2022/23

ANNUAL PERFORMANCE PLAN

JANUARY 2022

SOUTH AFRICAN HEALTH PRODUCTS REGULATORY AUTHORITY (SAHPRA) GENERAL INFORMATION

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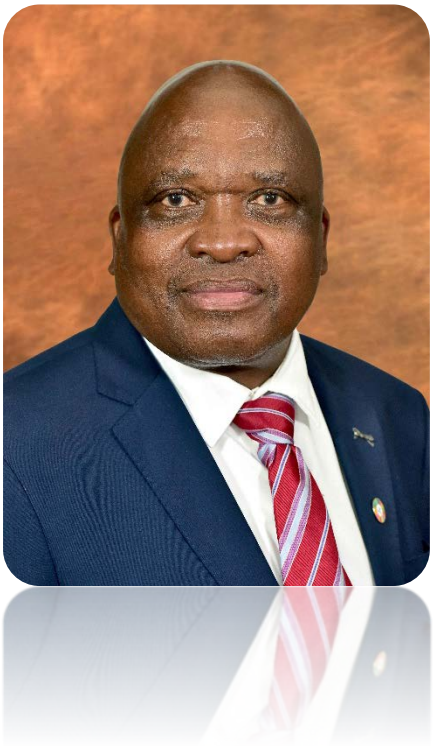
EXECUTIVE AUTHORITY STATEMENT



The South African Health Products Regulatory Authority (SAHPRA) is an essential component to ensure the health and well-being of human and animal health in the Republic.

This Annual Performance Plan for the 2022/23 financial year that has been developed by SAHPRA, represents the planned actions of the Board of SAHPRA to ensure that through their considered and responsible actions, they can, together with the staff at the Authority, assure and guide the Authority to grow into maturity; and reach its full potential to provide for the monitoring, evaluation, regulation, investigation, inspection, registration and control of medicines, scheduled substances, clinical trials, medical devices, radiation emitting devices and radioactive nuclides and related matters in the public interest.

In so implementing its mandate, the expectations are for SAHPRA to positively shift the provision of healthcare services towards justifiable expectations of quality, safe and efficacious health products.

The progress made by SAHPRA in its first three years while navigating considerable challenges including the COVID-19 pandemic is acknowledged. There is recognition that SAHPRA will provide crucial support for the establishment of the National Health Insurance and achieve greater accolades towards reforms in its pivotal area of health product regulation and registration.

We further acknowledge that the Board by virtue of this submission, remains cognisant of the powers vested in the Authority by the Medicines Related Substances Act, 1965 (Act No. 101 of 1965) as amended, the expectations placed on the Authority by the public and all those that represent and speak for the public.

DR MJ PHAAHLA, MP
MINISTER OF HEALTH

CHAIRPERSON OF THE BOARD STATEMENT

A compact and well-articulated legislative and policy environment is arguably a pivotal pillar and instrument for any regulator, and this gives effect to the critical role that SAHPRA is mandated to fulfill. Nowhere was that more evident than during the first full financial year of operating as SAHPRA, emerging out of the erstwhile Medicines Control Council.

SAHPRA operates in a complex legislative environment that straddles multiple areas and players. This amplifies a need for robust stakeholder engagement. Assuming an extended mandate that incorporates medical devices and radiation control necessitated a close scrutiny of development in the policy environment. Some of these developments have significant socio-economic implications, most notably, being in the area of cannabis pursuant to the new dynamics following the Constitutional Court Judgement in September 2018. This has spurred enormous commercial debates and interests and has placed some urgent regulatory considerations on the doorstep of SAHPRA. The Board has encouraged SAHPRA's direct engagement with the public on these matters in order to work collaboratively with relevant stakeholders to shape policy.

Another notable development is the advent of the Presidential Health Summit Compact which also has policy implications for SAHPRA. Collectively, these developments require policies that are both industry-wide and localised to SAHPRA's own internal operations; including a series of frameworks that require developments. The Compact recognises the need for capacitation of SAHPRA and other similar entities in the healthcare domain which includes a review of the funding model.

Despite the massive capacity constraints SAHPRA currently has, it continues to evolve. I am pleased with and have confidence in the leadership and support the Board has afforded to SAHPRA management through its committees; thereby ensuring that SAHPRA is able to assume leadership in its respective areas. It also gives the Board immense pleasure to confirm that all the executive positions have been filled, as one of the primary endeavours was to stabilise leadership in the organisation.

Our focus is on shaping a bright future for SAHPRA supported by a conducive legislative framework, internal processes and systems and human capital to build sustainable organisational capacity.

I also have pleasure in joining our honourable Minister and the CEO in presenting the Annual Performance Plan for the 2022/23 financial year.

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

ACCOUNTING OFFICER STATEMENT

Disruption is the best word that encapsulates how the coronavirus disease (COVID-19) impacted the world, our country and SAHPRA. The pandemic wreaked havoc with lives, livelihoods and the general well-being of societies.

SAHPRA found itself in the proverbial "eye of the storm" as it grappled with fast tracking priority health products to protect and save lives as the pandemic gripped society with deadly force. SAHPRA had to be agile in its response and outlook and craft a new "normal". This included re-engineering previous practices and embracing digitsation best practice so as to migrate business processes online.

All the application processes were digitised, staff were provided with the required tools of trade which enabled a large portion of the organisation to work remotely.

What has previously been characterised as a rigid regulatory authority with lengthy approval timelines had to modernise and be flexible and operate through high levels of efficiencies to keep up with the dynamic and fast paced changing landscape.

SAHPRA had to forge and strengthen several partnerships and leverage on the expertise of scientific experts to create systems and initiatives of world-class standards, whilst remaining locally relevant. The pandemic also provided ample opportunity for SAHPRA to work closely with other regulators, both globally and regionally. Owing to strong partnership with regulators such as the United States Food and Drug Administration (USFDA), Medicines and Healthcare Products Regulatory Agency (MHRA) and European Medicines Agency (EMA) as well as participation in global harmonisation programmes and associations such as International Collation of Medicines Regulatory Authorities (ICMRA), World Health Organization (WHO) and African Vaccine Regulatory Forum (AVAREF), SAHPRA was able to reduce the timeframe of vaccine approval, for example, from 20 months to 90 days.

The framework and guidelines in the medical devices and IVDs Unit had to be amended to ensure that SAHPRA provides adequate oversight of the COVID-19 molecular and serology tests. This also resulted in a strengthened partnership with the National Health Laboratory Services (NHLS) that served as a reference lab for validation testing.

As vaccines became the panacea of choice, SAHPRA had to be responsive to the regulation of vaccines, but to also monitor adverse reactions to the vaccines and other health products. SAHPRA, together with various stakeholders, developed a Med Safety App and launched it successfully. Following the launch of the Med Safety App, a microsite was launched to report on adverse events following immunisation (AEFIs) as well as adverse events of special interest (AESI) following vaccination.

In the midst of performing its regulatory functions, SAHPRA had to also debunk fake news, deal with anti-vax sentiments and respond to pressure from political and other parties. The communication of relevant, accurate and unbiased information took centre stage and SAHPRA used entities such as PATH, the National Press Club, Government Communication and Information System, 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 were updated regularly to ensure regular feedback to the public and relevant stakeholders.

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

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

I am immensely pleased to present our aforesaid 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 the SAHPRA will endeavour to achieve during the 2022/23 financial year.

ADV TEBOHO PETER NTHOTSO
COMPANY SECRETARY

MR KUDA KAPFUMVUTI
SENIOR MANAGER:
HEALTH PRODUCTS AUTHORISATION

MR DEON POOVAN
SENIOR MANAGER:
INSPECTORATE AND REGULATORY COMPLIANCE

MS SILVERANI PADAYACHEE
SENIOR MANAGER:
PHARMACEUTICAL EVALUATION MANAGEMEN

MR TOHLANG SEHLOHO
SENIOR MANAGER: CLINICAL EVALUATION MANAGEMENT

DR DIMAKATSO MATHIBE
SENIOR MANAGER: MEDICAL DEVICES AND RADIATION CONTROL

MS PORTIA NKAMBULE
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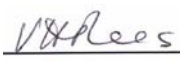
MR REGARDT GOUWS
CHIEF FINANCIAL OFFICER

MS CHRISTELNA REYNECKE
CHIEF OPERATIONS OFFICER
HEAD OF PLANNING

DR BOITUMELO SEMETE-MAKOKOTLELA
CHIEF EXECUTIVE OFFICER
ACCOUNTING OFFICER



PROFESSOR HELEN REES
CHAIRPERSON OF THE BOARD

APPROVED BY:

DR MJ PHAAHLA, MP
MINISTER OF HEALTH

LIST OF ABBREVIATIONS/ ACRONYMS

AMRH	African Medicines Regulatory Harmonisation Forum
COVID-19	Coronavirus disease
EDQM	European Directorate for Quality of Medicines and Health Care
GCP	Good Clinical Practice
GDP	Good Distribution Practice
GLP	Good Laboratory Practice
GMP	Good Manufacturing Practice
GVP	Good Vigilance Practice
GWP	Good Warehouse Practice
ICH	International Cooperation on Harmonisation
ICMRA	International Collation of Medicines Regulation Authorities
IPRP	International Pharmaceutical Regulators Programme
MTSF	Medium-Term Strategic Framework
NDoH	National Department of Health
NDP	National Development Plan
NHA	National Health Act
PFMA	Public Finance Management Act
SADC	Southern African Development Community
SAHPRA	South African Health Products Regulatory Authority
SAPC	South African Pharmacy Council
SDG	Sustainable Development Goals
WHO	World Health Organisation

GLOSSARY OF KEY TERMS AND DEFINITIONS

WORD	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 substance 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 benign 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 ionization in the medium through which it passes
In vitro diagnostic	In vitro diagnostic 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) - (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 -

WORD	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 or 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 ionize 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 ionization 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 progressively realise socio-economic rights, including access to healthcare.

Section 27 of Chapter 2 of the Bill of Rights of the Constitution states the following with regard to healthcare, food, water and social security:

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

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 and further matters related to the public interest.

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

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

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 co-operative governance and management of health services within national guidelines, norms and standards, in which each province, municipality and health district must address questions of health policy and delivery of quality health care services;
- Establish a health system based on decentralised management, principles of equity, efficiency, sound governance, internationally recognised standards of research and a spirit of enquiry and advocacy which encourage participation;
- Promote a spirit of co-operation and shared responsibility among public and private health professionals and providers and other relevant sectors within the context of national, provincial and district health plans;
- Create the foundations of the health care system, and
- Must 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

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

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

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

As per section 2b (1) of the Medicines Act, the Authority must, in order to achieve its objects, ensure:

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

In executing its functions, the Authority may:

- Liaise with any other regulatory authority or institution and may, without limiting the generality of this power, require the necessary information from, exchange information with and receive information from any such authority or institution in respect of:-

    - Matters of common interest; or
    - A specific investigation; and
    - Enter into agreements to co-operate with any regulatory authority in order to achieve the objects of the Medicines Act.

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

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

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

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

1.2.4 Other Related Legislations

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

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

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

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

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

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

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

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

Provides for the prohibition of the use or possession of, or the dealing in, drugs and of certain acts relating to the manufacture or supply of certain substances or the acquisition or conversion of the proceeds of certain crimes, the obligation to report certain information to the police, the exercise of

the powers of entry, search, seizure and detention in specified circumstances, the recovery of the proceeds of drug trafficking and related matters.

In relation to cannabis, on 18 September 2018 the Constitutional Court declared sections 4(b) and 5(b) (use and possession) read with Part III of Schedule 2 of the Drugs and Drug Trafficking Act, 1992 (the Drugs Act); and section 22A(9)(a)(i) of the Medicines and Related Substances Act, 1965, read with Schedule 7 of Government Notice No. R. 509 of 2003 unconstitutional on the premises that they amount to an impermissible limitation of the right to privacy. The Court suspended the order of invalidity for 24 months from 18 September 2018 to September 2020.

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

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

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

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

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

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

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

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

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

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

The South African Pharmacy Council (SAPC) in terms of section 35A of the Pharmacy Act, (Act No. 53 of 1974) regulates the practice of pharmacy within South Africa. SAPC ensures that all responsible pharmacists, pharmacy support personnel and pharmacy owners provide pharmaceutical services that comply with good pharmacy practice standards prescribed in the Pharmacy Act and relevant provisions of the Medicines and Related Substances Act. The Medicines Act, in section 16(d), provides for possession of medicines or scheduled substances for sale by the pharmacists or a person licensed to own a pharmacy in terms of the Pharmacy Act, 1974 or a person who is the holder of a license as completed in section 22C of the Medicines Act. The SAPC has, in terms of section 38A of the Pharmacy Act, appointed inspection officers with a view to monitoring pharmacies for compliance. The provisions of the Pharmacy Act include investigation of complaints received alleging misconduct or unprofessional conduct.

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

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

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

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

One of the key new responsibilities emanating from SAHPRA's extended mandate relates to radiation control, which has crucial elements within the ambit of the jurisdiction of the Department of Mineral Resources and Energy. Another responsibility is cannabis regulation, which - involves multiple

ministries such as the Department of Justice and Correctional Services and the Department of Agriculture and Rural Development, to effect the country's enhancement of access to this medicinal product. As SAHPRA continues to mature into its role, it is becoming increasingly evident that there is a critical need to harmonise roles and responsibilities to avert the risk of an internal leadership vacuum or duplication of efforts and subsequent potential "conflict."

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

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, in order 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.

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 in aligned to 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 health lives and promote well-being for all at all stages". The goal is further broken down to target is further broken down to target 3.8 that focuses 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" and target 3b that 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 health care 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 NDoH is 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 of the MTSF to the National Drug Policy; which was adopted in 1995 with extensive support from the World Health Organisation (WHO). The Policy was adopted to serve the health care needs of South Africa in the following ways:

1. It offers a clear description of the approach by which pharmaceutical services in the country will be managed.
2. It offers guidance to stakeholders, including health care providers, suppliers of goods and services, and governmental and non-governmental agencies of ways in which 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 an adequate pharmaceutical infrastructure.
4. It facilitates the design, production and implementation of appropriate programmes for human resource development in health care.

- **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 9 pillars are commitments to strengthening the health system:

1. Augment Human Resources 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 health care;
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 re-engineering the operational models and revising business processes. Collaborative structures to introduce new medicines into pilot programmes to address high burden diseases, particularly the human immunodeficiency virus, tuberculosis, cancer and other diseases of priority and adopted the novel regulatory mechanism of reliance and molecule-based registration.

Overall, as at 30 September 2021, the backlog applications were cleared by 89%. This figure comprises the 14 373 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.

Reduction in the average time frame for the registration of product

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' 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 effort 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, and may 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 complete scientific review for safety, quality, efficacy, Good Manufacturing Practice
- Abridged review – assess specific, pre-agreed areas of critical importance to SAHPRA's mandate to ensure safety the South African public
- Verified review – validate that application conforms to reference authorisation and provides required information.

- **Amendments to the Medicines Act**

The Medicines and Related Substances 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 National Department of Health 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 is 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/ innovative medicine/New Chemical Entities);
- That show a major therapeutic advantage in safety or efficacy 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 National Department of Health or
- Where security of supplies is a concern (guided by NDoH needs) and Department of Agriculture.

The policy applies to New Chemical Entities, New Biological medicines, interchangeable multi-source (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 New Chemical Entities, replicas of generic (multisource) products, submitted by either the same of by different applicants, identical active pharmaceutical ingredient (API) (same DMF number & 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**

During the 2021/2022 financial year, the following human resource policies were approved:

- Training and Development Policy
- Disciplinary Policy

- Recruitment and Selection Policy
- Performance Management Policy
- Recognition and Rewards Policy.

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

- Talent Management Policy
- Remuneration and Benefits Policy
- Leave 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 & Others	On 5 December 2018, the Constitutional Court declared section 22C(1)(a) of the Medicines and Related Substances Act unconstitutional for requiring the veterinarians to have a licence in order 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 which 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 his or her personal consumption in private; and • To cultivate cannabis in a private place for his or her 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 judgement. In response to this, the Minister of Health, through SAHPRA, amended the Schedules to the Medicines and Related Substances Act, Act 101 of 1965 and published these in the Government Notice No. 586, Government Gazette No. 43347, on 22 May 2020. These amendments included removal of Cannabis as a plant from Schedule 7 of the Medicines and Related Substances Act, 101 of 1965. 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 % percent or less

NO.	CASE	SUMMARY
		of 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 & Another [Case No:11203/2018]	On 1 October 2020, the Pretoria High the 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 twelve months to allow the 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 judgement, the General Regulations are therefore still in force

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 6th Administration following the recent elections has ushered in a renewed focus on reform and shift in policy. Public health reform is exemplified in the area prioritisation of Universal health coverage and the promulgation of the National Health Insurance Bill
2.	There is a plethora of legislations that affect the areas of SAHPRA's operations which straddle various departments that need to be co-ordinated through intergovernmental relations processes. This would include regulation of radiation emitting devices, management of opioid abuse as well as deregulation of cannabis
3.	Increasingly competitive government tenders, with punitive conditions attached for non-compliance, have been introduced
4.	The industry is still to transform and there is currently no sector chapter to promote self-regulation for sector transformation in line with government policies, mainly the B-BBEE 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 start to exert more pressure on pharmaceutical companies to drop their prices
2.	The SA medical device market is estimated at R30 billion in 2019 and presents an opportunity to garner 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 is growing at just over 9% in value and this growth is ascribed to the increased demand for generics
4.	Nearly every therapeutic class currently has at least one generic equivalent available and sales of over-the-counter generics now also outstrip brand name products by almost R1 billion in value and more than 53 million units
5.	Global shortages of active pharmaceutical ingredients, 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 fees 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 medication
8.	In response to the COVID-19 outbreak, government introduced a massive social relief and economic support package of R500 billion, and part of this budget was allocated to health to respond to the coronavirus
9.	Non-private medical costs increased and labour productivity declines are the main direct costs related to the COVID-19 outbreak

10.	South Africa has been approached by vaccine manufacturers to consider bilateral purchasing agreements. The risk is that price negotiations are confidential, up-front payments may be lost should the vaccine not prove safe and efficacious
SOCIAL/SOCIO-ECONOMIC	
1.	The increasing rates of inequity and poverty amongst the different population groups in South African society is a clear indication of an increase in the number of vulnerable individuals that need a social safety network against sub-optimal and falsified health products that flood across porous borders into vulnerable third world markets
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
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 which 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 the SAHPRA to ensure that whichever vaccine being recommended or made available through the COVAX Facility has met all the regulatory requirements of safety, efficacy, and quality
TECHNOLOGICAL	
1.	Digitisation of SAHPRA operations is imperative to optimise SAHPRA into a globally recognised space
2.	Technical advances and increasing trends in cyber-crimes create risks to unauthorised access to sensitive information. Data security is a growing business consideration that must prioritised
3.	Online purchasing sites are not adequately regulated and have a negative impact in that they enable ease of access to illegal importation of 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 relying on information technology. This has resulted in increased data costs for SAHPRA, within the limited budget in which it operates
ENVIRONMENTAL	
1.	An increase in reported cases of abandoned or recklessly handled radiation-emitting materials that are causing illnesses for neighbouring communities requires the urgent attention of SAHPRA's radiation control division
2.	SAHPRA must align to the global trends of greener industrial systems and should seek to align legislation and practice of licencing and inspections with stimulating industrial compliance
3.	The lockdown due to the COVID-19 pandemic has placed restrictions in terms of movement therefore resulting in a positive impact on the environment such as the improvement air quality and less wase and noise pollution
4.	The negative impact of the COVID-19 pandemic has been the increase of medical waste, haphazard use and disposal of personal protective equipment that creates environmental burden
LEGAL	
1.	There is a plethora of legislation that requires harmonisation in order to provide clarity for SAHPRA to discharge 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 so as to ensure the regulatory compliance unit is properly aligned to enforce regulation 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

SWOT Analysis

STRENGTHS	1. Agility and autonomy of a Schedule 3A entity permits quicker responsiveness to the health products regulatory environment 2. Re-engineered business process towards the novel reliance mechanisms places SAHPRA as a leader to develop rigor in this untested regulatory system and enable the entity to be a though leader in this space 3. Strong and diverse professional team 4. In a position to reframe the regulatory footprint in Africa 5. Sound strategic partnerships that advance the mandate of SAHPRA 6. Established key collaborations and memberships, such as AMRH, Zazibona and PIC/s, WHO Collaborative Review Process	**WEAKNESSES**	1. No quality management in place to fortify system changes and governance 2. Lack of a digitised track and trace system, including cost center and revenue 3. Critical positions filled by acting managers 4. Lack of skilled staff to support the programme changed business processes 5. Low staff morale with regard to transition and extensive change, with no staff climate surveys conducted. As yet, no proper human resource change management processes rolled out to support staff 6. Shortage of skilled assessors 7. Heavy reliance on external reviewers 8. Non-competitive remuneration policies allowing for benchmarking exercises 9. Inability to confirm which of the vacant positions are actually funded 10. A lack of fees review around business processes has resulted in loss of revenue from not collecting fees or not collecting adequate fees to match the cost of business processes 11. No way of confirming effectiveness of renewed performance review systems

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 of experience of 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. An opportunity to create a fee structure to generate more revenue necessary for financial sustainability 8. Implementing 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. 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 2. Poaching of staff from the industry remains a threat during the period of uncertainty in the transition 3. Current internal capacity challenges could lead to a creation of a new backlog 4. Fraud and corruption risks if internal audit is not fortified 5. Flight of scarce skills with increased professional emigration out of South Africa 6. Reliance on external expertise if skills transfer from senior experts is not facilitated in an active process of knowledge transfer 7. Low staff morale 8. No proper change management 9. Lack of funding expected to support the backlog project 10. Diminished revenue due to inadequate fees increase in the last three years 11. Treasury cuts leading to diminished fiscus, with government austerity measures currently underway 12. Inordinate pressure from the industry stakeholder threatens to sift SAHPRAs focus from its Public Health mandate towards an industry agenda if not managed properly

1.2 Internal Environment Analysis

Health Products Authorisation

There has been an increase in the number of applications received in Business-As-Usual from April 2020. This may be attributed towards the conclusion of the backlog Type 1 variations submissions via the Digital Variations Portal and some focus then shifting to the Business-As-Usual new application submissions. The closure of the resubmission windows in the Backlog Project has also contributed to the increase. The number of applications received range from 278 applications between April – June 2020 to 424 applications received between April – June 2021. It is noted that many of the new applications received are for generic medicines.

Inspectorate and Regulatory Compliance

The impact of the COVID-19 pandemic has required SAHPRA to implement measures to continue inspections in a virtual environment. With the easing of travel restrictions, physical international inspections will be able to recommence. The increased demand for inspections is being driven externally from a new application volume increase as well as an internally driven demand which is driven by the role that the Inspectorate needs to fulfill in terms of oversight, where routine and unannounced inspections are required to be conducted.

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 Department of Agriculture, Land Reform and Rural Development, 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. SAHPRA continues to face political pressure regarding frameworks to support rural cannabis farmers and the role that SAHPRA plays in enabling more farmers to be licensed to cultivate cannabis for producing scheduled substances. This aspect is considered in the development and implementation of the Cannabis Master Plan, which is being led by the Department of Agriculture, Land Reform and Rural Development. With the amendment of the schedules to remove cannabis plant, the regulation of industrial hemp (low- trandselta-9-tetrahydrocannabinol, low-cannabidiol cannabis) has also been transferred to the Department of Agriculture, Land Reform and Rural Development, to be regulated under the Plant Improvement Act.

With increased stakeholder engagement, both with industry and other government departments, SAHPRA guidelines will 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 ITAC has impact in the issuing of SAHPRA permits.

Clinical Evaluations Management

The advent of the COVID-19 pandemic has necessitated a radical adjustment of how resources are planned and deployed. There was an increased demand for repurposed medicines which had been discontinued and no longer marketed in the country due to the advent of the COVID-19 pandemic.

Vaccines already registered overseas increased the pressure on SAHPRA to keep up with the demand for vaccines in the country.

There was a sudden increase in the number of clinical trial applications for both therapeutics and vaccines, although the majority was for vaccines. The introduction of new vaccines on novel platforms required that both programmatic and regulatory pharmacovigilance be strengthened in the country, in order to both monitor adverse events and educate the public about what to expect and how to respond to any adverse events that may have not been detected during clinical trials.

COVID-19 also highlighted the need to augment regulatory expertise in the monitoring of repurposed therapeutics that had hitherto been used for other indications. Existing expertise in SAHPRA had to be augmented to deal with new clinical trial designs for new interventions against the pandemic. The new vaccine platforms and technologies highlighted new safety issues, not seen with older generation vaccine designs, that needed expert analysis to determine vaccine benefit:risk in all populations with different co-morbidities, regardless of age.

Pharmaceutical Evaluation Management

The use of reliance of work done by other regulators that SAHPRA aligns with has facilitated quicker review turnaround times for vaccine applications. The use of the World Health Organization 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, has subjected SAHPRA to multiple queries on authorisations granted by SAHPRA.

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 is inadequate to deal with the number of applications received. A solution was re-distribution of work to have the Bioequivalence studies reviewed by Clinical evaluations. Training of 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 the Bio-equivalence 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 therefore impacting on the timelines set which are per the European Medicines Agency guidelines.

The 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 less 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 them and seek out areas of co-operations. Civil society groups are influential not only in policy making but also in building a society wide narrative.

The medical industry is relatively new in terms of regulations which includes the establishment licensing and product registration, therefore skills set 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 organization with review of applications is crucial in the achieving the objective output of SAHPRA.

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

Collaborations

SAHPRA continues to strengthen its collaborations and partnership with fora such as AMRH, Zazibona and PIC/s, World Health Organisation Collaborative Review Process.

It has established key collaborations with other National Regulatory Authority within the African continent, such as Zimbabwe, Kenya, Tanzania and in international platform such as in the United Kingdom, Switzerland and the United States of America to mention few.

Partnership with other stakeholders is imperative in ensuring continuous successful medical devices products (both non-*in vitro* diagnostic and *in vitro* diagnostics) registration as well as ensuring access

to safe, quality and effective products in our market. SAHPRA rely in partners such as the South African National Accreditation Services to assist with ensuring certification of manufacturers and distributors for Quality Management System (ISO 13485) as well as performance evaluation to assure safety of products by working together with the National Reference Laboratory that is the National Health Laboratory Services.

SAHPRA participants in various platform both continentally and internationally such as the ones that follow. 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 is 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 regulatory fora such as the International Collation of Medicines Regulation Authorities (ICMRA), the European Directorate for Quality of Medicines and Health Care (EDQM), the African Medicines Regulatory Harmonisation Forum (AMRH), Southern African Development Community (SADC) harmonisation initiatives which enables SAHPRA to operate on regional and international regulatory best practices.

The World Health Organisation-International Regulatory Cooperation for Herbal Medicines Network that aims to amongst others, improve the regulation of herbal medicines, the World Integrated Medicine Forum on the regulation of homeopathic medicinal products and the International Over-The-Counter Medicine Regulators Forum.

In the monitoring of clinical trials, SAHPRA is part of a continental initiative called The African Vaccine Regulatory Forum (AVAREF), which is a network of African national regulatory authorities and ethics committees that uses harmonization and reliance as pillars for capacity building for clinical trial monitoring of studies conducted on the continent. AVAREF works to ensure collaboration between 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 AU3S 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 on the safety surveillance of COVID-19 vaccines in four countries. These pilot countries are Ethiopia, Ghana, Nigeria, and South Africa – altogether comprising ~30% of Africa's population. The AU-3S team works closely with the medical products National Regulatory Authorities (NRAs) and Expanded Programmes on Immunisation (EPIs) from countries involved.

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

The Southern African Development Community harmonisation initiative for regulation of veterinary medicines is still at inception phase and will amongst others, play the role in improving access to quality VMPs by reducing the registration time, eliminating unnecessary duplication of work, managing the increasing workload and building capacity on individual member states in the SADC.

Memorandum of Understanding

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

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

Financial Resources and Broad-Based Black Economic Empowerment

The fiscal constrains facing South Africa has had an impact on the funding received from National Treasury by SAHPRA seeing 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 establish systems and to reach full capacity by filling its approved structure which requires significant financial resources.

To overcome this challenge, SAHPRA has to prioritise own revenue generation and explore external funding opportunities. New fees were gazetted in December 2020 and a further review to add new

revenue streams is planned to be implemented during the 2022/23 financial year.

SAHPRA has implemented procurement policies and procedures to comply with the Broad-Based Black Economic Empowerment (BBBEE) procurement compliance requirements. A BBBEE compliance certificate was obtained for the 1st 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

It is anticipated that the South African economy will likely contract again this fiscal year. The lockdown restrictions that are in place to curb the spread of the coronavirus is resulting in shrinkages of the gross domestic product and the economy slowing down. The high unemployment rate and the load shedding are additional challenges. It is against this background that it has resulted in making consultations with organised labour very challenging as they demand higher salary increases and benefits for their members due to the state of the economic conditions. SAHPRA is continuously engaging with both organised labour and the employees assist in mitigating future challenges.

SAHPRA's strategic journey is communicated to all employees through various channels that include the Chief Executive Officer's engagements with staff and the Human Resources Indaba (engagement) 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. The Authority is laying the building blocks for change towards the way SAHPRA delivers to the South African citizens in the process of making sure that, the medicines are safe, efficacious and of good quality.

Although the lack of sufficient human resource capacity continues to be challenge, many vacancies were filled during the 2021/22 financial year, despite the challenge of not having competitive salaries. The associated risk is linked to the use of the Department of Public Service and Administration's salary scales. SAHPRA is in the process of developing its own salary scale, which will be able to resolve these challenges. This will be supported by a benchmarking report. Recruitment has been accelerated by targeting the prioritised and budgeted position. The training and development sessions for employees has been increased as per employees' Individual Development Plans.

Information and Communication Technology

SAHPRA's digital transformation journey is steadily progressing, although not at the desired pace, as it continues to implement new digital solutions, enhance and modernise existing and legacy systems. SAHPRA has indeed become virtually paperless as our engagements with stakeholders is now

exclusively through secure digital platforms.

As part of this transformation journey, SAHPRA will be embarking on a process to develop an Enterprise Architecture of 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 and ensure compliance with relevant legislation; and achieve an unqualified audit outcome by ensuring continuous management practices through compliance with standards operating procedures and systems within SAHPRA. Further, to review existing operational processes and recommend new or changed processes and work methods to ensure optimal organisational effectiveness and, measure and monitor the Authority's performance
Information Technology and Communication (ICT)	To develop and implement ICT integrated governance framework by focusing on the business continuity plan and support the needs and requirements of the end users. Further, to manage public relations, information and communication services to ensure proper management and dissemination of information to internal and external stakeholders, to ensure a seamless harmonious operational platform by building strong and sustainable relationships with all its stakeholders
Human Resource Management	To provide human resources and organisational development systems and solutions that meet the needs of the organisation and support the achievement of the Authority's strategic objectives

1.1.2 Outcomes, Outputs, Output Indicators and Targets

OUTCOMES	OUTPUTS	OUTPUT INDICATORS	AUDITED/ACTUAL PERFORMANCE			ESTIMATED PERFORMANCE 2021/22	No.	MEDIUM TERM EXPENDITURE FRAMEWORK TARGETS		
			2018/19	2019/20	2020/21			2022/23	2023/24	2024/25
Effective financial management (1)	Attain and maintain an unqualified overall AG Audit outcome on previous year's performance	Unqualified audit opinion obtained on the annual financial statements	Qualified audit opinion obtained for the 2018/19 financial year	Qualified audit opinion obtained for the 2019/20 financial year	Qualified audit opinion obtained for the 2020/21 financial year	Unqualified audit opinion obtained	1.1	Unqualified audit opinion obtained for the 2021/22 financial year	Unqualified audit opinion obtained for the 2022/23 financial year	Clean audit opinion obtained for the 2023/24 financial year
Financial sustainability achieved through revenue generated and enhanced operational efficiencies (2)	Total revenue generated from fees	Total revenue generated from fees in the financial year	-	-	R102 million	Revenue of R162 million generated from fees	1.2	Annual revenue of R170 million generated from fees	Annual revenue of R177 million generated from fees	Annual revenue of R185 million generated from fees
	Break-even of expenses and revenue by 31 March	Break-even of expenses and revenue by 31 March 2023	-	-	-R24.7 million	Zero	1.3	≥ zero amount on the budget versus income and expenditure report	≥ zero amount on the budget versus income and expenditure report	≥ zero amount on the budget versus income and expenditure report

OUTCOMES	OUTPUTS	OUTPUT INDICATORS	AUDITED/ACTUAL PERFORMANCE			ESTIMATED PERFORMANCE 2021/22	No.	MEDIUM TERM EXPENDITURE FRAMEWORK TARGETS		
			2018/19	2019/20	2020/21			2022/23	2023/24	2024/25
Continuously respond to the needs and expectations of SAHPRA stakeholders (3)	Recommendations implemented	Percentage of accepted recommendations from the 2022/23 stakeholder perception survey implemented	-	-	-	40% prioritised recommendations from the survey implemented	1.4	60% accepted recommendations from the 2022/23 stakeholder perception survey implemented	80% accepted recommendations from the 2022/23 stakeholder perception survey implemented	100% accepted recommendations from 2022/23 the stakeholder perception survey implemented
A positive and enabling working culture created (4)	Change management intervention implemented	Percentage of change management interventions implemented	-	-	-	50% of the change management intervention implemented	1.5	80% of the change management intervention implemented	100% of the change management intervention implemented	Review of the change management intervention conducted
	Workplace Skills Plan implemented	Percentage of Workplace Skills Plan implemented	-	-	-	30% of the Workplace Skills Plan implemented	1.6	50% of the Workplace Skills Plan implemented	60% of the Workplace Skills Plan implemented	80% of the Workplace Skills Plan implemented
Attract and retain superior talent (5)	Budgeted positions filled	Percentage of budgeted positions filled	-	-	Out of the 30 prioritised positions, 24 (80%) were filled	60% budgeted positions filled	1.7	95% budgeted positions filled	97% budgeted positions filled	80% of core business positions in the staff establishment filled

OUTCOMES	OUTPUTS	OUTPUT INDICATORS	AUDITED/ACTUAL PERFORMANCE			ESTIMATED PERFORMANCE 2021/22	No.	MEDIUM TERM EXPENDITURE FRAMEWORK TARGETS		
			2018/19	2019/20	2020/21			2022/23	2023/24	2024/25
Strengthened Information and Communication Technology and digitisation (6)	Enterprise Architecture	Enterprise Architecture developed	-	-	10% of processes digitised. The User Requirements Specification for the Regulatory Information Management Systems was developed and submitted for approval in March 2021	3 business processes digitalised	1.8	Enterprise Architecture approved by the Board	Phase 1 of the roadmap on the Enterprise Architecture implemented	Phase 2 of the roadmap on the Enterprise Architecture implemented

1.1.3 Output Indicators: Annual and Quarterly Targets

OUTPUT INDICATORS	No.	2022/23 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 2021/22 financial year	Annual financial statements prepared	Unqualified audit opinion obtained for 2021/22 financial year	-	-
Total revenue generated from fees in the financial year	1.2	Annual revenue of R170 million generated from fees	Revenue of R80 million generated from fees	Revenue of R30 million generated	Revenue of R30 million generated	Revenue of R30 million generated
Break-even of expenses and revenue by 31 March 2023	1.3	≥ zero amount on the budget versus income and expenditure report	≥ zero amount on the budget versus income and expenditure report	≥ zero amount on the budget versus income and expenditure report	≥ zero amount on the budget versus income and expenditure report	≥ zero amount on the budget versus income and expenditure report
Percentage of accepted recommendations from the 2022/23 stakeholder perception survey implemented	1.4	60% accepted recommendations from the 2022/23 stakeholder perception survey implemented	20% accepted recommendations from the 2022/23 stakeholder perception survey implemented	40% accepted recommendations from the 2022/23 stakeholder perception survey implemented	50% accepted recommendations from the 2022/23 stakeholder perception survey implemented	60% accepted recommendations from the 2022/23 stakeholder perception survey implemented
Percentage of change management interventions implemented	1.5	80% of the change management intervention implemented	20% of the change management intervention implemented	40% of the change management intervention implemented	60% of the change management intervention implemented	80% of the change management intervention implemented
Percentage of Workplace Skills Plan implemented	1.6	50% of the Workplace Skills Plan implemented	Workplace Skills Plan approved by the Executive Committee	20% of the Workplace Skills Plan implemented	35% of the Workplace Skills Plan implemented	50% of the Workplace Skills Plan implemented

OUTPUT INDICATORS	No.	2022/23 ANNUAL TARGETS	1ST QUARTER TARGETS (Apr - Jun)	2ND QUARTER TARGETS (Jul - Sep)	3RD QUARTER TARGETS (Oct - Dec)	4TH QUARTER TARGETS (Jan - Mar)
Percentage of budgeted positions filled	1.7	95% budgeted positions filled	25% budgeted positions filled	45% budgeted positions filled	65% budgeted positions filled	95% budgeted positions filled
Enterprise Architecture developed	1.8	Enterprise Architecture approved by the Board	Enterprise Architecture service provider appointed	Enterprise Architecture review conducted	Enterprise Architecture submitted to EXCO	Enterprise Architecture approved by the Board

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 whilst exploring additional funding for a comprehensive fully automated system later during 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 perception 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 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, these will be addressed within 24-48 hours. In instances were issues cannot be addressed within this time frame, it must be addressed within 7-14 working days.

Human Resources

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 its 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 and 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 by core business.

The attraction of competent talent is characterised by different dynamics which includes the job market, affordability of required skill, scarcity of skills, etc. SAHPRA continually benchmarks itself with the industry and other like organisations to ensure its hands are always on the pulse in terms of the availability of technical skills.

Information Technology

SAHPRA plans to embark on an enterprise architecture review process. The purpose of the enterprise architecture is to create a map of information technology 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 information technology. It is key for SAHPRA to ensure that this architecture exists to provide clarity and alignment between business processes and the information technology infrastructure (hardware and software).

SAHPRA will obtain the following 5 benefits when 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;
- Information technology infrastructure benefits through increased interoperability and integration; and
- Organisation benefits through improved information quality, sharing and documentation supported by positive cultural change.

1.1.5 Programme Resource Considerations

Resource considerations (R'000)

2019/20 Budget Estimates	2019/20 Audited Outcome	2020/21 Audited Outcome	2021/22 Budget Estimates	2022/23 Budget Estimates	2023/24 Budget Estimates	2024/25 Budget Estimates
90 355	79 842	110 727	116 510	130 390	148 376	154 652
Economic Classification						
Compensation of Employees	44 611	55 739	48 923	57 384	65 376	69 723
Goods and Services	32 961	54 988	67 587	73 006	83 000	84 929

Compensation of Employees and Goods and Services mainly earmarked to provide support services such in the form of Finance, Information and Communication Technology, Facilities, Governance and Compliance support to the organisation and core functions.

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

1.2.2 Outcomes, Outputs, Output Indicators and Targets

OUTCOMES	OUTPUTS	OUTPUT INDICATORS	AUDITED/ACTUAL PERFORMANCE			ESTIMATED PERFORMANCE 2021/22	No.	MEDIUM TERM EXPENDITURE FRAMEWORK TARGETS		
			2018/19	2019/20	2020/21			2022/23	2023/24	2024/25
High levels of organisational operational efficiency and effectiveness in the regulatory function maintained (7)	Backlog in medicine registration cleared	Percentage of medicine registrations in the backlog cleared	Not applicable for 2018/19	58%	Out of 5 320 backlog applications for medicine registrations, 2 819 (53%) were cleared	95% medicine registrations backlog cleared	2.1	100% medicine registrations backlog cleared	-	-
	Backlog in medicine variation applications cleared	Percentage of medicine variation applications in the backlog cleared	-	-	Out of the 7 440 backlog applications for variations, 7 165 (96%) were cleared	95% medicine variation applications backlog cleared	2.2	100% medicine variation applications backlog cleared	-	-
	New Chemical Entities applications finalised	Percentage of New Chemical Entities finalised within 490 working days	0%	100%	Out of the 72 New Chemical Entities registered, all 72 (100%) were finalised within 590 days	80% New Chemical Entities finalised within 590 working days	2.3	80% New Chemical Entities finalised within 490 working days	80% New Chemical Entities finalised within 400 working days	80% New Chemical Entities finalised within 360 working days

OUTCOMES	OUTPUTS	OUTPUT INDICATORS	AUDITED/ACTUAL PERFORMANCE			ESTIMATED PERFORMANCE 2021/22	No.	MEDIUM TERM EXPENDITURE FRAMEWORK TARGETS		
			2018/19	2019/20	2020/21			2022/23	2023/24	2024/25
	Generic medicines applications finalised	Percentage of generic medicines finalised within 250 working days	3%	-	Out of the 240 generic medicines registered, 131 (55%) were finalised within 250 days	60% generic medicines finalised within 250 working days	2.4	75% generic medicines finalised within 250 working days	80% generic medicines finalised within 250 working days	85% generic medicines finalised within 250 working days
	International Organization for Standardization 9001: 2015 certified	International Organization for Standardization 9001: 2015 certification obtained	-	-	Medicines Regulatory Quality Management system developed and implemented	40% Quality Management System requirements implemented	2.5	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
Global best practices maintained (8)	WHO global benchmarking conducted	WHO maturity level assessed	-	-	Commenced with preparations to conduct the survey and engagements were held with WHO to provide support to SAHPRA	WHO maturity level 3 obtained	2.6	WHO maturity level 3 obtained	WHO maturity level 3 maintained	WHO maturity level 4 obtained

1.2.3 Output Indicators: Annual and Quarterly Targets

OUTPUT INDICATORS	No.	2022/23 ANNUAL TARGETS	1ST QUARTER TARGETS (Apr - Jun)	2ND QUARTER TARGETS (Jul - Sep)	3RD QUARTER TARGETS (Oct - Dec)	4TH QUARTER TARGETS (Jan - Mar)
Percentage of medicine registrations backlog cleared	2.1	100% medicine registrations backlog cleared	96% medicine registration backlog cleared	97% medicine registration backlog cleared	100% medicine registration backlog cleared	-
Percentage of medicine variation applications backlog cleared	2.2	100% medicine variation applications backlog cleared	96% medicine variation applications backlog cleared	97% medicine variation applications backlog cleared	100% medicine variation applications backlog cleared	-
Percentage of New Chemical Entities finalised within 490 working days	2.3	80% New Chemical Entities finalised within 490 working days	80% New Chemical Entities finalised within 490 working days	80% New Chemical Entities finalised within 490 working days	80% New Chemical Entities finalised within 490 working days	80% New Chemical Entities finalised within 490 working days
Percentage of generic medicines finalised within 250 working days	2.4	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	2.5	International Organization for Standardization 9001: 2015 certified	50% Quality Management System requirements implemented	50% Quality Management System requirements implemented	Stage 1 certification audit conducted	International Organization for Standardization 9001: 2015 certified
WHO maturity level assessed	2.6	WHO maturity level 3 obtained	WHO maturity level 3 obtained	-	-	-

1.2.4 Explanation of Planned Performance over the Medium-Term Period

Backlog

Focus over the medium term will be on piloting and introducing risk-based assessment approaches, specifically in the area of quality and bio-equivalence, as the current progress pertaining to new registration application finalisation is still slow. Reliance interventions, such as abridged and verified review (with specific focus on internal reliance for the latter), will continue to form an integral part of the measures utilised to clear the backlog applications. Close monitoring of the evaluators engaged to assist the Backlog Clearance Programme will continue, in order to derive maximum output from these.

Furthermore, enhanced collaboration between SAHPRA and other medicines regulators (both regional and international) will remain a focus and solutions garnered by other agencies in terms of clearance of an application backlog will be considered within the SAHPRA backlog scenario. It is envisaged that these interventions will improve turnaround-times and accessibility to medicines.

Business-As-Usual (BAU)

BAU commenced a pilot, BAU New Medicine Applications for Registration, for new medicine applications submitted from 1 August - 30 September 2021. The purpose of the pilot is to provide a common understanding of what supporting documentation is required to evaluate an application as well as resolve any issues before the application is submitted. This will enable proper planning for submissions and enhance the management of both timeframes and resources.

SAHPRA envisages that the benefits of the pre-submission meeting will result in:

- Improved quality of subsequent applications
- Enhanced transparency of the review process
- Smoother review process
- Potentially shorter total review timelines should the application meet all requirements post pre-submission meetings and evaluation
- Provide the relevant SAHPRA units the opportunity to re-align resources to accommodate the arrival of the submission/application.

Pre-submission meetings were scheduled between SAHPRA and the applicants to discuss the applications to be included in the pilot. The new medicine applications submitted for this pilot will continue to be tracked and monitored throughout the registration process. The learnings will inform

the need for the pre-submission meetings. This will ensure that quality dossiers are submitted and will enable proper internal management of timeframes and resources.

Quality Management System

SAHPRA is committed to implementing a Quality Management System in order to co-ordinate 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 on institutionalising a quality culture throughout the organisation and obtaining International Organization for Standardization 9001: 2015 certification.

SAHPRA is targeting to be a WHO listed authority by attaining maturity level 3 (ML3) where 9 core regulatory functions will be operational and meet the criteria and standards set. The Authority will maintain the maturity level 3 status with fully functional regulatory systems.

1.2.5 Programme Resource Considerations

Resource considerations (R'000)

2019/20 Budget Estimates	2019/20 Audited Outcome	2020/21 Audited Outcome	2021/22 Budget Estimates	2022/23 Budget Estimates	2023/24 Budget Estimates	2024/25 Budget Estimates
68 663	28 883	34 223	72 534	52 866	29 049	31 073
Economic Classification						
Compensation of Employees	16 812	13 460	22 382	27 277	28 640	30 646
Goods and Services	12 071	20 763	50 152	25 589	409	427

Resources allocated for increased human resource expenditure to capacitate the unit as well as the envisioned finalisation of the backlog project in 2021/22 under goods and services.

1.3 Programme 3: Inspectorate and Regulatory Compliance

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

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

1.3.1 Sub-programmes

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

1.3.2 Outcomes, Outputs, Output Indicators and Targets

OUTCOMES	OUTPUTS	OUTPUT INDICATORS	AUDITED/ACTUAL PERFORMANCE			ESTIMATED PERFORMANCE 2021/22	No.	MEDIUM TERM EXPENDITURE FRAMEWORK TARGETS		
			2018/19	2019/20	2020/21			2022/23	2023/24	2024/25
High levels of organisational operational efficiency and effectiveness in the regulatory function maintained (7)	New GMP and GWP related licences finalised	Percentage of new GMP and GWP related licenses finalised within 125 working days	-	77%	Out of the 39 new GMP licence applications received, 29 (74%) new GMP licences were issued Out of the 29 new GMP licences issued, 17 (59%) were issued within 125 working days	60% new GMP and GWP related licenses finalised within 125 working days	3.1	60% new GMP and GWP related licenses finalised within 125 working days	70% new GMP and GWP related licenses finalised within 125 working days	80% new GMP and GWP related licenses finalised within 125 working days
	Permits finalised	Percentage of permits finalised within 20 working days	-	-	-	70% permits finalised within 20 working days	3.2	70% permits finalised within 20 working days	80% permits finalised within 20 working days	85% permits finalised within 20 working days

OUTCOMES	OUTPUTS	OUTPUT INDICATORS	AUDITED/ACTUAL PERFORMANCE			ESTIMATED PERFORMANCE 2021/22	No.	MEDIUM TERM EXPENDITURE FRAMEWORK TARGETS		
			2018/19	2019/20	2020/21			2022/23	2023/24	2024/25
	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	70% health product quality complaints reports produced within 30 working days	3.3	70% regulatory compliance investigation reports produced within 30 working days	80% 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.	2022/23 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 GMP and GWP related licenses finalised within 125 working days	3.1	60% new GMP and GWP related licenses finalised within 125 working days	60 % new GMP and GWP related licenses finalised within 125 working days	60 % new GMP and GWP related licenses finalised within 125 working days	60 % new GMP and GWP related licenses finalised within 125 working days	60 % new GMP and GWP related licenses finalised within 125 working days
Percentage of permits finalised within 20 working days	3.2	70% permits finalised within 20 working days	70% permits finalised within 20 working days	70% permits finalised within 20 working days	70% permits finalised within 20 working days	70% permits finalised within 20 working days
Percentage of regulatory compliance investigation reports produced within 30 working days	3.3	70% regulatory compliance investigation reports produced within 30 working days	70% regulatory compliance investigation reports produced within 30 working days	70% regulatory compliance investigation reports produced within 30 working days	70% regulatory compliance investigation reports produced within 30 working days	70% 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 safeguard the safety of medicines of all those that live in South Africa. This is one of the fundamentals necessary for SAHPRA to achieve its organisational impact.

As Good Manufacturing Practice and Good Warehouse Practice related licenses are only issued to South African manufacturers, importer/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 finalizing new licence applications for GMP-related and GWP-related licences.

With the risk of illicit, substandard or falsified medicine, 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 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 planned 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)

2019/20	2019/20	2020/21	2021/22	2022/23	2023/24	2024/25
Budget Estimates	Audited Outcome	Audited Outcome	Budget Estimates	Budget Estimates	Budget Estimates	Budget Estimates
56 209	40 026	35 696	35 827	37 313	39 118	41 660
Economic Classification						
Compensation of Employees	26 495	26 460	31 300	29 757	31 244	33 432
Goods and Services	13 351	9 236	4 527	7 556	7 874	8 228

Additional resources allocated for goods and services to enable the programme to do the required physical site inspections as well as adequate resourcing of the external committee reviews.

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

1.4.2 Outcomes, Outputs, Output Indicators and Targets

OUTCOMES	OUTPUTS	OUTPUT INDICATORS	AUDITED/ACTUAL PERFORMANCE			ESTIMATED PERFORMANCE 2021/22	No.	MEDIUM TERM EXPENDITURE FRAMEWORK TARGETS		
			2018/19	2019/20	2020/21			2022/23	2023/24	2024/25
High levels of organisational operational efficiency and effectiveness in the regulatory function maintained (7)	Applications for the sale of unregistered Category A (human) medicines finalised	Percentage applications for the sale of unregistered Category A (human) medicines finalised within 3 working days	80%	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	85% applications for the sale of unregistered Category A (human) medicines finalised within 24 working hours	4.1	85% 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 2021/22	No.	MEDIUM TERM EXPENDITURE FRAMEWORK TARGETS		
			2018/19	2019/20	2020/21			2022/23	2023/24	2024/25
	Human clinical trial applications finalised	Percentage of human clinical trial applications finalised within 90 working days	95%	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	80% human clinical trial applications finalised within 90 working days	4.2	80% human clinical trial applications finalised within 90 working days	80% human clinical trial applications finalised within 90 working days	80% human clinical trial applications finalised within 90 working days
	Health product safety signals issued	Percentage of reports on health product safety signals issued within 40 working days	Quarterly reports to the public for 3 quarters	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	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

OUTCOMES	OUTPUTS	OUTPUT INDICATORS	AUDITED/ACTUAL PERFORMANCE			ESTIMATED PERFORMANCE 2021/22	No.	MEDIUM TERM EXPENDITURE FRAMEWORK TARGETS		
			2018/19	2019/20	2020/21			2022/23	2023/24	2024/25
					actioned, 37 (43 %) were actioned within 20 working days					
	Safety awareness webinars held	Number of safety awareness webinars held	-	-	-	4 safety awareness webinars held	4.4	4 safety awareness webinars held	6 safety awareness webinars held	8 safety awareness webinars held
	Lot release requests finalised	Percentage of lot release requests finalised within 30 working days	-	-	-	-	4.5	95% of lot release requests finalised within 30 working days	95% of lot release requests finalised within 30 working days	95% of lot release requests finalised within 30 working days

1.4.3 Output Indicators: Annual and Quarterly Targets

OUTPUT INDICATORS	No.	2022/23 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	85% applications for the sale of unregistered Category A (human) medicines finalised within 3 working days	85% applications for the sale of unregistered Category A (human) medicines finalised within 3 working days	85% applications for the sale of unregistered Category A (human) medicines finalised within 3 working days	85% applications for the sale of unregistered Category A (human) medicines finalised within 3 working days	85% applications for the sale of unregistered Category A (human) medicines finalised within 3 working days
Percentage of human clinical trial applications finalised within 90 working days	4.2	80% human clinical trial applications finalised within 90 working days	80% human clinical trial applications finalised within 90 working days	80% human clinical trial applications finalised within 90 working days	80% human clinical trial applications finalised within 90 working days	80% human clinical trial applications finalised within 90 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 webinars held	4.4	4 safety awareness webinars held	1 safety awareness webinar held	1 safety awareness webinar held	1 safety awareness webinar held	1 safety awareness webinar held
Percentage of lot release requests finalised within 30 working days	4.5	95% of lot release requests finalised within 30 working days	95% of lot release requests finalised within 30 working days	95% of lot release requests finalised within 30 working days	95% of lot release requests finalised within 30 working days	95% of lot release requests finalised within 30 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 to the South African public. However, some of these health products may not be registered in the Republic but are available in other markets. Therefore, the Medicines Act (Act 101 of 1965, as amended) 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 public health intervention that has to promptly ensure access to life-saving health products where these would otherwise not be available to prevent disease complications.

This intervention will ensure that our response to COVID-19 will be agile and continue to promote access to repurposed medicines that would otherwise wait for registration before being made available to the public in a pandemic situation.

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 endeavored to be highly responsive to such signals but, due to lack of resources, only the most serious and high public health impact signals have been concluded within the targeted 80 % in 20 working days timeframe.

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 where a similar situation to COVID-19 arise.

Health product safety awareness webinars

Internationally, the rate of Adverse Drug Reaction 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 Adverse Drug Reactions, to continuously monitor the safety and efficacy of medicines over the life of the product. Frequent outreach initiatives, such as public and targeted webinars will improve the awareness.

During the past year, a lot of awareness has had to be created around the importance of reporting adverse drug reactions and adverse events following immunization 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. Lot release is performed on every batch of specific vaccines by manufacturers prior to releasing it to the market for sale.

Currently, the processing of lot release by SAHPRA involves review of the lot summary protocols with independent testing or review of lot summary protocol with 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)

2019/20	2019/20	2020/21	2021/22	2022/23	2023/24	2024/25
Budget Estimates	Audited Outcome	Audited Outcome	Budget Estimates	Budget Estimates	Budget Estimates	Budget Estimates
56 209	59 435	73 666	92 962	95 858	100 651	107 000
Economic Classification						
Compensation of Employees	27 936	52 638	50 742	62 694	65 829	70 436
Goods and Services	31 499	21 028	42 220	33 164	34 822	36 564

Resources allocated to capacitate the unit. Adequate resources made available under Goods and Services relating to the National Control Laboratory function, external evaluator and review committee expenditure.

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 the radiation safety of radionuclides and listed electronic products emitting ionizing radiation. To protect patients, radiation workers, the public and the environment against possible adverse effects of ionizing radiation without limiting its beneficial uses

1.5.2 Outcomes, Outputs, Output Indicators and Targets

OUTCOMES	OUTPUTS	OUTPUT INDICATORS	AUDITED/ACTUAL PERFORMANCE			ESTIMATED PERFORMANCE 2021/22	No.	MEDIUM TERM EXPENDITURE FRAMEWORK TARGETS		
			2018/19	2019/20	2020/21			2022/23	2023/24	2024/25
High levels of organisational operational efficiency and effectiveness in the regulatory function maintained (7)	Medical device establishment licence applications finalised	Percentage of medical device establishment licence applications finalised within 90 working days	70%	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	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
	Medical device registration regulations implemented	Medical device registration regulations implemented	73%	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	Guidelines to support the medical device registration regulations approved by the Executive Committee	5.2	7 guidelines to support the medical device registration regulations published	Survey conducted on the number of medical device and *in vitro* diagnostics	Call up of Class D (high risk)

OUTCOMES	OUTPUTS	OUTPUT INDICATORS	AUDITED/ACTUAL PERFORMANCE			ESTIMATED PERFORMANCE 2021/22	No.	MEDIUM TERM EXPENDITURE FRAMEWORK TARGETS		
			2018/19	2019/20	2020/21			2022/23	2023/24	2024/25
					review in September 2020					
	Radionuclide authorities finalised	Percentage of applications for radionuclide authorities finalised within 30 working days	An approved system to register medical devices has been implemented	99%	Out of the 2 719 new application licences for ionizing radiation-emitting devices and radioactive nuclides authorities received, 2 519 (92%) were issued Out of the 2 519 issued, 2 302 (91%) were issued within 30 working days	70% applications for radionuclide authorities finalised within 30 working days	5.3	50% applications for radionuclide authorities finalised within 30 working days	70% applications for radionuclide authorities finalised within 30 working days	70% applications for radionuclide authorities finalised within 30 working days

OUTCOMES	OUTPUTS	OUTPUT INDICATORS	AUDITED/ACTUAL PERFORMANCE			ESTIMATED PERFORMANCE 2021/22	No.	MEDIUM TERM EXPENDITURE FRAMEWORK TARGETS		
			2018/19	2019/20	2020/21			2022/23	2023/24	2024/25
	Licence applications for listed-electronic products finalised	Percentage of licence applications for listed-electronic products finalised within 30 working days	-	-	-	70% licence applications for listed-electronic products finalised within 30 working days	5.4	70% licence applications for listed-electronic products finalised within 30 working days	70% licence applications for listed-electronic products finalised within 30 working days	70% licence applications for listed-electronic products finalised within 30 working days
	Co-Regulation Model	Approved Co-Regulation Model	-	-	-	Board approved Co-Regulation Model with the National Nuclear Regulator	5.5	Board approved Co-Regulation Model with the National Nuclear Regulator	-	-

1.5.3 Output Indicators: Annual and Quarterly Targets

OUTPUT INDICATORS	No.	2022/23 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
Medical device registration regulations implemented	5.2	7 guidelines to support the medical device registration regulations published	Medical device regulations submitted to Executive Committee for approval	4 guidelines to support the medical device registration regulations submitted to the Executive Committee for review	2 guidelines to support the medical device registration regulations approved by the Executive Committee	1 guideline to support the medical device registration regulations published
Percentage of applications for radionuclide authorities finalised within 30 working days	5.3	50% applications for radionuclide authorities finalised within 30 working days	50% applications for radionuclide authorities finalised within 30 working days	50% applications for radionuclide authorities finalised within 30 working days	50% applications for radionuclide authorities finalised within 30 working days	50% applications for radionuclide authorities finalised within 30 working days
Percentage of licence applications for listed-electronic products finalised within 30 working days	5.4	70% licence applications for listed-electronic products finalised within 30 working days	70% licence applications for listed-electronic products finalised within 30 working days	70% licence applications for listed-electronic products finalised within 30 working days	70% licence applications for listed-electronic products finalised within 30 working days	70% licence applications for listed-electronic products finalised within 30 working days
Approved Co-Regulation Model	5.5	Board approved Co-Regulation Model with the National Nuclear Regulator	Draft Co-Regulation Model submitted to the Executive Committee for approval	Board approved Co-Regulation Model with the National Nuclear Regulator	-	-

1.5.4 Explanation of Planned Performance over the Medium-Term Period

Medical device establishment licences

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

The review and approval 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 quantity 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 finalization of the digitalized system for receiving license application is imperative and key in improving the operational efficient and effective of the unit.

Internal training of current resource is important in ensuring compliance and improvement to daily operations.

Medical device registration regulations

The publication and implementation of the amended medical devices regulations enables the facilitation and development of the medical device registration pathways, which in turn enables the publication of the call-up for 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 filing of technical vacant position will assist with delivering the mandate of SAHPRA. The appointment of the manager will ensure timely delivery of the medium target set.

Radiation control

Currently, SAHPRA issues licenses 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 inclusion

of Group III and Group IV hazardous substances (as defined in Act 15 of 1973) into the definition of a medical device in Act 101 of 1965, 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 and Related Substances Act 101 of 1965, as amended and the Hazardous Substances Act, Act 15 of 1973 and its regulations. SAHPRA will continue to maintain the highest levels of protection of radiation workers, patients, public and the environment against the possible adverse effects of ionizing radiation without limiting its beneficial uses.

There has been ongoing engagement of SAHPRA and NNR that will define a roadmap related to co-regulation of the Group III and Group IV products. The discussion points will lead to a further clarified roles and responsibility and mandate of the two (2) entities (i.e., 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 both the CEO of NNR and SAHPRA) established, to amongst others, the working group will develop a framework for co-regulation between the two entities, share recommendation regarding the co-regulation framework with both the CEOs.

Newly appointment of Radiation Control Manager, Deputy Managers and technical reviewers will assist with leadership of the unit to ensure that the deliver on the planned target and mandate of SAHPRA is implemented. Training (internal and external) of employees must be planned and implemented so to ensure improved operational efficiency of Radiation control unit**.**

1.5.5 Programme Resource Considerations

Resource considerations (R'000)

2019/20	2019/20	2020/21	2021/22	2022/23	2023/24	2024/25
Budget Estimates	Audited Outcome	Audited Outcome	Budget Estimates	Budget Estimates	Budget Estimates	Budget Estimates
65 440	22 231	38 128	39 717	32 929	34 545	36 865
Economic Classification						
Compensation of Employees	15 746	16 129	31 831	29 168	30 626	32 770
Goods and Services	6 485	21 999	7 886	3 761	3 919	4 095

Resources mainly allocated to travel expenditure to enable Radiation Control Inspectorate to perform the required physical inspection, external evaluators and review committees.

2. UPDATED KEY RISKS AND MITIGATION FROM THE STRATEGIC PLAN

OUTCOMES	KEY RISKS	RISK MITIGATIONS
Effective financial management (1)	*Inadequate financial governance systems and processes	Re- engineer, document and provide training on financial management business processes
Financial sustainability achieved through revenue generated and enhanced operational efficiencies (2)	Inability to sustain financial viability for SAHPRA	Source single entry point system (Implementation of 1@logit system)
		Follow up on long outstanding payments to ensure timeous invoicing of industry
Continuously respond to the needs and expectations of SAHPRA stakeholders (3)	Perceived negative perceptions about SAHPRA as a result of receiving external funding and non-alignment with stakeholder needs	Monitor implementation and compliance with the Donor Funding Policy; Declaration of interest and SAHPRA's Code of Conduct
		Assess stakeholder awareness, 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 superior talent (5)	Difficulty in attracting and retaining talent	Development of workplace skills policy and plan
Strengthened Information and Communication Technology and digitisation (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
High levels of organisational operational efficiency and effectiveness in the regulatory function 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

OUTCOMES	KEY RISKS	RISK MITIGATIONS
Other Strategic Risks		
Governance risks	Non-compliance with legislation, policies, procedures, and standards	Continuous monitoring of compliance
	Fraud, theft and corruption	Development of Anti-Fraud and Prevention Strategy/Plan
External Risks	Nonalignment of the National Priorities	Review of the Medicines Act
	Increased global pandemic occurrences / environmental threats	Adhere to National lockdown rules and development of Business Continuity Policy and processes
	Uncertainty on national changes due to political changes	Continuous engagement with shareholder and other stakeholders (Regulatory Authorities)

**Operational risks*

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 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 turn around the current qualified audit outcome 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 1 and 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	Total revenue generated from fees in the financial year
Definition	The total revenue generated from collection of fees for services rendered
Source of Data	Income statements
Method of Calculation or Assessment	Total revenue recognised based on service rendered
Means of Verification	Finance quarterly reports and Annual Financial Statements
Assumptions	• The quantity of services completed outside of the predefined timelines can result in a deviation from target • The assumption of number of applications made with the applicator is supplier dependent and this in turn is dependent on the economy and state of investment
Disaggregation of Beneficiaries (where applicable)	Not applicable
Spatial Transformation (where applicable)	Not applicable
Calculation Type	Cumulative (year-end)
Reporting Cycle	Quarterly
Desired Performance	To strive towards optimised fees collection for services rendered by ensuring all monies paid are accounted for by a completed service rendered
Indicator Responsibility	Chief Financial Officer

1.3 Indicator Title	Break-even of expenses and revenue by 31 March 2023
Definition	A zero balance or surplus at the end of the financial year post reconciling income and expenses
Source of Data	Budget vs Income/Expenditure Report
Method of Calculation or Assessment	Total income less total expenditure
Means of Verification	Finance quarterly reports and Annual Financial Statements
Assumptions	Rigorous control over budget spending
Disaggregation of Beneficiaries (where applicable)	Not applicable
Spatial Transformation (where applicable)	Not applicable
Calculation Type	Non-cumulative
Reporting Cycle	Quarterly
Desired Performance	To achieve a ≥ zero or surplus balance at end of financial year in accordance with the Public Finance Management Act
Indicator Responsibility	Chief Financial Officer

1.4 Indicator Title	Percentage of accepted recommendations from the 2022/23 stakeholder perception survey implemented
Definition	Biennial stakeholder perception survey recommendations defined, addressed and monitored *The process for accepting recommendations will be determined in due course
Source of Data	Web-based enquiries, information technology tracking system, application tracking tool, human resource climate survey, reports from the communications office, human resource updates on positions filled and skills audit, final stakeholder perception survey report, including recommendations
Method of Calculation or Assessment	Numerator: Number of accepted recommendations implemented / Denominator: Number of accepted recommendations x 100
Means of Verification	Supporting documents to prove that recommendations were implemented
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	Cumulative (year-to-date)
Reporting Cycle	Quarterly
Desired Performance	All recommendations from the survey implemented
Indicator Responsibility	Manager: Communications

1.5 Indicator Title	Percentage of change management interventions implemented
Definition	Collective initiatives conducted to prepare, support and assist individuals and teams to adjust to transformational changes within the organisation
Source of Data	Change management implementation plan and proof of initiatives implemented
Method of Calculation or Assessment	Numerator: Number of change management interventions implemented / Denominator: Number of change management interventions x 100
Means of Verification	Report on the implementation of the change management intervention and evidence of interventions implemented
Assumptions	Availability of funds to implement the activities
Disaggregation of Beneficiaries (where applicable)	Not applicable
Spatial Transformation (where applicable)	Not applicable
Calculation Type	Cumulative (year-to-date)
Reporting Cycle	Quarterly
Desired Performance	Implementation of all the change management interventions
Indicator Responsibility	Executive Manager: Human Resources

1.6 Indicator Title	Percentage of Workplace Skills Plan implemented
Definition	A tool to assist SAHPRA identify and address their learning and development needs
Source of Data	Workplace Skills Plan
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	Report on the implementation of the Workplace Skills Plan. Evidence of training attended
Assumptions	Availability of funds to implement the Plan
Disaggregation of Beneficiaries (where applicable)	Not applicable
Spatial Transformation (where applicable)	Not applicable
Calculation Type	Cumulative (year-to-date)
Reporting Cycle	Quarterly
Desired Performance	Full implementation of the Workplace Skills Plan
Indicator Responsibility	Executive Manager: Human Resources

1.7 Indicator Title	Percentage of budgeted positions filled
Definition	Vacant position identified for relevant recruitment phase and with approved budget are filled before commencement of next phase in the next financial year
Source of Data	Staff establishment, published advertisements, new contracts dated with date of on boarding
Method of Calculation or Assessment	Numerator: Number of budgeted positioned filled in the financial year / Denominator: Number of budgeted positions in the financial year x 100
Means of Verification	Human resource documents in the Personnel File. Recruitment update
Assumptions	• Recruitment process is supported by organised labour • Availability of funds
Disaggregation of Beneficiaries (where applicable)	Targets for female staff must align with targets set as per 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

1.8 Indicator Title	Enterprise Architecture developed
Definition	A business wide and organisation wide system review of the organisation's business processes, strategy and information technology 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
Calculation Type	Non-cumulative
Reporting Cycle	Quarterly
Desired Performance	Approved integrated plan to be used to implement information system for SAHPRA
Indicator Responsibility	Chief Operations Officer

2. PROGRAMME 2: HEALTH PRODUCTS AUTHORISATION

2.1 Indicator Title	Percentage of medicine registrations in the backlog cleared
Definition	Quantification of backlog applications lodged by pharmaceutical sector that the regulator can process and finalise within a period of 250 working days counting from the day when the applications are deemed to be meeting minimum requirements
Source of Data	Applications that were received from abovementioned applicants through 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) until 30 November 2020 x 100
Means of Verification	Trackers generated from Google Sheets and supporting documentation thereof (product registration certificates, rejection letters, official withdrawal letters from applicants and non-acceptance letters from the SAHPRA Backlog Clearance Unit)
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 stakeholder to submit within the stipulated window
Disaggregation of Beneficiaries (where applicable)	Not applicable
Spatial Transformation (where applicable)	Not applicable
Calculation Type	Cumulative (year-to-date)
Reporting Cycle	Quarter 1 - 3
Desired Performance	To eradicate the backlog of applications by 2022
Indicator Responsibility	Project Manager: Backlog

2.2 Indicator Title	Percentage of medicine variation applications in the 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 abovementioned 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) until 30 November 2020 x 100
Means of Verification	Trackers generated from Google Sheets and supporting documentation thereof (variation approval letters, rejection letters, official withdrawal letters from applicants)
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
Calculation Type	Cumulative (year-to-date)
Reporting Cycle	Quarter 1 - 3
Desired Performance	To eradicate the backlog of applications by 2022
Indicator Responsibility	Project Manager: Backlog

2.3 Indicator Title	Percentage of New Chemical Entities finalised within 490 working days
Definition	Quantification of new chemical entities (active substances that have not yet been registered by the Regulator) finalised within 490 working days, calculated from the day when the applications passes technical screening
Source of Data	New Medicines Application Google Sheets tracker and an Internal registration database called SIAMED
Method of Calculation or Assessment	Numerator: Number of NCE medicines finalised within 490 working days / Denominator: Number of NCE applications due for finalisation within 490 working days as at the end of each quarter x 100
Means of Verification	Line listing and supporting documentation thereof i.e application letters, Registration Committee documents, minutes of Registration Committee, signed registration certificates, screening evidence, 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 • Tedious processes currently in terms of 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 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

2.4 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 day when the applications passes technical screening
Source of Data	New Medicines Application Google Sheets tracker and an Internal registration database called SIAMED
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, Registration Committee documents, minutes of Registration Committee, signed registration certificates, screening evidence, 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 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

2.5 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 to ISO 9001:2015 requirements. ISO 9001:2015 is a standard designed to help organizations to be more efficient and process driven
Source of Data	• Q1-Q2: Evidence of completion in the implementation plan • Q3: Stage 1 gap report from the certification body • Q4: ISO 9001:2015 audit report from the certification body
Method of Calculation or Assessment	• Q1-Q2: Numerator: Number of initiatives in the Quality Management System Implementation Plan implemented / Denominator: Number of initiatives in the Quality Management System Implementation Plan x 100 • Q3- Stage 1 gap report from the certification body • Q4: ISO 9001:2015 audit report from the certification body
Means of Verification	ISO 9001:2015 audit report from the certification body
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) – Quarter 2
Reporting Cycle	Quarterly
Desired Performance	Full implementation of the Quality Management System requirements
Indicator Responsibility	Chief Operations Officer

2.6 Indicator Title	WHO maturity level assessed
Definition	Global benchmarking is a means by which WHO evaluates regulatory systems through a comprehensive and systematic benchmarking process in order to determine the regulatory authority maturity level on a scale of 1 (existence of some elements of regulatory system) to 4 (operating at advanced level of performance and continuous improvement). SAHPRA is targeting maturity level 3 indicating a well-functioning and integrated regulatory systems
Source of Data	WHO benchmarking assessment report
Method of Calculation or Assessment	WHO benchmarking assessment report
Means of Verification	WHO benchmarking assessment report
Assumptions	Improvements will be made on the institutional development plan arising from the WHO GBT assessment
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 in African continent and globally
Indicator Responsibility	Chief Operations Officer

3. PROGRAMME 3: INSPECTORATE AND REGULATORY COMPLIANCE

3.1 Indicator Title	Percentage of new GMP and GWP related licenses finalised within 125 working days
Definition	Quantification of new Good Manufacturing Practice (GMP) and Good Wholesaling Practice (GWP) related licence applications lodged by health product sector manufacturers, importer/exporters and wholesalers/distributors, that the regulator can process and finalise within a period of 125 working days, counting from the day when the applications are deemed to be meeting minimum requirements (administration screening completed and acknowledgement letter sent) for processing.
Source of Data	Licensing Unit that receives applications submitted by abovementioned applicants through dedicated email inbox for license 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 outcome documentation • E-mail Inspection report sent • E-mail Inspection response received
Assumptions	• New applications will continue to be received by the regulator • Inspections preceding the finalisation of applications will be undertaken and completed timeously • The calculated working days of an application does not include time spent with applicant • Sites will be found to be meeting minimum requirements as per 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 (QSE) 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, importer/exporters, wholesalers/distributors and other authorized persons, that the regulator can process and finalise within a period of 20 working days counting from the day when the applications are received
Source of Data	Regulatory Compliance Unit that receives applications submitted by abovementioned applicants through 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 carryover applications) x 100
Means of Verification	• Application Email • Issued Permit • Chief Executive Officer approval date on 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 the regulator that the regulator can process and finalise within 30 working days of when complaint is received to when investigations is either closed, actioned or handed over to 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 carryover investigations) x 100
Means of Verification	• Complaint trigger evidence or documented receipt details from inspector • Completed investigation report • Investigation Report tracker • Line Listings
Assumptions	• That new recruits will be successfully on boarded to fill current critical vacancies • Internal business processes are in place and optimized 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 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 is able to distinguish between date when application is created and 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 possible access 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 90 working days
Definition	Quantification of clinical trial applications lodged with the regulator by applicants who intend to undertake clinical trials for purposes of assessing Good Clinical Practices (GCP) which are international standards of 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 90 working days / Denominator: Number of clinical trial applications due for finalisation within 90 working days as at the end of each quarter x 100
Means of Verification	• Emailed CTF1 • Emailed Proof of Payment • CTC meeting minutes • Approval/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, safety signals. • Dear healthcare professional letters: safety concern for immediate attention of healthcare professionals from safety notifications, 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, internet, and media searches; and • Safety signal: Adverse drug reaction reports from Healthcare professionals, consumers and applicants, literature, VigiBase®
Source of Data	Media Releases generated; DHCPLs generated; 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 the Authority of foreign Regulatory Authority decisions which concerns their health products • Applicants will comply with Authority's recommendations • Necessary resources such as reliable Internet connectivity, reference material, adequate, competent human resources 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 product, to promote public health of South Africans
Indicator Responsibility	Senior Manager: Clinical Evaluations Management

4.4 Indicator Title	Number of safety awareness webinars held
Definition	A workshop to educate the public and other stakeholders on the importance of health product safety reporting
Source of Data	Webinar agenda and video
Method of Calculation or Assessment	Simple count on the number of webinars held
Means of Verification	Webinar agenda and video
Assumptions	• Regulator will continually receive ADR reports from applicants, healthcare professionals and consumers • Necessary resources such as reliable Internet connectivity, reference material, adequate, competent human resources 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 30 working days
Definition	Quantification of the percentage of the lot released through the NRA/NCL National Control Laboratory in accordance with the Section 15 of the Medicines and Related Substance Act 101 of 1965 as amended
Source of Data	Lot release request submitted to SAHPRA for registered vaccines and authorised vaccines through Section 21 of Public Health Emergency authorisation
Method of Calculation or Assessment	Numerator: Number of lot release finalised within 30 working days / Denominator: Number of lot release request due for finalisation within 30 working days as at the end of each quarter x 100
Means of Verification	Lot release certificate/Notice of rejection (Approved or rejection) List of lot release spreadsheet or database/linelisting, Lot release application, Lot release certificate or lot release rejection notification
Assumptions	All tools necessary for lot release processing 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 quality, efficacy and safety for all vaccines imported to South Africa and manufactured locally to ensure the public receive 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 and Related Substances Act, 1965 (Act No. 101 of 1965), 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 license 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 of medical devices to ensure the public and the environmental safety
Indicator Responsibility	Senior Manager: Medical Devices and Radiation Control

5.2 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 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 to 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
Calculation Type	Non-cumulative
Reporting Cycle	Quarterly
Desired Performance	Framework to register medical devices implemented
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 finalised of new applications for licences lodged with the regulator by holders of radionuclides as prescribed by the Hazardous Substances Act, 1973, as amended
Source of Data	Line listing extracted from radionuclide Oracle database and as per received via the dedicated e-mail 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 online listing and supporting documentation (E-mail correspondence and License/authorities issued) thereof
Assumptions	That 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 of radiation workers, patients, public and the environment against the adverse effects of radiation. efficient processing. Maintaining most effective possible processing of license applications.
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 finalised of new applications for licences to import listed electronic products lodged with the regulator as prescribed by the Hazardous Substances Act, 1973 (Act No. 15 of 1973), 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 (License 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 health and safety of patients, healthcare workers, industry and the public
Indicator Responsibility	Senior Manager: Medical Devices and Radiation Control

5.5 Indicator Title	Approved Co-Regulation Model
Definition	A framework on how SAHPRA and the National Nuclear Regulator will work together on radiation control matters
Source of Data	Minutes, Memorandum of Understanding and other related documents (i.e., Recommendations)
Method of Calculation or Assessment	Approved Co-Regulation Model
Means of Verification	Co-Regulation Model that is approved by the Board
Assumptions	Cooperation between the two regulators
Disaggregation of Beneficiaries (where applicable)	Not applicable
Spatial Transformation (where applicable)	Not applicable
Calculation Type	Non-cumulative
Reporting Cycle	Quarterly
Desired Performance	Approved Co-Regulation Model with the National Nuclear Regulator
Indicator Responsibility	Legal Regulatory Advisor

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, being quantitative and qualitative aspects.

Materiality can be based on a number of financial indicators. Detailed below is an indicative table of financial indicators 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 007 615. 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 the 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 the SAHPRA

In assessing the control risk of the SAHPRA, and concluding that a materiality level higher than 0.5 % can be used due to a good control environment being present cognizance was given to amongst others:

- Proper and appropriate governance structures have been established;
- An audit and risk committee that closely monitors the control environment of the 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 by the audit committee;
- All executive positions have been filled; and
- A reduction in the number of audit qualifications and findings.

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 007 615 (R267 682 084 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 amongst others:

i) New ventures that the SAHPRA has entered into.
ii) Unusual transactions entered into that are not of a repetitive nature and are disclosable

purely due to the nature thereof 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 of SAHPRA.

v) Procedures/processes required by legislation or regulation (e.g. PFMA and the 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 action of the executive authority or that legislature	Transactions exceeding 0.75% which may influence the decisions or action of the National Department of Health	The Board will disclose to the National Department of Health all material facts as requested and all material facts not requested, including those reasonably discoverable, which in any way may influence the decisions or action of the National Department of Health, 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; and	None	Full particulars to be disclosed to the Minister of Health for approval after which it is 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 exceeds (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 exceeds (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 / core business of the Authority and that exceeds the Qualifying transactions exceeds Qualifying transactions exceeds (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 exceeds Qualifying transactions exceeds (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 Ac, 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 financial 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 through revenue generated and enhanced operational efficiencies (2)	1.2 Total revenue generated from fees in the financial year	R21.3 million	Annual revenue of R185 million generated from fees
Continuously respond to the needs and expectations of SAHPRA stakeholders (3)	1.3 Percentage of accepted recommendations from the stakeholder perception survey implemented	-	100% accepted recommendations from the stakeholder perception survey implemented
A positive and enabling working culture created (4)	1.4 Percentage of the change management intervention implemented	-	Review of the change management intervention conducted
Attract and retain superior talent (5)	1.5 Percentage of positions in the staff establishment filled	76%	80% of core business positions in the staff establishment filled

MEDIUM TERM STRATEGIC FRAMEWORK PRIORITY 3: EDUCATION, SKILLS AND HEALTH			
OUTCOMES	**OUTCOME INDICATORS**	**BASELINE**	**FIVE-YEAR TARGET**
Strengthened Information and Communication Technology and digitisation (6)	1.6 Enterprise Architecture developed	-	Phase 2 of the roadmap on the Enterprise Architecture implemented
High levels of organisational operational efficiency and effectiveness in the regulatory function 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
	1.10 WHO maturity level obtained	-	WHO maturity level 4 obtained
	1.11 Percentage of new Good Manufacturing Practice (GMP) and Good Warehouse Practice (GWP) related licenses finalised within 125 working days	77%	80% new GMP and GWP related licenses finalised within 125 working days
	1.12 Percentage of human clinical trial applications finalised within 90 working days	100%	80% human clinical trial applications finalised within 90 working days
	1.13 Medical device registration regulations implemented	-	Call up of Class D (high risk)

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 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 turn around the current qualified audit outcome 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	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	Total revenue generated from fees in the financial year
Definition	The total revenue generated from collection of fees for services rendered
Source of Data	Income statements
Method of Calculation or Assessment	Total revenue recognised based on service rendered
Means of Verification	Finance quarterly reports and Annual Financial Statements
Assumptions	• The quantity of services completed outside of the predefined timelines can result in a deviation from target • The assumption of number of applications made with the applicator is supplier dependent and this in turn is dependent on the economy and state of investment
Disaggregation of Beneficiaries (where applicable)	Not applicable
Spatial Transformation (where applicable)	Not applicable
Desired Performance	To strive towards optimised fees collection for services rendered by ensuring all monies paid are accounted for by a completed service rendered
Indicator Responsibility	Chief Financial Officer

1.3 Indicator Title	Percentage of accepted recommendations from the stakeholder perception survey implemented
Definition	Biennial stakeholder perception survey recommendations defined, addressed and monitored *The process for accepting recommendations will be determined in due course
Source of Data	Web-based enquiries, information technology tracking system, application tracking tool, human resource climate survey, reports from the communications office, human resource updates on positions filled and skills audit, final stakeholder perception survey report, including recommendations.
Method of Calculation or Assessment	Numerator: Number of accepted recommendations implemented / Denominator: Number of accepted recommendations x 100
Means of Verification	Supporting documents to prove that recommendations were implemented
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
Desired Performance	All recommendations from the survey implemented
Indicator Responsibility	Manager: Communications

1.5 Indicator Title	Percentage of positions in the staff establishment filled
Definition	Vacant position identified for relevant recruitment phase and with approved budget are filled before commencement of next phase in the next financial year
Source of Data	Staff establishment, published advertisements, new contracts dated with date of on boarding.
Method of Calculation or Assessment	Numerator: Number of core business positioned 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 as per 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 the organisation's business processes, strategy and information technology 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

1.9 Indicator Title	Percentage of New Chemical Entities finalised within 490 working days
Definition	Quantification of new chemical entities (active substances that have not yet been registered by the Regulator) finalised within 490 working days, calculated from the day when the applications passes technical screening
Source of Data	New Medicines Application Google Sheets tracker and an Internal registration database called SIAMED
Method of Calculation or Assessment	Numerator: Number of NCE medicines finalised within 490 working days / Denominator: Number of NCE applications due for finalisation within 490 working days as at the end of each quarter x 100
Means of Verification	Line listing and supporting documentation thereof i.e application letters Registration Committee (RC) documents, minutes of Registration Committee,signed registration certificates, screening evidence, 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 • Tedious processes currently 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

1.11 Indicator Title	Percentage of new GMP and GWP related licenses finalised within 125 working days
Definition	Quantification of new Good Manufacturing Practice (GMP) and Good Wholesaling Practice (GWP) related licence applications lodged by health product sector manufacturers, importer/exporters and wholesalers/distributors, that the regulator can process and finalise within a period of 125 working days, counting from the day when the applications are deemed to be meeting minimum requirements (administration screening completed and acknowledgement letter sent) for processing
Source of Data	Licensing Unit that receives applications submitted by abovementioned applicants through dedicated email inbox for license 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 outcome documentation • E-mail Inspection Report sent • E-mail Inspection Response received
Assumptions	• New applications will continue to be received by the regulator • Inspections preceding the finalisation of applications will be undertaken and completed timeously • The calculated working days of an application does not include time spent with applicant • Sites will be found to be meeting minimum requirements as per applicable guidelines communicated to industry
Disaggregation of Beneficiaries (where applicable)	Not applicable
Spatial Transformation (where applicable)	Not applicable
Desired Performance	To strive to expeditiously process the highest possible number of licence applications to ensure that health products meet quality, safety and efficacy (QSE) standards without compromising the quality of the application process
Indicator Responsibility	Senior Manager: Inspectorate and Regulatory Compliance

1.12 Indicator Title	Percentage of human clinical trial applications finalised within 90 working days
Definition	Quantification of clinical trial applications lodged with the regulator by applicants who intend to undertake clinical trials for purposes of assessing Good Clinical Practices (GCP) in the conduct of clinical trials in humans and ethical compliance for 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 90 working days / Denominator: Number of clinical trial applications due for finalisation within 90 working days as at the end of each quarter x 100
Means of Verification	• Emailed CTF1 • Emailed Proof of Payment • CTC meeting minutes • Approval/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	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

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 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 to 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