SAHPRA

South African
Health Products
Regulatory Authority

2020/21 – 2024/25 STRATEGIC PLAN

JANUARY 2021

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

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EXECUTIVE AUTHORITY STATEMENT

The South African Health Products Regulatory Authority's (SAHPRA) Strategic Plan 2020/21 - 2024/25 serves as a guide for the entity to deliver on its core mandate as prescribed in the Medicines and Related Substances Act, 1965 (Act No. 101 of 1965), as amended.

In addition, the Strategic Plan comprehensively responds to the priorities identified by Cabinet of 6th administration of democratic South Africa, which are embodied in the Medium-Term Strategic Framework (MTSF) for period 2019 - 2024. Over the next five years SAHPRA is structured to support delivery on the National Development Plan (NDP): Vision 2030; the Sustainable Development Goals (SDGs) which builds on the work started under the Millennium Development Goals; the National Health Insurance which lays the foundation for moving South Africa towards universal access to quality health care services in accordance with section 27 of the Constitution. The Strategic Plan is also aligned to the Presidential Health Compact (2019), towards achieving social justice; through enabling access to affordable good quality, safe and efficacious medicines and medical devices.

SAHPRA was recently established as a schedule 3A public entity, however the Board places high on its agenda SAHPRA's proper alignment to achieve the requisite social and economic impact, which is the primary reason for its existence. The Ministry of Health therefore commits itself to providing the necessary support to accelerate performance towards the achievement of the ultimate goals of MTSF, NDP, SDGs and the Presidential Health Compact; as SAHPRA claims its rightful place as one of the leading regulators in the continent and globally.

I wish the Board and management well as they work shoulder to shoulder in pursuit of the fulfillment of these national aspirations.

DR ZWELINI MKHIZE, MP
EXECUTIVE AUTHORITY
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 to give 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.

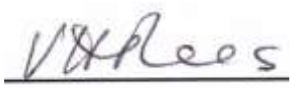
SAHPRA operates in a complex legislative environment that straddles multiple areas and players. This amplifies a need for robust stakeholder engagement. Assuming an extended mandate that incorporates medical devices and radiation control in addition to an older mandate necessitated a close scrutiny of 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 in the public discourse on these matters at all possible levels of the organisation so as 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 funding processes.

Appreciating the massive capacity gaps SAHPRA currently has as 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.

Our focus is on shaping a bright future for SAHPRA based on a solid organisation with a clear direction; 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 Chief Executive Officer in presenting the Strategic Plan.



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

ACCOUNTING OFFICER STATEMENT

The year 2020 was characterised by unparalleled levels of change and uncertainty as the world grappled with the pandemic caused by the Coronavirus disease (COVID-19), an infectious disease caused by a newly discovered coronavirus, SARS- CoV-2. The rapid spread of this virus resulted in the COVID-19 pandemic that led to a dramatic loss of human life worldwide and presented an unprecedented challenge to public health, food systems and the world of work. The economic and social disruption caused by the pandemic has been devastating.

The advent of COVID-19 saw an increasing dependence on SAHPRA for its science-based regulatory decisions and leadership in ensuring that all health products including those for the treatment of COVID-19 are safe, efficacious and of high quality so that the health and well-being of South Africans are protected. As SAHPRA joined the country and the world at large to embrace 4IR in response to the pandemic, the need for digitised workflows and smart digital tools became an essential requirement. SAHPRA had to fast track the digitisation of some of its processes to enable remote working as well as introduce an online submission portal and smart digital tools to enable uninterrupted interactions with the stakeholders. This prevented cumbersome paper submissions and moved to more environmentally friendly and efficient online processes. Being stringent, yet agile in its approaches remains to be a key response approach by the regulator as South Africa continues to be plagued by this disease.

While SAHPRA responds to the COVID-19 pandemic, it cannot lose focus on supporting key national priorities such as the implementation of National Health Insurance (NHI) Scheme aimed at ensuring universal health care access. Furthermore, critical projects such as the clearance of the backlog remain to be a priority for the Authority. An additional priority for the regulator that was made acute during the country's response to COVID-19 is post market surveillance and pharmacovigilance. As regulators across the globe apply reliance mechanisms and joint regional assessment programs, it is anticipated that this will enable them to invest the required resources to strengthen the national post market surveillance and pharmacovigilance programs.

To ensure health products that are safe, efficacious and of high quality, SAHPRA is responsible for the monitoring, detection, assessment, understanding and prevention of adverse effects. An important aspect of pharmacovigilance are the systems and processes that holders of certificates of registration

employ to ensure that safety related data is collected, analysed, reported with mitigations and Corrective and Prevention Actions, where required. SAHPRA aims to strengthen its capacity and capabilities to inspect the pharmacovigilance systems of holders of certificates of registration against established SAHPRA and global guidelines. Proactive post-market surveillance is necessary to prevent the risk of having sub-standard or falsified health products in the country thus compromising the safety of the people of South Africa. SAHPRA's relationship with the Centre for Quality Assurance Medicines laboratory is being formalised and this will assist SAHPRA in sampling products from the market for testing and ensure that licensed entities are complaint and unlicensed entities are brought to book.

The amendment to the Medical Device Regulations is currently in progress. The proposed amendments take into consideration mandatory requirements for the quality management systems of manufacturers and distributors, thereby paving the way for a more robust regulatory process. SAHPRA will focus on the medical devices and in vitro diagnostics unit to ensure that these long-awaited regulations are implemented post consultation with the relevant stakeholder. The operational framework for Radiation Control, which is the implementation unit within SAHPRA of the Hazardous Substances Act and regulations related to Group III and Group IV hazardous substances need to be reviewed and aligned with international standards and best practices. The current gaps in the regulation of these products in partnership with the National Nuclear Regulator need urgent attention to ensure the safety of the public.

The Health Summit Compact recognised that capacity was a stumbling block for SAHPRA's ability to deliver fully on its mandate. To this effect, SAHPRA has embarked on a phased capacitation plan to ensure that it is a well-capacitated and a high-performance organisation that executes its mandate by achieving the desired national health outcomes. Filling of critical vacant positions, while retaining highly skilled individuals in its core business will be priority for the 2021/22 financial year. Being able to generate the required revenue for the many programs that SAHPRA needs to implement to ensure that it is an efficient regulator remains to be a priority. The new fees were gazetted on 22 December 2020 and are being implemented. It will however be important that the marked increase in fees will be accompanied by improved effectiveness of SAHPRA.

SAHPRA recognises that it needs to be locally relevant and work with various national stakeholders to contribute to addressing the socio-economic challenges of the country. To this effect, SAHPRA has initiated mechanisms wherein it is reviewing its processes to determine if it is enabling to the local sector as it contributes to the national agenda while it positions itself internationally.

SAHPRA needs to align itself with other international health product regulators in order to ensure it achieves world-class standards while being relevant to the local context. SAHPRA's affiliation to the Pharmaceutical Inspection Co-operation Scheme (PIC/S) in 2007 was a noteworthy achievement,

enabling SAHPRA to become a globally recognised Inspectorate. SAHPRA will be undergoing re-assessment by PIC/s in 2021 to maintain its current membership. It is anticipated that in 2021 SAHPRA will achieve a WHO Maturity level 3, while it works towards a WHO Maturity level 4 in the year 2025.

Its journey from a fledgling entity to a professional, efficient and effective regulator will require considerable effort from SAHPRA management and the Board in ensuring the organisation is adequately resourced to achieve its strategic objectives. For SAHPRA to be relevant and to achieve world-class standards, it is obligatory for this evolving entity to address the needs of its stakeholders, especially the South African public.

As SAHPRA works towards deepening its scientific review base and to also build globally aligned review methodologies and practices, it will focus on the following priorities:

- Applying global standards of Good Review Practices;
- Applying reliance on a risk-based approach;
- Working towards being a member of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use; and
- Becoming a World Health Organisation Listed Authority.

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

I am immensely pleased to present our Strategic Plan.

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

OFFICIAL SIGN-OFF

It is hereby certified that this Strategic 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 over the 2020/21 – 2024/25 period.

ADV TEBOHO PETER NTHOTSO
COMPANY SECRETARY

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SENIOR MANAGER:
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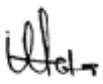
SENIOR MANAGER: CLINICAL EVALUATION MANAGEMENT

VACANT
SENIOR MANAGER: MEDICAL DEVICES AND RADIATION CONTROL



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CHIEF REGULATORY OFFICER

MS SIMPHIWE MATSABE
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MS CHRISTELNA REYNECKE
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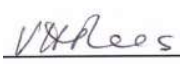
ACCOUNTING OFFICER

APPROVED BY:



PROF HELEN REES
CHAIRPERSON OF THE BOARD

DR ZWELINI MKHIZE, MP
MINISTER OF HEALTH

LIST OF ABBREVIATIONS/ ACRONYMS

API	Active Pharmaceutical Ingredient
B-BBEE	Broad-Based Black Economic Empowerment
COVID-19	Coronavirus disease
GMP	Good Manufacturing Practice
GWP	Good Warehouse Practice
HFC	Healthcare Finance Committee
ICT	Information and Communication Technology
IT	Information Technology
IVD	*In Vitro* Diagnostic
MTSF	Medium Term Strategic Framework
NCE	New Chemical Entity
NDP	National Development Plan
NDoH	National Department of Health
NHA	National Health Act
NHI	National Health Insurance
PIC/S	Pharmaceutical Inspection Co-operation Scheme
SAHPRA	South African Health Products Regulatory Authority
SAPC	South African Pharmacy Council
SDGs	Sustainable Development Goals
WHO	World Health Organization

GLOSSARY OF KEY TERMS AND DEFINITIONS

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 (IVD) means a medical device, whether used alone or in combination, intended by the manufacturer for the in vitro examination of specimens derived from the human body solely or principally to provide information for diagnostic, monitoring or compatibility purposes
Medical Devices	A "medical device" means any instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, software, material or other similar or related article, including Group III and IV Hazardous Substances contemplated in the Hazardous Substances Act, 1973 (Act No. 15 of 1973) - (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 - (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. 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 regards 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, including appropriate social assistance if they are unable to support themselves and their dependents.
- The state must take reasonable legislative and other measures within its available resources to achieve the progressive realisation of each of these rights, and no one may be refused emergency medical treatment.

2. LEGISLATIVE AND POLICY MANDATES

2.1 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 relate matters in 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, to incorporate inter alia, the regulation and control of radiation-emitting devices and radioactive materials the following are various pieces of legislation that define the legislative framework within which SAHPRA executes its mandate:

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

It provides a framework for a structured uniform health system within the Republic, taking into account the obligations imposed by the Constitution and other laws on national, provincial and local government with regard to health services. The objectives of the National Health Act (NHA) are to:

- Unite the various elements of the national health system into a common goal to actively promote and improve the national health system in South Africa;
- Provide for 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.

2.1.2 The Medicines and Related Substances Act, 1965 (Act No. 101 of 1965) as Amended

Amended by 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 related matters in 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;
- That evidence of existing and new adverse events and reactions, interactions, and signals emerging from post-marketing surveillance and vigilance activities are investigated, monitored, analysed and 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.

2.1.3 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 Hazardous Substances Act refers to regulation of Group III hazardous substances, i.e. listed electronic products, and section 3A refers to regulation of Group IV hazardous substances, i.e. radionuclides.

2.1.4 Other Related Legislations

Due to the complex environment that SAHPRA operates in, the following is a series of related legislation impacting on, and influencing the functioning of SAHPRA:

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

  Provides for the registration of fertilisers, farm feeds, agricultural remedies, stock remedies, sterilising plants and pest control operators. To regulate or prohibit the importation, sale, acquisition, disposal or use of fertilisers, farm feeds, agricultural remedies, and stock remedies. Furthermore, it governs the use of antimicrobials for growth promotion and prophylaxis/metaphylaxis, and the purchase of antimicrobials over the counter by the lay public (chiefly farmers).

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

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

- **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, for the registration of persons practising veterinary professions and para-veterinary professions, for control over the practising of veterinary professions and para-veterinary profession and for matters connected there with. It further makes provision for the compounding and or dispensing of any medicine which is prescribed by the veterinarian for use in the treatment of an animal which is 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; for the obligation to report certain information to the police; for the exercise of the powers of entry, search, seizure and detention in specified circumstances; for the recovery of the proceeds of drug trafficking; and for matters connected therewith.

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 still in the process of addressing the addressing the Concourt judgement.

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

  Provides for the regulation of foodstuffs, cosmetics and disinfectants, 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):**

  Provide 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 to provide for matters connected therewith.

- **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 to provide for matters incidental thereto.

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

  To consolidate and amend the laws relating to the professions of registered or enrolled nurses, nursing auxiliaries and midwives, and to provide for matters incidental thereto.

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

  The South African Pharmacy Council (SAPC) in terms of Section 35A of the Pharmacy Act, 53 of 1974 regulates the practice of pharmacy within South Africa. SAPC ensures that all responsible pharmacists, pharmacists, pharmacy support personnel and pharmacy owners provide pharmaceutical services that complies with good pharmacy practice standards prescribed in both the Pharmacy Act and the relevant provisions of the Medicines and Related Substances Act. The Medicines Act, in Section 16(d), provides for possession of medicines or scheduled substance 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 to inspect pharmacies for monitoring 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 for matters incidental thereto.

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

  In the first instance, SAHPRA's role exists amid an extremely complex legislative context where there is a series of other players involved 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 their 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 falling within the jurisdiction of the Department of Mineral Resources and Energy. Another responsibility concerns cannabis regulation, which cross-pollinates multiple ministries such as the Department of Justice and Correctional Services and the Department of Agriculture and Rural Development, to effect the country's focus on enhancing 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 so as to avert the risk of an internal leadership vacuum or duplication of efforts and subsequent potential "conflict".

2.2 Policy Mandate

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

A second critical national policy discussion that SAHPRA is engaged in pertains to localisation of the pharmaceuticals sector. These deliberations, led by the National Economic Development and Labour Council, will culminate into a national policy framework that would guide SAHPRA in executing its mandate in support of a national policy position.

3. INSTITUTIONAL POLICIES AND STRATEGIES GOVERNING THE FIVE-YEAR PLANNING PERIOD

In fulfilling its mandate, SAHPRA has taken the following key policies and strategies into consideration and has ensured that its worked 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 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 processed. 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.

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.

- **Global Alignment**

As SAHPRA is positioning itself to ensure that it aligns with global regulatory frameworks and approaches, it is crucial that it undertakes the Global Benchmarking Assessment which is used by the World Health Organization to evaluate the regulatory systems of regulatory authorities. The benchmarking tool enables WHO to, amongst others, identify areas of strength and improvement as well as develop institutional development plans.

SAHPRA also plans to actively participate in the global regulatory environment to achieve global standards and its vision of being a globally relevant and competitive regulator. The engagement and active participation with international and regional regulators are key in reaching global standards as a regulator and its ability to work alongside other regulators in delivering its mandate.

- **Public Awareness**

SAHPRA will make a concerted effort to partner with relevant stakeholders to educate the public through implementing a public awareness programme. The programme will include providing access to the latest information on cutting edge advances in the health sector, new SAHPRA regulatory

approaches for various health products as well as aspects pertaining to health products safety. Furthermore, SAHPRA aims to position its website as a trusted source of information. Other communication tools will also be used to engage with the public.

4. RELEVANT COURT RULINGS

NO.	CASE	SUMMARY
1.	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 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
2.	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 0n 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. VISION

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

2. MISSION

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

3. VALUES

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

Acronym: U-RITEE

4. SITUATIONAL ANALYSIS

The environment in which SAHPRA performs its regulatory role is largely shaped by the developments that emanate from its immediate internal and external milieu. These developments include significant internal structural, cultural, governance and organisational changes that are a natural consequence of the journey to transition into a Schedule 3A Public Entity. The changing political landscape, as well as and socio-economic factors have placed a greater emphasis on health systems reform. The way that these developments will influence the organisation's overall regulatory performance in the short to medium term is of great significance to SAHPRA. It is also important to reflect on public health, government policy and industry trends that may have a considerable influence on our current and future regulatory role.

4.1 External Environment Analysis

4.1.1 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

4.1.2 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

4.2 Internal Environment Analysis

Proposed Amendments to the Medicines Act

The Medicines and Related Substances Act, (101 of 1965) as amended has been place since 1965. The Act has been amended several times to close critical gaps that existed at the time, with the last amendment being made in 2015. Since the SAHPRA Board came into office in January 2018, no amendments have been effected. SAHPRA has noted the following amendments that will be addressed in 2021:

1. Some definitions need clarification such as;
2. New definitions need to be inserted;
3. Some sections of the Act are not arranged in an orderly fashion and this has lead to confusion and interpretation challenges;
4. Some sections may have to be repealed;
5. Some sections of the Act are incomplete and need to be expanded on fully;
6. Some chapters of the Act require clarification and/or strengthening;

7. New sections must be introduced;
8. The Act should be aligned and consistent for proper administration of the Act; and
9. New regulations must be introduced.

It is anticipated that a complete overhaul of the Medicines Act will be implemented in 2021. This will focus on aspects as such introducing new section that focus on Medical devices and IVDs as well as sections creating harmonization with the hazardous substances Act.

Human Resources

The timely filing of vacant positions in SAHPRA is a priority as this an impact on the delivery of its services. SAHPRA has prioritised the filing of posts into the following categories: critical, core and scarce business positions. Sufficient capacity has been established by the availability of the administration staff from the NDoH transferred to SAHPRA as per the Labour Relations Act, Section 197 process. The transition of employees transferred from the NDoH to SAHPRA will be completed by placing them in the organisational structure. In addition, all the executive positions have been filled and this will expedite the filling of all vacancies in the various programmes.

As a new institution and a learning organisation, the training and development of employees will also be prioritised. A culture of high performance will be instilled through implementing the change management interventions. To drive successful performance, SAHPRA will improve the implementation of the Performance Management System.

Information and Communication Technology

SAHPRA's digital transformation is a priority as the focus is on building capabilities and systems that will allow the institution to be more agile, innovative, streamlined and efficient in the delivery of its mandate. At the center of this digitisation will be intuitive self -service customer portals for the end user, as well as intelligent internal management and review systems to streamline the entire regulatory process.

The potential of digitalisation has already been tested in SAHPRA with the introduction of a number of digital platforms such as the Electronic Document Submission System, Digital Variations Portal and the Complimentary Medicines Licensing Portal, amongst others.

The introduction of the various information technology (IT) initiatives has allowed employees to work remotely during the COVID-19 pandemic. What is encouraging is that remote working has resulted in increased productivity for core business but also resulted in SAHPRA incurring high data costs for employees to access the IT systems remotely.

The development of an integrated Regulatory Information Management System will be a flagship project for the digital transformation of SAHPRA, bringing all regulatory processes onto one platform with the built-in automation, intelligence and powerful report capabilities.

Financial Resources

The South African government faces fiscus constraints which has impacted on the funding SAHPRA receives from National Treasury. SAHPRA as a recently established public entity has a significant expenditure as compared to an established entity. The combination of a decreased fiscus-funding and the significant expenditures will continue to challenge SAHPRA while stabilising as a fledgling schedule 3A entity and moving seamlessly out of the current transitional operational environment.

Management is acutely aware of the need to innovatively match the available resources to priorities that maximize outputs whilst keeping in mind the significant opportunities to boost earnings revenue from the provision of a range of services such as registering medical devices and licensing of radioactive nuclides. SAHPRA is aiming to achieve an unqualified audit in the coming financial years wherein measures have been implemented to this end including improved management oversight, increased policy and procedure clarity, investments in training and development as well as a focus on adequate staffing. SAHPRA is in the process of automation of mundane tasks and integration of key activities which will create substantial efficiencies and liberate valuable time that could be redirected to high-end value-added activities.

Overview of 2021/2022 Budget and Medium Term Expenditure Framework Estimates

Summary *of the Medium Term Expenditure Framework Budget*

SUMMARY OF ECONOMIC CLASSIFICATION OF PAYMENTS	Current Year Budget	Medium Term Estimates		
	2020/21	2021/22	2022/23	2023/24
	R'000	R'000	R'000	R'000
REVENUE	**387,763**	**357,550**	**322,899**	**336,586**
- Fees	196,771	162,264	168,755	179,666
- Interest received	6,000	3,999	4,179	4,367
- Deferred income	25,840	45,000		
- Treasury allocation	159,152	146,287	149,965	152,553
TOTAL CURRENT PAYMENTS	**387,763**	**357,550**	**322,899**	**336,586**
Compensation of employees	215,772	185,177	187,156	194,369
Goods and services	171,991	172,373	135,743	142,217
TOTAL PAYMENTS	**387,763**	**357,550**	**322,899**	**336,586**
Excess / (shortfall)		-	-	-

Budget per programme

Programme	Current Year Budget	Medium Term Estimates (SAHPRA)		
	2020/21	2021/22	2022/23	2023/24
	R'000	R'000	R'000	R'000
1) Administration	137,985	116,510	113,222	118,884
2) Authorisation management	69,098	72,534	32,595	33,636
3) Inspectorate and regulatory compliance	38,504	35,827	38,630	40,221
4) Medicines evaluation and registration	88,217	92,962	97,139	101,078
5) Devices and radiation control	53,959	39,717	41,312	42,767
	387,763	**357,550**	**322,899**	**336,586**

Fees

During the 2019/20 financial year, the Board approved the review of SAHPRA fees. The fees had not been reviewed since 2017. Recommendations were made to the Minister of Health and the revised fees were published for comment in June 2020. The comments were considered by SAHPRA and further recommendations were made to the Minister of Health. These fees would be implemented in the later part of the 2020/21 financial year.

There is currently a significant opportunity to boost earnings revenue from the provision of a range of services such as registering medical devices and licensing of electronic generators of radiation and radionuclides. The frameworks to efficiently regulate these sectors has not come to full fruition due to a lack of internal processes, other internal constraints and competing business priorities such as eradicating the backlog and re-engineering of the business-as-usual operations. Thus, as the organisation reviews its fees, the services relating to medical devices, radiation control and complementary medicines, among others, will be developed.

Status of compliance with the Broad-Based Black Economic Empowerment Act

During the 2020/21 financial year, SAHPRA had a series of engagements with the Broad-Based Black Economic Empowerment Commission. The purpose of the engagements was to seek alignment on the status of SAPHRA's BEE compliance. A legal opinion on how SAHPRA should comply with BEE legislation was sourced. The Board will hold further deliberations on the implementation of the recommendations in the later part of the 2020/21 financial year. It is expected that these recommendations will be implemented from 2021/22 financial year.

PART C: MEASURING OUR PERFORMANCE

1. INSTITUTIONAL PERFORMANCE INFORMATION

1.1 Impact Statement

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

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	Unqualified audit opinion obtained
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	Revenue of R230 million generated from fees
Continuously respond to the needs and expectations of SAHPRA stakeholders (3)	1.3 Percentage of prioritised recommendations from the survey implemented	-	100% prioritised recommendations from the 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%	100% of 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 Number of business processes digitalised	-	All business processes digitalised
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 maintained
	1.11 Percentage of new Good Manufacturing Practice (GMP) and Good Warehouse Practice (GWP) related licenses finalised within 125 working days	77%	90% of new GMP and GWP related licenses finalised within 125 working days
	1.12 Percentage of human clinical trial applications finalised within 60 working days	100%	80% human clinical trial applications finalised within 60 working days
	1.13 Medical device registration regulations implemented	-	50% call-up products registered

1.3 Explanation of Planned Performance over the Five-Year Planning Period

SAHPRA adheres to the highest global standards and thus aspires to achieve and maintain these standards by the end of the five-year cycle. Its success in achieving its own effectiveness as a regulator depends to a large extent on the ability to leverage its new institutionalisation as a Section 3A public entity that affords it the degree of flexibility which the Medicines Control Council did not have. This in turn depends on the ability to put systems in place first and foremost, which include building internal capacity to be able to execute its mandate seamlessly. The more the institution matures into its role, the greater the enhancement of its targeted impact based on the ability to prove its performance. Therefore, the first few years of SAHPRA will focus on capacitation as per commitments made in the Health Summit Compact which recognises the current shortcomings pertaining to capacity. As a result of this consideration, in addition to the two priority outcomes that are linked to organisational impact, SAHPRA has developed a further outcome conceptualised primarily to serve as an enabler, namely a well-capacitated and compliant high-performance organisation that effectively and efficiently executes its mandate by achieving the desired national health outcomes.

Cannabis

Licensing of cultivators of cannabis for purposes of producing scheduled substances has commenced. Markets for these products are mostly export markets and South Africa does not have a national policy framework for the marketing and use of cannabis in South Africa. A framework will be required for beneficiation of the cultivated cannabis for South Africa. Applications have been received for the use of cultivated cannabis containing scheduled substances in manufacturing of finished medicinal goods and the sector is expected to grow, thus requiring SAHPRA to align with INCB requirements and current manufacturing practice requirements to enable and regulate the manufacturers of finished goods that use cannabis cultivated for medicinal use.

In terms of licensing, the issue of SAHPRA not including B-BEEE as a requirement in the registration process has been highlighted by a number of external stakeholders. This matter is currently under discussion with the B-BBEE Commission and the Department of Health and legal opinions have been sought. The SAHPRA position on this matter will be finalised in the 2021/22 financial year.

Maintaining membership to the Pharmaceutical Inspection Co-operation Scheme (PIC/S)

SAHPRA's accession to the PIC/S in 2007 was a milestone in SAHPRA becoming a globally recognised inspectorate. SAHPRA will be undergoing reassessment by PIC/S in 2021 to maintain its current membership.

Licensing of Active Pharmaceutical Ingredient manufacturers and importers

Although licensing is mandated by Act 101, the import or manufacturing of Active Pharmaceutical Ingredients (APIs) requires a clearer framework and guidance from SAHPRA for the adequate regulation and licensing of establishments in the API chain. SAHPRA has embarked on an internal working group to develop a clearer framework.

Post-market surveillance

The proactive post-market surveillance of products marketed and available in South Africa by SAHPRA reduces the risk of substandard or falsified medicines by increasing the detectability of these items thus ensuring the safety of the public. The relationship with Centre for Quality Assurance Medicines laboratory is in the process of being formalized and a continued relationship with them will assist SAHPRA in sampling product from the market for purposes of testing.

Good Pharmacovigilance Practices

SAHPRA is responsible for the monitoring, detection, assessment, understanding and prevention of adverse effects or any other medicine-related problems. This is to ensure that only safe and effective medicines of high quality are used in South Africa. An important aspect of pharmacovigilance are the systems and processes that holders of certificates of registration employ to ensure that safety related data is collected, analysed, reported with mitigations and Corrective and Preventive Actions where required. SAHPRA needs to create and strengthen capacity within the Inspectorate to inspect the Pharmacovigilance systems of holders of certificates of registration against established SAHPRA and global guidelines. SAHPRA has drafted the Good Vigilance Inspection guideline and intends to finalise and implement it in 2021.

Clinical and Pharmaceutical Evaluation

The key priorities for SAHPRA are to deepen its scientific review base and also build globally aligned review methodologies and practices. Specifically, SAHPRA will prioritise the following:

- Applying global standards of Good Review Practices;
- Applying reliance on a risk-based approach;
- Working towards being an International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) member by the end of the 2021/22 financial year; and
- Becoming a WHO Listed Authority.

Medical Devices and Radiation Control

The amendment to the Medical Device Regulations is currently in process and is under review at the State Law Advisors. The amendments make mandatory requirements for the quality management systems of manufacturers and distributors.

The Hazardous Substances Act and regulations related to Group III and Group IV hazardous substances needs to be reviewed and aligned with international standards and best practices.

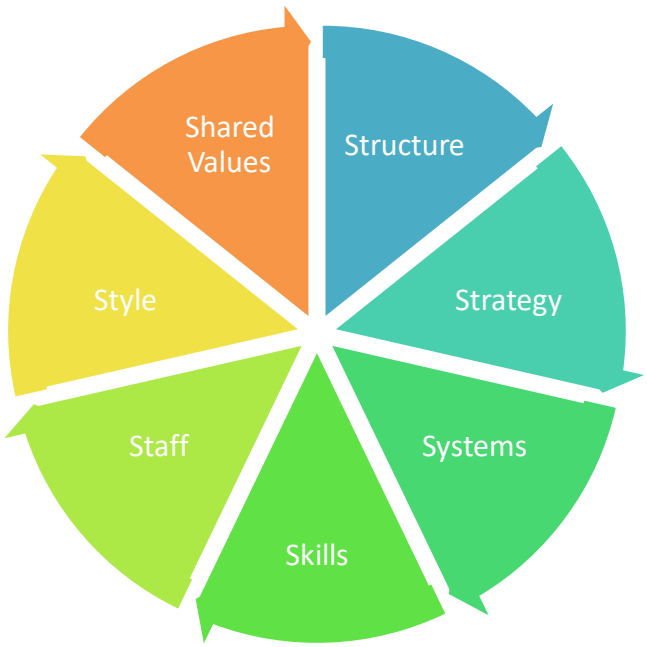
1.3.1 Balanced Scorecard Rationale

This being the first Strategic Plan for SAHPRA for the new full Medium Term Strategic Framework cycle, applying the guidelines in the revised Framework for Strategic Plans and Annual Performance Plans, SAHPRA deemed it prudent to incorporate the rationale for the approach taken with regards to the targets; also given SAHPRA's own infancy as an entity.


FINANCIAL
STAKEHOLDERS
INTERNAL BUSINESS PROCESSES
ORGANISATIONAL CAPACITY
CLEAN AUDITS AND ELIMINATION OF WASTAGE
Striving to achieve more with less particularly considering a severely strained fiscal environment (an incentive for continuous improvements in efficiencies that benefit SAHPRA's key stakeholders)
Ability to account for prudent use public funds to maintain focus on advancing business objectives without costly distractions
Good reputation improves attractiveness as an employer of choice and makes a case for required funding through state or potential donor funding
FINANCIAL SUSTAINABILITY THROUGH IMPROVED REVENUE GENERATION CAPACITY AND CAPABILITIES
Financial sustainability improves organisational sustainability of SAHPRA and its stature as a global player capable of attracting and retain best talent in a highly specialised and competitive environment
Ability to leverage resource availability for constantly increase investment in innovation that enhances effective execution of SAHPRA's mandate and recognition as an effective regulator and a sector thought leader
CUSTOMER NEEDS & EXPECTATIONS CONSISTENTLY MET
Highly satisfied sector customers happy to pay a premium for guaranteed and convenient services which enhances SAHPRA's financial positioning
Greater confidence in SAHPRA as an efficient regulator enhances attractiveness of South Africa as a jurisdiction to register health products and encourages investments locally; thus contributing to creation of job opportunities
Enhanced predictability with regards to processes empowers SAHPRA customers to plan better (including their product launches)
PUBLIC CONFIDENCE IN THE ROLE OF SAHPRA'S SAFEGUARDS
Public confidence in SAHPRA's effectiveness in safeguarding their health enhance its public profile
The greater the confidence and the more public is educated about their rights and responsibilities the greater allies of SAHPRA they become in monitoring the sector and helping the entity to effectively executive its mandate
ALL CORE BUSINESS PROCESSES AUTOMATED
Improved efficiencies in handling and processing applications – shortened turnaround times
Enhanced predictability with regards to processes empowers SAHPRA applicants to plan better (including their product launches) – transparency and ability to track application processes
Ability for SAHPRA to run operations cost-effectively
Ability to streamline operations across related functional areas across value chain/s
Secure & stable systems trusted by SAHPRA customers
Improved performance management by SAHPRA management
Ability to detect and tackle nefarious activities or practices
ALL CORE BUSINESS PROCESSES DOCUMENTED & IMPLEMENTATATION ENFORCED
Efficiency and effectiveness through getting job done right the first time
Sustaining uninterrupted operations
Constant process reengineering for continuous improvement
QUALITY STRATEGIC PARTNERSHIPS /ALLIANCES
Improve efficiencies through Reliance protocols
Minimise research costs through harnessing pertinent partner insights
Enhanced quality assurance and speedy evaluations through laboratory partnerships
ADEQUATE, SUITABLY QUALIFIED TALENT ATTRACTED & RETAINED AND MAINTAINING MINIMAL VACANCY RATE
Suitably qualified staff, competitively remunerated
Adequate staff complement to cover workload – no over-burdening
Happy and job-satisfied with growth prospects
Efficiently structured SAHPRA to fast track decision making processes
Elimination of vacancies in funded critical positions
INTELLECTUALLY CAPACITATED TEAM MEETING COMPETENCY CRITERIA
Ongoing training contributing to continuous improvement in all key areas of performance
Lower staffing costs through capacitation of internal staff
Potential to expand/diversify product/service offerings
Optimised career pathing opportunities of individuals within SAHPRA through continuous competency and skills training

1.3.2 Building a High Performance and High Impact SAHPRA

Informed by outcomes of its environmental scan as well as the strategic review process, SAHPRA identified specific interventions that seek to create and maintain a high performance organisation over the MTSF period. This structured approach is predicated on the principals of the McKinsey 7S Model for organisational high performance or impact, which focuses on:



7 S Mckinsey Model

The following are considered high-impact initiatives and interventions aimed at enabling SAHPRA to become a sustainably high performance and high impact organisation future proofed for new developments through its agility. Specific action plans will be developed and assigned to relevant managers and/or task teams.

Interventions per focus area according to 7 S Model

Focus Areas	Intervention	
Finance	• Prudent use of subsidy funds including elimination of wastage • Improve business efficiencies to help the industry thrive and make a compelling offering for annual fee increases • Enhance revenue generation through a well-coordinated fee structure framework among other means	Strategy
Stakeholders	• Incorporate annual climate surveys into the organisational culture to ensure that staff are motivated and there are no avoidable hindrances to their high performance • Improved relations with staff unions through recognition agreements and regular engagements	Staff

Focus Areas	Intervention	
Internal Business	• Minimise SAHPRA's current reliance on external evaluators over time since SAHPRA has limited control over their performance. Focus on building internal capacity. • Review the framework of assessing evaluators to improve their throughput • Clear the existing backlog, by reengineering the framework and processes • Develop clear evaluation criteria and improve communication with industry • Partner with private laboratories in order to expedite the post market surveillance and pharmacovigilance activities • Leverage technology to create transparency in processing of applications and allowing applicants to track applications • Conduct regular and random inspections to ensure consistent compliance by licence and permit holders. Enhance proactivity in conducting investigations • Create platforms for members of public to interact more with the regulator including improving public education and leveraging community outreach programmes to interact more with and educate members of community about the role of SAHPRA and their rights and responsibilities and community members	Strategy
	• Review the organisational structure and align it to the strategy internal business • Ensure that the structure does not create bureaucratic red tape adversely affects quick decision-making processes • Introduce platforms for management to interact with each other more often on strategic and operational matters	Structure
	• Prioritise the harmonisation of legislative framework that is fundamental to success in effectively discharging the mandate • Prioritise business processes that will support the advancement of the sector for purposes of being able to measure the sector performance using all the measurements in the World Health Organisation Toolkit • Conclude an annual Shareholder Compact with the NDOH in order to maintain high levels of cooperation, improve delegations of authority arrangements, etc • Strengthen organisational governance systems • Formalise all strategic partnerships and coordinate stakeholder relations from a single point in the Office of the Chief Executive Officer • Conduct biennial stakeholder perception surveys in order to identify area of improvement to optimise value of partnerships • Enhance confidence in the operations of SAHPRA by enabling applicants to track their applications • Automate all key business processes to enhance operational efficiencies • Introduce ICT maturity index to inter alia, ensure protection of crucial industry data and Intellectual Property as well as stabilising operations as part of the Business Continuity Plan	Systems

Focus Areas	Intervention	
Organisational Development	• Break down the silo mentality and formalise bilateral engagements between business units that share areas of common strategic and operational interest	Structure
	• Adopt a strategic human capital management approach by developing an overall strategy that will optimise the matching of talent acquisition to strategic business needs. • Optimise organisational development initiatives with a view to tackling threats of skills flights, whether due to push or pull factors. This will seek to address the threats of staff poaching whilst appreciating the phenomenon of skill mobility in the modern era; particularly among younger people. • Train current and future staff to handle and optimally use advanced business systems; including user training on basic cyber security.	Skills
	• Prioritise filling all vacancies especially in core functional areas to avoid overburdening existing staff with work • Prioritise implementation of change management processes and improve internal communications • Develop a Performance Management Strategy that addresses the key areas: • Succession planning • Staff retention in order to reduce flight of critical skills to stabilise the organisation • Introduce and conduct salary benchmarking and communicate openly • Ensure that vacancies are kept to the absolute minimum	Staff
	• Introduce a structured and coordinated organisational development process to define, develop and adopt a new organisational culture which new recruits will be assimilated into	Style
	• Introduce organisational development initiatives targeted at improving organisational culture underpinned by organisational values to encourage staff to actually practice and live the values	Shared Values
Culture and Values	• Conduct annual research on the state of the sector to command a firm grasp on sector developments and leverage that knowledge to manage the • Strive to introduce industry innovations that assert the authority and leadership role of SAHPRA within industry; steeped in better knowledge • Prioritise the processing of local applications to support local industry • How do we deliberately engender sector transformation in our strategic approach (as noted in the sector insights report under external environment); including adopting a Pharmaceutical Sector Charter (or similar) to be gazetted under Section 9(1) of the B-BBEE Act	Strategy
	• Create a culture of a learning organisation (explore collaborative arrangements) particularly with institutions that could potentially provide targeted skills development for SAHPRA's specific needs	Skills
	• Conduct cultural diversity training to maintain sound relations among staff members	Staff

Focus Areas	Intervention	
	• Engender a participative culture in relation to all operations of SAHPRA, e.g. inclusion in developing business processes to improve buy-in and minimise implementation resistance • Leverage infancy of SAHPRA to engender new corporate culture as part of a change management process (to achieve required operational effectiveness and efficiencies of a kind of public entity that SAHPRA is that is not constrained by heavy bureaucracy)	Style
	• Improve SAHPRA's professional culture – adopt professionalism as one of SAHPRA's core values • Infuse into change management processes the appreciation of the value of organisational values and their implications for ability to achieve business objectives	Shared Values

2. KEY RISKS AND MITIGATION

OUTCOMES	KEY RISKS	RISK MITIGATIONS
Effective financial management (1) Financial sustainability achieved through revenue generated and enhanced operational efficiencies (2)	Inadequate financial governance systems and processes resulting in unsustainable financial viability	1. Conduct financial management training 2. Review policies for alignment with GRAP standard 3. Re- engineer and document Financial Management Policies and Processes
The needs and expectations of all SAHPRA stakeholders continuously met (3)	Negative perceptions about SAHPRA due to non-alignment with stakeholder needs	1. Implementation of ICT Strategy for logging complaints, queries, etc. 2. Conduct the annual independent survey for stakeholders needs
A positive and enabling working culture created (4) Attract and retain superior talent (5)	Difficulty in attracting and retaining talent	1. Develop and implement roadmap (skill gaps audit) for capacity building program 2. Development of workplace skills policy and plan

OUTCOMES	KEY RISKS	RISK MITIGATIONS
Strengthened Information and Communication Technology and digitisation (6)	Inability to invest in ICT infrastructure to enable automation and integration of SAHPRA processes	1. Establish ICT Governance policies, structures and processes
High levels of organisational operational efficiency and effectiveness in the regulatory function maintained (7)	Increasing backlog on new applications - Business as usual (BAU)	1. Continuous improvement of application process to improve turn - around time based on stakeholder feedback 2. Formalisation of strategic partnership with stakeholders to reduce application processes
	Inadequate monitoring systems to monitor organisational performance	1. Develop and approve performance management policy 2. Develop performance management systems in line with IT Digitization Strategy
	Inadequate Business Performance and Quality Standards	1. Benchmarking of strategies and policies on Governance and Quality Management Systems
Operational Risks		
Governance risks	Non-compliance with legislation, policies, procedures, and standards	1. Recruitment strategy in place to build internal capacity to meet compliance requirements
	Fraud, theft and corruption	1. Implement the Anti-Fraud and Prevention Strategy and conduct training and awareness sessions to build an ethical culture

3. PUBLIC ENTITIES

Not applicable.

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
Source of Data	Availability of the external or Auditor-General's audit opinion available in Quarter 2, based on the previous financial year's performance
Method of Calculation or Assessment	Document verification based on the existence and availability of the external or Auditor-General's audit opinion issued during Quarter 3, 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 both collection of fees for services rendered
Source of Data	Income statements
Method of Calculation or Assessment	Monies received recognised as revenue for services 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 prioritised recommendations from the survey implemented
Definition	Annual survey recommendations defined, addressed and monitored
Source of Data	Web-based enquiries, IT tracking system, Application tracking tool, HR climate survey, Reports from the communications office, HR updates on positions filled and skills audit
Method of Calculation or Assessment	Numerator: Number of prioritised recommendations implemented / Denominator: Number of prioritised 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

1.4 Indicator Title	Percentage of the change management intervention implemented
Definition	Initiatives conducted towards change management practices
Source of Data	Change management implementation plan
Method of Calculation or Assessment	The number of change management interventions implemented
Means of Verification	Report on the implementation of the change management intervention
Assumptions	Availability of funds to implement the activities
Disaggregation of Beneficiaries (where applicable)	Not applicable
Spatial Transformation (where applicable)	Not applicable
Desired Performance	Implementation of all the change management interventions
Indicator Responsibility	Executive Manager: Human Resources

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 positioned filled / Denominator: Number of positions in the staff establishment x100
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	Number of business processes digitalised
Definition	Convert SAHPRA core business processes from manual or semi-automated functioning to fully digital end to end electronic document and process oversight solution Processes to be mapped: orthodox medicine registration, Section 21 and veterinary medicines
Source of Data	ICT strategic implementation plan
Method of Calculation or Assessment	Number of core business processes digitalised /number of core business processes
Means of Verification	Actual business processes digitalised
Assumptions	• Capital • Business process mapping completed
Disaggregation of Beneficiaries (where applicable)	Not applicable
Spatial Transformation (where applicable)	Not applicable
Desired Performance	The core programmes will have an end-to-end track and trace system to permit oversight and checkpoint reporting with ability to determine root cause of non-performing sectors
Indicator Responsibility	Senior Manager: Information Technology

1.7 Indicator Title	Percentage of medicine registrations backlog cleared
Definition	Quantification of backlog applications lodged by pharmaceutical sector that the regulator can process and finalise within 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 by 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) / x100
Means of Verification	Trackers generated from Google Sheets and supporting documentation thereof
Assumptions	• The project will continue to receive funding to support accelerated output • The programme will recruit evaluators as per the stated timeline • Ongoing collaboration with Industry stakeholder to submit within the stipulated window
Disaggregation of Beneficiaries (where applicable)	Not applicable
Spatial Transformation (where applicable)	Not applicable
Desired Performance	To eradicate the backlog of applications by 2022
Indicator Responsibility	Project Manager: Backlog

1.8 Indicator Title	Percentage of medicine variation applications backlog cleared
Definition	Quantification of variation applications lodged by pharmaceutical sector that the Backlog Clearance Programme can process and approve or reject
Source of Data	Variation applications that were received from 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) x 100
Means of Verification	Trackers generated from Google Sheets and supporting documentation thereof
Assumptions	• The project will continue to receive funding to support accelerated output • The programme will recruit evaluators as per the stated timeline
Disaggregation of Beneficiaries (where applicable)	Not applicable
Spatial Transformation (where applicable)	Not applicable
Desired Performance	To eradicate the backlog of applications by 2022
Indicator Responsibility	Project Manager: Backlog

1.9 Indicator Title	Percentage of New Chemical Entities finalised within 360 working days
Definition	Quantification of new chemical entities finalised within 360 working days, calculated from the day when the applications passes technical screening
Source of Data	SAHPRA Project Management Office generated from Google Sheets
Method of Calculation or Assessment	Numerator: Number of NCE medicines finalised within 360 days / Denominator: Number of NCE applications finalised x 100
Means of Verification	Line listing and supporting documentation thereof
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

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

1.11 Indicator Title	Percentage of new GMP and GWP related licenses finalised within 125 working days
Definition	Quantification of new GMP and 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 125working days counting from the day when the applications are deemed to be meeting minimum requirements 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 finalised x 100
Means of Verification	• Application Email • Acknowledgment Letter • Inspection outcome documentation • Issued Licence • CEO Approval date
Assumptions	• New applications will continue to be received by the regulator • Inspections preceding the processing of applications will be undertaken and completed timeously • 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 60 working days
Definition	Quantification of clinical trial applications lodged with the regulator by applicants who intend to undertake clinical trials for purposes of assessing GCP 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 60 working days / Denominator: Number of clinical trial applications finalised x100
Means of Verification	• Emailed CTF1 • Emailed Proof of Payment • CTC meeting minutes • Approval/Rejection letter
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 (R&D) within an environment that guarantees the safety of clinical trial participants
Indicator Responsibility	Senior Manager: Clinical Evaluation and 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	Revised medical device roadmap, TORS minutes, Progress report to the Chief Regulatory Officer and Chief Executive Officer
Method of Calculation or Assessment	Count steps in framework completed
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