ACRONYMS

ADR	Adverse Drug Reaction
AEFI	Adverse Event Following Immunisation
AESI	Adverse Events of Special Interest
AMRH	African Medicines Regulatory Harmonisation Forum
API	Active Pharmaceutical Ingredient
AU-3S	African Union Smart Safety Surveillance
AVAREF	African Vaccine Regulatory Forum
Business As Usual	BAU
COVAX	COVID-19 Vaccines Global Access
COVID-19	Coronavirus disease
CRM	Customer Relationship Management
CSR	Corporate Social Responsibility
DALRRD	Department of Agriculture and Rural Development
DHCPL	Direct Healthcare Professional Communication
DMF	Drug Master File
EDQM	European Directorate for Quality of Medicines and Health Care
EPI	Expanded Programme on Immunisation
HR	Human Resources
GCIS	Government Communication and Information System
GCP	Good Clinical Practice
GDP	Good Distribution Practice
GLP	Good Laboratory Practice
GMP	Good Manufacturing Practice
GVP	Good Vigilance Practice
GWP	Good Warehouse Practice
GxP	Good Practices
ICH	International Cooperation on Harmonisation
ICMRA	International Collation of Medicines Regulation Authorities
ICT	Information and Communications Technology

IMDRF	International Medical Device Regulators Forum
IPRP	International Pharmaceutical Regulators Programme
ISO	International Organization for Standardization
IT	Information Technology
ITAC	International Trade Administration Commission
IVD	*In Vitro* Diagnostic
MoU	Memorandum of Understanding
MTSF	Medium-Term Strategic Framework
NCE	New Chemical Entity
NCL	National Control Laboratory
NDoH	National Department of Health
NDP	National Development Plan
NHA	National Health Act
NNR	National Nuclear Regulator
NPC	National Press Club
NRA	National Regulatory Authority
PATH	Program for Appropriate Technology in Health
PFMA	Public Finance Management Act
PIC/S	Pharmaceutical Inspection Co-operation Scheme
QSE	Quality, Safety and Efficacy
SAAS	South African Auditing Standard
SADC	Southern African Development Community
SAHPRA	South African Health Products Regulatory Authority
SAPC	South African Pharmacy Council
SCA	Supreme Court of Appeal
SDG	Sustainable Development Goal
SLA	Service-Level Agreement
SOP	Standard Operating Procedure
SWOT	Strengths, Weaknesses, Opportunities and Threats
TORS	Terms of Reference
VMP	Validation Master Plan

WHO	World Health Organization
WSP	Workplace Skills Plan

GLOSSARY OF KEY TERMS AND DEFINITIONS

TERM	EXPLANATION
Complementary medicines	The term "complementary medicines" means any substance or mixture of substances that: (a) originates from plants, fungi, algae, seaweeds, lichens, minerals, animals, or other substances as determined by the Authority; (b) is used or purporting to be suitable for use or manufactured or sold for use: (i) in maintaining, complementing or assisting the physical or mental state; or (ii) to diagnose, treat, mitigate, modify, alleviate or prevent disease or illness, or the symptoms or signs thereof, or abnormal physical or mental state of a human being or animal; and (c) is used: (i) as a health supplement.
Health product	The term "health product", as is contained within the ambit of this document only, means medicines, medical devices, radioactive nuclides, listed electronic products (medical), complementary medicines, veterinary medicines, biological and biosimilars.
Ionising radiation	This means radiation consisting of high energy radiation, i.e., X-rays or gamma rays and/or sub-atomic particles, with sufficient energy to cause ionisation in the medium through which it passes.
In vitro diagnostic	*In vitro* diagnostic (IVD) means a medical device, whether used alone or in combination, intended by the manufacturer for the *in vitro* examination of specimens derived from the human body solely or principally to provide information for diagnostic, monitoring or compatibility purposes.
Medical devices	A "medical device" means any instrument, apparatus, implement, machine, appliance, implant, reagent for *in vitro* use, software, material, or other similar or related article, including Group III and IV Hazardous Substances contemplated in the Hazardous Substances Act, 1973 (Act No. 15 of 1973) that is: (a) intended by the manufacturer to be used, alone or in combination, for humans or animals, for one or more of the following: (i) diagnosis, prevention, monitoring, treatment, or alleviation of disease; (ii) diagnosis, monitoring, treatment, alleviation of, or compensation for an injury; (iii) investigation, replacement, modification, or support of the anatomy or of a physiological process; (iv) supporting or sustaining life; (v) control of conception; (vi) disinfection of medical devices; or (vii) providing information for medical or diagnostic purposes by means of *in vitro* examination of specimens derived from the human body; and (b) which does not achieve its primary intended action by pharmacological, immunological, or metabolic means in or on the human or animal body, but which may be assisted in its intended function by such means.
Medicine	The term "medicine": (a) means any substance or mixture of substances used or purporting to be suitable for use or manufactured or sold for use in:

TERM	EXPLANATION
	(i) the diagnosis, treatment, mitigation, modification, or prevention of disease, abnormal physical or mental state or the symptoms thereof in humans; or (ii) restoring, correcting, or modifying any somatic, psychic, or organic function in humans; and (b) includes any veterinary medicine.
Non-ionising radiation	This means radiation that does not carry enough energy to break molecular bonds and ionise atoms.
Radiation	This means the emission of electromagnetic energy moving through space. It includes radiowaves, microwaves, infrared light, ultraviolet, X-rays, gamma rays, and sub-atomic particles. High-energy radiation causes ionisation in the medium through which it passes.

PART A: OUR MANDATE

1. UPDATES TO THE RELEVANT LEGISLATIVE AND POLICY MANDATES

1.1 Constitutional Mandate

The Constitution of the Republic of South Africa, 1996, places an obligation on the State to realise socio-economic rights progressively, 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.

1.2 Relevant 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 (IVDs), and further matters related to the public interest.

Since its establishment in February 2018 as a Schedule 3A entity of the National Department of Health (NDoH), there have been no updates to the Authority's legislative and policy mandates. The cornerstone legislative mandates of SAHPRA are derived from the Constitution of the Republic of South Africa, 1996; National Health Act, 2003 (Act No. 61 of 2003) (NHA); Hazardous Substances Act (Act No. 15 of 1973); and 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:

1.2.1 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 cooperative governance and management of health services within national guidelines, norms and standards, in which each province, municipality and health district must address questions of health policy and delivery of quality healthcare services;
- Establish a health system based on decentralised management, principles of equity, efficiency, sound governance, internationally recognised standards of research, and a spirit of enquiry and advocacy which encourage participation;
- Promote a spirit of cooperation and shared responsibility among public and private health professionals and providers and other relevant sectors within the context of national, provincial and district health plans;
- Create the foundations of the healthcare system; and
- Be understood alongside other laws and policies that relate to health.

1.2.2 The Medicines and Related Substances Act, 1965 (Act No. 101 of 1965), as amended

The Medicines 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 Medicines Act also provides for the registration and control of veterinary medicines so 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.

In terms of Section 2b(1) of the Medicines Act, the Authority must do the following to ensure it achieves its objects:

- The efficient, effective and ethical evaluation or assessment and regulation of medicines, medical devices, radiation-emitting devices, and radioactive nuclides that meet the defined standards of quality, safety, efficacy, and performance, where applicable;
- That the process of evaluating or assessing and registering medicines, medical devices, radiation-emitting devices, and radioactive nuclides is transparent, fair, objective, and concluded timeously;
- The periodic re-evaluation or re-assessment and ongoing monitoring of medicines, medical devices, radiation-emitting devices, and radionuclides;
- The investigation, monitoring and analysis of evidence of existing and new adverse events as well as reactions, interactions and signals emerging from post-marketing surveillance and vigilance activities, while ensuring that these are acted upon;
- That compliance with existing legislation is promoted and achieved through a process of active inspection and investigation; and
- That clinical trial or clinical performance study protocols are assessed according to prescribed scientific, ethical and professional criteria and defined standards.

In executing its functions, the Authority may:

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

1.2.3 Hazardous Substances Act, 1973 (Act No. 15 of 1973)

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

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

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

1.2.4 Other Related Legislation

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

- **Fertilisers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 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 OTC antimicrobials by the lay public (chiefly farmers).

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

This Act 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)**

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

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

The Act 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 Act, 1965, read with Schedule 7 of Government Notice No. R 509 of 2003, unconstitutional on the premise that they amount to an impermissible limitation of the right to privacy. The Court suspended the order of invalidity for 24 months from 18 September 2018 to September 2020.

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

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

This Act 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.

- **National Environmental Management: Waste Management Act, 2008 (Act No. 59 of 2008)**

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

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

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

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

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

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

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

A favourable legislative environment is fundamental to the operations of a regulator such as SAHPRA when it comes to supporting the effective execution of its mandate. 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 that SAHPRA should be fulfilling through its representation at key ports of entry where there are goods entering the country that fall within its legislative obligations and are for its inspection, as per the Customs and Excise Act.

One of the vital 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 (DALRRD), 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".

- **Public Finance Management Act, 1999 (Act No. 1 of 1999), as amended**

The Public Finance Management Act (PFMA) regulates financial management in the national government and provincial governments to ensure that all revenue, expenditure, assets, and liabilities of those governments are managed efficiently and effectively. The PFMA provides for the responsibilities of persons entrusted with financial management in those governments and provides for matters connected therewith. The objective of the PFMA is to secure transparency, accountability and sound management of the revenue, expenditure, assets, and liabilities of institutions such as SAHPRA.

The PFMA serves to modernise financial management in the South African public service to support those processes of public administration which are focused on achieving sustainable development and high-level public services. The PFMA lays down the basic rules for sound financial management and serves to effect Section 216 of the Constitution.

- **Labour Relations Act, 1995 (Act No. 66 of 1995)**

This Labour Relations Act regulates the organisational rights of trade unions to promote and facilitate collective bargaining at the workplace and at the sectoral level.

The Act regulates the right to strike and the recourse to lockout in conformity with the Constitution and promotes employee participation in decision-making through the establishment of workplace forums.

It provides simple procedures for the resolution of labour disputes through statutory conciliation, mediation and arbitration and through independent alternative dispute resolution services accredited for that purpose.

- **Basic Conditions of Employment Act, 1997 (Act No. 75 of 1997), as amended**

The Basic Conditions of Employment Act gives effect to the right to fair labour practices and establishes the basic conditions of employment.

- **Occupational Health and Safety Act, 1993 (Act No. 85 of 1993)**

This Act provides for the health and safety of persons at work and for the health and safety of persons in connection with the use of plant and machinery. It also provides for the protection of persons other than persons at work against hazards to health and safety arising out of or in connection with the activities of persons at work.

- **Broad-Based Black Economic Empowerment Act, 2003 (Act No. 53 of 2003)**

The Broad-Based Black Economic Empowerment (BBBEE) Act establishes a legislative framework for the promotion of black economic empowerment and empowers the Minister to issue codes of good practice and publish transformation charters.

- **Promotion of Access to Information Act, 2000 (Act No. 2 of 2000)**

The Promotion of Access to Information Act (PAIA) gives effect to the constitutional right of access to any information held by the State or another person, and that is required for the exercise or protection of any rights.

- **Protection of Personal Information Act, 2013 (Act No. 4 of 2013)**

The Protection of Personal Information Act (POPIA) promotes the protection of personal information processed by public and private bodies. It introduces certain conditions to establish minimum requirements for the processing of personal information. The Act provides for the establishment of an Information Regulator to exercise certain powers and to perform certain duties and functions in terms of this Act and the PAIA.

The POPIA provides for the rights of persons regarding unsolicited electronic communications and automated decision-making, and it regulates the flow of personal information across the borders of the Republic.

2. UPDATES TO INSTITUTIONAL POLICIES AND STRATEGIES

In fulfilling its mandate, SAHPRA has taken the following key policies and strategies into consideration and has ensured that its work is aligned with these:

- **United Nations Sustainable Development Goals**

The 2030 Agenda for Sustainable Development provides a blueprint for peace and prosperity for people and the planet. It contains 17 Sustainable Development Goals (SDGs) that need to be achieved through the partnership of all countries. More relevant to SAHPRA is SDG Goal 3, which aims to "Ensure healthy lives and promote well-being for all at all ages". This SDG is further broken down into two targets. Target 3.8 aims to:

> Achieve universal health coverage including financial risk protection, access to quality essential health-care services and access to safe, effective, quality and affordable essential medicines and vaccines for all.

Target 3b focuses on supporting the:

> research and development of vaccines and medicines for the communicable and non-communicable diseases that primarily affect developing countries, provide access to affordable essential medicines and vaccines, in accordance with the Doha Declaration on TRIPS Agreement and Public Health, which affirms the right of developing countries to use to the full the provisions in the Agreement on Trade-Related Aspects of Intellectual Property Rights regarding flexibilities to protect public health, and in particular, provide access to medicines for all.

- **The National Development Plan, Vision 2030**

The National Development Plan (NDP) is the blueprint for the South African government that aims to eliminate poverty and reduce inequality by 2030. Chapter 10 of the NDP focuses on providing quality healthcare for all. The implementation of the NDP is translated into the Medium-Term Strategic Framework (MTSF) 2019-2024. Priority 3: "Education, Skills and Health" of the MTSF is the responsibility of the NDoH.

Although SAHPRA does not have a task directly allocated to it in the MTSF, it will support the NDoH in achieving certain targets, such as the outcome: "Universal health coverage for all South Africans achieved through the National Health Insurance" by being an enabler of accelerated product registration and regulation.

- **The National Drug Policy**

To ensure alignment with the MTSF, the National Drug Policy was adopted in 1995 with extensive support from the WHO. The Policy was adopted to serve the healthcare needs of South Africa in the following ways:

1. It offers a clear description of the approach to managing pharmaceutical services in the country.
2. It offers guidance to stakeholders, including healthcare providers, suppliers of goods and services, and governmental and non-governmental agencies, on how they can contribute to achieving the Policy's main aim.
3. It follows a clear and logical system for reducing inefficiency and waste and improving efficiency and effectiveness through the development of adequate pharmaceutical infrastructure.
4. It facilitates the design, production and implementation of appropriate programmes for HR development in healthcare.

- **The Nine-Pillar Presidential Health Summit Compact, 2018**

The primary goal of the Health Summit Compact is to strengthen and improve universal access to health and healthcare in South Africa. The following nine pillars are commitments to strengthening the health system:

1. Augment Human Resources (HR) for health;
2. Ensure improved access to essential medicines, vaccines and medical products through better management of supply chains, equipment and machinery;
3. Execute the infrastructure plan to ensure adequate, appropriately distributed, and well-maintained health facilities;
4. Engage the private sector in improving the access, coverage and quality of health services;
5. Improve the quality, safety and quantity of health services provided with a focus on primary healthcare;
6. Improve the efficiency of public sector financial management systems and processes;
7. Strengthen the governance and leadership to improve oversight, accountability and health system performance at all levels;
8. Engage and empower the community to ensure adequate and appropriate community-based care; and
9. Develop an information system that will guide the health system policies, strategies and investments.

Pillar 2 focuses on ensuring improved access to essential medicines, vaccines and medical products through better management of supply chain equipment and machinery. Within Pillar 2, SAHPRA is responsible for leading the intervention on regulation and registration through the support of the NDoH and private sector by ensuring that "through a collaborative process re-engineer regulatory processes to reduce delays in the registration of products and value innovation, thereby providing reasonable access to safe, effective and affordable products". SAHPRA has developed strategies to address the areas identified as follows:

Clearing the current backlog

SAHPRA inherited a backlog of over 16 000 medicine applications from its predecessor (the Medicines Control Council), which comprised new registrations and variations.

SAHPRA has prioritised medicine applications based on the public health need and expedited the processes that take into account reliance approaches for medicines of public health benefit as a matter of critical concern. The regulatory processes have been re-engineered to reduce unnecessary bureaucracy and delays by revising the operational models and business processes. Collaborative structures to introduce new medicines into pilot programmes to address high-burden diseases, particularly the human immunodeficiency virus (HIV), tuberculosis, cancer, and other diseases of priority, have been created, and SAHPRA has adopted the novel regulatory mechanism of reliance and molecule-based registration.

Overall, as of September 2022, the backlog applications were cleared by 99.6%. This figure comprises the 16 098 applications finalised over the 16 170 applications received. The figure also takes into account clearance initiatives prior to the Go-Live, such as applicant opt-outs, Starburst, certification variations, as well as non-resubmissions.

SAHPRA will have finalised the inherited application backlog by the end of December 2022.

Reduction in the average time frame for the registration of products

The approach taken by SAHPRA to accelerate the licensing of products in the backlog required a fundamental re-engineering of its processes, and this new methodology was also introduced into SAHPRA's "Business as Usual" (BAU) work. Key components of this effort included the harmonisation of SAHPRA's regulatory requirements and guidelines to reflect global best practice and the introduction of 'reliance' review pathways which allow sharing of product evaluation information between regulatory authorities, resulting in streamlining of decisions, reduced duplication of efforts,

and acceleration of licensure processes.

Implement reliance model

In terms of Section 2b of the Act, SAHPRA may liaise with other authorities or institutions to exchange and receive information in a matter of common interest or a specific investigation. In terms of this Section, SAHPRA may also enter into agreements to cooperate with any regulatory authority in order to achieve the objects of the Act. SAHPRA has adopted the following reliance policies:

- Full review – Conduct a complete scientific review for safety, quality, efficacy, and Good Manufacturing Practice (GMP).
- Abridged review – Assess specific, pre-agreed areas of critical importance to SAHPRA's mandate to ensure the safety of the South African public.
- Verified review – Validate that an application conforms with the reference authorisation and provides the required information.

- **Amendments to the Medicines Act**

The Medicines Act has been amended several times and, as such, a new SAHPRA Bill is being drafted. The development of the first draft SAHPRA Bill is in progress and will be submitted to the NDoH for consideration.

- **Priority Review Policy**

The Policy on Priority Review Pathways for medicines was approved. The purpose of this policy is to make provision for priority review or registration with conditions for the assessment and registration of medicines that treat serious diseases and are of major public interest. The Policy will provide priority review to facilitate greater accessibly and availability of medicines:

- That address an unmet clinical need in the South African market (novel or innovative Medicines or New Chemical Entities (NCEs));
- That show a major therapeutic advantage in safety or efficacy compared to existing treatment options;
- For life-threatening or seriously debilitating conditions;
- For public health and animal health emergency;
- For a limited target disease for a patient population (orphan disease);
- In the event of national priorities guided by the NDoH; or
- Where the security of supplies is a concern (guided by NDoH needs) and the DALRRD.

The policy applies to NCEs, new biological medicines, generic medicines, and biosimilars for both new registrations and their lifecycle management.

- **Policy for the Registration of Clones and Replicas**

The Policy for Registration of Clones and Replicas was approved to facilitate the registration of clones and replicas. The purpose of this policy is to improve the processing time for certain categories of applications, namely clones of NCEs, replicas of generic (multisource) products, submitted by either the same or by different applicants, and identical APIs (same Drug Master File (DMF) number and same manufacturer) previously approved and/or submitted for a different product by the same applicant or a different applicant. This policy applies to all clones and replicas of registered products, as well as to instances where reliance is placed on prior work done by the Medical Controls Council or SAHPRA (internal reliance).

- **Human Resources**

The following are approved Human Resources (HR) policies:

- Training and Development Policy
- Disciplinary Policy
- Recruitment and Selection Policy
- Performance Management Policy
- Recognition and Rewards Policy
- Talent Management Policy
- Leave Policy

The development of the following policies will be prioritised during the financial year:

- Remuneration and Benefits Policy
- Bereavement Support Policy
- Employment Equity Policy.

3. UPDATES TO RELEVANT COURT RULINGS

NO.	CASE	SUMMARY
1.	South African Veterinary Association v The Speaker of the National Assembly and Others	On 5 December 2018, the Constitutional Court declared Section 22C(1)(a) of the Medicines Act unconstitutional for requiring veterinarians to have a licence to compound and dispense.
2.	Minister of Justice and Constitutional Development and Others v Prince; National Director of Public Prosecutions and Others v Rubin; National Director of Public Prosecutions and Others v Acton and Others [2018] ZACC 30	On 18 September 2018, the Constitutional Court found sections of the Medicines Act that restrict cannabis use to be unconstitutional in certain limited circumstances. It is, therefore, not a criminal offence for an adult person to: • Use or be in possession of cannabis for their personal consumption in private; and • Cultivate cannabis in a private place for their personal consumption in private. The Court did not make a distinction between using, possessing or cultivating cannabis for recreational or medicinal use. SAHPRA was required, within 24 months from 18 September 2018, to amend the Medicines Act to comply with this judgment. In response to this, the Minister of Health, through SAHPRA, amended the Schedules to the Medicines Act and published these in Government Notice No. 586, Government Gazette No. 43347, on 22 May 2020. These amendments included the removal of cannabis as a plant from Schedule 7 of the Medicines Act. Instead, the psycho-active ingredient tetrahydrocannabinol (THC) is listed in Schedule 6, with specific exemptions made for industrial application of low-THC cannabis, which contains 0.2% or less THC as a raw plant material, or processed products manufactured from such material, intended for industrial purposes and not for human or animal ingestion.
3.	Alliance Natural Health Products of South Africa v THE Minister of Health and Another [Case No.: 11203/2018]	On 1 October 2020, the Pretoria High Court reviewed and set aside the General Regulations promulgated on 25 August 2017 under General Notice 859 in GG 41064 to the extent that they apply to complementary medicines and health supplements that are not medicines or scheduled substances as defined in Section 1 of the Medicines Act. The declaration of invalidity is, however, suspended for a period of 12 months to allow SAHPRA to correct the defect. On 29 October 2020, the Minister and SAHPRA filed an application for leave to appeal to have this judgment overturned. Since the Minister and SAHPRA are appealing the judgment, the General Regulations are, therefore, still in force.

NO.	CASE	SUMMARY
		On 7 March 2022, the appeal was heard by the Supreme Court of Appeal (SCA). The SCA handed down its judgment on 11 April 2022, dismissing an appeal with costs and the cross-appeal with costs. Therefore, the Minister and SAHPRA have 12 months to amend the Regulations to align them with the judgment. The draft Complementary Medicines Regulations have been submitted to the NDoH.
4.	Association of Compounding Pharmacists of South Africa v The Minister of Health and Others [Case No.: 15758/2018]	On 13 December 2021, the Pretoria High Court ruled that Regulation 3 of the General Regulations be reviewed and set aside. The court suspended the operation of the judgment for a period of seven months to allow the Minister to amend the Regulations. In July 2022, SAHPRA approached the court for an extension of seven months to expire in December 2022 instead of July 2022, as per the initial court order. The draft Compounding Regulations were submitted to the NDoH for publication for comments. The comment period lapsed on 30 October 2022, and SAHPRA has considered the comments. The final draft of the Regulations will be submitted to the NDoH.

PART B: OUR STRATEGIC FOCUS

1. UPDATED SITUATIONAL ANALYSIS

1.1 External Environment Analysis

1.1.1 PESTEL Analysis

A PESTEL analysis is a framework to analyse the key factors (Political, Economic, Sociological, Technological, Environmental and Legal) influencing an organisation from the outside.

PESTEL Analysis

POLITICAL	
1.	The introduction of the Sixth Administration following the recent elections has led to a renewed focus on reform and a shift in policy. Public health reform is exemplified in the prioritisation of Universal health coverage and the promulgation of the National Health Insurance Bill.
2.	There is a plethora of legislation that affects the areas of SAHPRA's operations and which straddles various departments that need to be coordinated through intergovernmental relations processes. This would include the regulation of radiation-emitting devices, the management of opioid abuse, the deregulation of cannabis, and the introduction of the Border Management Agency.
3.	Increasingly competitive government tenders, with punitive conditions attached for non-compliance, have been introduced.
4.	The industry is in the process of transformation, and there is currently no sector chapter to promote self-regulation for sector transformation in line with government policies, mainly the BBBEE Act.
ECONOMIC (FINANCIAL)	
1.	There has been a change in the balance of power across the healthcare value chain, as governments and medical aid providers have started to exert more pressure on pharmaceutical companies to decrease their prices.
2.	The South African medical device market value was estimated at R30 billion in 2019 and presents an opportunity to generate greater revenue and stimulate the local manufacturing industry. Compared with the pharmaceutical market, where domestic manufacturers are now able to meet 50% of demand in volume terms, South Africa's domestic medical device industry is small, with imports catering for 90% of the market by value.
3.	The local pharmaceutical market indicates steady growth over the next five years, with an annual compounded growth of 6.7% and an expected increase in the demand for generics.
4.	Nearly every therapeutic class currently has at least one generic equivalent available, and sales of over-the-counter (OTC) generics now also outstrip brand-name products by almost R1 billion in value and more than 53 million units.
5.	Global shortages of APIs, which are key ingredients in the manufacturing process, impact licensing and access within the South African market.
6.	Weak economic growth means that the public health sector will be required to do more with fewer resources than initially planned. In essence, a weaker fiscus translates into South Africa needing to drive the transition to a greater fee contribution to its revenue, as opposed to the fiscal contribution to its revenue.
7.	There is a need for generic medicines in South Africa, as more doctors and consumers opt for affordable yet effective alternatives to expensive brand-name medications.
8.	Lack of orders for COVID-19 vaccines could halt vaccine production and the need for lot release testing.
9.	Non-private medical costs increased and labour productivity declines are the main direct costs related to the COVID-19 outbreak.

SOCIAL/SOCIO-ECONOMIC	
1.	The increasing rates of inequity and poverty across South African society are a clear indication of an increase in the number of vulnerable individuals who need a social safety network against sub-optimal and falsified health products that flood across porous borders into vulnerable markets in developing nations.
2.	In South Africa, generics are fast becoming the pillar of healthcare because of their affordability to public health and the fact that they make medicine accessible to the most vulnerable in society.
3.	There seems to be social scepticism surrounding the success prospects of the NHI Scheme due to challenges that have been witnessed in State-owned enterprises and the weaknesses in service delivery in the public service.
4.	There is a danger of misinterpretation of the Constitutional Judgement on the recreational use of cannabis. This could affect the medicinal use aspects that SAHPRA is responsible for. This may necessitate urgent public education interventions and collaboration with other government departments such as Social Development, Trade and Industry, and Finance.
5.	South Africa has participated in the COVID-19 vaccines global access (COVAX) Facility, which was created to establish a pooled procurement mechanism to secure adequate and equitable supplies of vaccines at competitive prices for countries throughout the world, irrespective of their wealth status.
6.	The NDoH will work with SAHPRA to ensure that whichever vaccine is recommended or made available through the COVAX Facility has met all the regulatory requirements of safety, efficacy, and quality.
7.	The growth of organised crime has a negative effect on socio-economic development.
TECHNOLOGICAL	
1.	Digitisation of SAHPRA operations is imperative to optimise its operations in a globally recognised space.
2.	Technical advances and the increase in cyber-crimes create risks in terms of unauthorised access to sensitive information. Data security is a growing business consideration that must be prioritised.
3.	Online purchasing sites are not adequately regulated and have a negative impact in that they enable ease of access to illegally imported drugs that could make it hard for SAHPRA to detect.
4.	Due to the COVID-19 outbreak, staff have been working remotely and, therefore, heavily rely on information technology. This has resulted in increased data costs for SAHPRA within the limited operational budget.
ENVIRONMENTAL	
1.	An increase in reported cases of abandoned or recklessly handled radiation-emitting materials that are causing illnesses among neighbouring communities requires the urgent attention of SAHPRA's radiation control division.
2.	SAHPRA must align with the global trends of greener industrial systems and should seek to align legislation and practice of licensing and inspections with stimulating industrial compliance.
3.	The lockdown due to the COVID-19 pandemic has placed restrictions in terms of movement, thus resulting in a positive impact on the environment, such as the improvement in air quality and less waste and noise pollution.
4.	The negative impact of the COVID-19 pandemic includes an increase in medical waste, and the haphazard use and disposal of personal protective equipment that creates an environmental burden.
LEGAL	
1.	There is a plethora of legislation that requires harmonisation in order to provide clarity for SAHPRA to fulfil its role with greater efficiency and confidence, given the critical importance of legislation for SAHPRA's regulatory function.
2.	The Constitutional Court judgment on cannabis requires urgent interventions in terms of proper policy frameworks.
3.	The evolving universe of health product regulation necessitates focused efforts from SAHPRA to review the legal framework to ensure the Regulatory Compliance Unit is properly aligned to enforce regulations at a global level.
4.	A key area of law enforcement is that of false and misleading advertising that adversely impacts public safety.

1.1.2 SWOT Analysis

A Strengths, Weaknesses, Opportunities and Threats (SWOT) analysis is provided below.

SWOT Analysis

STRENGTHS	1. Agility and autonomy of a Schedule 3A entity permit quicker responsiveness to the health products regulatory environment. 2. Achieved Maturity Level 3 status from the WHO. 3. Respected as a regulator and recognised as a leader in Africa. 4. Committed and ethical Board concerned about good governance. 5. Re-engineered business process towards the novel reliance mechanisms places SAHPRA as a leader in developing rigour in this untested regulatory system and enables the entity to be a thought leader in this space. 6. Implemented Quality Management System for better and consistent control of business processes. 7. Strong and diverse professional team. 8. In a position to reframe the regulatory footprint in Africa. 9. Sound strategic partnerships that advance the mandate of SAHPRA. 10. Established key collaborations and memberships, such as the African Medicines Regulatory Harmonisation Forum (AMRH), Zazibona, Pharmaceutical Inspection Co-operation Scheme (PIC/S), and WHO Collaborative Review Process. 11. The majority of the critical positions are being filled. 12. All Executive and Manager positions are filled. 13. Multiple interventions are being deployed and skilled staff are being recruited.	**WEAKNESSES**	1. Lack of a digitised track and trace system, including cost centre and revenue. 2. Lack of robust pharmacovigilance. 3. Low staff morale with regard to transition and extensive change, with no staff climate surveys conducted. 4. No proper HR change management processes rolled out to support staff. 5. Shortage of skilled assessors. 6. Heavy reliance on external reviewers. 7. Non-competitive remuneration policies allowing for benchmarking exercises. 8. A lack of automated business processes has a negative impact on organisational efficiency and effectiveness, with potential delays or inaccurate revenue recognitions. 9. The Performance Moderation Process.

OPPORTUNITIES	1. SAHPRA is in a position to grow, despite an adverse economy, as operational efficiency will stimulate higher fees. 2. Improved efficiencies through digitisation. 3. Change in legislation to accommodate reliance arrangements. 4. Lessons from experiences with the backlog clearance project and other Authorities. 5. As a Schedule 3A, SAHPRA can now inculcate a new SAHPRA corporate culture underpinned by professionalism. 6. Opportunity to secure donor funding as a Schedule 3A entity. 7. Opportunity to create a fee structure to generate more revenue necessary for financial sustainability. 8. Implementing a renewed performance review system, both for management and staff to improve individual performance and consequence management. 9. Establishing a framework for regular and efficient interactions with all stakeholders and partner agencies. 10. Conducting independent stakeholder surveys.	THREATS	1. Low staff morale. 2. There is currently no documented process that regulates the working relationship between the Department of Health and SAHPRA. Shareholder Compacts are not legislated for Section 3A entities, but there are no preclusions. 3. Poaching of staff by the industry remains a threat during the period of uncertainty in the transition. 4. Current internal capacity challenges could lead to the creation of a new backlog. 5. Fraud and corruption risks are inherent in a regulatory organisation. 6. Flight of scarce skills with increased professional emigration out of South Africa. 7. Reliance on external expertise if skills transfer from senior experts is not facilitated in an active process of knowledge transfer. 8. Change management continues to be a threat. 9. Lack of a Regulatory Information Management System resulting in inefficient manual processing practices. 10. Treasury cuts leading to a diminished fiscus, with government austerity measures currently underway. 11. Pressure from the industry stakeholder threatens to shift SAHPRA's focus from its Public Health mandate towards an industry agenda if not managed properly.

1.1.3 Sustainability Reporting

Globally, there is a growing need for organisations to contribute to sustainability initiatives while conducting their operations. This will ultimately result in improved quality of life while protecting the environment. As a responsive regulator, SAHPRA will endeavour to make a more meaningful contribution going forward. In the interim, SAHPRA has embarked on the following initiatives with regard to the three common pillars of sustainability:

- Environment – The organisation has moved its business processes from paper-based to digital. To ensure that undesirable health products are out of reach of the public and do not affect the environment adversely, SAHPRA ensures the implementation of safe disposal or destruction of such health products through Section 23, Regulation 44, guidelines and inspections. On a regular basis, SAHPRA instructs companies to destroy substandard or falsified health products, and the Authority is present when destruction occurs to prevent and minimise environmental hazards. The Head Office is currently housed in a green building office park. During the 2023/24

financial year, SAHPRA will develop an Energy Management Policy and consider solutions to minimise material waste, and actively promote the use of recyclables.

- Social – SAHPRA has a vested interest in the public at large and plans to embark on more Corporate Social Responsibility (CSR) projects. As part of its CSR programme, SAHPRA will engage in initiatives, such as donating obsolete computer equipment to schools and/or community centres, and partnering with a credible humanitarian organisation, such as Gift of the Givers.
- Governance – Good governance is being promoted as SAHPRA has fully functional governance structures, such as the Board and Executive Committee, in place. Several policies have been introduced, and these are monitored on a regular basis. For example, SAHPRA has a Fraud Prevention Policy and Framework to manage fraud and corruption within the organisation. The unqualified audit opinion obtained during the 2021/22 financial year serves as a confirmation that SAHPRA is practising good governance.

1.2 Internal Environment Analysis

Health Products Authorisation

Since the implementation of the priority review requests process, there has been an influx of relevant applications by applicants. This has resulted in a delay in reviews of routine applications, considering that more focus has been directed towards priority reviews.

Inspectorate and Regulatory Compliance

SAHPRA has commenced with physical inspections, both locally and internationally, due to the easing of travel restrictions. The demand for inspections remains high and is driven by new licence and product registration applications as well as routine and unannounced inspections. The Inspectorate Unit continues to capacitate itself in terms of inspector skills and number of inspectors.

The cannabis industry continues to grow and evolve. SAHPRA is an important stakeholder in the development and implementation of the Cannabis Master Plan, which involves other government departments, such as the DALRRD, South African Police Service, Department of Justice and Constitutional Development, Department of Small Business Development, Department of Trade and Industry, and Department of Science and Innovation. Political pressure remains high in terms of government frameworks to support rural cannabis farmers and the space that enables their cultivation and legal supply chain. On the medicinal cannabis side, SAHPRA continues to inspect and licence cultivators of cannabis for the purposes of producing scheduled substances. SAHPRA activities in the medicinal sector form an important aspect of the broader Cannabis Master Plan, which is led

by the DALRRD. In terms of the cannabis plant, whether low-THC hemp for industrial purposes or medicinal cannabis, the regulation of the supply chain continues through the DALRRD and SAHPRA, respectively. Collaboration between the government departments involved in the Cannabis Master Plan continues.

With increased stakeholder engagement, both with industry and other government departments, SAHPRA guidelines will continue to be monitored for effectiveness from a control and an enabling perspective, taking into account South Africa's participation and affiliation with the International Narcotics Control Board.

In terms of SAHPRA's mandate of issuing permits for the control of narcotic, psychotropic and controlled substances, the efficiency of other regulatory bodies, such as the International Trade Administration Commission (ITAC), continues to have an impact on the issuing of SAHPRA permits.

Clinical Evaluations Management

The COVID-19 pandemic necessitated a radical adjustment of how resources are planned and deployed, and lessons were learnt in the process. More staff were recruited to increase agility and adaptability to a fluid external environment and meet fairly unpredictable service demands as they arose. More emphasis was placed on automation initiatives of vigilance and clinical trials operating environments in order to release technical resources to focus on application review activities mainly.

The increase in the number of clinical trial applications for both therapeutics and vaccines continues unabated, although the focus has shifted back to therapeutic areas that became of secondary importance during the pandemic. New vaccines on novel platforms have continued to exert pressure on both programmatic and regulatory pharmacovigilance to be resilient and responsive in the monitoring of adverse events and public education about what to expect and how to respond to any adverse events that may not have been detected during clinical trials.

Several expression of interest initiatives have been launched to build technical capacity in order to augment regulatory expertise in all areas of the programme. Existing expertise in SAHPRA is being increased to deal with new clinical trial designs highlighted during the pandemic. Also, the new vaccine platforms and technologies highlighted new safety issues not seen with older generation vaccine designs and that needed expert analysis to determine vaccine benefits and risks in all populations with different co-morbidities, regardless of age.

Pharmaceutical Evaluation Management

The reliance on work done by other regulators that SAHPRA aligns with has facilitated shorter review turnaround times for vaccine applications. The use of the WHO listing has improved review considerations for vaccine emergency use and registrations. This reliance has also been useful for facilitating vaccine lot release, thereby enabling quicker access to COVID-19 vaccines. The use of external evaluators has increased due to the increased requests for COVID-19 vaccine applications. The availability of external evaluators is a concern due to their limited availability. Due to the increased public awareness of COVID-19 vaccines and treatments, SAHPRA has had multiple queries on authorisations that it granted.

The majority (90%) of the review work conducted is for generic applications, as the quality and efficacy (bioequivalence studies) aspects are reviewed. The resources currently in pharmaceutical evaluation management are inadequate to deal with the number of applications received. A solution was the re-distribution of work to have the bioequivalence studies reviewed by clinical evaluations. Training was conducted for clinical evaluation management reviewers in bioequivalence review to enable capacitation with the long-term view of taking on the role of bioequivalence evaluations. In other regulatory agencies, bioequivalence reviews are done by the Clinical Unit.

The increase in the number of variations is partly due to the COVID-19 pandemic, wherein raw materials used by local manufacturers are imported. Due to COVID-19 restrictions in other jurisdictions, variations have been submitted for alternative suppliers. This has had a significant impact on SAHPRA's workload and has impacted the timelines set, which are in line with the European Medicines Agency guidelines.

Veterinary and complementary medicines have seen a decline in Section 21 applications, and this may be attributable to more veterinary registrations taking place and also the COVID-19 situation resulting in fewer people obtaining Section 21 for complementary medicines.

Medical Devices and Radiation Control

South Africa has a vibrant civil society community, and SAHPRA should collaborate with civil society and seek out areas for cooperation. Civil society groups are influential not only in policy-making but also in building a society-wide narrative.

The medical device industry is relatively new in terms of regulations, which includes the establishment licensing and product registration. Therefore, individuals with the skill set and who are inclined to internal regulatory requirements are scarce. It is against this backdrop that attaining

relevant skills to be part of the workforce of the Authority is a challenge, especially regarding the external reviewers, as the availability to assist the organisation with the review of applications is crucial to achieving the objective output of SAHPRA.

An increase in reported cases of abandoned or recklessly handled radiation-emitting materials is of concern in terms of radiological safety in the environment and society and requires urgent attention by SAHPRA. SAHPRA, together with other stakeholders (i.e., the National Nuclear Regulator (NNR) and Department of Minerals Resources and Energy), has a national responsibility to manage radiation and nuclear safety in South Africa. The entities must ensure they comply with the requirements of the International Atomic Energy Agency and Integrated Regulatory Review Service.

Collaborations

SAHPRA continues to strengthen its collaborations and partnerships with fora, such as the AMRH, Zazibona and PIC/S, and the WHO Collaborative Review Process.

SAHPRA has established key collaborations with other NRAs on the African continent, such as Zimbabwe, Kenya, and Tanzania, and on international platforms, with the United Kingdom, Switzerland, and the United States of America, to mention a few.

Partnerships with other stakeholders are imperative in ensuring continuous successful medical device products (both non-IVDs and IVDs) registration as well as ensuring access to safe, quality and effective products in our market. SAHPRA relies on partners, such as the South African National Accreditation System, to assist in ensuring the certification of manufacturers and distributors in terms of their Quality Management System (ISO 13485) as well as performance evaluation to assure the safety of products by working together with the National Reference Laboratory, that is, the National Health Laboratory Services.

SAHPRA participates on various platforms continentally and internationally. SAHPRA is an observer at the International Cooperation on Harmonisation (ICH) and intends to be a member which aligns with global standards of medicines regulation. SAHPRA also actively participates in the International Pharmaceutical Regulators Programme (IPRP), which engages with other regulatory members and observers to exchange information on matters of mutual interest and enable regulatory cooperation. This initiative covers aspects of generic and biosimilar medicines as well as cell and gene therapy.

SAHPRA participates in other regulator fora, such as the International Collation of Medicines Regulation Authorities (ICMRA), European Directorate for Quality of Medicines and Health Care (EDQM), AMRH, and Southern African Development Community (SADC) harmonisation initiatives,

which enables SAHPRA to operate on regional and international regulatory best practices.

SAHPRA is involved with the WHO International Regulatory Cooperation for Herbal Medicines Network, which aims to, among others, improve the regulation of herbal medicines. SAHPRA is also involved in the World Integrated Medicine Forum on the regulation of homoeopathic medicinal products and the International Over-The-Counter Medicine Regulators Forum.

In the monitoring of clinical trials, SAHPRA is part of a continental initiative led by the African Vaccine Regulatory Forum (AVAREF). AVAREF is a network of African NRAs and ethics committees that use harmonisation and reliance as pillars for capacity building in clinical trial monitoring for studies conducted on the continent. AVAREF works to ensure collaboration among key stakeholders across the continent—including donors, health professionals, and regional economic blocs—by promoting joint reviews and the sharing of work and expertise. As a result of AVAREF's efforts, vaccines against meningitis, malaria, rotavirus, pneumococcal pneumonia, and Ebola have been developed, and medicines against neglected diseases, such as human African trypanosomiasis and leishmaniasis, are currently being developed.

To further enhance medicine safety surveillance on the continent, SAHPRA is part of the African Union's Smart Safety Surveillance (AU-3S) programme. The primary mission of the AU-3S initiative is to strengthen the safety surveillance of priority medical products across the African continent. The programme aims to address limited health system and safety surveillance capacity across Africa through efficiencies like technological innovation, pooling of resources, and work sharing.

With COVID-19 further reinforcing the need for strong African PV systems, AU-3S is currently piloting its approach to the safety surveillance of COVID-19 vaccines in four countries. These countries are Ethiopia, Ghana, Nigeria, and South Africa – altogether comprising about 30% of Africa's population. The AU-3S team works closely with the medical products NRAs and Expanded Programmes on Immunisation (EPIs) from countries involved.

With regards to veterinary medicines, SAHPRA engages with the ICH of Technical Requirements for Registration of Veterinary Medicinal Products, aimed at harmonising the technical requirements for the registration of veterinary medicines.

The SADC harmonisation initiative for the regulation of veterinary medicines is still in the inception phase and will, among others, play a role in improving access to quality Validation Master Plans (VMPs) by reducing the registration time, eliminating unnecessary duplication of work, managing the increasing workload, and building capacity among individual member states in the SADC.

Memorandum of Understanding

SAHPRA has entered into a memorandum of understanding (MoU) with the United States Food and Drug Administration, Swissmedic and Zazibona. It has also aligned with the European Medicines Agency and the WHO Pre-Qualification.

In future, SAHPRA plans to enter into agreements with Japan's Pharmaceuticals and Medical Devices Agency, Health Canada, the Australian Therapeutic Goods Administration, the Brazilian Health Regulatory Agency, and Singapore's Health Sciences Authority.

Financial Resources and BBBEE

The fiscal constraints facing South Africa have had an impact on the funding received from National Treasury by SAHPRA, with a reduction during the 2020/21 financial year and limited growth over the Medium-Term Expenditure Framework period. As a recently established entity, the priority is to implement well-established systems and reach full capacity by filling its approved structure, which requires significant financial resources.

To overcome this challenge, SAHPRA has to prioritise its own revenue generation and explore external funding opportunities. Furthermore, SAHPRA will continue to monitor the funding mix. New fees were gazetted in December 2020, and a further review to add new revenue streams is planned to be implemented during the 2023/24 financial year.

The projected revenue and expenditure for SAHPRA are as follows:

Revenue	2023/24 Budget	2024/25 Budget	2025/26 Budget	2026/27 Budget
Transfers – DoH Grant	152 553 000	159 418 000	166 559 926	174 021 811
Fee income	212 671 890	237 682 147	246 491 019	257 583 115
Interest	15 670 741	15 514 034	15 358 893	14 590 949
TOTAL REVENUE	**380 895 631**	**412 614 180**	**428 409 839**	**446 195 875**

Expenditure	2023/24 Budget	2024/25 Budget	2025/26 Budget	2026/27 Budget
Compensation of Employees	**266 965 294**	**278 389 429**	**288 153 469**	**298 626 781**
Cost of employment	265 006 506	276 348 372	286 020 565	296 397 896
Directors' remuneration	1 958 788	2 041 057	2 132 904	2 228 885
Goods and Services	**124 870 336**	**131 116 751**	**136 992 969**	**144 142 524**
Office rentals	21 287 536	22 990 539	24 829 782	26 816 164

Contracted services - National Control Laboratory (NCL)	24 116 794	25 322 633	26 588 765	27 918 203
Operating expenditure	79 466 007	82 803 579	85 574 422	89 408 156
Capital expenditure	2 960 000	3 108 000	3 263 400	3 426 570
TOTAL EXPENDITURE	**394 795 630**	**412 614 180**	**428 409 839**	**446 195 875**

SAHPRA has implemented procurement policies and procedures to comply with the BBBEE procurement requirements. A BBBEE compliance certificate was obtained for the first time during the 2021/22 financial year, and an action plan has been developed to improve the overall BBBEE score in the 2022/23 financial year.

Human Resources (HR)

The South African economy will continue to contract this financial year. The impact of the lockdown continues to be a challenge to the economy. The high unemployment rate and load-shedding are additional challenges. It is against this background that consultations with organised labour have become very challenging, as they demand higher salary increases and benefits for their members due to economic conditions. SAHPRA is continuously engaging with both organised labour and employees to assist in mitigating future challenges.

SAHPRA's strategic journey is communicated to all employees through various channels that include the CEO's engagements with staff and the HR Indaba (engagements) sessions. This is also part of the change management initiatives of creating a SAHPRA culture. The COVID-19 pandemic introduced significant changes in the work environment in that employees work from home more frequently than before the pandemic. A Hybrid and Remote Working Policy has been developed and is the subject of consultations with the unions. SAHPRA continues to apply its pillars of safety, efficacy, and quality for South African citizens and our animals.

The Authority received funds that assist in closing the technical and core business resources needs gap. SAHPRA is developing a new Remuneration Policy to attract and retain core, critical and scarce skills. The completed Compa Ratio (Benchmarking) exercise will address the salary disparities experienced at the Authority. An annual Recruitment Plan has been developed, which guides the recruitment processes. The first Workplace Skills Plan (WSP) has been submitted for SAHPRA. Training has been intensified since employees can travel to other countries for training as well.

Information and Communication Technology (ICT)

SAHPRA's digital transformation journey is steadily progressing, although not at the desired pace, as

it continues to implement new digital solutions, and enhance and modernise existing and legacy systems. SAHPRA has indeed become virtually paperless, as our engagements with stakeholders are now exclusively through secure digital platforms.

As part of this transformation journey, SAHPRA will be embarking on a process to develop an Enterprise Architecture for the organisation to define the business, data, application systems, and technology architecture.

PART C: MEASURING OUR PERFORMANCE

1. INSTITUTIONAL PROGRAMME PERFORMANCE INFORMATION

1.1 Programme 1: Leadership and Support

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

1.1.1 Sub-programmes

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

1.1.2 Outcomes, Outputs, Output Indicators and Targets

OUTCOMES	OUTPUTS	OUTPUT INDICATORS	AUDITED/ACTUAL PERFORMANCE			ESTIMATED PERFORMANCE 2022/23	NO.	MEDIUM-TERM EXPENDITURE FRAMEWORK TARGETS		
			2019/20	2020/21	2021/22			2023/24	2024/25	2025/26
Effective compliance, financial and performance management (1)	Attain and maintain an unqualified overall Auditor-General Audit outcome on the previous year's performance	Unqualified audit opinion obtained on the annual financial statements	Qualified audit opinion obtained for the 2019/20 financial year	Qualified audit opinion obtained for the 2020/21 financial year	Qualified audit opinion obtained (2020/21 financial year)	Unqualified audit opinion obtained for the 2021/22 financial year	1.1	Unqualified audit opinion obtained for the 2022/23 financial year	Clean audit opinion obtained for the 2023/24 financial year	Clean audit opinion obtained for the 2024/25 financial year
Financial sustainability achieved (2)	Liquidity ratio of ≥ 1	Current assets ≥ than current liabilities	-	-	-	-	1.2	Current ratio of 1≥1 maintained	Current ratio of 1≥1 maintained	Current ratio of 1≥1 maintained
Responsive to stakeholder needs (3)	Survey conducted	Progress report on the implementation plan produced	Material developed and disseminated Responses and report to be reviewed in Q1 2020	SAHPRA obtained a 68% positive rating for its effectiveness and efficiency, as rated by private and public direct users of SAHPRA's	67% prioritised recommendations from the survey implemented Out of 3 prioritised recommendations from the survey, the following 2 (67%) were	60% accepted recommendations from the 2022/23 stakeholder perception survey implemented	1.3	Progress report on the implementation plan from the 2023/24 stakeholder perception survey submitted to the Executive Committee	Customer Relationship Management (CRM) system fully implemented	All recommendations from the 2023/24 stakeholder perception survey implemented

OUTCOMES	OUTPUTS	OUTPUT INDICATORS	AUDITED/ACTUAL PERFORMANCE			ESTIMATED PERFORMANCE 2022/23	NO.	MEDIUM-TERM EXPENDITURE FRAMEWORK TARGETS		
			2019/20	2020/21	2021/22			2023/24	2024/25	2025/26
				services	implemented: • A web query system. Out of the 1 103 queries received, 623 (56%) were responded to • Out of a staff establishment of 395, 266 (67%) posts were occupied, which included positions that were filled by employees placed on higher grades during the administrative placement exercise					

OUTCOMES	OUTPUTS	OUTPUT INDICATORS	AUDITED/ACTUAL PERFORMANCE			ESTIMATED PERFORMANCE 2022/23	NO.	MEDIUM-TERM EXPENDITURE FRAMEWORK TARGETS		
			2019/20	2020/21	2021/22			2023/24	2024/25	2025/26
A positive and enabling working culture created (4)	Survey conducted	Progress report on the implementation plan produced	-	-	-	-	1.4	Progress report on the implementation plan from the staff satisfaction survey submitted to the Executive Committee	40% recommendations from the staff satisfaction survey implemented	80% recommendations from the staff satisfaction survey implemented
	Learning and development initiatives implemented	Percentage of learning and development initiatives implemented	-	-	39% of the Workplace Skills Plan implemented Out of 23 planned training interventions in the Workplace Skills Plan, 9 (39%) were implemented	50% of the Workplace Skills Plan implemented	1.5	70% employees trained	80% employees trained	90% employees trained

OUTCOMES	OUTPUTS	OUTPUT INDICATORS	AUDITED/ACTUAL PERFORMANCE			ESTIMATED PERFORMANCE 2022/23	NO.	MEDIUM-TERM EXPENDITURE FRAMEWORK TARGETS		
			2019/20	2020/21	2021/22			2023/24	2024/25	2025/26
Attract and retain talent (5)	Budgeted positions filled	Percentage of budgeted positions filled	-	Out of the 30 prioritised positions, 24 (80%) were filled	96% budgeted positions filled Out of 55 budgeted positions, 53 (96%) were filled	95% budgeted positions filled	1.6	95% budgeted positions filled	80% core business positions in the staff establishment filled	90% core business positions in the staff establishment filled
	Technical staff retained	Percentage of staff retained	-	-	-	-	1.7	Staff turnover rate less than 10%	50% technical staff retained	80% technical staff retained
Digital transformation (6)	Enterprise Architecture	Percentage of Phase 1 Enterprise Architecture implemented	-	10% of processes digitised. The User Requirements Specification for the Regulatory Information Management Systems was developed and submitted for approval in March 2021	Section 21 business process was digitised in June 2021 Development of an online application submission system was in progress Leave application process was digitalised	Enterprise Architecture approved by the Board	1.8	100% Enterprise Architecture Phase 1 implemented	100% Enterprise Architecture Phase 2 implemented	Electronic Common Technical Document system implemented

1.1.3 Output Indicators: Annual and Quarterly Targets

OUTPUT INDICATORS	NO.	2023/24 ANNUAL TARGETS	1ST QUARTER TARGETS (Apr - Jun)	2ND QUARTER TARGETS (Jul - Sep)	3RD QUARTER TARGETS (Oct - Dec)	4TH QUARTER TARGETS (Jan - Mar)
Unqualified audit opinion obtained on the annual financial statements	1.1	Unqualified audit opinion obtained for the 2022/23 financial year	-	Unqualified audit opinion obtained for the 2022/23 financial year	-	-
Current assets ≥ than current liabilities	1.2	Current ratio of 1≥1 maintained	Current ratio of 1≥1 maintained	Current ratio of 1≥1 maintained	Current ratio of 1≥1 maintained	Current ratio of 1≥1 maintained
Stakeholder survey conducted Progress report on the implementation plan produced	1.3	2023/24 stakeholder perception survey conducted Progress report on the implementation plan from the 2023/24 stakeholder perception survey submitted to the Executive Committee	2023/24 stakeholder perception survey request for quotation completed	2023/24 stakeholder perception survey conducted	Implementation plan from the 2023/24 stakeholder perception survey approved by the Executive Committee	Progress report on the implementation plan from the 2023/24 stakeholder perception survey submitted to the Executive Committee
Staff survey conducted Progress report on the implementation plan produced	1.4	Staff satisfaction survey conducted Progress report on the implementation plan from the staff satisfaction survey submitted to the Executive Committee	Staff satisfaction survey conducted	Implementation plan from the staff satisfaction survey approved by the Executive Committee	Progress report on the implementation plan from the staff satisfaction survey submitted to the Executive Committee	Progress report on the implementation plan from the staff satisfaction survey submitted to the Executive Committee
Percentage of learning and development	1.5	70% employees trained	Workplace Skills Plan submitted to the Health and Welfare Sector Education and Training Authority	25% employees trained	50% employees trained	70% employees trained

OUTPUT INDICATORS	NO.	2023/24 ANNUAL TARGETS	1ST QUARTER TARGETS (Apr - Jun)	2ND QUARTER TARGETS (Jul - Sep)	3RD QUARTER TARGETS (Oct - Dec)	4TH QUARTER TARGETS (Jan - Mar)
initiatives implemented						
Percentage of budgeted positions filled	1.6	95% budgeted positions filled	Recruitment Plan approved by the Executive Committee	50% budgeted positions filled	75% budgeted positions filled	95% budgeted positions filled
Percentage of staff retained	1.7	Staff turnover rate less than 10%	Staff turnover rate less than 10%	Staff turnover rate less than 10%	Staff turnover rate less than 10%	Staff turnover rate less than 10%
Percentage of Phase 1 Enterprise Architecture implemented	1.8	100% Enterprise Architecture Phase 1 implemented	30% Enterprise Architecture Phase 1 implemented	50% Enterprise Architecture Phase 1 implemented	70% Enterprise Architecture Phase 1 implemented	100% Enterprise Architecture Phase 1 implemented

1.1.4 Explanation of Planned Performance over the Medium-Term Period

Finance

The focus over the medium term will be on capacitating SAHPRA with the current vacant critical positions that the available funding allows. Funding has been made available to assist with basic automation of current manual processes, while additional funding was made available to initiate procurement for a comprehensive, fully automated system with full implementation over the Medium-Term Expenditure Framework period. The majority of the expenditure for Programme 1 relates to goods and services supporting the core operational programmes.

Communications

A biennial stakeholder perception survey will be conducted. The purpose of the survey is to gauge stakeholder perceptions, including public perceptions of SAHPRA. This survey will guide SAHPRA in assisting stakeholders with regard to SAHPRA business. Once final, the recommendations will be implemented in conjunction with SAHPRA business units.

Once funding is received, a dedicated Customer Relationship Management (CRM) System will be implemented to address all queries and complaints timeously. All queries and complaints will be directed to the System, and if the query is not too complex, it will be addressed within 24-48 hours. In instances were issues cannot be addressed within this time frame, they must be addressed within 7-14 working days.

Human Resources (HR)

The change management interventions are initiated to embrace the transition period that SAHPRA is undergoing. The interventions will focus on enhancing the communication channels within the organisation. Enhanced communication channels will assist in creating a unified understanding of core processes, procedures and values. The change management interventions will include leadership coaching sessions to empower the leadership team to drive the transitions and related dynamics.

SAHPRA is registered with the Health and Welfare Sector Education and Training Authority and has an obligation to submit the Workplace Skills Plan annually, monitor the implementation of the plan, and submit the progress report accordingly. For the Workplace Skills Plan, SAHPRA will ensure that 80% of the identified training interventions focus on technical skills required for the core business.

The attraction of competent talent is characterised job market dynamics, affordability of required skills, scarcity of skills, etc. SAHPRA continually benchmarks itself with the industry and similar organisations to ensure its finger is always on the pulse in terms of the availability of technical skills.

Information Technology (IT)

SAHPRA plans to embark on an enterprise architecture review process. The purpose of the enterprise architecture is to create a map of IT assets and business processes as well as a set of governing principles that drive the ongoing discussion about the organisation's strategy and how it can be expressed through IT. It is key for SAHPRA to ensure that this architecture exists to provide clarity and alignment between business processes and the IT infrastructure (hardware and software).

SAHPRA will obtain the following five benefits by conducting the enterprise architecture review process:

- Operational benefits through increased efficiency and optimised processes;
- Managerial benefits by reducing complexity and improved compliance with regulations, standards and auditability;
- Strategic benefits by ensuring improved project and organisational goal achievement;
- IT infrastructure benefits through increased interoperability and integration; and
- Organisation benefits through improved information quality and sharing, and documentation supported by positive culture.

1.1.5 Programme Resource Considerations

Resource considerations (R'000)

	2020/21	2021/22	2022/23	2023/24	2024/25	2025/26
	Audited Outcome	Audited Outcome	Budget Estimates	Budget Estimates	Budget Estimates	Budget Estimates
Budget allocated	110 727	115 586	127 736	135 444	140 562	145 706
Economic classification						
Compensation of Employees	55 739	48 773	57 384	63 432	64 695	66 557
Goods and Services	54 988	66 813	70 352	72 012	75 867	79 149

1.2 Programme 2: Health Products Authorisation

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

1.2.1 Sub-programmes

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

1.2.2 Outcomes, Outputs, Output Indicators and Targets

OUTCOMES	OUTPUTS	OUTPUT INDICATORS	AUDITED/ACTUAL PERFORMANCE			ESTIMATED PERFORMANCE 2022/23	NO.	MEDIUM-TERM EXPENDITURE FRAMEWORK TARGETS		
			2019/20	2020/21	2021/22			2023/24	2024/25	2025/26
Efficient and effective regulatory practices maintained (7)	New Chemical Entities (NCEs) applications finalised	Percentage of New Chemical Entities finalised within 400 working days	100%	Out of the 72 New Chemical Entities registered, all 72 (100%) were finalised within 590 days	100% New Chemical Entities finalised within 590 working days Out of 246 New Chemical Entities applications received, 44 (18%) were finalised. Out of the 44 finalised, all 44 (100%) were finalised within 590 working days	80% New Chemical Entities finalised within 490 working days	2.1	80% New Chemical Entities finalised within 400 working days	80% New Chemical Entities finalised within 360 working days	80% New Chemical Entities finalised within 360 working days
	Generic medicines applications finalised	Percentage of generic medicines finalised within 250 working days	-	Out of the 240 generic medicines registered, 131 (55%) were finalised	80% generic medicines finalised within 250 working days Out of 2 075 generic medicine applications	75% generic medicines finalised within 250 working days	2.2	75% generic medicines finalised within 250 working days	85% generic medicines finalised within 250 working days	85% generic medicines finalised within 250 working days

OUTCOMES	OUTPUTS	OUTPUT INDICATORS	AUDITED/ACTUAL PERFORMANCE			ESTIMATED PERFORMANCE 2022/23	NO.	MEDIUM-TERM EXPENDITURE FRAMEWORK TARGETS		
			2019/20	2020/21	2021/22			2023/24	2024/25	2025/26
				within 250 days	received, 184 (9%) were finalised. Out of the 184 finalised, 148 (80%) were finalised within 250 working days					
Global best practices maintained (8)	International Organization for Standardization (ISO) 9001: 2015 certified	International Organization for Standardization 9001: 2015 certification obtained	-	Medicines Regulatory Quality Management system developed and implemented	73% Quality Management System requirements implemented	International Organization for Standardization 9001: 2015 certified	2.3	International Organization for Standardization 9001: 2015 certified	Certification status of the International Organization for Standardization 9001: 2015 maintained	Certification status of the International Organization for Standardization 9001: 2015 maintained

OUTCOMES	OUTPUTS	OUTPUT INDICATORS	AUDITED/ACTUAL PERFORMANCE			ESTIMATED PERFORMANCE 2022/23	NO.	MEDIUM-TERM EXPENDITURE FRAMEWORK TARGETS		
			2019/20	2020/21	2021/22			2023/24	2024/25	2025/26
	World Health Organization global benchmarking conducted	World Health Organization Maturity Level assessed	-	Commenced with preparations to conduct the survey and engagements were held with WHO to provide support to SAHPRA	Based on the World Health Organization provisional assessment report received in November 2021, an Institutional Development Plan was created to address the recommendations	World Health Organization Maturity Level 3 obtained	2.4	World Health Organization Maturity Level 4 self-assessment conducted	World Health Organization Maturity Level 4 obtained	World Health Organization Maturity Level 4 maintained

1.2.3 Output Indicators: Annual and Quarterly Targets

OUTPUT INDICATORS	NO.	2023/24 ANNUAL TARGETS	1ST QUARTER TARGETS (Apr - Jun)	2ND QUARTER TARGETS (Jul - Sep)	3RD QUARTER TARGETS (Oct - Dec)	4TH QUARTER TARGETS (Jan - Mar)
Percentage of New Chemical Entities finalised within 400 working days	2.1	80% New Chemical Entities finalised within 400 working days	80% New Chemical Entities finalised within 400 working days	80% New Chemical Entities finalised within 400 working days	80% New Chemical Entities finalised within 400 working days	80% New Chemical Entities finalised within 400 working days
Percentage of generic medicines finalised within 250 working days	2.2	75% generic medicines finalised within 250 working days	75% generic medicines finalised within 250 working days	75% generic medicines finalised within 250 working days	75% generic medicines finalised within 250 working days	75% generic medicines finalised within 250 working days
International Organization for Standardization 9001: 2015 certification obtained	2.3	International Organization for Standardization 9001: 2015 certified	100% closure of Quality Management System internal audit non-conformances	Stage 1 certification audit conducted	Final certification audit conducted	International Organization for Standardization 9001: 2015 certified
World Health Organization Maturity Level assessed	2.4	World Health Organization Maturity Level 4 self-assessment conducted	50% World Health Organization Maturity Level 3 recommendations implemented	100% World Health Organization Maturity Level 3 recommendations implemented	World Health Organization Maturity Level 4 project plan approved by the Executive Committee	World Health Organization Maturity Level 4 self-assessment conducted

1.2.4 Explanation of Planned Performance over the Medium-Term Period

Business-As-Usual (BAU)

BAU commenced the implementation of priority reviews during the 4th quarter of the 2021/22 financial year. This follows the approval of the Policy on Priority Review Pathways by the SAHPRA Board in the preceding quarter. The purpose of this policy is to make provision for priority review or registration with conditions, and for the assessment and registration of medicines that treat serious diseases of major public interest. This policy is intended to provide priority review to facilitate greater accessibly and availability of medicines:

- That address an unmet clinical need in the South African Market (novel or innovative medicine or NCEs);
- That show a major therapeutic advantage in safety and efficacy compared to existing treatment options;
- For life-threatening or seriously debilitating conditions;
- For public health and animal health emergencies;
- For a limited target disease for a patient population (orphan disease);
- In the event of national priorities guided by the NDoH; or
- Where the security of supplies is a concern (guided by the NDoH needs and the DALRRD).

This policy applies to NCEs, new biological medicines, interchangeable generic medicines, and biosimilars for both new registrations and their lifecycle management.

SAHPRA envisages that the benefits of the implementation of the policy on priority reviews will result in improved review timelines for priority medicines.

Quality Management System

SAHPRA is committed to implementing a Quality Management System in order to coordinate and direct the organisation's activities and adequately execute its regulatory mandate. In implementing Quality Management System, SAHPRA expects to continually improve the efficiency and effectiveness of its processes and, therefore, meet and exceed our stakeholder requirements. The key focus areas will be on institutionalising a quality culture throughout the organisation and obtaining ISO 9001: 2015 certification.

WHO Maturity Level

SAHPRA intends to reach the highest Maturity Level (ML4) based on the WHO global benchmarking requirements and become a WHO-listed authority. Obtaining ML4 will indicate that SAHPRA is operating at an advanced level of performance and continually improving. The focus for the financial year will be on implementing the ML4 requirements and ensuring that they are well-embedded within the organisation.

1.2.5 Programme Resource Considerations

Resource considerations (R'000)

	2020/21	2021/22	2022/23	2023/24	2024/25	2025/26
	Audited Outcome	Audited Outcome	Budget Estimates	Budget Estimates	Budget Estimates	Budget Estimates
Budget allocated	34 223	73 660	51 615	36 268	38 078	39 978
Economic classification						
Compensation of Employees	13 460	21 341	27 277	35 561	37 339	39 206
Goods and Services	20 763	52 319	24 338	707	739	772

1.3 Programme 3: Inspectorate and Regulatory Compliance

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

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

1.3.1 Sub-programmes

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

1.3.2 Outcomes, Outputs, Output Indicators and Targets

OUTCOMES	OUTPUTS	OUTPUT INDICATORS	AUDITED/ACTUAL PERFORMANCE			ESTIMATED PERFORMANCE 2022/23	NO.	MEDIUM-TERM EXPENDITURE FRAMEWORK TARGETS		
			2019/20	2020/21	2021/22			2023/24	2024/25	2025/26
Efficient and effective regulatory practices maintained (7)	New Good Manufacturing Practice and Good Warehouse Practice related licences finalised	Percentage of new Good Manufacturing Practice and Good Warehouse Practice related licences finalised within 125 working days	77%	Out of the 39 new Good Manufacturing Practice licence applications received, 29 (74%) new Good Manufacturing Practice licences were issued Out of the 29 new Good Manufacturing Practice licences issued, 17 (59%) were issued within 125 working days	42% new Good Manufacturing Practice and Good Warehouse Practice related licences finalised within 125 working days Out of 64 new Good Manufacturing Practice and Good Warehouse Practice related licence applications received, 31 (48%) were finalised. Out of the 31 finalised, 13 (42%) were	60% new Good Manufacturing Practice and Good Warehouse Practice related licences finalised within 125 working days	3.1	70% new Good Manufacturing Practice and Good Warehouse Practice related licences finalised within 125 working days	80% new Good Manufacturing Practice and Good Warehouse Practice related licences finalised within 125 working days	80% new Good Manufacturing Practice and Good Warehouse Practice related licences finalised within 125 working days

OUTCOMES	OUTPUTS	OUTPUT INDICATORS	AUDITED/ACTUAL PERFORMANCE			ESTIMATED PERFORMANCE 2022/23	NO.	MEDIUM-TERM EXPENDITURE FRAMEWORK TARGETS		
			2019/20	2020/21	2021/22			2023/24	2024/25	2025/26
					finalised within 125 working days					
	Permits finalised	Percentage of permits finalised within 20 working days	-	-	71% permits finalised within 20 working days Out of 4 553 permit applications received, 4 474 (98%) were finalised. Out of the 4 474 finalised, 3 186 (71%) were finalised within 20 working days	70% permits finalised within 20 working days	3.2	80% permits finalised within 20 working days	85% permits finalised within 20 working days	85% permits finalised within 20 working days

OUTCOMES	OUTPUTS	OUTPUT INDICATORS	AUDITED/ACTUAL PERFORMANCE			ESTIMATED PERFORMANCE 2022/23	NO.	MEDIUM-TERM EXPENDITURE FRAMEWORK TARGETS		
			2019/20	2020/21	2021/22			2023/24	2024/25	2025/26
	Regulatory compliance investigation reports	Percentage of regulatory compliance investigation reports produced within 30 working days	-	Out of the 101 health product quality complaints received, 84 (83%) were investigated and reports produced	72% health product quality complaints reports produced within 30 working days Out of 130 health product quality complaints received, 93 (72%) reports were produced within 30 working days	70% regulatory compliance investigation reports produced within 30 working days	3.3	80% regulatory compliance investigation reports produced within 30 working days	85% regulatory compliance investigation reports produced within 30 working days	85% regulatory compliance investigation reports produced within 30 working days

1.3.3 Output Indicators: Annual and Quarterly Targets

OUTPUT INDICATORS	NO.	2023/24 ANNUAL TARGETS	1ST QUARTER TARGETS (Apr - Jun)	2ND QUARTER TARGETS (Jul - Sep)	3RD QUARTER TARGETS (Oct - Dec)	4TH QUARTER TARGETS (Jan - Mar)
Percentage of new Good Manufacturing Practice and Good Warehouse Practice related licences finalised within 125 working days	3.1	70% new Good Manufacturing Practice and Good Warehouse Practice related licences finalised within 125 working days	70% new Good Manufacturing Practice and Good Warehouse Practice related licences finalised within 125 working days	70% new Good Manufacturing Practice and Good Warehouse Practice related licences finalised within 125 working days	70% new Good Manufacturing Practice and Good Warehouse Practice related licences finalised within 125 working days	70% new Good Manufacturing Practice and Good Warehouse Practice related licences finalised within 125 working days
Percentage of permits finalised within 20 working days	3.2	80% permits finalised within 20 working days	80% permits finalised within 20 working days	80% permits finalised within 20 working days	80% permits finalised within 20 working days	80% permits finalised within 20 working days
Percentage of regulatory compliance investigation reports produced within 30 working days	3.3	80% regulatory compliance investigation reports produced within 30 working days	80% regulatory compliance investigation reports produced within 30 working days	80% regulatory compliance investigation reports produced within 30 working days	80% regulatory compliance investigation reports produced within 30 working days	80% regulatory compliance investigation reports produced within 30 working days

1.3.4 Explanation of Planned Performance over the Medium-Term Period

Licences, permits, and the investigation of quality complaints are mechanisms to exercise regulatory control in order to attain and maintain the desired levels of industry compliance in the quest to ensure the safety of medicines for all those who live in South Africa. This is one of the fundamentals necessary for SAHPRA to achieve its organisational impact.

As GMP- and GWP-related licences are only issued to South African manufacturers, importers and exporters, and wholesalers, the focus on processing and finalising new applications contributes to the increase in local pharmaceutical industry economic activity. SAHPRA will continue to monitor the performance in terms of finalising new applications for GMP- and GWP-related licences.

With the risk of illicit, substandard or falsified medical products, the timeous investigation of complaints related to regulatory compliance ensures that any detected risk is resolved and persons involved are held accountable.

Ensuring that narcotics and psychotropics entering and leaving the country are monitored is crucial to the control required by the International Narcotics Control Board. The timeous processing of permits for these substances also contributes to the economy and the availability of medicines. SAHPRA will monitor the performance of processing these permits within target timelines.

The performance targets are planned to increase over the medium term, as efficiencies are driven by improving internal processes and adequate resource use.

1.3.5 Programme Resource Considerations

Resource considerations (R'000)

	2020/21	2021/22	2022/23	2023/24	2024/25	2025/26
	Audited Outcome	Audited Outcome	Budget Estimates	Budget Estimates	Budget Estimates	Budget Estimates
Budget allocated	35 696	35 370	37 314	52 769	55 368	58 053
Economic classification						
Compensation of Employees	26 460	31 156	29 757	42 825	44 966	47 172
Goods and Services	9 236	4 214	7 557	9 944	10 402	10 881

1.4 Programme 4: Clinical and Pharmaceutical Evaluation

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

1.4.1 Sub-programmes

Sub-Programme	Purpose
Clinical Evaluation	To evaluate the safety and efficacy of orthodox medicines.
Clinical Trials	To evaluate clinical trial applications of orthodox medicines, complementary medicines, and medical devices to ensure that trials conducted are scientifically sound, in accordance with the South African Good Clinical Practice guidelines and to ensure the safety and protection of the rights of patients.
Pharmaceutical Evaluations	To perform pharmaceutical and analytical evaluations of new and registered medicines inclusive of clinical aspects of veterinary medicines and biological.
Authorisation of the Sale of Unregistered Medicines	To conduct an abbreviated evaluation of applications to authorise the sale of unregistered medicines based on quality, safety and efficacy (QSE) standards.
Vigilance and Post-Marketing Surveillance	To establish a regimen of vigilance for the collection and evaluation of information relevant to the benefit-to-risk balance of medicines and medical devices on the South African market, the continuous monitoring of the safety profiles of these products, and taking appropriate action where necessary.
Complementary and Alternative Medicines	To perform evaluations of new and registered complementary medicines in order to determine their safety, quality and efficacy and to register and/or regulate them for use where applicable.
Veterinary Medicines	To evaluate the safety, efficacy and quality of veterinary medicines.

1.4.2 Outcomes, Outputs, Output Indicators and Targets

OUTCOMES	OUTPUTS	OUTPUT INDICATORS	AUDITED/ACTUAL PERFORMANCE			ESTIMATED PERFORMANCE 2022/23	NO.	MEDIUM-TERM EXPENDITURE FRAMEWORK TARGETS		
			2019/20	2020/21	2021/22			2023/24	2024/25	2025/26
Efficient and effective regulatory practices maintained (7)	Applications for the sale of unregistered Category A (human) medicines finalised	Percentage applications for the sale of unregistered Category A (human) medicines finalised within 3 working days	96%	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	57% applications for the sale of unregistered Category A (human) medicines finalised within 24 working hours Out of the 16 435 applications received, 14 780 (90%) were finalised, of which 9 385 (57%) were finalised 24 working hours	85% applications for the sale of unregistered Category A (human) medicines finalised within 3 working days	4.1	90% applications for the sale of unregistered Category A (human) medicines finalised within 3 working days	90% applications for the sale of unregistered Category A (human) medicines finalised within 3 working days	90% applications for the sale of unregistered Category A (human) medicines finalised within 3 working days

OUTCOMES	OUTPUTS	OUTPUT INDICATORS	AUDITED/ACTUAL PERFORMANCE			ESTIMATED PERFORMANCE 2022/23	NO.	MEDIUM-TERM EXPENDITURE FRAMEWORK TARGETS		
			2019/20	2020/21	2021/22			2023/24	2024/25	2025/26
	Human clinical trial applications finalised	Percentage of human clinical trial applications finalised within 80 working days	100%	Out of the 233 human clinical trial applications received, 203 (87%) were finalised Out of the 203 applications finalised, 194 (96%) were finalised within 120 working days	95% human clinical trial applications finalised within 90 working days Out of 274 human clinical trial applications received, 248 (91%) were finalised. Out of the 248 finalised, 235 (95%) were finalised within 90 working days	80% human clinical trial applications finalised within 90 working days	4.2	80% human clinical trial applications finalised within 80 working days	80% human clinical trial applications finalised within 60 working days	80% human clinical trial applications finalised within 60 working days

OUTCOMES	OUTPUTS	OUTPUT INDICATORS	AUDITED/ACTUAL PERFORMANCE			ESTIMATED PERFORMANCE 2022/23	NO.	MEDIUM-TERM EXPENDITURE FRAMEWORK TARGETS		
			2019/20	2020/21	2021/22			2023/24	2024/25	2025/26
	Health product safety signals issued	Percentage of reports on health product safety signals issued within 40 working days	4 quarterly reports	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	28% reports on health product safety signals issued within 40 working days Out of the 235 applications received, 95 (40%) reports were issued, of which 66 (28%) were issued within 40 working days	70% reports on health product safety signals issued within 40 working days	4.3	70% reports on health product safety signals issued within 40 working days	70% reports on health product safety signals issued within 40 working days	70% reports on health product safety signals issued within 40 working days
	Number of safety awareness campaigns held	Number of safety awareness webinars held	-	-	13 safety awareness webinars held	4 safety awareness webinars held	4.4	6 safety awareness campaigns held	8 safety awareness campaigns held	8 safety awareness campaigns held

OUTCOMES	OUTPUTS	OUTPUT INDICATORS	AUDITED/ACTUAL PERFORMANCE			ESTIMATED PERFORMANCE 2022/23	NO.	MEDIUM-TERM EXPENDITURE FRAMEWORK TARGETS		
			2019/20	2020/21	2021/22			2023/24	2024/25	2025/26
	Lot release requests finalised	Percentage of lot release requests finalised within 50 working days	-	-	-	95% lot release requests finalised within 30 working days	4.5	95% lot release requests finalised within 50 working days	95% lot release requests finalised within 50 working days	95% lot release requests finalised within 50 working days

1.4.3 Output Indicators: Annual and Quarterly Targets

OUTPUT INDICATORS	NO.	2023/24 ANNUAL TARGETS	1ST QUARTER TARGETS (Apr – Jun)	2ND QUARTER TARGETS (Jul – Sep)	3RD QUARTER TARGETS (Oct – Dec)	4TH QUARTER TARGETS (Jan – Mar)
Percentage applications for the sale of unregistered Category A (human) medicines finalised within 3 working days	4.1	90% applications for the sale of unregistered Category A (human) medicines finalised within 3 working days	90% applications for the sale of unregistered Category A (human) medicines finalised within 3 working days	90% applications for the sale of unregistered Category A (human) medicines finalised within 3 working days	90% applications for the sale of unregistered Category A (human) medicines finalised within 3 working days	90% applications for the sale of unregistered Category A (human) medicines finalised within 3 working days
Percentage of human clinical trial applications finalised within 80 working days	4.2	80% human clinical trial applications finalised within 80 working days	80% human clinical trial applications finalised within 80 working days	80% human clinical trial applications finalised within 80 working days	80% human clinical trial applications finalised within 80 working days	80% human clinical trial applications finalised within 80 working days
Percentage of reports on health product safety signals issued within 40 working days	4.3	70% reports on health product safety signals issued within 40 working days	70% reports on health product safety signals issued within 40 working days	70% reports on health product safety signals issued within 40 working days	70% reports on health product safety signals issued within 40 working days	70% reports on health product safety signals issued within 40 working days
Number of safety awareness campaigns held	4.4	6 safety awareness campaigns held	2 safety awareness campaigns held	2 safety awareness campaigns held	1 safety awareness campaign held	1 safety awareness campaign held
Percentage of lot release requests finalised within 50 working days	4.5	95% lot release requests finalised within 50 working days	95% lot release requests finalised within 50 working days	95% lot release requests finalised within 50 working days	95% lot release requests finalised within 50 working days	95% lot release requests finalised within 50 working days

1.4.4 Explanation of Planned Performance over the Medium-Term Period

Sale of Unregistered Category A (Human) Medicines

SAHPRA's mandate includes ensuring timely access to safe, efficacious and quality health products for the South African public. Some of these health products may not be registered in the Republic but are available in other markets. Therefore, the Medicines Act provides for the sale of unregistered medicines and other health products on application to SAHPRA for unmet medical needs, where a registered alternative is either not available or does not meet the identified medical need. This is an important legislated public health intervention that has to ensure prompt access to life-saving health products where these would otherwise not be available to prevent disease progression and complications.

This intervention ensures that our response to COVID-19 and other unmet medical needs will be agile and continue to promote access to medicines that would otherwise require registration before being made available to the public.

Human Clinical Trials

SAHPRA's mandate includes oversight of human clinical trials conducted within the Republic. This objective entails ensuring and facilitating efficient processing of clinical trial protocol applications and approving the conduct of clinical trials to enable timely access to health research and development within an environment that guarantees the safety of clinical trial participants.

This capacity to monitor and control the conduct of clinical trials will allow SAHPRA to continue to ensure speedy but thorough evaluation of protocols intended for COVID-19 therapeutic interventions. This will also allow us to use the lessons learnt and apply the same operational agility to future emergency pandemic situations.

Health Product Safety Signals

SAHPRA's mandate includes monitoring the safety, efficacy, and quality of health products distributed and sold in the Republic. Such monitoring should be comprehensive, and the response to any signals of declining safety and lack of clinical efficacy should be timely and evidence-based. To that end, the Programme has endeavoured to be highly responsive to such signals but, due to a lack of resources, only the most serious and important public health impact signals have been concluded within the target timeframe of 70% within 40 working days.

Capacities built in the past year will allow SAHPRA to effectively, efficiently, and comprehensively monitor the safety of all and any pharmaceutical and vaccine interventions that may be needed in future should a similar situation to COVID-19 arise.

Health Product Safety Awareness Campaigns

Internationally, the rate of Adverse Drug Reaction (ADR) reporting is not more than 5%. The same applies to South Africa. One of the reasons is the lack of information, education and awareness about the need to report ADRs and continuously monitor the safety and efficacy of medicines over the life of the product. Frequent outreach initiatives, such as public and targeted campaigns, will improve awareness.

During the past year, heightened awareness was created around the importance of reporting ADRs and adverse events following immunisation (AEFIs) due to the sudden and devastating impact of the COVID-19 pandemic. Lessons learnt will be used going forward and help to maintain the outreach momentum created.

Lot Release

Lot release is the process of evaluating each individual lot of a registered vaccine in South Africa before giving approval for its release into the market.

Currently, the processing of lot release by SAHPRA involves the review and independent testing of lot summary protocols, with the recognition of tests (acceptance of lot release certificates) from the responsible National Regulatory Authorities or National Control Laboratories that SAHPRA aligns with.

To date, lot release has been performed on all vaccines for use by the South African public, and hence regulatory oversight on vaccines by SAHPRA is ensured.

1.4.5 Programme Resource Considerations

Resource considerations (R'000)

	2020/21	2021/22	2022/23	2023/24	2024/25	2025/26
	Audited Outcome	Audited Outcome	Budget Estimates	Budget Estimates	Budget Estimates	Budget Estimates
Budget allocated	73 666	80 402	100 293	125 472	131 537	135 397
Economic classification						
Compensation of Employees	52 638	50 594	66 980	82 456	86 579	88 306
Goods and Services	21 028	29 808	33 313	43 016	44 958	47 091

1.5 Programme 5: Medical Devices and Radiation Control

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

1.5.1 Sub-programmes

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

1.5.2 Outcomes, Outputs, Output Indicators and Targets

OUTCOMES	OUTPUTS	OUTPUT INDICATORS	AUDITED/ACTUAL PERFORMANCE			ESTIMATED PERFORMANCE 2022/23	NO.	MEDIUM-TERM EXPENDITURE FRAMEWORK TARGETS		
			2019/20	2020/21	2021/22			2023/24	2024/25	2025/26
Efficient and effective regulatory practices maintained (7)	Medical device establishment licence applications finalised	Percentage of medical device establishment licence applications finalised within 90 working days	99%	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	76% medical device establishment licence applications finalised within 90 days Out of 1 105 medical device establishment licence applications received, 804 (73%) were finalised. Out of the 804 finalised, 613 (76%) were finalised within 90 working days	70% medical device establishment licence applications finalised within 90 working days	5.1	70% medical device establishment licence applications finalised within 90 working days	80% medical device establishment licence applications finalised within 90 working days	80% medical device establishment licence applications finalised within 90 working days

OUTCOMES	OUTPUTS	OUTPUT INDICATORS	AUDITED/ACTUAL PERFORMANCE			ESTIMATED PERFORMANCE 2022/23	NO.	MEDIUM-TERM EXPENDITURE FRAMEWORK TARGETS		
			2019/20	2020/21	2021/22			2023/24	2024/25	2025/26
	Medical device registration regulations implemented	Notice of medical device products published	The medical device system has not been implemented. Regulations, fees schedule, guidelines, and Standard Operating Procedures to be implemented	The draft regulations, which will form part of the medical registration framework, were re-submitted to the State Law Adviser for review in September 2020	19 guidelines to support the medical device registration regulations were drafted	7 guidelines to support the medical device registration regulations were published	5.2	Call-up notice of pilot Class D (high-risk) medical device products published	Call-up of Class D (high risk)	Call-up of Class C
	Radionuclide authorities (licences) finalised	Percentage of applications for radionuclide authorities (licences) finalised within 30 working days	99%	Out of the 2 719 new application licences for ionising radiation-emitting devices and radioactive nuclides authorities received, 2	72% applications for radionuclide authorities finalised within 30 working days Out of 4 740 applications for radionuclide authorities received,	50% applications for radionuclide authorities finalised within 30 working days	5.3	60% applications for radionuclide authorities (licences) finalised within 30 working days	70% applications for radionuclide authorities (licences) finalised within 30 working days	70% applications for radionuclide authorities (licences) finalised within 30 working days

OUTCOMES	OUTPUTS	OUTPUT INDICATORS	AUDITED/ACTUAL PERFORMANCE			ESTIMATED PERFORMANCE 2022/23	NO.	MEDIUM-TERM EXPENDITURE FRAMEWORK TARGETS		
			2019/20	2020/21	2021/22			2023/24	2024/25	2025/26
				519 (92%) were issued Out of the 2 519 issued, 2 302 (91%) were issued within 30 working days	3 803 (80%) were finalised. Out of the 3 803 finalised, 2 747 (72%) were finalised within 30 working day					
	Licence applications for listed-electronic products finalised	Percentage of licence applications for listed-electronic products finalised within 30 working days	-	-	99% licence applications for listed-electronic products finalised within 30 working days Out of 944 licence applications for listed-electronic products received, 934 (99%) were finalised. Out of	70% licence applications for listed-electronic products finalised within 30 working days	5.4	90% licence applications for listed-electronic products finalised within 30 working days	90% licence applications for listed-electronic products finalised within 30 working days	90% licence applications for listed-electronic products finalised within 30 working days

OUTCOMES	OUTPUTS	OUTPUT INDICATORS	AUDITED/ACTUAL PERFORMANCE			ESTIMATED PERFORMANCE 2022/23	NO.	MEDIUM-TERM EXPENDITURE FRAMEWORK TARGETS		
			2019/20	2020/21	2021/22			2023/24	2024/25	2025/26
					the 934 finalised, 924 (99%) were finalised within 30 working days					
	Guidelines produced	Number of approved guidelines for the management of medical device vigilance	-	-	-	-	5.5	3 approved guidelines for the management of medical device vigilance	Online system for management of medical devices/*in vitro* diagnostics vigilance implemented	4 safety awareness webinars held

1.5.3 Output Indicators: Annual and Quarterly Targets

OUTPUT INDICATORS	NO.	2023/24 ANNUAL TARGETS	1ST QUARTER TARGETS (Apr – Jun)	2ND QUARTER TARGETS (Jul – Sep)	3RD QUARTER TARGETS (Oct – Dec)	4TH QUARTER TARGETS (Jan – Mar)
Percentage of medical device establishment licence applications finalised within 90 working days	5.1	70% medical device establishment licence applications finalised within 90 working days	70% medical device establishment licence applications finalised within 90 working days	70% medical device establishment licence applications finalised within 90 working days	70% medical device establishment licence applications finalised within 90 working days	70% medical device establishment licence applications finalised within 90 working days
Notice of medical device products published	5.2	Call-up notice of pilot Class D (high risk) medical device products published	-	-	Call-up notice of pilot Class D (high-risk) medical device products approved by the Executive Committee	Call-up notice of pilot Class D (high-risk) medical device products published
Percentage of applications for radionuclide authorities (licences) finalised within 30 working days	5.3	60% applications for radionuclide authorities (licences) finalised within 30 working days	60% applications for radionuclide authorities (licences) finalised within 30 working days	60% applications for radionuclide authorities (licences) finalised within 30 working days	60% applications for radionuclide authorities (licences) finalised within 30 working days	60% applications for radionuclide authorities (licences) finalised within 30 working days
Percentage of licence applications for listed-electronic products finalised within 30 working days	5.4	90% licence applications for listed-electronic products finalised within 30 working days	90% licence applications for listed-electronic products finalised within 30 working days	90% licence applications for listed-electronic products finalised within 30 working days	90% licence applications for listed-electronic products finalised within 30 working days	90% licence applications for listed-electronic products finalised within 30 working days
Number of approved guidelines for the management of medical device vigilance	5.5	3 approved guidelines for the management of medical device vigilance	3 draft medical device guidelines developed	3 draft medical device guidelines published for public comments	3 guidelines for the management of medical device vigilance approved by the Executive Committee	3 medical device vigilance guidelines published

1.5.4 Explanation of Planned Performance over the Medium-Term Period

Medical Device Establishment Licences

The focus over the medium term will be on improving management oversight of applications and fees received. The recent appointment of a manager will assist with leadership, control, monitoring, and implementation of processes towards improved service delivery and response time.

The reviews and approvals of medical device establishment licences are mechanisms implemented to exercise regulatory quality control over the manufacturers, distributors and wholesalers of medical devices to ensure products of the intended quality, safety and performance are either manufactured or imported into South Africa, and to attain and maintain the desired levels of industry compliance. Assessing the number of licence applications finalised in a particular year is a transparent indicator and true reflector of the level of compliance of medical device establishments in South Africa. The finalisation of the digitalised system for receiving licence applications is imperative to improving the operational efficiency and effectiveness of the unit.

Internal training of current human resources is important in ensuring compliance and improvement in daily operations.

Medical Device Registration Regulations

The publication and implementation of the amended medical device regulations enable the facilitation and development of the medical device registration pathways. This, in turn, enables the publication of the call-up for the registration of medical device notices. In addition to the licensing mechanism (mentioned above), the registration of medical devices allows for additional regulatory control to ensure the quality, safety and performance of medical devices on the South African market. The planned performance targets are defined to increase over the medium term, as efficiencies are driven by improving internal processes and adequate resource use. Timely filling of vacant technical positions will assist with delivering the mandate of SAHPRA. The appointment of the manager will ensure timely delivery of the medium-term target set.

Radiation Control

Currently, SAHPRA issues licences for medical device establishments to importers, manufacturers, distributors, and wholesalers. The scope of work for SAHPRA includes the regulation of all applications of radiation protection used outside the nuclear fuel cycle in South Africa. This was done by the inclusion of Group III and Group IV hazardous substances (as defined in the Hazardous

Substances Act) into the definition of a medical device in the Medicines Act, as amended, in 2017. These include electromedical devices (Group III) and radionuclides and electronic generators of ionising radiation (Group IV). Regulation of these products is provided for by both the Medicines Act, as amended, and the Hazardous Substances Act and its regulations. SAHPRA will continue to maintain the highest levels of protection of radiation workers, patients, the public, and the environment from the possible adverse effects of ionising radiation without limiting its beneficial uses.

There has been ongoing engagement between SAHPRA and NNR on defining a roadmap related to coregulation of the Group III and Group IV products. The discussion points will lead to further clarified roles, responsibilities and mandates for SAHPRA and NNR. The preferred model would be to retain the functions that have health and medical applications within SAHPRA and implement a coregulation mechanism with the NNR. An appointed working group (chaired by the CEOs of NNR and SAHPRA) was established to, among others, develop a framework for coregulation between the two entities and share recommendations regarding the coregulation framework.

The newly appointed Radiation Control Manager, Deputy Managers, and technical reviewers will assist in leading the unit to ensure that the planned target is delivered and the mandate of SAHPRA is implemented. Training (internal and external) of employees must be planned and implemented to ensure improved operational efficiency of the Radiation Control unit.

1.5.5 Programme Resource Considerations

Resource considerations (R'000)

	2020/21	2021/22	2022/23	2023/24	2024/25	2025/26
	Audited Outcome	Audited Outcome	Budget Estimates	Budget Estimates	Budget Estimates	Budget Estimates
Budget allocated	38 128	34 290	32 399	44 843	47 069	49 276
Economic classification						
Compensation of Employees	16 129	30 086	29 168	40 733	42 770	44 780
Goods and Services	21 999	4 204	3 231	4 110	4 299	4 496

2. UPDATED KEY RISKS AND MITIGATION FROM THE STRATEGIC PLAN

OUTCOMES	KEY RISKS	RISK MITIGATIONS
Effective compliance, financial and performance management (1)	Inadequate financial governance systems and processes*	Ongoing financial management training and workshop sessions
Financial sustainability achieved (2)	Inability to sustain financial viability for SAHPRA	Source single entry point system (implementation of customer service portal)
		Follow up on long outstanding payments to ensure timeous invoicing of industry
Responsive to stakeholder needs (3)	Perceived negative perceptions about SAHPRA as a result of receiving external funding and non-alignment with stakeholder needs	Formalisation of strategic partnership with stakeholders (SLA or MoU)
		Assess stakeholder awareness and perceptions, and act on recommendations
A positive and enabling working culture created (4)	Inadequate monitoring systems to monitor organisational performance*	Development of Performance Information management system in line with the Information Technology Digitization Strategy
Attract and retain talent (5)	Difficulty in attracting and retaining talent	Develop and implement roadmap for capacity-building programme, including succession planning
Digital transformation (6)	Inability to invest in Information and Communication Technology infrastructure to enable automation and integration of SAHPRA processes	Secure Information and Communication Technology capacity and resources to implement end-to-end information technology system
Efficient and effective regulatory practices maintained (7)	Increasing backlog on new applications – Business-As-Usual	Continuous improvement of application process to improve turnaround time based on stakeholder feedback Develop capacity to deal with Business-As-Usual demands
Other Strategic Risks		
Governance risks	Non-compliance with legislation, policies, procedures, and standards	Continuous monitoring of compliance
	Fraud, theft and corruption	Continuous monitoring of fraud and corruption

OUTCOMES	KEY RISKS	RISK MITIGATIONS
External Risks	Non-alignment of the National Priorities as a result of an outdated Act and poorly streamlined processes among entities with similar mandates	Review of the Medicines Act
	Increased global pandemic occurrences or environmental threats	Continuous monitoring and management of pandemics and threats Implementation of Business Continuity Policy and continuous development and review of processes
	Cyber security	Continuous monitoring and management of threats
	Disruption of SAHPRA activities due to the unstable supply of utilities (load-shedding and water-shedding)	Implementation of the hybrid model
	Labour unrest	Continuous engagements with staff and labour
	Litigation against SAHPRA due to an outdated Act	Review of the Medicines Act to minimise gaps that expose SAHPRA to litigation Regular update of policies, processes and guidelines
	Ineffective execution of SAHPRA mandate due to NDoH and other stakeholder inefficiencies	Strengthen communication channels between SAHPRA and NDoH

**These risks are managed at an Operational level (Corporate Risk Register).*

3. PUBLIC ENTITIES

Not applicable.

4. INFRASTRUCTURE PROJECTS

Not applicable.

5. PUBLIC-PRIVATE PARTNERSHIPS

Not applicable.

PART D: TECHNICAL INDICATOR DESCRIPTIONS

1. PROGRAMME 1: LEADERSHIP AND SUPPORT

1.1 Indicator Title	Unqualified audit opinion obtained on the annual financial statements
Definition	The results of the audits that are undertaken annually by the Auditor-General based on the assessment of performance during the preceding year, which factors in both financial performance and performance against predetermined objectives or non-financial performance, as prescribed by the Public Finance Management Act (PFMA), indicating that the financial statements present fairly, in all material respects, the financial position, performance, and cashflows for the year-end
Source of Data	Report of the Auditor-General of South Africa
Method of Calculation or Assessment	Report of the Auditor-General of South Africa based on the previous financial year's performance
Means of Verification	Auditor-General's Report
Assumptions	• Desired performance to improve audit outcomes will be supported by risk management issues being effectively institutionalised and introducing rigorous processes necessary to produce a positive audit outcome • No legislative or policy changes to the current auditing plans and cycles
Disaggregation of Beneficiaries (where applicable)	Not applicable
Spatial Transformation (where applicable)	Not applicable
Calculation Type	Non-cumulative
Reporting Cycle	Quarter 2
Desired Performance	To first attain and then maintain an unqualified audit outcome annually over the MTSF period, evidenced by the external or Auditor-General's audit opinion available in Quarter 2, based on the previous financial year's performance
Indicator Responsibility	Chief Financial Officer

1.2 Indicator Title	Current assets ≥ than current liabilities
Definition	A current ratio equal to or greater than 1 by the financial year-end
Source of Data	Statement of financial position
Method of Calculation or Assessment	Total current assets divided by total current liabilities
Means of Verification	Finance quarterly reports and annual financial statements
Assumptions	• Revenue budgeted for will be collected for the financial year • Expenditure incurred will be in line with expectations budgeted for
Disaggregation of Beneficiaries (where applicable)	Not applicable
Spatial Transformation (where applicable)	Not applicable
Calculation Type	Non-cumulative
Reporting Cycle	Quarterly
Desired Performance	Indication whether SAHPRA has sufficient cash on hand to pay current liabilities and is financially sustainable
Indicator Responsibility	Chief Financial Officer

1.3 Indicator Title	Progress report on the implementation plan produced
Definition	Stakeholder perception survey done and recommendations defined, addressed and monitored
Source of Data	Stakeholder perception survey and implementation plan
Method of Calculation or Assessment	Progress report on the implementation plan of the stakeholder perception survey
Means of Verification	• Stakeholder perception survey report • Implementation plan • Progress report
Assumptions	• Functional tracking checker • Managers are responding to the complaints sent via the web-based tracking tool
Disaggregation of Beneficiaries (where applicable)	Not applicable
Spatial Transformation (where applicable)	Not applicable
Calculation Type	Non-cumulative
Reporting Cycle	Quarterly
Desired Performance	All recommendations from the survey implemented
Indicator Responsibility	Manager: Communications

1.4 Indicator Title	Progress report on the implementation plan produced
Definition	Measurement of SAHPRA employees' satisfaction and engagement
Source of Data	Employee survey and implementation plan
Method of Calculation or Assessment	Progress report on the implementation plan of the staff satisfaction survey
Means of Verification	• Staff survey report • Implementation plan • Progress report
Assumptions	At least 60% of employees will participate in the survey
Disaggregation of Beneficiaries (where applicable)	Not applicable
Spatial Transformation (where applicable)	Not applicable
Calculation Type	Non-cumulative
Reporting Cycle	Quarterly
Desired Performance	75% of employees are satisfied with SAHPRA
Indicator Responsibility	Executive Manager: Human Resources

1.5 Indicator Title	Percentage of learning and development initiatives implemented
Definition	Training received by staff members based on the approved Individual Development Plan and Workplace Skills Plan
Source of Data	Attendance registers, certificates, and course programmes
Method of Calculation or Assessment	Numerator: Number of training initiatives in the Plan implemented ÷ Denominator: Number of training initiatives planned x 100
Means of Verification	• Workplace Skills Plan • Quarterly training reports
Assumptions	The business units will allow attendance of training sessions
Disaggregation of Beneficiaries (where applicable)	Not applicable
Spatial Transformation (where applicable)	Not applicable
Calculation Type	Cumulative (year-to-date)
Reporting Cycle	Quarterly
Desired Performance	Employees are attending training as planned. Substantially improved performance is expected after training towards a high-performing organisational culture
Indicator Responsibility	Executive Manager: Human Resources

1.6 Indicator Title	Percentage of budgeted positions filled
Definition	Vacant positions identified for relevant recruitment phase, with approved budget, are filled before commencement of the next phase in the following financial year
Source of Data	Staff establishment, published advertisements, and new contracts with the date of onboarding
Method of Calculation or Assessment	Numerator: Number of positions filled ÷ Denominator: Number of budgeted positions x 100 *Based on the assumption that the position will be filled. Permanent employees only
Means of Verification	• Human resource documents in the Personnel File • New employee form (signed) • Approved budgeted positions
Assumptions	• Executive Manager: Human Resources will be appointed before the beginning of the 2021/22 financial year • Recruitment process is supported by organised labour • Availability of funds
Disaggregation of Beneficiaries (where applicable)	Targets for female staff must align with targets set in the HR Recruitment and Selection Policy
Spatial Transformation (where applicable)	Not applicable
Calculation Type	Cumulative (year-to-date)
Reporting Cycle	Quarterly
Desired Performance	SAHPRA establishes a competent workforce through timeous recruitment against the phased plan
Indicator Responsibility	Executive Manager: Human Resources

1.7 Indicator Title	Percentage of staff retained
Definition	The staff establishment is filled, employees are satisfied, and the turnover is within the target range. SAHPRA is the Employer of Choice
Source of Data	Turnover report
Method of Calculation or Assessment	Numerator: Number of employees who resign ÷ Denominator: Number of employees x 100 (as at the end of each quarter)
Means of Verification	Turnover report – headcount at the beginning of the period compared to headcount at the end of the period (quarterly)
Assumptions	Turnover must meet the target of less than 10%
Disaggregation of Beneficiaries (where applicable)	Not applicable
Spatial Transformation (where applicable)	Not applicable
Calculation Type	Cumulative (year-to-date)
Reporting Cycle	Quarterly
Desired Performance	Increased productivity and living the values of SAHPRA
Indicator Responsibility	Executive Manager: Human Resources

1.8 Indicator Title	Percentage of Phase 1 Enterprise Architecture implemented
Definition	A business organisational review of SAHPRA's business processes strategy and information technology systems that support it, which provides an integrated view
Source of Data	Enterprise Architecture review document
Method of Calculation or Assessment	Numerator: Number of processes completed ÷ Denominator: Number of processes to be completed x 100
Means of Verification	Roadmap of the Enterprise Architecture
Assumptions	• Business processes mapping completed • To-Be processes detailed • Information infrastructure is in place • User requirements specifications for the Regulatory Information Management System procured
Disaggregation of Beneficiaries (where applicable)	Not applicable
Spatial Transformation (where applicable)	Not applicable
Calculation Type	Cumulative (year-to-date)
Reporting Cycle	Quarterly
Desired Performance	Phased implementation of the Regulatory Information Management System
Indicator Responsibility	Chief Operations Officer

2. PROGRAMME 2: HEALTH PRODUCTS AUTHORISATION

2.1 Indicator Title	Percentage of New Chemical Entities finalised within 400 working days
Definition	Quantification of new chemical entities (active substances that have not yet been registered by the Regulator) finalised within 400 working days, calculated from the date an application passes technical screening
Source of Data	New Medicines Application Google Sheets tracker and an Internal registration database
Method of Calculation or Assessment	Numerator: Number of NCE medicines finalised within 400 working days ÷ Denominator: Number of NCE applications due for finalisation within 400 working days as at the end of each quarter x 100
Means of Verification	Line listing and supporting documentation thereof, i.e., application letters, signed registration certificates, screening evidence, and Excel spreadsheet for the calculation of the registration timeline
Assumptions	• Introduction of the new technology system will not disrupt operations and reporting ability • Suitably qualified staff will be successfully recruited • Competing priorities for resources with backlog will be resolved • Internal processes such as reliance arrangements and batch processing are in place and work effectively • Tedious processes related to new requirements and templates will have been resolved
Disaggregation of Beneficiaries (where applicable)	Not applicable
Spatial Transformation (where applicable)	Not applicable
Calculation Type	Cumulative (year-to-date)
Reporting Cycle	Quarterly
Desired Performance	Efficient registration of innovator or novel medications that meet high quality, safety and efficacy standards to enable access to medicines for the benefit of the South African public
Indicator Responsibility	Senior Manager: Health Products Authorisations

2.2 Indicator Title	Percentage of generic medicines finalised within 250 working days
Definition	Quantification of generic medicines (multi-source medicines that contain the same chemical substance as the new chemical entity) finalised within 250 working days, calculated from the date an application passes technical screening
Source of Data	New Medicines Application Google Sheets tracker and an Internal registration database
Method of Calculation or Assessment	Numerator: Number of generic medicines finalised within 250 working days ÷ Denominator: Number of generic medicines due for finalisation within 250 working days as at the end of each quarter x 100
Means of Verification	Line listing and supporting documentation thereof, i.e., application letters, signed registration certificates, screening evidence, and Excel spreadsheet for the calculation of the registration timeline
Assumptions	• Introduction of the new technology system will not disrupt the operations and the reporting ability • Suitably qualified staff will be successfully recruited to meet the demands of the increasing number of generic applications • Alignment with processes implemented in terms of new requirements and templates will have been resolved • Competing priorities for resources with backlog will be resolved • Internal processes, such as reliance arrangements and batch processing, are in place and work effectively • Regulator will continually receive applications for registration of generic medicines as part of its core business
Disaggregation of Beneficiaries (where applicable)	Not applicable
Spatial Transformation (where applicable)	Not applicable
Calculation Type	Cumulative (year-to-date)
Reporting Cycle	Quarterly
Desired Performance	Efficient registration of generic medication that meets high quality, safety and efficacy standards to enable access to medicines for the benefit of the South African public
Indicator Responsibility	Senior Manager: Health Products Authorisations

2.3 Indicator Title	International Organization for Standardization 9001: 2015 certification obtained
Definition	Implementing the requirements of ISO 9001:2015 and then completing a successful certification audit confirming compliance with ISO 9001:2015 requirements. ISO 9001:2015 is a standard designed to help organisations be more efficient and process driven
Source of Data	ISO 9001:2015 audit report from the certification body
Method of Calculation or Assessment	• Audit report • ISO 9001:2015 Certificate issued to SAHPRA
Means of Verification	ISO 9001:2015 Certificate
Assumptions	An internal audit will be conducted on Quality Management System requirements
Disaggregation of Beneficiaries (where applicable)	Not applicable
Spatial Transformation (where applicable)	Not applicable
Calculation Type	Cumulative (year-end)
Reporting Cycle	Quarterly
Desired Performance	Full implementation of the Quality Management System requirements
Indicator Responsibility	Chief Operations Officer

2.4 Indicator Title	World Health Organization Maturity Level assessed
Definition	Global benchmarking is a means by which WHO evaluates regulatory systems through a comprehensive and systematic benchmarking process to determine a regulatory authority's Maturity Level on a scale of 1 (existence of some elements of a regulatory system) to 4 (operating at an advanced level of performance and continuous improvement). SAHPRA is targeting Maturity Level 4
Source of Data	Self-benchmarking assessment tool
Method of Calculation or Assessment	Self-benchmarking assessment report
Means of Verification	Self-benchmarking assessment report
Assumptions	Continuous implementation of the institutional development plan
Disaggregation of Beneficiaries (where applicable)	Not applicable
Spatial Transformation (where applicable)	Not applicable
Calculation Type	Non-cumulative
Reporting Cycle	Quarterly
Desired Performance	Establish SAHPRA legitimacy as a key health product regulator on the African continent and globally
Indicator Responsibility	Chief Operations Officer

3. PROGRAMME 3: INSPECTORATE AND REGULATORY COMPLIANCE

3.1 Indicator Title	Percentage of new Good Manufacturing Practice and Good Warehouse Practice related licences finalised within 125 working days
Definition	Quantification of new Good Manufacturing Practice and Good Wholesaling Practice related licence applications lodged by health product sector manufacturers, importers and exporters, wholesalers and distributors that the Regulator can process and finalise within 125 working days, from the date an application is deemed to meet the minimum requirements (administration screening completed and acknowledgement letter sent) for processing
Source of Data	Licensing Unit that receives applications submitted by above-mentioned applicants through a dedicated email inbox for licence applications
Method of Calculation or Assessment	Numerator: Number of applications finalised within 125 working days ÷ Denominator: Number of applications due for finalisation within 125 working days as at the end of each quarter x 100
Means of Verification	• Application email • Acknowledgement letter • Issued licence • Chief Executive Officer approval date • Line listing • Inspection resolution letter • Email inspection report sent
Assumptions	• New applications will continue to be received by the Regulator • Inspections preceding the finalisation of applications will be undertaken and completed timeously • Applicants are ready for inspection • The calculated working days for an application do not include time spent with the applicant from the date when the report was sent to the date when the resolution letter was sent • Sites will be found to meet the minimum requirements according to the applicable guidelines communicated to industry
Disaggregation of Beneficiaries (where applicable)	Not applicable
Spatial Transformation (where applicable)	Not applicable
Calculation Type	Cumulative (year-to-date)
Reporting Cycle	Quarterly
Desired Performance	To strive to expeditiously process the highest possible number of licence applications to ensure that health products meet quality, safety and efficacy standards without compromising the quality of the application process
Indicator Responsibility	Senior Manager: Inspectorate and Regulatory Compliance

3.2 Indicator Title	Percentage of permits finalised within 20 working days
Definition	Quantification of permits lodged by health product sector manufacturers, importers and exporters, wholesalers and distributors, and other authorised persons that the regulator can process and finalise within 20 working days, from the date when an application is received
Source of Data	Regulatory Compliance Unit receives applications submitted by above-mentioned applicants to a dedicated email inbox for permit applications
Method of Calculation or Assessment	Numerator: Number of applications finalised within 20 working days ÷ Denominator: Number of applications received (including carry-over applications) x 100
Means of Verification	• Application email • Issued permit • Chief Executive Officer approval date on the approval routing form • Line listings
Assumptions	• New applications will continue to be received by the Regulator • All permits processed are approved • Possession permits are not included in the scope of the indicator • Chief Executive Officer maintains delegation from the Director-General: Health for authorising permits, or legislation is amended from Director-General: Health approval to Chief Executive Officer approval in the Medicines Act
Disaggregation of Beneficiaries (where applicable)	Not applicable
Spatial Transformation (where applicable)	Not applicable
Calculation Type	Cumulative (year-to-date)
Reporting Cycle	Quarterly
Desired Performance	Permits are finalised within 20 working days
Indicator Responsibility	Senior Manager: Inspectorate and Regulatory Compliance

3.3 Indicator Title	Percentage of regulatory compliance investigation reports produced within 30 working days
Definition	Quantification of investigations conducted in response to complaints related to regulatory compliance received by SAHPRA that it can process and finalise within 30 working days, from the date when a complaint is received by the Regulatory Compliance Unit to the date when the investigation is closed, actioned or handed over to an alternate authority
Source of Data	Signed investigations reports received
Method of Calculation or Assessment	Numerator: Number of investigation reports finalised within 30 working days ÷ Denominator: Number of complaints received (including carry-over investigations) x 100
Means of Verification	• Complaint trigger evidence or documented receipt details from the inspector • Completed investigation report • Investigation report tracker • Line listings
Assumptions	• New recruits will be successfully on-boarded to fill current critical vacancies • Internal business processes are in place and optimised with policies and procedures to support operations • Digitisation solution in place
Disaggregation of Beneficiaries (where applicable)	Not applicable
Spatial Transformation (where applicable)	Not applicable
Calculation Type	Cumulative (year-to-date)
Reporting Cycle	Quarterly
Desired Performance	To endeavour to conduct the highest possible number of post-marketing investigations to keep the public and consumers protected from the effects of negative post-marketing behaviour, poor product quality, and product safety concerns
Indicator Responsibility	Senior Manager: Inspectorate and Regulatory Compliance

4. PROGRAMME 4: CLINICAL AND PHARMACEUTICAL EVALUATION

4.1 Indicator Title	Percentage applications for the sale of unregistered Category A (human) medicines finalised within 3 working days
Definition	Timebound indicator reflecting the response to public health needs for unregistered Category A medicines. Unregistered medicines are medicines that do not appear on the SAHPRA medicine register. Category A medicines are pharmaceuticals for human use and exclude complementary medicines (Category D)
Source of Data	• SAHPRA's Section 21 Unit applications and authorisation letters generated through the Section 21 portal • Line listing
Method of Calculation or Assessment	Numerator: Number of applications finalised within 3 working days from the date of receipt of a complete application ÷ Denominator: Number of applications received x 100
Means of Verification	• S21 applications captured on the Section 21 portal • Proof of payment submitted on the Section 21 portal • Letter of S21 authorisation issued by the Section 21 portal • Line listing
Assumptions	• System is running continually without disruptions • Applicants observe application rules and procedures, as communicated to them • IT system can distinguish between the date when an application is created and the date it is complete and ready for evaluation
Disaggregation of Beneficiaries (where applicable)	Not applicable
Spatial Transformation (where applicable)	Not applicable
Calculation Type	Cumulative (year-to-date)
Reporting Cycle	Quarterly
Desired Performance	Facilitate the most efficient access possible to unregistered Category A medicines that fulfil a public health mandate of the Regulator
Indicator Responsibility	Senior Manager: Clinical Evaluations Management

4.2 Indicator Title	Percentage of human clinical trial applications finalised within 80 working days
Definition	Quantification of clinical trial applications lodged with the Regulator by applicants who intend to undertake clinical trials for the purposes of assessing Good Clinical Practices (GCPs), which are international standards for conducting clinical trials in humans and compliance with ethical principles of human participation in clinical trials
Source of Data	Clinical Trials Business Unit generated from dated clinical trial reports signed off by the Clinical Trials Unit manager with supplementary evidence of minutes signed off by the Clinical Trial Committee Chairperson
Method of Calculation or Assessment	Numerator: Number of clinical trial applications finalised within 80 working days ÷ Denominator: Number of clinical trial applications due for finalisation within 80 working days as at the end of each quarter x 100
Means of Verification	• Emailed CTF1 • Emailed proof of payment • Approval or rejection letter • Line listing
Assumptions	• Clinical trials not completed within a cycle will be included in the following cycle • SOPs guiding the work of the external evaluators will be concluded timeously • Necessary delegations will be finalised for sign-off purposes
Disaggregation of Beneficiaries (where applicable)	Not applicable
Spatial Transformation (where applicable)	Not applicable
Calculation Type	Cumulative (year-to-date)
Reporting Cycle	Quarterly
Desired Performance	Facilitation of efficient processing of clinical trial applications to enable access to research and development within an environment that guarantees the safety of clinical trial participants
Indicator Responsibility	Senior Manager: Clinical Evaluations Management

4.3 Indicator Title	Percentage of reports on health product safety signals issued within 40 working days
Definition	Quantification of medicine safety communication alerts relating to new adverse events and signals that have been subjected to necessary assessments after their receipt by the Regulator and the decision is reached to publish them to alert the public. Such alerts are handled in the following forms: • Media releases: Local safety concerns that warrant immediate public awareness, published safety decisions by other regulatory authorities, and safety signals • Dear healthcare professional letters: Safety concerns for immediate attention of healthcare professionals, safety notifications, and internal reviews • Medicines safety alerts: Educational or informational material for healthcare professionals on health products safety issues from internal reviews • Safety surveillance: Notifications from applicants, the Internet, and media searches • Safety signal: adverse drug reaction reports from healthcare professionals, consumers and applicants, literature, and VigiBase®
Source of Data	Media releases, Dear Healthcare Professional Letters, and Medicines Safety Alerts generated
Method of Calculation or Assessment	Numerator: Number of safety concerns issued within 40 working days ÷ Denominator: Number of safety concerns due for finalisation within 40 working days as at the end of each quarter x 100
Means of Verification	• Media releases generated • DHCPLs generated • Medicines Safety Alerts generated • Line listings
Assumptions	• Applicants will notify SAHPRA of foreign regulatory authority decisions that concern their health products • Applicants will comply with the Authority's recommendations • Necessary resources, such as reliable Internet connectivity, reference material, and adequate, competent HR and ICT support, are in place • Active surveillance of medicine safety issues will remain in force
Disaggregation of Beneficiaries (where applicable)	Not applicable
Spatial Transformation (where applicable)	Not applicable
Calculation Type	Cumulative (year-to-date)
Reporting Cycle	Quarterly
Desired Performance	Timeous communication of regulatory decisions on the safety of health products to promote the public health of South Africans
Indicator Responsibility	Senior Manager: Clinical Evaluations Management

4.4 Indicator Title	Number of safety awareness campaigns held
Definition	A campaign to educate the public and other stakeholders on the importance of health product safety reporting. The campaign includes initiatives such as interviews by media, training of stakeholders, and webinars
Source of Data	Videos, recordings of interviews, training agenda, and attendance register
Method of Calculation or Assessment	Simple count of the number of awareness campaigns held
Means of Verification	Videos, recordings of interviews, training agenda, and attendance register
Assumptions	• Regulator will continually receive ADR reports from applicants, healthcare professionals and consumers • Necessary resources, such as reliable Internet connectivity, reference material, and adequate, competent HR and ICT support, are in place
Disaggregation of Beneficiaries (where applicable)	Not applicable
Spatial Transformation (where applicable)	Not applicable
Calculation Type	Cumulative (year-end)
Reporting Cycle	Quarterly
Desired Performance	Increase in vigilance reports
Indicator Responsibility	Senior Manager: Clinical Evaluations Management

4.5 Indicator Title	Percentage of lot release requests finalised within 50 working days
Definition	Quantification of the percentage of the lots released or rejected through SAHPRA in accordance with Section 15 of the Medicines Act, as amended
Source of Data	Lot release request applications accepted by SAHPRA for registered vaccines and authorised vaccines through Section 21 of Public Health Emergency authorisation and lot release certificates or rejection notices issued
Method of Calculation or Assessment	Numerator: Number of lot releases finalised within 50 working days ÷ Denominator: Number of lot release applications accepted due for finalisation within 50 working days as at the end of each quarter x 100
Means of Verification	• Lot release certificate or notice of rejection (approved or rejected) • List of lot release spreadsheet or database or line listing • Lot release applications accepted • Lot release certificate or lot release rejection notification
Assumptions	All tools necessary for lot release processing are available and function optimally, and there are no outstanding regulatory approvals
Disaggregation of Beneficiaries (where applicable)	Not applicable
Spatial Transformation (where applicable)	Not applicable
Calculation Type	Cumulative (year-to-date)
Reporting Cycle	Quarterly
Desired Performance	Maintaining the highest possible levels of quality, efficacy and safety for all vaccines imported to South Africa and manufactured locally to ensure the public receives products that are safe, effective and of good quality
Indicator Responsibility	Senior Manager: Pharmaceutical Evaluation Management

5. PROGRAMME 5: MEDICAL DEVICES AND RADIATION CONTROL

5.1 Indicator Title	Percentage of medical device establishment licence applications finalised within 90 working days
Definition	Quantification of the percentage of new medical device establishment applications for licences lodged with the Regulator, as prescribed by the Medicines Act, as amended
Source of Data	Medical device applications and licences issued line listing
Method of Calculation or Assessment	Numerator: Number of new licence applications finalised within 90 working days ÷ Denominator: Number of new licence applications received due for finalisation within 90 working days as at the end of each quarter x 100
Means of Verification	The licence signed by the Chief Executive Officer and the licence-issuing fee will serve as proof of payments for licence applications and licences line listing
Assumptions	All tools necessary for processing applications are available and function optimally
Disaggregation of Beneficiaries (where applicable)	Not applicable
Spatial Transformation (where applicable)	Not applicable
Calculation Type	Cumulative (year-to-date, including open carry-over applications)
Reporting Cycle	Quarterly
Desired Performance	Maintaining the highest possible levels of quality and safety for medical device establishments manufacturing or importing and exporting medical devices to ensure public and environmental safety
Indicator Responsibility	Senior Manager: Medical Devices and Radiation Control

5.2 Indicator Title	Notice of medical device products published
Definition	Call-up notification published for a pilot study for selected specific high-risk Class D medical devices (IVDs)
Source of Data	• Information from NDoH • Current product listing
Method of Calculation or Assessment	Notice published in the Government Gazette
Means of Verification	Published call-up notice
Assumptions	All tools necessary are available and functioning optimally (including those of external stakeholders, e.g., national reference laboratories)
Disaggregation of Beneficiaries (where applicable)	Not applicable
Spatial Transformation (where applicable)	Not applicable
Calculation Type	Non-cumulative
Reporting Cycle	Quarter 3 and 4
Desired Performance	Published product call-up notice
Indicator Responsibility	Senior Manager: Medical Devices and Radiation Control

5.3 Indicator Title	Percentage of applications for radionuclide authorities finalised within 30 working days
Definition	Quantification of the percentage of new applications finalised for licences lodged with the Regulator by holders of radionuclides, as prescribed by the Hazardous Substances Act, as amended
Source of Data	Line listing extracted from radionuclide Oracle database and as received via the dedicated email address
Method of Calculation or Assessment	Numerator: Number of new licences finalised within 30 working days ÷ Denominator: Number of new licence applications received due for finalisation within 30 working days as at the end of each quarter x 100
Means of Verification	Excel calculation performed on line listing and supporting documentation (email correspondence and licence or authorities issued) thereof
Assumptions	All resources necessary for processing applications and measuring performance are available and function optimally
Disaggregation of Beneficiaries (where applicable)	Not applicable
Spatial Transformation (where applicable)	Not applicable
Calculation Type	Cumulative (year-to-date)
Reporting Cycle	Quarterly
Desired Performance	Maintaining the highest possible levels of protection for radiation workers, patients, the public and the environment against the adverse effects of radiation. Maintaining the most effective and efficient processing of licence applications possible
Indicator Responsibility	Senior Manager: Medical Devices and Radiation Control

5.4 Indicator Title	Percentage of licence applications for listed-electronic products finalised within 30 working days
Definition	Quantification of the percentage of new applications finalised for licences to import listed electronic products lodged with the Regulator, as prescribed by the Hazardous Substances Act, as amended
Source of Data	Import licence applications, licences, and not-licensable letters
Method of Calculation or Assessment	Numerator: Number of new applications finalised within 30 working days ÷ Denominator: Number of new licence applications received due for finalisation within 30 working days as at the end of each quarter x 100
Means of Verification	Line listing and supporting documentation (licence issued to applicants) thereof
Assumptions	All resources necessary for processing applications and measuring performance are available and function optimally
Disaggregation of Beneficiaries (where applicable)	Not applicable
Spatial Transformation (where applicable)	Not applicable
Calculation Type	Cumulative (year-to-date)
Reporting Cycle	Quarterly
Desired Performance	Maintaining the required levels of safety, quality and performance of imported listed electronic products to ensure the health and safety of patients, healthcare workers, and the public
Indicator Responsibility	Senior Manager: Medical Devices and Radiation Control

5.5 Indicator Title	Number of approved Guidelines for the management of medical device vigilance
Definition	Implementation and strengthening of the regulatory oversight of medical devices through the development and maintenance of relevant guidelines (vigilance)
Source of Data	International published guidelines – WHO, International Medical Device Regulators Forum (IMDRF), and other NRAs
Method of Calculation or Assessment	Simple count
Means of Verification	Published guidelines
Assumptions	All published guidelines will be available (accessible)
Disaggregation of Beneficiaries (where applicable)	Not applicable
Spatial Transformation (where applicable)	Not applicable
Calculation Type	Cumulative (year-to-date)
Reporting Cycle	Quarterly
Desired Performance	Regulatory oversight of medical devices through increased vigilance reports
Indicator Responsibility	Senior Manager: Medical Devices and Radiation Control

ANNEXURES

ANNEXURE A: MATERIALITY AND SIGNIFICANCE FRAMEWORK

Background

In terms of the Treasury Regulation Section 28.3.1:

> For purposes of material [sections 55(2) of the Public Finance Management Act (PFMA)] and significant [section 54(2) of the PFMA], the accounting authority must develop and agree on a framework of acceptable levels of materiality and significance with the relevant executive authority.

The South African Auditing Standard (SAAS 320.03) defines materiality as follows:

> Information is material if its omission or misstatement could influence the economic decisions of users taken on the basis of the financial statements. Materiality depends on the size of the item or error judged in the particular circumstances of its omission or misstatement. Thus, materiality provides a threshold or cut-off point, rather than being a primary qualitative characteristic, which information must have if it is to be useful.

Accordingly, we will be dealing with this framework under two main categories: the quantitative and qualitative aspects.

Materiality can be based on a number of financial indicators. An indicative table of financial indicators is provided below, as documented in the Treasury Practice note on applications under S.54 of the PFMA.

Basis	Acceptable Percentage Range
Total assets	**1% - 2%**
Total revenue	**0.5% - 1%**
Profit after tax	**2% - 5%**

SAHPRA will use 0.75% of the latest available audited total revenue to determine materiality, which amounts to R2 756 585. SAHPRA operations are driven mainly by applications received and are, therefore, essentially revenue driven. In determining the materiality value as 0.75%, we have considered the following factors:

a) Nature of SAHPRA's Business

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, clinical trials and medical devices, radiation control, and related matters in the public interest.

b) The Control and Inherent Risks Associated with SAHPRA

In assessing the control risk of SAHPRA and concluding that a materiality level higher than 0.5% but below 1% can be used due to a good control environment being present, cognisance was given to the following, among others:

- Proper and appropriate governance structures have been established;
- An Audit and Risk Committee that closely monitors the control environment of SAHPRA was established;
- The function of internal audit was partly outsourced to a firm with SAHPRA-specific experience;
- A three-year internal audit plan, based on annual risk assessments being performed, is annually reviewed and agreed upon by the Audit Committee;
- All executive positions have been filled;
- A reduction in the number of audit qualifications and/or findings or unqualified audit opinion obtained; and
- The manual way of working is still a challenge, and the top end of the financial indicators was not considered.

c) Quantitative Aspects

Materiality Level

The level of materiality for 2022/23 has been set as follows: 0.75% of the latest audited total revenue amounting to R2 756 585 (R367 544 767 x 0.75%).

d) Qualitative Aspects

Materiality is not merely related to the size of the entity and the elements of its financial statements. Obviously, misstatements that are large, either individually or in the aggregate, may affect a "reasonable" user's judgement. However, misstatements may also be material on qualitative grounds. These qualitative grounds include, among others:

i) New ventures that SAHPRA has entered into;

ii) Unusual transactions entered into that are not of a repetitive nature and are disclosable purely as a result of their nature due to knowledge thereof affecting the decision-making of the user of the financial statements;

iii) Transactions entered into that could result in reputational risk to SAHPRA;

iv) Any fraudulent or dishonest behaviour of an officer or staff member of SAHPRA; and

v) Procedures and processes required by legislation or regulation (e.g., the PFMA and Treasury Regulations).

Statutory Application

Section 50: Fiduciary duties of accounting authorities

1) The accounting authority for a public entity must:

PFMA Section		Quantitative (Amount)	Qualitative (Nature)
(c)	on request, disclose to the executive authority responsible for that public entity, or the legislature to which the public entity is accountable, all material facts, including those reasonably discoverable, which in any way may influence the decisions or actions of the executive authority or that legislature	Transactions exceeding 0.75%, which may influence the decisions or actions of NDoH	The Board will disclose to NDoH all material facts as requested and all material facts not requested, including those reasonably discoverable, which in any way may influence the decisions or actions of NDoH, at the discretion of the Board

Section 51: General responsibilities of accounting authorities

1) An accounting authority for a public entity:

PFMA Section		Quantitative (Amount)	Qualitative (Nature)
(g)	must promptly inform the National Treasury on any new entity which that public entity intends to establish or in the establishment of which it takes the initiative, and allow the National Treasury a reasonable time to submit its decision prior to formal establishment	None	Full particulars to be disclosed to the Minister of Health for approval, after which they are to be presented to Treasury

Section 54: Information to be submitted by accounting authorities

2) Before a Public Entity concludes any of the following transactions, the Accounting Authority for the Public Entity must promptly and in writing inform the relevant Treasury of the transaction and submit relevant particulars of the transaction to its Executive Authority for approval of the transaction:

PFMA Section		Quantitative (Amount)	Qualitative (Nature)
a)	establishment of a company;	Any proposed establishment of a legal entity	Full particulars to be disclosed to the Minister of Health and Minister of Finance (National Treasury) for approval (simultaneous submission)
b)	participation in a significant partnership, trust, unincorporated joint venture, or similar arrangement;	Qualifying transactions exceeded (based on 0.75% of total audited SAHPRA Revenue, as at 31 March). This includes collaborative arrangements	
c)	acquisition or disposal of a significant shareholding in a company;	Greater than 20% of shareholding	
d)	acquisition or disposal of a significant asset;	Qualifying transactions exceeded (based on 0.75 % of total audited SAHPRA revenue, as at 31 March), including financial leases	Any asset that would increase or decrease the overall operational functions of the Authority outside of the approved strategic plan and budget
e)	commencement or cessation of a significant business activity; and	Any activity not covered by the mandate or core business of the Authority and that exceeds the qualifying transactions exceeded (based on 0.75% of total audited SAHPRA revenue, as at 31 March)	Full particulars to be disclosed to the Minister of Health and Minister of Finance (National Treasury) for approval (simultaneous submission)
f)	a significant change in the nature or extent of its interest in a significant partnership, trust, unincorporated joint venture, or similar arrangement	Qualifying transactions exceeded (based on 0.75% of total audited SAHPRA revenue, as at 31 March)	

Section 55: Annual report and financial statements

2) The annual report and financial statements referred to in subsection (1)(d) ("financial statements") must:

a) fairly present the state of affairs of the Public Entity, its business, its financial results, its performance against predetermined objectives, and its financial position as at the end of the financial year concerned;

b) include particulars of:

PFMA Section	Quantitative (Amount)	Qualitative (Nature)
(i) any material losses through criminal conduct and any irregular expenditure and fruitless and wasteful expenditure that occurred during the financial year;	All instances	• Report quarterly to the Minister of Health • Report annually in the annual financial statements
(ii) any criminal or disciplinary steps taken as a consequence of such losses or irregular expenditure or fruitless and wasteful expenditure;		
(iii) any losses recovered or written off;		
(iv) any financial assistance received from the State and commitments made by the State on its behalf; and		
(v) any other matters that may be prescribed	All instances, as prescribed	

Section 56: Assignment of powers and duties by accounting authorities

PFMA Section	Quantitative (Amount)	Qualitative (Nature)
1) The accounting authority for a public entity may— (a) In writing, delegate any of the powers entrusted or delegated to the accounting authority in terms of this Act, to an official in that public entity; (b) Instruct an official in that public entity to perform any of the duties assigned to the accounting authority in terms of this Act	Values excluded from the Delegation of Authority Framework Policy	Instances that are excluded from the Delegation of Authority Framework Policy
2) A delegation or instruction to an official in terms of subsection (1)— (c) Is subject to any limitations and conditions the accounting authority may impose; (d) May either be to a specific individual or to the holder of a specific post in the relevant public entity; and (e) Does not divest the accounting authority of the responsibility concerning the exercise of the delegated power or the performance of the assigned duty	Values excluded from the Delegation of Authority Framework Policy	Instances that are excluded from the Delegation of Authority Framework Policy

ANNEXURE B: REVISIONS TO THE 2020/21 – 2024/25 STRATEGIC PLAN

1.2 Measuring Our Outcomes

MEDIUM-TERM STRATEGIC FRAMEWORK PRIORITY 3: EDUCATION, SKILLS AND HEALTH			
OUTCOMES	**OUTCOME INDICATORS**	**BASELINE**	**FIVE-YEAR TARGET**
Effective compliance, financial and performance management (1)	1.1 Unqualified audit opinion obtained on the annual financial statements	Qualified audit outcome	Clean audit opinion obtained for the 2023/24 financial year
Financial sustainability achieved (2)	1.2 Current assets ≥ than current liabilities	-	Current ratio of 1≥1 maintained
Responsive to stakeholder needs (3)	1.3 Customer Relationship Management system implemented	SAHPRA obtained a 68% positive rating for its effectiveness and efficiency from private and public direct users of its services	Customer Relationship Management system fully implemented
A positive and enabling working culture created (4)	1.4 Percentage of recommendations from the staff satisfaction survey implemented	-	40% recommendations from the staff satisfaction survey implemented
Attract and retain talent (5)	1.5 Percentage of core business positions in the staff establishment filled	76%	80% core business positions in the staff establishment filled
Digital transformation (6)	1.6 Enterprise Architecture developed	-	Phase 2 of the roadmap on the Enterprise Architecture implemented
Efficient and effective regulatory practices maintained (7)	1.7 Percentage of medicine registrations in the backlog cleared	58%	100% medicine registrations backlog cleared
	1.8 Percentage of medicine variation applications in the backlog cleared	58%	100% medicine variation applications backlog cleared
	1.9 Percentage of New Chemical Entities finalised within 360 working days	100%	80% New Chemical Entities finalised within 360 working days
Global best practices maintained (8)	1.10 World Health Organization Maturity Level obtained	-	World Health Organization Maturity Level 4 obtained
Efficient and effective regulatory practices maintained (7)	1.11 Percentage of new Good Manufacturing Practice and Good	77%	80% new Good Manufacturing Practice and Good Warehouse Practice related licences

MEDIUM-TERM STRATEGIC FRAMEWORK PRIORITY 3: EDUCATION, SKILLS AND HEALTH			
OUTCOMES	**OUTCOME INDICATORS**	**BASELINE**	**FIVE-YEAR TARGET**
	Warehouse Practice related licences finalised within 125 working days		finalised within 125 working days
	1.12 Percentage of human clinical trial applications finalised within 60 working days	100%	80% human clinical trial applications finalised within 60 working days
	1.13 Medical device registration regulations implemented	-	Call-up of Class D (high risk)

2. KEY RISKS AND MITIGATION

OUTCOMES	KEY RISKS	RISK MITIGATIONS
Effective compliance, financial and performance management (1)	Inadequate financial governance systems and processes*	Ongoing financial management training and workshop sessions
Financial sustainability achieved (2)	Inability to sustain financial viability for SAHPRA	Source single entry point system (implementation of customer service portal)
		Follow up on long outstanding payments to ensure timeous invoicing of industry
Responsive to stakeholder needs (3)	Perceived negative perceptions about SAHPRA as a result of receiving external funding and non-alignment with stakeholder needs	Formalisation of strategic partnership with stakeholders (SLA or MoU)
		Assess stakeholder awareness and perceptions, and act on recommendations
A positive and enabling working culture created (4)	Inadequate monitoring systems to monitor organisational performance*	Development of Performance Information management system in line with the Information Technology Digitization Strategy
Attract and retain talent (5)	Difficulty in attracting and retaining talent	Develop and implement roadmap for capacity-building programme, including succession planning
Digital transformation (6)	Inability to invest in Information and Communication Technology infrastructure to enable automation and integration of SAHPRA processes	Secure Information and Communication Technology capacity and resources to implement end-to-end information technology system
Efficient and effective regulatory practices maintained (7)	Increasing backlog on new applications – Business-As-Usual	Continuous improvement of application process to improve turnaround time based on stakeholder feedback Develop capacity to deal with Business-As-Usual demands
Other Strategic Risks		
Governance risks	Non-compliance with legislation, policies, procedures, and standards	Continuous monitoring of compliance
	Fraud, theft and corruption	Continuous monitoring of fraud and corruption

OUTCOMES	KEY RISKS	RISK MITIGATIONS
External Risks	Non-alignment of the National Priorities as a result of an outdated Act and poorly streamlined processes among entities with similar mandates	Review of the Medicines Act
	Increased global pandemic occurrences or environmental threats	Continuous monitoring and management of pandemics and threats Implementation of Business Continuity Policy and continuous development and review of processes
	Cyber security	Continuous monitoring and management of threats
	Disruption of SAHPRA activities due to the unstable supply of utilities (load-shedding and water-shedding)	Implementation of the hybrid model
	Labour unrest	Continuous engagements with staff and labour
	Litigation against SAHPRA due to an outdated Act	Review of the Medicines Act to minimise gaps that expose SAHPRA to litigation Regular update of policies, processes and guidelines
	Ineffective execution of SAHPRA mandate due to NDoH and other stakeholder inefficiencies	Strengthen communication channels between SAHPRA and NDoH

PART D: TECHNICAL INDICATOR DESCRIPTIONS

1.1 Indicator Title	Unqualified audit opinion obtained on the annual financial statements
Definition	The results of the audits that are undertaken annually by the Auditor-General based on the assessment of performance during the preceding year, which factors in both financial performance and performance against predetermined objectives or non-financial performance, as prescribed by the Public Finance Management Act, indicating that the financial statements present fairly, in all material respects, the financial position, performance and cashflows for the year-end
Source of Data	Report of the Auditor-General of South Africa
Method of Calculation or Assessment	Report of the Auditor-General of South Africa based on the previous financial year's performance
Means of Verification	Auditor-General's Report
Assumptions	• Desired performance to improve audit outcomes will be supported by risk management issues being effectively institutionalised and introducing rigorous processes necessary to produce a positive audit outcome • No legislative or policy changes to the current auditing plans and cycles
Disaggregation of Beneficiaries (where applicable)	Not applicable
Spatial Transformation (where applicable)	Not applicable
Desired Performance	Non-cumulative
Indicator Responsibility	Quarter 2

1.2 Indicator Title	Current assets ≤ than current liabilities
Definition	A current ratio of equal or greater than 1 by the financial year-end.
Source of Data	Statement of financial position
Method of Calculation or Assessment	Total current assets ÷ Total current liabilities
Means of Verification	Finance quarterly reports and annual financial statements
Assumptions	• Revenue budgeted for will be collected for the financial year • Expenditure incurred will be in line with expectations budgeted for
Disaggregation of Beneficiaries (where applicable)	Not applicable
Spatial Transformation (where applicable)	Not applicable
Desired Performance	Indication whether SAHPRA has sufficient cash on hand to pay current liabilities and is financially sustainable
Indicator Responsibility	Chief Financial Officer

1.3 Indicator Title	Customer Relationship Management (CRM) system implemented
Definition	In order to be responsive to stakeholders, there is a need to gauge their concerns and address their needs by implementing a functional CRM system
Source of Data	Stakeholder perception survey report, including recommendations
Method of Calculation or Assessment	Fully functional CRM system implemented
Means of Verification	Reports from CRM system
Assumptions	• The stakeholder perception survey includes recommendations to be implemented There is sufficient funding to sustain the CRM system and the unit is capacitated adequately
Disaggregation of Beneficiaries (where applicable)	Not applicable
Spatial Transformation (where applicable)	Not applicable
Desired Performance	A fully capacitated and functioning CRM Unit at SAHPRA
Indicator Responsibility	Manager: Communication and Public Relations

1.4 Indicator Title	Percentage of recommendations from the staff satisfaction survey implemented
Definition	Measurement of SAHPRA employees' satisfaction and engagement
Source of Data	Employee Survey
Method of Calculation or Assessment	Survey conducted
Means of Verification	• Survey report • Implementation plan
Assumptions	At least 60% of employees will participate in the survey
Disaggregation of Beneficiaries (where applicable)	Not applicable
Spatial Transformation (where applicable)	Not applicable
Desired Performance	75% of employees are satisfied with SAHPRA
Indicator Responsibility	Executive Manager: Human Resources

1.5 Indicator Title	Percentage of core business positions in the staff establishment filled
Definition	Vacant positions identified for relevant recruitment phase and with approved budget are filled before commencement of the next phase in the following financial year
Source of Data	Staff establishment, published advertisements, and new contracts with the date of onboarding
Method of Calculation or Assessment	Numerator: Number of core business positions filled ÷ Denominator: Number of core business positions in the staff establishment x 100
Means of Verification	Human resource documents in the Personnel File
Assumptions	• Executive Manager: HR will be appointed before the beginning of the 2021/22 financial year • Recruitment process is supported by organised labour • Availability of funds
Disaggregation of Beneficiaries (where applicable)	Targets for female staff must align with targets set in the HR Recruitment and Selection Policy
Spatial Transformation (where applicable)	Not applicable
Desired Performance	SAHPRA establishes a competent workforce through timeous recruitment against the phased plan
Indicator Responsibility	Executive Manager: Human Resources

1.6 Indicator Title	Enterprise Architecture developed
Definition	A business-wide and organisation-wide system review of SAHPRA's business processes, strategy and IT systems that support it. It provides an integrated view
Source of Data	Architecture review document
Method of Calculation or Assessment	Board approval of the Enterprise Architecture
Means of Verification	Minutes of the Board meeting
Assumptions	• Business processes are in place • Information infrastructure is in place • User requirements specifications for the Regulatory Information Management System
Disaggregation of Beneficiaries (where applicable)	Not applicable
Spatial Transformation (where applicable)	Not applicable
Desired Performance	Approved integrated plan to be used to implement information system for SAHPRA
Indicator Responsibility	Chief Operations Officer

1.7 Indicator Title	Percentage of medicine registrations backlog cleared
Definition	Quantification of backlog applications lodged by pharmaceutical sector that the regulator can process and finalise within 250 working days, from the date when an application is deemed to meet the minimum requirements
Source of Data	Applications that were received by above-mentioned applicants through the SAHPRA backlog eradication project
Method of Calculation or Assessment	Numerator: Number of registrations, rejections and official withdrawals ÷ Denominator: Number of new registration applications received (actual resubmissions) from Go-Live (1 August 2019) x 100
Means of Verification	Trackers generated from Google Sheets and supporting documentation thereof
Assumptions	• the project will continue to receive funding to support accelerated output • the programme will recruit evaluators as per the stated timeline • ongoing collaboration with industry stakeholders to submit within the stipulated window
Disaggregation of Beneficiaries (where applicable)	Not applicable
Spatial Transformation (where applicable)	Not applicable
Desired Performance	To eradicate the backlog of applications by 2022
Indicator Responsibility	Project Manager: Backlog

1.8 Indicator Title	Percentage of medicine variation applications backlog cleared
Definition	Quantification of variation applications lodged by pharmaceutical sector that the Backlog Clearance Programme can process and approve or reject
Source of Data	Variation applications that were received from above-mentioned applicants through SAHPRA backlog eradication project
Method of Calculation or Assessment	Numerator: Number of approvals, rejections and official withdrawals ÷ Denominator: Number of variation applications received (actual resubmissions) from Go-Live (1 August 2019) x 100
Means of Verification	Trackers generated from Google Sheets and supporting documentation thereof
Assumptions	• The project will continue to receive funding to support accelerated output • The programme will recruit evaluators as per the stated timeline
Disaggregation of Beneficiaries (where applicable)	Not applicable
Spatial Transformation (where applicable)	Not applicable
Desired Performance	To eradicate the backlog of applications by 2022
Indicator Responsibility	Project Manager: Backlog

1.9 Indicator Title	Percentage of New Chemical Entities finalised within 360 working days
Definition	Quantification of NCEs (active substances that have not yet been registered by the Regulator) finalised within 360 working days, calculated from the date when an application passes technical screening
Source of Data	New Medicines Application Google Sheets tracker and an internal registration database
Method of Calculation or Assessment	Numerator: Number of NCE medicines finalised within 360 working days ÷ Denominator: Number of NCE applications due for finalisation within 360 working days as at the end of each quarter x 100
Means of Verification	Line listing and supporting documentation thereof, i.e., application letters, signed registration certificates, screening evidence, and Excel spreadsheet for the calculation of the registration timeline
Assumptions	• Introduction of the new technology system will not disrupt the operations and the reporting ability • Suitably qualified staff will be successfully recruited • Competing priorities for resources with backlog will be resolved • Internal processes, such as reliance arrangements and batch processing, are in place and work effectively • Current tedious processes in terms of new requirements and templates will have been resolved
Disaggregation of Beneficiaries (where applicable)	Not applicable
Spatial Transformation (where applicable)	Not applicable
Desired Performance	Efficient registration of innovator or novel medication that meets high quality, safety and efficacy standards to enable access to medicines for the benefit of the South African public
Indicator Responsibility	Senior Manager: Health Products Authorisations

1.10 Indicator Title	World Health Organization Maturity Level obtained
Definition	Successful completion of the WHO benchmarking audit
Source of Data	WHO audit outcome and report
Method of Calculation or Assessment	Maturity Level obtained
Means of Verification	Report on the WHO benchmarking audit
Assumptions	Preparedness of SAHPRA for the audit in 2021
Disaggregation of Beneficiaries (where applicable)	Not applicable
Spatial Transformation (where applicable)	Not applicable
Desired Performance	Establish SAHPRA's legitimacy as a key health product regulator on the African continent and globally
Indicator Responsibility	Chief Operations Officer

1.11 Indicator Title	Percentage of new Good Manufacturing Practice and Good Warehouse Practice related licences finalised within 125 working days
Definition	Quantification of new GMP and GWP related licence applications lodged by health product sector manufacturers, importers and exporters, and wholesalers and distributors that the Regulator can process and finalise within 125 working days, counting from the date when an application is deemed to meet the minimum requirements (administration screening completed and acknowledgement letter sent) for processing.
Source of Data	Licensing Unit that receives applications submitted by above-mentioned applicants through a dedicated email inbox for licence applications
Method of Calculation or Assessment	Numerator: Number of applications finalised within 125 working days ÷ Denominator: Number of applications due for finalisation within 125 working days as at the end of each quarter x 100
Means of Verification	• Application email • Acknowledgment letter • Issued licence • Chief Executive Officer approval date • Line listing • Inspection resolution letter • Email inspection report sent
Assumptions	• New applications will continue to be received by the regulator • Inspections preceding the finalisation of applications will be undertaken and completed timeously • Applicants are ready for inspection • The calculated working days for an application do not include time spent with the applicant from the date when the report was sent to the date when the resolution letter was sent • Sites will be found to meet the minimum requirements according to the applicable guidelines communicated to industry
Disaggregation of Beneficiaries (where applicable)	Not applicable
Spatial Transformation (where applicable)	Not applicable
Desired Performance	Cumulative (year-to-date)
Indicator Responsibility	Quarterly

1.12 Indicator Title	Percentage of human clinical trial applications finalised within 60 working days
Definition	Quantification of clinical trial applications lodged with the Regulator by applicants who intend to undertake clinical trials for the purposes of assessing Good Clinical Practices which are international standards for conducting clinical trials in humans and compliance with ethical principles of human participation in clinical trials
Source of Data	Clinical Trials Business Unit generated from dated clinical trial reports signed off by the Clinical Trials Unit manager with supplementary evidence of minutes signed off by the Clinical Trial Committee Chairperson
Method of Calculation or Assessment	Numerator: Number of clinical trial applications finalised within 60 working days ÷ Denominator: Number of clinical trial applications due for finalisation within 60 working days as at the end of each quarter x 100
Means of Verification	• Emailed CTF1 • Emailed proof of payment • Approval or rejection letter • Line listing
Assumptions	• Clinical trials not completed within a cycle will be included in the following cycle • SOPs guiding the work of the external evaluators will be concluded timeously • Necessary delegations will be finalised for sign-off purposes
Disaggregation of Beneficiaries (where applicable)	Not applicable
Spatial Transformation (where applicable)	Not applicable
Desired Performance	Cumulative (year-to-date)
Indicator Responsibility	Quarterly

1.13 Indicator Title	Medical device registration regulations implemented
Definition	Quantification of the extent of progress made in developing and implementing the medical device framework for registration of medical devices
Source of Data	Published medical device regulations, revised Medical Device Regulations, Revised medical device roadmap, TORS minutes, progress report to the Chief Regulatory Officer and Chief Executive Officer
Method of Calculation or Assessment	Simple count of medical device registration guidelines published aligned with the regulations
Means of Verification	• Published regulations and guidelines • Finalised and signed framework
Assumptions	Human resource capacity to champion project
Disaggregation of Beneficiaries (where applicable)	Not applicable
Spatial Transformation (where applicable)	Not applicable
Desired Performance	Framework to register medical devices implemented
Indicator Responsibility	Senior Manager: Medical Devices and Radiation Control