ANNUAL PERFORMANCE PLAN

2020-21

CULTIVATING A HIGH PERFORMANCE CULTURE,
FOR A STREAMLINED HEALTH PRODUCTS REGULATOR

SAHPRA
South African Health Products Regulatory Authority

MISSION

To safeguard public and animal health by licensing of safe, effective and good quality medicines, medical devices, IVD's, radiation devices and radioactive materials. Further, to monitor clinical trials, maintain vigilance and ensure regulatory compliance of these health products in South Africa.

VISION

An agile, conscientious and socially transformative, globally positioned health products regulator with sustainable positive impact on long and healthy lives of all those living in South Africa.

CORE VALUES

- Care and Service Excellence
- Unity of Purpose
- Transformation
- Innovation
- Ethics and Integrity

SAHPRA
South African Health Products Regulatory Authority

CONTENTS

ACRONYMS AND ABBREVIATIONS

ADR	Adverse Drug Reaction
AMRH	African Medicine Regulatory Authority
APP	Annual Performance Plan
API	Active Pharmaceutical Ingredient
ATM	African Traditional Medicines
CAGR	Compound Annual Growth Rate
CCOD	Compensation Commission for Occupational Diseases
CEO	Chief Executive Officer
CMs	Complementary Medicines
CSIR	Council for Scientific and Industrial Research
CMS	Council for Medical Schemes
CTC	Clinical Trials Committee
DMRE	Department of Mineral Resources and Energy
DPME	Department of Planning, Monitoring and Evaluation
eCTD	Electronic Common Technical Document
EMA	European Medicines Agency
FDA	Food and Drug Administration of the United States of America
GCP	Good Clinical Practice
GDP	Good Distribution Practice
GLP	Good Laboratory Practice
GMP	Good Manufacturing Practice
GRP	Good Regulatory Practice
GVP	Good Vigilance Practice
GWP	Good Wholesaling Practice
HFC	Health Finance Committee
HIV	Human Immuno-Deficiency Virus
HPTTT	Health Products Technical Task Team
ICH	The International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use
ICT	Information and Communication Technology
IMDRF	International Medical Device Regulatory Forum
ITG	Industry Task Group
IVD	In Vitro Diagnostic
KPA	Key Performance Area
MCC	Medicines Control Council
MHRA	Medicines and Health Products Regulatory Agency
MOU	Memorandum of Understanding
MRA	Medicines Regulatory Authority
MTEF	Medium Term Expenditure Framework
MTSF	Medium -Term Strategic Framework
NCD	Non Communicable Diseases
NCE	New Chemical Entity
NDP	National Development Plan
NDoH	National Department of Health
NHA	National Health Act
NHI	National Health Insurance

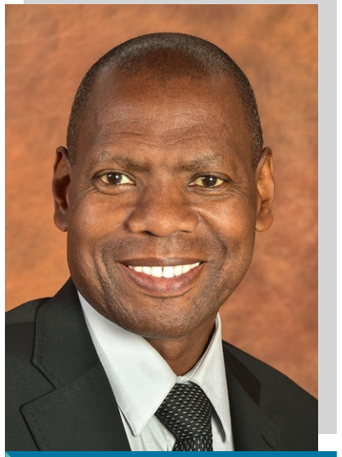
ACRONYMS AND ABBREVIATIONS

NNR	National Nuclear Regulator
NRA	National Regulatory Authority
OHSC	Office of Health Standards Compliance
OTC	Over the Counter
PFMA	Public Finance Management Act
PIC/S	Pharmaceutical Inspection Cooperation Scheme
PSUR	Periodic Safety Update Report
QMS	Quality Management Systems
SAHPRA	South African Health Products Regulatory Authority
SANAS	South African National Accreditation System
SDGs	Sustainable Development Goals
SEP	Single Exit Pricing
SONA	State of the Nation Address
TB	Tuberculosis
TGA	Therapeutic Goods Administration, Australia
UHC	Universal Health Coverage
WHO	World Health Organization

GLOSSARY OF KEY TERMS & DEFINITIONS

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;
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;
IVD	"IVD" (in vitro diagnostic) means a medical device, whether used alone or in combination, intended by the manufacturer for the in vitro examination of specimens derived from the human body solely or principally to provide information for diagnostic, monitoring or compatibility purposes;
Health Product	The term 'health product'as is contained within the ambit of this document only, means medicines, medical devices, radiation emitting devices and radioactive nuclides, complementary medicines, veterinary medicines, biological and biosimilars.
Complementary Medicines	The term "complementary medicines" means any substance or mixture of substances that- (a) originates from plants, fungi, algae, seaweeds, lichens, minerals, animalsor 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;
Radiation	This means the emission of energy as electromagnetic waves or as moving subatomic particles, especially high-energy particles which cause ionization

FOREWORD ▶ BY THE MINISTER OF HEALTH



Dr Zwelini Mkhize

The South African Health Products Regulatory Authority's (SAHPRA) Annual Performance Plan 2020/21, which is based on the 2020/21-2021/25 Strategic Plan 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 Annual Performance 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 Annual Performance 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

PREFACE ▶ BY THE CHAIRPERSON OF THE BOARD

Professor Helen Rees

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 its 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 organization so as to work collaboratively with relevant stakeholders to shape policy.

Another notable development is the advent of Presidential Health Summit Compact which also has policy implications for SAHPRA. Collectively, these developments require policies that are both industry-wide and those that are 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.

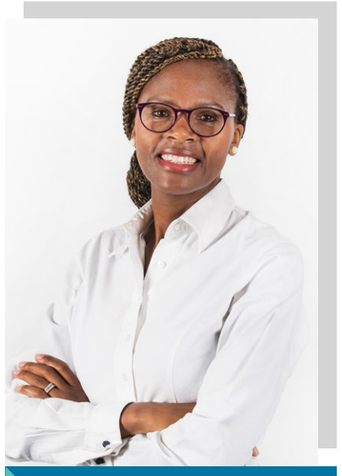
Appreciating the massive capacity gaps SAHPRA currently has as it continues to evolve, I am pleased with, and have confidence, in the leadership and support the Board has afforded to SAHPRA management through its committees; ensuring that SAHPRA is able to assume leadership in its respective areas. It also gives the Board immense pleasure to confirm that SAHPRA has appointed a new Chief Executive Officer who has assumed duties in January; as one of the primary endeavours to stabilise the leadership of the organisation, starting at the top. This will be soon followed by the filling of other senior management vacancies in positions that have hitherto been occupied by acting incumbents.

As we enter a new era of a new five-year planning cycle for SAHPRA and are nearing the end of term for the current Board, our focus is on shaping a bright future for SAHPRA and on handing over 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 to join our Honourable Minister and the CEO in presenting this Strategic Plan for the 2020 – 2024 period as well as the Annual Performance Plan for 2020 – 2021 medium-term period.

Professor Helen Rees
Board Chairperson

STATEMENT ▶ BY THE CHIEF EXECUTIVE OFFICER



Dr Boitumelo Semete -Makokotlela

My journey with SAHPRA commenced in January 2020 and promises to be both challenging and exciting. I take the reins of an infant entity evolving through its developmental phases and emerging from a year that was without a doubt arduous but definitely very informative in helping determine the direction SAHPRA must take to grow.

There is growing appreciation among management of the mammoth task to address the needs of stakeholders so as to cascade to meeting the needs of the people of South Africa. One of the exciting developments is being part of the era and generation that plays a crucial and direct role in effecting the existence and implementation of the NHI scheme and to enforce the ethos of accountability with the election of the 6th administration.

Our enthusiasm for the beckoning future in the realm of healthcare service and our regulatory role therein is matched by our drive to improve our planning processes. Among other things, this means taking advantage of the infancy of SAHPRA to breed a professional organisational culture that will be beneficial to all our stakeholders. To this end, we believe we have formulated a fit-for-purpose Strategic Plan for the 2020 – 2024 five-year cycle; guided by the revised Framework for Strategic and Annual Performance Plan recently published by the Department of Planning, Monitoring and Evaluation (DPME).

We have endeavoured to align our planning process with the need to constantly keep our organisational effectiveness in check. In line with our extended mandate of ensuring that health products in our South African jurisdiction meet quality, safety and efficacy standards, we have re-formulated our core business outcomes as:

These are the outcomes around which we will be rallying our current Team SAHPRA as well as the future recruits as we embark on a major drive to strengthen our organisational capacity to become a more proactive regulator.

- Ensure effective financial management, governance and alignment of budget allocation with strategic priorities
- Achieve and maintain financial sustainability through revenue generated and enhanced operational efficiencies
- Consistently meet the needs and expectations of all SAHPRA's stakeholders
- Achieve and maintain high levels of regulatory operational efficiency and effectiveness delivering to its stakeholders timeous and ensuring safe, efficacious and quality products
- Strengthened ICT capacity to support digital transformation
- Create a culture of excellence, while ensuring that SAHPRA's people are valued
- Attract and retain superior talent
- Promote the observance and upholding of organisational values and culture to advance business objectives and image/ reputation

Some of the new indicators that underpin these outcomes are aligned to the World Health Organisation (WHO) standards which necessitates that we gear up our mechanisms to collect new healthcare data that pertains to our regulatory function. Therefore, this calls for our operations to be underpinned by sound internal controls and good governance as well as strong organisational capacity to advance efficient implementation of plans. This has a direct implication for our ability or otherwise to collect crucial data and serve as an aggregating repository for the sector; as we simultaneously seek to provide sector thought leadership.

We have confidence in successfully attaining our recrafted vision: being an agile, conscientious and socio-economically transformative globally positioned African health products regulator with sustainable positive impact on long and healthy lives of South Africans.

I am immensely proud and pleased to present both our aforesaid Strategic Plan and the Annual Performance Plan for the 2020 – 2021 Mid-Term Expenditure Framework (MTEF).

Dr Boitumelo Semete-Makokotlela
Chief Executive Officer

OFFICIAL SIGN OFF

It is hereby certified that this Annual Performance Plan:

- Was developed by the management under the guidance and support of the South African Health Products Regulatory Authority (SAHPRA) Board.
- Takes into account all the relevant policies, legislation and other mandates for which SAHPRA is responsible.
- Accurately reflects the outcomes and outputs which SAHPRA will endeavour to achieve over the period 2020/21.

MANAGEMENT: SIGN OFF				
PROGRAMME 1	**PROGRAMME 2**	**PROGRAMME 3**	**PROGRAMME 4**	**PROGRAMME 5**
Adv Teboho Peter Nthotso	**Mrs Santhamala Chetty**	**Mr Jerry Molokwane**	**Mrs Silverani Padayachee**	**Ms Emma Snyman**
Company Secretary	**Acting Senior Manager**	**Acting Senior Manager**	**Senior Manager**	**Acting Senior Manager**
DATE: 31/01/2020	**DATE: 31/01/2020**	**DATE: 31/01/2020**	**DATE: 31/01/2020**	**DATE: 31/01/2020**

EXECUTIVE: SIGN OFF				
Ms Portia Nkambule	**Mr Molatlegi Kgauwe**	**Dr Boitumelo Semete-Makokotlela**	**Prof Helen Rees**	**Approved by Dr Zwelini Mkhize (MP)**
Chief Regulatory Officer	**Chief Financial Officer**	**Chief Executive Officer**	**Chairperson Of Board**	**Minister Of Health**
DATE: 31/01/2020	**DATE: 31/01/2020**	**DATE: 31/01/2020**	**DATE: 31/01/2020**	**DATE: 24/03/2020**

PART A:
OUR MANDATE

PART A: OUR MANDATE

1. UPDATES TO THE RELEVANT LEGISLATIVE AND POLICY MANDATES

1.1 RELEVANT LEGISLATIVE MANDATE

The South African Health Products Authority (SAHPRA) is responsible for the:

- Regulation of health products intended for human and animal use;
- Licensing of manufacturers, wholesalers and distributors of medicines, medical devices, radiation emitting devices and radioactive nuclides; and
- Conduct of clinical trials.

Since its establishment in February 2018, as a section 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 the 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:

1.1.1 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 in 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 decentralized management, principles of equity, efficiency, sound governance, internationally recognized standards of research and a spirit of enquiry and advocacy which encourage participation;
- Promote a spirit of co-operation and shared responsibility among public and private health professionals and providers and other relevant sectors within the context of national, provincial and district health plans;
- Create the foundations of the health care system, and
- Must be understood alongside other laws and policies that relate to health.

1.1.2 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, 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.

It 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 radioactive nuclides;
- 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.

1.1.3 Hazardous Substances Act (Act No. 15 of 1973)
The Hazardous Substances Act provides for the efficient, effective and ethical evaluation and licensing of electronic generators of ionizing radiation and radionuclides.

The Hazardous Substances Act classifies such substances and products in groups according to the risk associated with them. 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 which are electronic generators of ionizing radiation. Section 3A refers to regulation of Group IV hazardous substances, which are radionuclides.

1.1.4 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, stock remedies. Furthermore, it governs the use of antimicrobials for growth promotion and prophylaxis/ metaphylaxis, and the purchase of antimicrobials over-the-counter (OTC) 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 professions; 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 Drugs 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 substance 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.

- 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:

  Provides for the regulation of the pharmacy profession, including community service by pharmacists.

PART A: OUR MANDATE CONTINUED

- 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 but 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.

Concerning one of the key new responsibilities emanating from SAHPRA's extended mandate are functions relating to radiation control, which have crucial elements falling within the jurisdiction of the Department of Mineral Resources and Energy (DMRE). Another key collaborative partnerships needed to be nurtured is cannabis regulation which cross pollinates multiple ministries to effect the countries focus on enhancing access to this medicinal product. As SAHPRA continues to mature into role, it is becoming increasingly evident that there is a critical need to harmonise roles and responsibilities to avert the risk of an internal leadership vacuum or duplication of efforts and subsequent potential 'conflict'.

1.2 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 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 be engaged with these matters that pertain to legislative and policy framework considerations, in tandem with other relevant industry bodies and government departments.

2. UPDATES TO INSTITUTIONAL POLICIES AND STRATEGIES

2.1 INSTITUTIONAL POLICIES

SAHPRA recognises the value of institutional policies for its effective and efficient operations in giving effect to its mandate. Given the infancy of the entity, despite having developed policies over the many months since its inception, the Regulator is still largely utilising the National Department of Health (NDoH) corporate services and policies to guide its compliance universe for both internal and external operations. Consequently, there will be a heightened focus on crafting a series of both policies and frameworks that are fundamental to SAHPRA's operations.

There is equally a number of strategies that still need to be developed as the entity on-boards various specialists, particularly in the area of organisational development which is critical to building organisational capacity. Some of the noteworthy outstanding SAHPRA specific policies and strategies include performance management, change management, communications and so forth. However, in the interim, it will continue to rely on NDoH policies.

Furthermore, 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 radioactive nuclides. 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.

2.2 INSTITUTIONAL STRATEGIES

In compiling the Strategic Plan for the 2020-2024 Medium Term Strategic Framework (MTSF) and the 2020-2020 Medium Term Expenditure Framework (MTEF), SAHPRA took cognisance of, and factored the following key policy and strategic developments:

- The National Development Plan (NDP): Vision 2030 and the National Drug Policy

  In terms of the overarching government socio-economic plans, SAHPRA has taken due cognisance of the National Development Plan's Outcome 2, "A long and healthy life for all South Africans" and its various outputs. However, this was essentially for purposes of ensuring alignment of this outcome plan 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 NDP Five-Year Implementation Plan

  In terms of the NDP Five-Year Plan emanating from the Seven National Priorities as announced in the State of the Nation Address (SONA) 2019, SAHPRA locates its contribution under Priority 2. In this regard, the target for health is outlined as, "Implement the enabling legislative framework and create institutional capacity for NHI by 2024 to achieve universal health coverage for all South Africans by 2030," with its outcome being, "Universal access to good quality health care for all South Africans achieved." In terms of impact, SAHPRA is aligned to, "Enhanced access to good quality health services for all South Africans, based on need and not ability to pay."

  Similarly, the policy fundamentals of SAHPRA's link to these plans are predicated on the National Drug Policy as outlined above.

- The Nine -Pillar Presidential Health Summit Compact, 2018

  The Health Compact has aims at finding solutions to the crisis facing our health system. As such, the identified nine (9) pillars need to be strengthened to improve the health system in the country. They are as follows:

1. Augment human resources
2. Ensure improved access to essential medicines, vaccines and medical products through better management
3. Execute the infrastructure plan to ensure adequate, appropriately distributed and well maintained health facilities
4. Engaging 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 governance and leadership to improve oversight, accountability and systems performance at all levels.
8. Engage and empower the community to ensure adequate and appropriate community based care
9. Develop an information system that will guide the health system policies, strategies and investment.

The Health Compact contains numerous prominent references to SAHPRA, its roles and responsibilities and other interventions that require its direct involvement, as set out below.

- There is a need to address the current SAHPRA backlog of registration of medicines, which is a primary focal area for the Board and management. Regulation and registration interventions to address SAHPRA's backlog include:
  - To prioritise medicine applications based on the public health need and expedite processes that take into account mutual recognition for medicines of public health benefit as a matter of critical concern;
  - To re-engineer regulatory processes to reduce unnecessary bureaucracy and delays by re-engineering the operational models and revising business processed;
  - To create collaborative structures to introduce new medicines into pilot programmes so as to address high burden diseases, particularly HIV, TB, cancer and other diseases of priority; and
  - To adopt the novel regulatory mechanism of reliance and molecule-based registration.
- It would be remiss not to note that, while innovative, the rigour of the reliance mechanisms remains to be established within the global regulatory environment, and as such the full effectiveness of this strategy may not be realised in the initial implementation. Therefore, the December 2019 deadline articulated in the Health Compact, determined by independent stakeholders and without input from the SAHPRA Board and managers, will not be feasible without compromising SAHPRA's core mandate of quality, safety and efficacy.
- Operationally, it is imperative to note that operational and policy frameworks will also require concurrent alignment to the business-as-usual environment, as well as the use of automation and leveraging collaborative

PART A: OUR MANDATE CONTINUED

structures to achieve the timeous introduction of new medicines so as to address high-burden diseases. The process towards reducing the turnaround times will therefore need to be measured and deliberate to be effective.

- Further considerations towards supporting the presidential Health Compact include the need to review the level of funding of crucial health sector entities such as SAHPRA, the Office of Health Standards Compliance (OHSC), the Council for Medical Schemes (CMS) and the Compensation Commission for Occupational Diseases (CCOD) institutions, together with the review of the budget allocations to the public health sector and the provincial and municipal health services. An objective system of determining the allocation of resources to these entities needs to be established.
- There is a need for an improved Communication Strategy and approach as SAHPRA currently does not timeously communicate decisions that affect the availability of medicines.
- Further considerations towards supporting the presidential compact include, include; the level of funding of crucial health sector entities such as SAHPRA, OHSC, CMS, and the CCOD institutions needs to be reviewed; together with the review of the budget allocations to the public health sector and the provincial and municipal health services. An objective system of determining the allocation of resources to these entities needs to be established.

A need for an improved Communication Strategy and approach as SAHPRA currently does not timeously communicate decisions that affect medicines availability

- The Minister of Health's Budget Vote and Policy Statement
  - The policy statement reiterates and reemphasises that SAHPRA will be strengthened to ensure that the registration of medicines and capacity for local production of active ingredients as well as removal of application backlogs are accelerated.
  - In terms of stakeholder management there is a strong need for cooperation between the public and private sector, civil society, patients' associations, academics, researchers including labour in transforming the health system. The Ministry will have a dialogue with a wide range of stakeholders to aid the flow of information amongst parties within the next six months.
- The Revised Framework for Strategic and Annual Performance Plans (FSAPPs)

  Key issues to note and respond to with regards to the Framework are:
  - The application of diagnostic tools such as PESTEL and SWOT analyses, scenario planning, problem tree analysis among others, as well as adopting a balanced scorecard approach to strategic planning.
  - It provides guidelines for the development of Operational Plans which must be approved by March annually. These Operational Plans are particularly enormously important in the context of SAHPRA in institutionalising the performance culture at programme and individual levels.

PILLAR 2: ENSURE IMPROVED ACCESS TO ESSENTIAL MEDICINES, VACCINES AND MEDICAL PRODUCTS THROUGH BETTER MANAGEMENT OF SUPPLY CHAIN EQUIPMENT AND MACHINERY

KEY INTERVENTIONS	KEY ACTIVITIES	INDICATORS	TIMELINES	ACCOUNTABILITY (LEAD) / RESPONSIBILITY (SUPPORT)
Implement Centralised Procurement of Medicines and Medical technology	Establish a centralised procurement and logistical management system with standardised procurement systems and processes at the national level for medicines and medical products	Policy on centralised procurement fi nalized and adopted by the National Health Council	April 2021	**Lead:** National DoH **Support:** National Treasury Provincial DoH Provincial Treasuries Academia Private Sector
Training/Human Resource Capacitation	Implement Centralised Procurement of Medicines and Medical technology	Number of joint support training programmes established	Nine programmes by April 2021 (one in each Province)	**Lead:** National DoH **Support:** Pharmacy Council South African Nursing Council and Pharmaceutical IndustryPrivate sector
Regulation and Registration	SAHPRA will, through a collaborative process re-engineer regulatory processes to reduce unnecessary bureaucracy, reduce delays in the registration of products and value innovation, thereby providing reasonable access to safe, effective and affordable products.	Reduction in the average time frame for the registration of products. Clear current backlog. Implement reliance model.	Dec 2019	**Lead:** SAHPRA **Support:** National DoH Private sector
Development of a Health Technology Assessment Strategy	Develop a Health Technology Assessment Strategy and costed implementation plan	Health Technology Assessment Strategy developed and costed, with an implementation plan An independent HTA Agency established	Dec 2020 April 2022	**Lead:** National DoH **Support:** National Treasury Schools of Public Health, User Groups, Private Sector
Public Private Partnerships to Indigenisation of Pharmaceutical Production	Explore options for collaborative partnerships for pharmaceutical production	Off -take agreements signed by the National DoH with Ketlaphela State-owned Pharmacetuical Company	April 2020	**Lead:** Ketlaphela State-owned Pharmacetuical Company **Support:** Science and Technology; National DoH; Trade and Industry (DTI); Public Enterprises, Academia

Figure 1: Pillar 2 Action Plan on improved access to essential medicines, vaccines and medical products

Source: Presidential Health Summit Compact, 2018

PART A: OUR MANDATE CONTINUED

- Key SAHPRA Strategic objectives

The key strategic focus of SAHPRA for this next 5 years is to stabilise SAHPRA as a fledgling schedule 3A entity and move seamlessly out of the current transitional operational environment. Further SAHPRA must realise greater operational efficiency This will permit eradication of the backlog and prevention of and future backlogs.

Key SAHPRA Strategic objectives

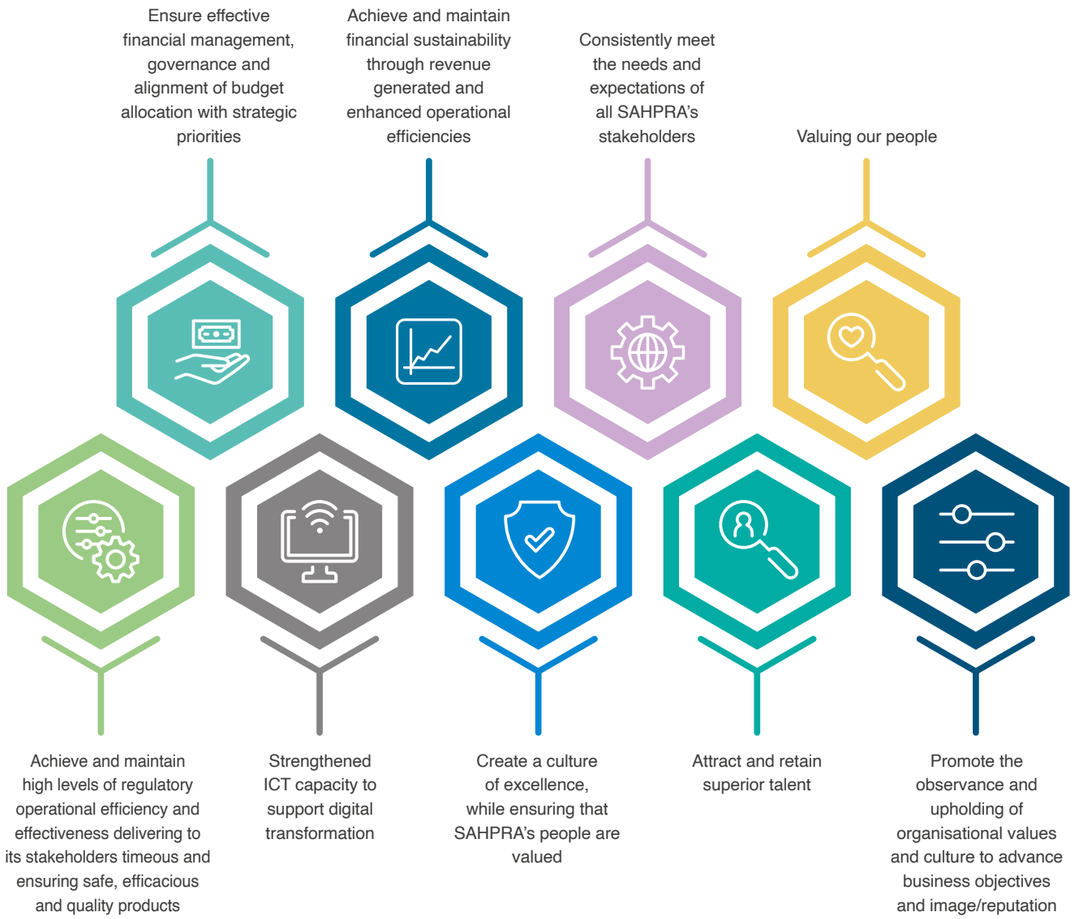


Figure 2: Strategic Objectives for 2020-2024

3. RELEVANT COURT RULINGS

On the 18th of 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 will therefore be required, within 24 months from 18th September 2018, to amend the Medicines Act to comply with this judgement.

PART B: OUR STRATEGIC FOCUS

PART B: OUR STRATEGIC FOCUS

4. UPDATED SITUATIONAL ANALYSIS

4.1 OVERVIEW:

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 3 A 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.

4.1.1 External environment analysis

SAHPRA has not been sheltered from the key social, economic and political developments in the environment in which it executes its regulatory mandate. The economic forecasts on GDP growth from 2018/19 have been downgraded several times by different agencies. The annual GDP growth rate found itself in negative territory in the last 2 quarters of 2019. The GDP growth rate for 2020 is most likely to hover around 1% One particular focus area for SA in reaching the 1.4% to 1.6% range forecasted by the SA Reserve Bank is improved utilisation of state finances and reducing cost drivers. These factors are crucial in addressing the challenges of unemployment and poverty.

It has been reported that up to a third of the South African population is living below the poverty line. The increase in poverty, which is accompanied by joblessness, has a negative impact on the ability of individuals to privately access quality safe and effective health services and products. Public health commodity security therefore becomes increasingly vital and is thus an influencing factor focusing SAHPRA's public health priority policy.

These external influencers have ushered in a change in the balance of power across the healthcare value chain as governments; advocacy agencies and medical aid providers start to exert more pressure on pharmaceutical companies to drop their prices. There is a move from reactive healthcare to prevention, which is bound to attract new entrants and unsettle the status quo. The trend to register generic medicines in SA as more doctors and consumers opt for affordable, yet effective alternatives to expensive brand name medication will support greater affordable access

Several key developments in this environment have had a direct impact on SAHPRA and its regulatory role. The major recent development in the policy sphere is the promulgation of the National Health Insurance Implementation Policy and its gazetted implementation advisory committees.

The broader health sector has enjoyed a period of relative stability from a political perspective. This has ensured that the policy developments in the sector have progressed without major, unexpected obstacles; however; access to quality health services is still a gap in the country.

Despite life expectancy showing an increasing trend in the past few years, the average life expectancy is still low at 63.1 years for females and 59.1 years for males. The average life expectancy is expected to rise to 70 if the health sector reform is successful. SAHPRA's public health priority focus will therefore need to align to the current and emerging health needs.

The country is currently facing an increasing burden of diseases that negatively affects the health of the population and results in poor health outcomes. Epidemiologically, South Africa is confronted with a quadruple burden of disease resulting from communicable diseases such as HIV/AIDS and TB; maternal and child mortality; NCDs such as hypertension and cardiovascular diseases, diabetes, cancer, mental, behavioural and neurological illnesses and chronic lung diseases like asthma; as well as injury and trauma., The alarming rise of abuse and misuse of licensed medicines, particularly the opiates and the resultant implications on public health has direct consequences on the work of SAHPRA

There is also the invisible burden of adverse drug reactions towards medicines used to treat these conditions. Studies in South Africa estimate that 6-8% of medical ward admissions are caused by adverse drug reactions, a significant proportion of which are deemed to be preventable; but nevertheless continue to add to the disease burden experienced by the public.

In addressing the health care burden, the health sector faces increasing costs of medical products and technologies. The main cost drivers in the public sector (other than human resources) are pharmaceuticals; laboratory services; blood and blood products; equipment; and surgical consumables..

To address some of the gaps in offering quality health services to the people of South Africa, the National Health Insurance (NHI) Bill has been promulgated and will be implemented in the coming years. The NHI is a health financing system that is designed to pool funds to provide access to quality affordable personal health services (including health products) for all South Africans based on their health needs, irrespective of their socioeconomic status.

It naturally follows that in executing its mandate effectively and efficiently, SAHPRA has a fundamental role to play as a regulator in assuring medicine commodity security, product safety and quality monitoring within this system of universal health coverage (UHC). Whilst the mandate of SAHPRA is focused on regulating quality, safety and efficacy of health products; the indirect impact on access and cost is inevitable. More efficient health product registration, post-market surveillance and execution of other health product regulatory roles; enhances investment in the pharmaceutical market, improve access and diminish the threat of unsafe, substandard and/or counterfeit health products. At greatest risk from these health product threats is the growing numbers of vulnerable individuals arising from the widening socio-economic gap in the population

The local pharmaceutical market is growing at just over 9% in value and this growth is ascribed to the increased demand for generics. Nearly every therapeutic class currently has at least one generic equivalent available and sales of over-the-counter (OTC) generics now also outstrip brand name products by almost R1 billion in value and more than 53 million units. In SA, generics are fast becoming the pillar of healthcare because of the affordability to public health and accessibility by the most vulnerable in society. It is therefore imperative that the existing medicine registration backlog inherited by SAHPRA, which primarily comprises generics, be eradicated.

It is prudent to consider the challenges experienced by the industry for whom the efficiency and effectiveness of SAHPRA will have consequences. These challenges include:

- Currency weakness increases the cost of imported active pharmaceutical ingredients (APIs), which are key ingredients in the manufacturing process, as well as the cost of finished pharmaceutical products (FPPs) or health products not manufactured in this country.
- The level of single exit pricing (SEP) increases does not adequately cover the cost base of pharmaceutical companies, of which currency is a substantial driver.
- Another challenge is the increasingly competitive government tenders, with punitive conditions attached for non-compliance.

Weak economic growth means that SAHPRAs improved business format could stimulate the health sector and encourage submission of applications in this country. Eradication of the backlog and efficiency in turnaround times at SAHPRA is a key under-pinners to how the regulator opts to respond to industry related difficulties. This response to industry challenges will seek to ensure diverse access of health products to meet the diverse public health needs More efficient licensing of health product manufacturing facilities secures the quality of health products SAHPRA wishes to assure. further, Efficiency in the registration process will help to negate the threat related to our other competing regulatory mandates in this period that SAHPRA seeks to build its full capacity as a Schedule 3A entity.

The same arguments hold true for the medical technology industry, commonly referred to as medical devices, consisting of instruments, devices, apparatuses, or machines that are used in the prevention, diagnosis or treatment of illness or disease, or for detecting, measuring, restoring, correcting, or modifying the structure or function of the body for some health purpose. Efficiency of licensing and effective post-marketing surveillance are key a considerable determinant of ensuring the positive impact of the medical technology industry on public health in South Africa

The South African medical device market was estimated at R30 billion in 2019 and ranks among the top 30 largest in the world. 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 remains underdeveloped, with imports catering for 90% of the market by value. This has direct bearing on SAHPRA's regulatory strategy. South Africa's medical device production firms tend to be small or medium-sized businesses and often combine their distribution activity with manufacturing. Multinational companies present in South Africa often operate in a joint venture capacity with local firms. Most South African manufacturers focus on producing basic medical equipment and supplies, with production focused mainly on bandages and dressings, medical furniture and low technology items.

The global medical device market is expected to reach an estimated $409.5 billion by 2023, and it is forecast to grow at a compound annual growth rate (CAGR) of 4.5% from 2018 to 2023.[1] Major factors for the growth in the industry are healthcare expenditure, technological development, an aging population and chronic diseases. Clinical trials for devices in Europe are controlled by member states under a competent authority. Another role of a competent authority is compliance and enabling enforcement, ensuring that the Medical Devices Act is being complied with and working with collaborative partners such as the Hawks and South African Police to potentially prosecute anyone who places a device on the market without authorisation or a device that is inappropriately labelled.

Recent research suggests that up to 30% of pharmaceutical research and development is now directed toward combination products. There are three basic groups of these products, namely:

- Drug–device combinations, which fall under pharmaceutical law;
- Device–drug combinations, where the lead is device law; and
- Diagnostic–drug combinations or "companion diagnostics", which may require new legislation to be appropriately handled.

SAHPRA's strategic focus will seek to influence this sector to ensure global regulatory alignment and to support innovative product development where relevant while safeguarding against the registration of irrational or potentially unsafe combinations while supporting the licensing innovative products that meet the regulatory standards of safety, efficacy and quality and have public health value.

Another key emerging sector that SAHPRA needs to strategically respond to must align with strategically is the global trend of regulation of cannabis and cannabis-

PART B: OUR STRATEGIC FOCUS CONTINUED

containing products. In November 2017, SAHPRA implemented a licensing framework to regulate proposed growers of cannabis for medicinal use. This would in effect enable cultivation, manufacture and supply of standardised high-quality cannabis for medicinal use and cannabis-containing medicines. Licensed domestic cultivation of cannabis for medicinal use is aimed at ensuring sufficient local supply for medical, scientific and clinical research purposes. This will require the implementation of control measures and vigilance approaches necessary to prevent diversion and misuse as well as ensuring patient safety. South Africa's current regulatory requirements for registration of medicines would also apply to cannabis-containing products intended for sale in South Africa.

The way forward for SAHPRA will be to build capacity to both register products and license manufactures in line with its quality, safety and efficacy mandate for legitimate operation, as well as monitor the performance of these licensed products, regulate; in collaboration with key law enforcement partners and other government agencies; illegitimate operations that transact in substandard or falsified products.

Similarly, SAHPRA needs to take a lead in addressing the scourge of codeine misuse and abuse that has reportedly reached alarming rates in South Africa as well as in neighboring countries. This problem requires a coordinated multi-sectoral approach that will explore regulatory solutions while building on our collaborative relationships with health professionals, law enforcement, the media and the pharmaceutical industry

On the 15th November 2013, the Minister of Health published amendments to the General Regulations made in terms of the Medicines and Related Substance Act, 1965 (Act 101 of 1965), which established a category of medicines, complementary medicines (Category D), and effectively established a regulatory framework for this category.

The medicines which fall under this definition originate from the six (6) major disciplines recognised by SAHPRA, namely Aromatherapy, Ayurveda, Homeopathy, Traditional Chinese Medicine, Unani Tibb and Western Herbal Medicine 1, as well as combination products identified in the accompanying Guideline for Complementary Medicines (Quality, Safety and Efficacy) published in the same year.

Following further interaction with various stakeholders, the category of complementary medicines was broadened to establish two sub-categories of Category D (complementary medicines), reflected in the General Regulations published and implemented as per Government Notice 859 in Government Gazette 41064 on 25 August 2017. This resulted in the inclusion of new sub-categories of Category D, including those traditional disciplines that are not indigenous to South Africa (discipline-specific medicines) but also the more modern supplement-type of medicines (health supplements).

The original deadlines for submission of applications for registration prescribed by Regulation 48C of the General Regulations in 2013 were deleted by the General Regulations in 2017. A new timeline will be established by way of the publication of declarations that categories, sub-categories or classes of Category D medicines (complementary medicines) shall be subject to registration ("call-up notices") in terms of section 14 of the Medicines and Related Substance Act, 1965 (Act 101 of 1965).

In the next five years, resources will be dedicated to reviving this process and giving it a stronger momentum to ensure the public accesses to these products with greater assurance of safety and fortification against false claims as well as substandard- and falsified CMs.

A significant strategy enabling SAHPRA to attain these mandates is alignment and collaboration with other regulatory authorities; especially in the continent. Of special note is SAHPRA's affiliation to the African Medicines Regulatory Harmonisation initiative (AMRH) and Zazibona,

The AMRH seeks to address the availability of safe, good quality and affordable medicines; which is a challenge for many African countries due to non-existent, weak or outdated legal frameworks and limited capacity. AMRH works to improve access to quality, safe and efficacious medicines by providing an enabling regulatory environment for pharmaceutical sector development in Africa. SAHPRA seeks to support; learn from; work with and provide thought leadership to this endeavour.

Zazibona promotes a collaborative model to facilitate access to good-quality medicines through work-sharing in assessment of medicines and inspection of medicine manufacturing and testing facilities. Products that meet assessment criteria are then granted registration in the participating countries, in which CTD-format applications for registration would have been submitted. Where countries agree that is necessary, variations to the products which have been registered under this collaboration may be handled through the same process.

SAHPRA's footprint in the Southern African Development Community (SADC) and the continent of Africa is fundamental to establishing the entity as one of the leaders in Africa's health product regulatory environment. This outcome will help to fortify the legitimacy of Africa, not just South Africa, in the global responses to issues and challenges in the health product access and safety arena.

4.1.2 Internal environment analyses

SAHPRA was established in February 2018 on the platform set up by the South African Medicines Control Council. The shift to a Schedule 3A Public Entity was to enable the Regulator to achieve autonomy, alignment with global trends and hence increased agility, effectiveness and efficiency in executing its mandate.

The entity has made positive strides since its inception, but the birth of this new entity was not without challenges.

At the outset, SAHPRA should have been regarded as a "start-up" organisation and should have been provided with adequate corporate service support and sufficient technical staff to deliver on its expanded mandate and inherited challenges.

Limited capacity of these essential underpinners was provided to SAHPRA, resulting in significant gaps in the operationalisation of the entity. This transitional period coincided with industrial action in the NDoH's Civitas building where SAHPRA was still housed, and this limited the support that these NDoH departments could offer SAHPRA.

The SAHPRA staff themselves were affected by the industrial action. At the beginning of 2019, the Regulator had to precipitously move out of Civitas and into new premises on the campus of the Council for Scientific and Industrial Research (CSIR) to enable work to resume. Lack of secure IT and communication infrastructure further hampered the Regulator's work. The spread of its activities across five remotely situated buildings within the CSIR campus continues to make SAHPRA's work challenging. This entire context puts enormous strain on the existing and newly appointed staff at a time when they have been asked to undertake many turnaround processes. Despite these challenges, a team of committed and resilient staff and Board members rolled up their sleeves and led SAHPRA through this difficult period, enabling it to emerge as a growing organisation into a good and positive space.

Despite the troubleshooting that had to take place in the past year, the catchwords for the Regulator during this period have been re-envisioning and re-engineering. SAHPRA will soon have more fit-for-purpose premises, supported by new IT systems designed for the complex needs of a regulatory authority that aims to become fully digitalised within the next year.

The Authority is in the process of employing over 100 new and much needed staff at all levels and in all departments of the organisation over the next three years. The crucial leadership roles of the CEO, CFO, CRO and Company Secretary were filled in the 2019 financial year. Efforts have been intensified to secure other key critical senior positions in both the corporate services and core programmes to keep up the momentum of establishing the entity's leadership. Filling these critical leadership roles will enable a phased approach of recruitment at the technical and administration levels without impacting outputs.

While the operational aspects are being tackled as indicated above, the core business of SAHPRA will equally receive the required attention. Established SAHPRA mandates, such as pharmacovigilance, are receiving renewed attention, while new portfolios, including radiation control and medical devices, are receiving priority attention so as to address identified shortcomings. Radiation control, a service that is essential both for public health and for heath security, will see major changes and improvements in the coming year aimed at streamlining its mandate and addressing backlogs. Registration of medical devices will continue to be aligned with global best practices and its staff contingent will be bolstered to implement new strategies.

The new vision for pharmacovigilance, which is key to ensuring the safety of all health products, includes electronic reporting, facilitating good vigilance practice within the industry and proactive multi-stakeholder communication, prioritizing public engagement and reporter feedback. The complementary medicines registration and regulation unit will be bolstered with capacity and resources to implement the framework established and approved.

The critical priority for SAHPRA since its launch in February 2018 has been the clearance of the medical products backlog. SAHPRA inherited the backlog from the Medicines Control Council, but at the outset the backlog size and scope were unclear. Using the current strategies, it would take eight years to clear the backlog even if no new applications were received. It is impossible to achieve SAHPRA's vision of establishing a state-of-the-art, world-class regulatory authority while this burden of the backlog continues to weigh the entity down.

To address this immense challenge, SAHPRA required and received the buy-in of the pharmaceutical industry who have agreed to adopt fundamentally different ways of doing business.

The SAHPRA team have put an ambitious roadmap in place to clear the backlog within a period of two years, using totally re-engineered approaches for medicines registration. This includes digitisation, reliance procedures that allow SAHPRA to exchange information with recognised regional and international regulatory authorities, and standardisation of evaluation processes that will enable applicants and regulators alike to know what is excepted of them and how long it should take. The same processes are now being introduced for "business as usual" applications. These radically different strategies will reduce the timelines for the registration of both cutting-edge, innovative medicines and of generic medicines..

In summary, over the next five years SAHPRA needs to focus on achieving stabilisation and momentum out of this transitional phase towards greater autonomy, effective governance and operational efficiency.

As the entity looks to strengthen its stakeholder engagement, a new communication strategy will be introduced, which places at its core the wellbeing of all who live in South Africa. A comprehensive communication strategy has been developed which supports SAHPRA's business strategy.. It is envisaged that in 2020 SAHPRA will redesign its website and implement the use of all forms of media to proactively and interactively communicate with the public, professionals and industry.

PART B: OUR STRATEGIC FOCUS CONTINUED

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

TABLE 1: SAHPRA'S 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 (NHI) 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 opiod 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 BBBEE Act.
ECONOMIC (FINANCIAL)	
1.	There has been a change in the balance of power across the healthcare value chain as governments and medical aid providers 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 (OTC) 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 (APIs), which are key ingredients in the manufacturing process impact licensing and access within SA market
6.	
7.	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
8.	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.
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.
TECHNOLOGICAL	
1.	Digitisation of SAHPRA operations is imperative to optimize SAHPRA into a globally c recognised space.
2.	Technical advances and increasing trends in cyber-crimes create risks to unauthorized access to sensitive information. Data security is a growing business consideration that must prioritized
3.	On line 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.
ENVIRONMENTAL	
1.	An increase in reported cases of abandoned or recklessly handled radiation-emitting materials that are causing illnesses for neighboring 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.
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

4.1.4 Internal environment analysis
The Board which was appointed in October 2017, has one year left in their term. It has established the following committees which are fully operational and functional:

1. Finance
2. Risk, Audit and Governance
3. Technical Oversight and Strategy
4. Information Technology
5. Stakeholder Communications
6. Human Resources and Remuneration

The Board and senior management are acutely aware of the importance of good corporate governance and of the medium and long term sustainability of SAHPRA. Having been established in February 2018, SAHPRA's operations are predicated on the operational framework as set out in Figure 3 below, and structured into five programme areas, as follows:

- Programme 1: Administration
  - Responsible for leadership and administrative support to enable SAHPRA to deliver on its mandate and comply with all relevant legislative requirements.
  - This function is represented by the Office of the CEO, CFO, and Chief Support Officer.
- Programme 2: Authorisation Management
  - Serves as a project office responsible for providing specialised administration support necessary for SAHPRA's core functional programmes to enable the entity to deliver on its roles in specific reference to processing licences and permits.
- Programme 3: Inspectorate and Regulatory Compliance
  - Responsible for ensuring public access to safe and quality health products through conducting inspections and regulatory compliance facilitating GMP, GWP, GDP, GCP and GLP compliance.
- Programme 4: Medicines Evaluation and Registration
  - Conducts evaluation of safety, quality and therapeutic efficacy of medicines and register them for use as per delegated authority in terms of relevant legislation.
- Programme 5: Medical Devices, Diagnostics and Radiation Control
  - Develops and maintains regulations and guidelines pertaining to the regulatory oversight of medical devices, ionising and non-ionising radiation-emitting devices and radioactive nuclides.

PART B: OUR STRATEGIC FOCUS CONTINUED

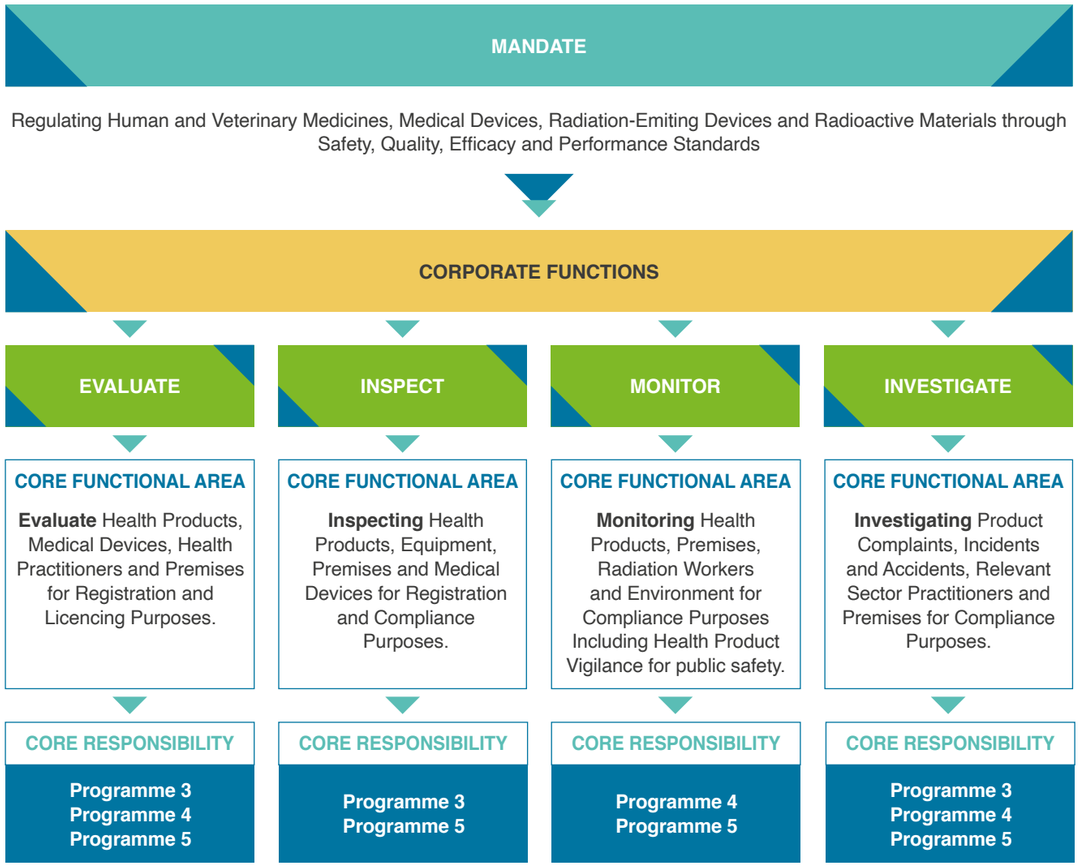


Figure 3: SAHPRA's Operational Framework

Whilst programmes 1 and 2 both provide administration-related support, there are fundamental differences in that the latter operates as a project management office (PMO) supporting specifically programmes 3, 4 and 5 which carry a registration responsibility.

Building internal capacity has been singled out as the most critical area where accelerated performance needs to happen. The processes are underway to recruit the necessary talent.

In addition to internal organisational capacity, there are critical issues pertaining to business processes which incorporate important matters of various frameworks including a framework for services for which SAHPRA can charge fees

The entity is still grappling with internal issues which have caused it not to be able to fully leverage on its institutional status as a Schedule 3A entity. Overcoming these issues should allow for greater efficiencies in its operations.

- At the core of the challenges are severe deficiencies in organisational capacity with the most acute shortages in SAHPRA's institutional capacity being in the current programmes 1 and 5. Building necessary internal capacity is paramount to the entity's ability to be fully functional against the backdrop of additional responsibilities that form part of its extended mandate since transitioning from its forerunner, the Medicines Control Council (MCC). while ensuring the quality review of applications.
- Notwithstanding capacity challenges, core functional programmes are fully functional, in spite of their chronic inefficiency challenges such as heavy reliance on external evaluators. Even as the organisation seeks to develop technical capacity in these programmes through focused and earnest recruitment, the lag period between recruitment and full competency for a senior evaluator is significant and hence a diminished reliance on external evaluators will need to be phased in. External evaluators will never be completely eliminated as the depth and breadth of technical competency in the clinical space needed is too diverse to be able to house all experts as full time staff.
- SAHPRA is still reeling from the aftermath of industrial action that has hampered its ability to clear the applications backlog, further complicated by the aforementioned capacity challenges. In developing this Strategic Plan, there is clear acknowledgement that building internal capacity that is supported by necessary human resource change management processes may take no less than another two years at best.
- The current reality is that SAHPRA's inherited institutional inefficiencies may compromise timely access to essential and innovative medicines. . Linked to this are issues relating to business systems, particularly for core business processes that need to be automated to achieve necessary levels of efficiencies. The entity is still in the process of migrating out of the technology platforms of the NDoH towards establishing its own platforms that will allow for necessary customisation considerations.
- As a regulator, SAHPRA is gearing itself to assert its authority in the sector through among other ways, investing in sector thought-leadership predicated on servicing as an authoritative repository of strategic sector information
- There are other issues that require urgent attention, including inter alia, work in Programme 5 which falls in the domain of radiation control falls outside the mandate of SAHPRA. As much as 90% of the radionuclides of radioactive source materials that are regulated under Programme 5 is for industrial application. Engagement with the Minister of Energy to work out a solution to reframe this space is underway and will be a significant focus in the short to medium term strategies.

4.1.5. SAHPRA Macro-Structure

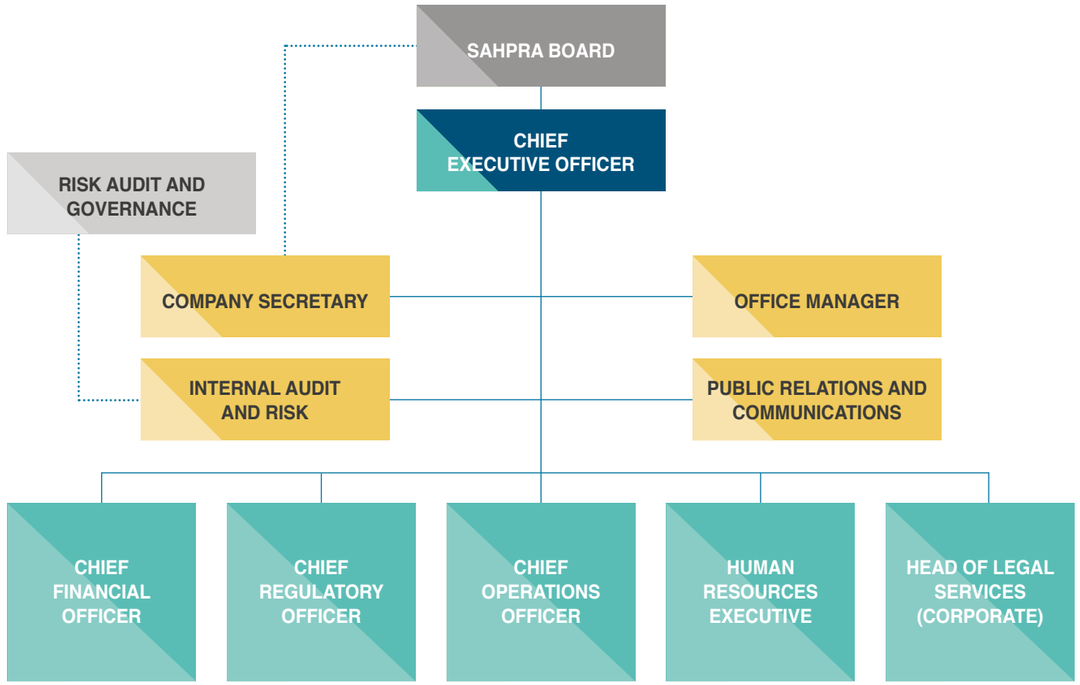


Figure 4: SAHPRA Macro Structure below provides an overview of SAHPRA s Macrostructure and the organisation of executive leadership in the entity.

PART B: OUR STRATEGIC FOCUS CONTINUED

4.1.6. SWOT Analysis

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

TABLE 1: SAHPRA'S PESTEL ANALYSIS

STRENGTHS	WEAKNESSES	OPPORTUNITIES	THREATS
1. Agility and autonomy of a Schedule 3 A entity permits quicker responsiveness to the health products regulatory environment	1. No quality management in place to fortify system changes and governance	1. SAHPRA is in a position to grow despite an adverse economy as operational efficiency will stimulate higher fees	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. 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	2. Lack of a digitised track and trace system, including cost center and revenue	2. Improved efficiencies through digitisation	2. Poaching of staff from the industry remains a threat during the period of uncertainty in the transition
3. Strong and diverse professional team	3. Critical positions filled by acting managers	3. Change in legislation to accommodate reliance arrangements	3. Current internal capacity challenges could lead to a creation of a new backlog
4. In a position to reframe the regulatory footprint in Africa	4. Lack of Skilled staff to support the programme changed business processes	4. Lessons of experience of backlog clearance project and other Authorities	4. Fraud and corruption risks if internal audit is not fortified
5. Sound strategic partnerships that advance the mandate of SAHPRA	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	5. As a Schedule 3A, SAHPRA can now inculcate a new SAHPRA corporate culture underpinned by professionalism	5. Flight of scarce skills with increased professional emigration out of SA
6. Established key collaborations and memberships, such as AMRH . Zazibona and PIC/s	6. Shortage of skilled assessors	6. Opportunity to secure donor funding as a schedule 3 A entity	6. Reliance on external expertise if skills transfer from senior experts is not facilitated in an active process of knowledge transfer
	7. Heavy reliance on external reviewers	7. An opportunity to create a fee structure to generate more revenue necessary for financial sustainability	7. Low staff morale
	8. Non-competitive remuneration policies allowing for benchmarking exercises	8. Implementing renewed performance review system both for management and staff to improve individual performance and consequence management	8. No proper change management
	9. Inability to confirm which of the vacant positions are actually funded	9. Establishing a framework for regular and efficient interactions with all stakeholders and partner agencies	9. Lack of funding expected to support the backlog project
	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	10. Conducting independent stakeholder surveys	10. Diminished revenue due to inadequate fees increase in the last three years
	11. No way of confirming effectiveness of renewed performance review systems		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

PART B: OUR STRATEGIC FOCUS CONTINUED

5. OVERVIEW OF 2020/2021 BUDGET AND MEDIUM TERM EXPENDITURE FRAMEWORK ESTIMATES

5.1. SUMMARY OF THE MTEF BUDGET

SUMMARY OF ECONOMIC CLASSIFICATION OF PAYMENTS	Medium term estimates (SAHPRA)		
	2020/21	2021/22	2022/23
	R'000	R'000	R'000
REVENUE	***387,763***	***399,787***	***417,965***
- Fees	183,811	233,000	253,000
- Interest received	6,000	3,000	2,000
- Deferred income	38,800	17,500	13,000
- Treasury allocation	159,152	146,287	149,965
TOTAL CURRENT PAYMENTS	387,763	399,787	417,965
Compensation of employees	215,772	232,714	251,011
Goods and services	171,991	167,073	166,954
TOTAL PAYMENTS	***387,763***	***399,787***	***417,965***
Excess / (shortfall)	-	-	-

5.2. BUDGET PER PROGRAMME

Programme	2020/21	2021/22	2022/23
	R'000	R'000	R'000
1) Administration	137,985	148,862	159,629
2) Authorisation management	69,098	56,311	49,881
3) Inspectorate and regulatory compliance	38,504	41,174	43,899
4) Medicines evaluation and registration	88,217	95,145	101,818
5) Devices and radiation control	53,959	58,295	62,738
	387,763	399,787	417,965

PART C:
MEASURING OUR PERFORMANCE

PART C: MEASURING OUR PERFORMANCE

6. INSTITUTIONAL PROGRAMME PERFORMANCE INFORMATION

6.1 ADMINISTRATION

PROGRAMME 1	ADMINISTRATION
Purpose	To provide the leadership and administrative support necessary for SAHPRA to deliver on its mandate and comply with all legislative requirements.
Sub-Programme 1	**Financial and Supply Chain Management**
Purpose	To serve all business units in SAHPRA, the senior management team and the Board by maintaining an efficient, effective and transparent system of financial, and risk management that complies with the applicable legislation
Sub-Programme 2	**Governance and Compliance**
Purpose	To provide support services and ensure compliance with relevant legislation; and achieve an unqualified audit outcome by ensuring continuous management practices through compliance with standards operating procedures and systems within SAHPRA. Further, to review existing operational processes and recommend new or changed processes and work methods to ensure optimal organisational effectiveness and, measure and monitor the Authority's performance.
Sub-Programme 3	**Information Technology and Communication (ICT)**
Purpose	to develop and implement ICT integrated governance framework by focusing on the business continuity plan and support the needs and requirements of the end users. Further, to manage public relations, information and communication services to ensure proper management and dissemination of information to internal and external stakeholders, to ensure a seamless harmonious operational platform by building strong and sustainable relationships with all its stakeholders
Sub-Programme 4	**Human Resource Management**
Purpose	To provide human resources and organisational development systems and solutions that meet the needs of the organisation and support the achievement of the Authority's strategic objectives.

OUTCOMES, OUTPUTS, PERFORMANCE INDICATORS AND TARGETS

Strategic Objective/ Outcome	Outputs	Output Indicators	Audited / Actual Performance			Medium-term Targets			
			2016/17	2017/18	2018/19	2019/20	2020/21	2021/22	2022/23
Ensure effective financial management and alignment of budget allocation with strategic priorities (1)	**Attain and maintain an unqualified overall AG Audit outcome on previous year's performance**	**An unqualified audit opinion**	-	-	Qualified Audit opinion	Unqualified audit opinion	Unqualified audit opinion	Unqualified audit opinion	Unqualified audit opinion

QUARTERLY PERFORMANCE AGAINST OUTCOMES, OUTPUTS, PERFORMANCE INDICATORS AND TARGETS

Output Indicators	2020/21 Annual Target	Quarterly Targets			
		Q1 Apr - Jun 2020	Q2 Jul - Sep 2020	Q3 Oct - Dec 2020	Q4 Jan - Mar 2021
An unqualified opinion issued by the Auditor-General on the annual financial statements by 31 July each year	Unqualified Audit Opinion	▸ Preparation of interim financial statements ▸ Implement recommendations of internal and external auditors	Unqualified Audit opinion	▸ Preparation of interim financial statements ▸ Implement recommendations of internal and external auditors	▸ Preparation of interim financial statements ▸ Implement recommendations of internal and external auditors

PART C: MEASURING OUR PERFORMANCE CONTINUED

OUTCOMES, OUTPUTS, PERFORMANCE INDICATORS AND TARGETS

Strategic Objective/ Outcome	Outputs	Output Indicators	Audited / Actual Performance			Estimated Performance	Medium-Term Targets		
			2016/17	2017/18	2018/19	2019/20	2020/21	2021/22	2022/23
Achieve and maintain financial sustainability through revenue generated and enhanced operational efficiencies (2)	Total revenue generated in financial year (2.1)	Total revenue generated in financial year	-	-		R231.3 million	R387 million	R399.7 million	R417.9 million
	Total revenue generated from fees in financial year (2.2)	Total revenue generated from fees in financial year	-	-		R72.1 million	R196.7 million	R250.5 million	R266 million
	Break-even of expenses and revenue by 31 March each year (2.3)	Break-even of expenses and revenue by 31 March each year	-			Surplus of R31.1 million	≥ zero based balance	≥ zero based balance	≥ zero based balance

QUARTERLY PERFORMANCE AGAINST OUTCOMES, OUTPUTS, PERFORMANCE INDICATORS AND TARGETS

Output Indicators	2020/21 Annual Target	Quarterly Targets			
		Q1 Apr - Jun 2020	Q2 Jul - Sep 2020	Q3 Oct - Dec 2020	Q4 Jan - Mar 2021
Total revenue generated in financial year	R387million	-	-	-	R387 million
Total revenue generated from fees in financial year	▸ R196.7 million				R196.7million
Break-even of expenses and revenue by 31 March each year	▸ ≥ zero based balance			-	≥ zero based balance

OUTCOMES, OUTPUTS, PERFORMANCE INDICATORS AND TARGETS

Strategic Objective/ Outcome	Outputs	Output Indicators	Audited / Actual Performance			Estimated Performance	Medium-Term Targets		
			2016/17	2017/18	2018/19	2019/20	2020/21	2021/22	2022/23
Consistently meet the needs and expectations of all SAHPRA's stakeholders (3)	SAHPRA effectiveness and efficiency by industry rated by public and private sector players aligned to aspects of mandate	Percentage positive ratings of SAHPRA's effectiveness and efficiency as rated by private and public direct users of SAHPRAs services	-	-	-	TBD in 2019/20	50% positive rating	60% positive rating	70% positive rating
	Appraise Public* perceptions of SAHPRA's effectiveness *Public includes end users of health products	Percentage of public sampled, accurately engaging with SAHPRA				New indicator	Baseline public engagement with SAHPRA determined	Positive (50%) rating of SAHPRA services and offering	Positive (65%) rating of SAHPRA services and offering

QUARTERLY PERFORMANCE AGAINST OUTCOMES, OUTPUTS, PERFORMANCE INDICATORS AND TARGETS

Output Indicators	2020/21 Annual Target	Quarterly Targets			
		Q1 Apr - Jun 2020	Q2 Jul - Sep 2020	Q3 Oct - Dec 2020	Q4 Jan - Mar 2021
Percentage positive ratings of SAHPRA's effectiveness and efficiency as rated by private and public direct users of SAHPRAs services	60% positive rating	Service provider secured	Survey conducted	▸ 50% positive rating ▸ Report with recommendation to Stakeholder committee	Report with recommendations to Stakeholder Committee
Percentage of public sampled, accurately engaging with SAHPRA	Positive (50%) positive rating of SAHPRA services and offerings	Service provider secured	Survey conducted	Baseline public awareness determined	Report with recommendations to Stakeholder committee

PART C: MEASURING OUR PERFORMANCE CONTINUED

OUTCOMES, OUTPUTS, PERFORMANCE INDICATORS AND TARGETS

Strategic Objective/ Outcome	Outputs	Output Indicators	Audited / Actual Performance			Estimated Performance	Medium-Term Targets		
			2016/17	2017/18	2018/19	2019/20	2020/21	2021/22	2022/23
Valuing our people(4)	**Annual staff engagement/ climate surveys conducted**	**Positive responses in staff climate surveyed dimensions**	-	-	-	New Indicator	50% positive responses in all surveyed dimensions	60% positive responses in all surveyed dimensions	75% positive responses in all surveyed dimensions

QUARTERLY PERFORMANCE AGAINST OUTCOMES, OUTPUTS, PERFORMANCE INDICATORS AND TARGETS

Output Indicators	2020/21 Annual Target	Quarterly Targets			
		Q2 Jan - Mar 2021	Q2 Jul - Sep 2020	Q3 Oct - Dec 2020	Q4 Jan - Mar 2021
Assess and action recommendations of staff climate survey	50% positive responses in all surveyed dimensions	Secure Service provider	Develop and approve survey	Conduct survey	50% positive responses in all surveyed dimensions recommendations to Stakeholder Committee

OUTCOMES, OUTPUTS, PERFORMANCE INDICATORS AND TARGETS

Strategic Objective/ Outcome	Outputs	Output Indicators	Audited / Actual Performance			Estimated Performance	Medium-Term Targets		
			2016/17	2017/18	2018/19	2019/20	2020/21	2021/22	2022/23
Achieve and maintain high levels of organisational operational efficiency and effectiveness in the regulatory function (5)	**SAHPRA regulatory processes and practices are standardised with standardised policies, procedures and frameworks**	**Percentage implementation of Medicines Regulatory Quality Management System**	-	-	-	New Indicator	Medicines Regulatory Quality Management system developed and implemented	50% implementation of QMS	70% implementation of QMS

QUARTERLY PERFORMANCE AGAINST OUTCOMES, OUTPUTS, PERFORMANCE INDICATORS AND TARGETS

Output Indicators	2020/21 Annual Target	Quarterly Targets			
		Q1 Apr - Jun 2020	Q2 Jul - Sep 2020	Q3 Oct - Dec 2020	Q4 Jan - Mar 2021
Percentage implementation of Medicines Regulatory Quality Management System	Medicines Regulatory Quality Management system developed and implemented	Appoint service provider	Road Map developed and approved	Business process mapping complete	Policy and procedure framework completerecommendations to Stakeholder Committee

OUTCOMES, OUTPUTS, PERFORMANCE INDICATORS AND TARGETS

Strategic Objective/ Outcome	Outputs	Output Indicators	Audited / Actual Performance			Estimated Performance	Medium-Term Targets		
			2016/17	2017/18	2018/19	2019/20	2020/21	2021/22	2022/23
Strengthened ICT capacity(6)	**Digital transformation of SAHPRA's process**	**Percentage of SAHPRA business processes digitised**			New Indicator	New Indicator	60% digitisation of SAHPRA processes	70% digitisation of SAHPRA processes	80% digitisation of SAHPRA processes

QUARTERLY PERFORMANCE AGAINST OUTCOMES, OUTPUTS, PERFORMANCE INDICATORS AND TARGETS

Output Indicators	2020/21 Annual Target	Quarterly Targets			
		Q1 Apr - Jun 2020	Q2 Jul - Sep 2020	Q3 Oct - Dec 2020	Q4 Jan - Mar 2021
Percentage of SAHPRA business processes digitised	60% digitization of SAHPRA processes	Scoping and business process mapping	Proof of concept	Implementation of minimal viable proposition for go-live	40% digitisation of SAHPRA processes

PART C: MEASURING OUR PERFORMANCE CONTINUED

OUTCOMES, OUTPUTS, PERFORMANCE INDICATORS AND TARGETS

Strategic Objective/ Outcome	Outputs	Output Indicators	Audited / Actual Performance			Estimated Performance	Medium-Term Targets		
			2016/17	2017/18	2018/19	2019/20	2020/21	2021/22	2022/23
Attract and retain superior talent(7)	**Vacant positioned prioritised in annual staffing plan and budgeted for filled**	**Percentage of prioritised positions filled**				New Indicator	100% of prioritised positions filled	100% of prioritised positions filled	100% of prioritised positions filled
	Total staff complement reflected as filled positions in staff establishments	**Percentage of staff establishment positions filled**				70% of positions in staff establishment filled in current year	70% of positions in staff establishment filled in current year	80% of positions in staff establishment filled in current year	90% of positions in staff establishment filled in current year
	Staff in key core business functions earmarked for capacity building initiatives trained	**Percentage staff trained in key core business functions**				New Indicator	5% of staff in core business trained	40% of staff in core business trained	50% of staff in core business trained

QUARTERLY PERFORMANCE AGAINST OUTCOMES, OUTPUTS, PERFORMANCE INDICATORS AND TARGETS

Output Indicators	2020/21 Annual Target	Quarterly Targets			
		Q1 Apr - Jun 2020	Q2 Jul - Sep 2020	Q3 Oct - Dec 2020	Q4 Jan - Mar 2021
Percentage of prioritised positions filled	100% of prioritised positions filled	40 % of prioritized positions filled	60 % of prioritized positions filled	80 % of prioritized positions filled	100 % of prioritized positions filled
Percentage of staff establishment positions filled	70% of positions in staff establishment filled in current year	20% of positions in staff establishment filled in current year	35% of positions in staff establishment filled in current year	50% of positions in staff establishment filled in current year	70% of positions in staff establishment filled in current year
Percentage staff trained in key core business functions	25% of staff in core business trained	Develop and approve training plan for key core staff	10% of staff in key core functions trained	15% of staff in key core functions trained	25% of staff in key core functions trained

OUTCOMES, OUTPUTS, PERFORMANCE INDICATORS AND TARGETS

Strategic Objective/ Outcome	Outputs	Output Indicators	Audited / Actual Performance			Estimated Performance	Medium-Term Targets		
			2016/17	2017/18	2018/19	2019/20	2020/21	2021/22	2022/23
To promote the work of SAHPRA as a means of advancing the business objectives and organisational reputation (8)	**Disseminate thought leadership and regulatory science pieces in magazines, websites, journals and media**	**Percentage increase of sector thought leadership and regulatory science pieces in magazines, websites, journals and media sources**				New Indicator	Determine base-line disseminated sector thought and regulatory science pieces disseminated	Year on year increase of 10%	Year on year increase of 10

QUARTERLY PERFORMANCE AGAINST OUTCOMES, OUTPUTS, PERFORMANCE INDICATORS AND TARGETS

Output Indicators	2020/21 Annual Target	Quarterly Targets			
		Q1 Apr - Jun 2020	Q2 Jul - Sep 2020	Q3 Oct - Dec 2020	Q4 Jan - Mar 2021
Percentage increase of sector thought leadership and regulatory science pieces in magazines, websites, journals and media sources	Determine base-line disseminated sector thought and regulatory science pieces disseminated	Scoping to determine relevant area of interest	Publish expression of interest	Review applications	Determine base-line disseminated sector thought and regulatory science pieces disseminated

PART C: MEASURING OUR PERFORMANCE CONTINUED

OUTCOMES, OUTPUTS, PERFORMANCE INDICATORS AND TARGETS									
Strategic Objective/ Outcome	Outputs	Output Indicators	Audited / Actual Performance			Estimated Performance	Medium-Term Targets		
			2016/17	2017/18	2018/19	2019/20	2020/21	2021/22	2022/23
To ensure that SAHPRA attains and maintains global best practices (9)	WHO Global benchmarking conducted	Determine WHO maturity level				New Indicator	Maturity level 3	Maturity level 3	Maturity level 4

QUARTERLY PERFORMANCE AGAINST OUTCOMES, OUTPUTS, PERFORMANCE INDICATORS AND TARGETS					
Output Indicators	2020/21 Annual Target	Quarterly Targets			
		Q1 Apr - Jun 2020	Q2 Jul - Sep 2020	Q3 Oct - Dec 2020	Q4 Jan - Mar 2021
Determine WHO maturity level		-	Conduct Survey	-	Maturity level 3

These outputs ensure SAHPRA's observance of fundamental legislative requirements that affect its operations as part of strengthened internal controls and governance that ensures the continued and thriving existence of the entity to deliver effectively on its mandate.

These outputs ensure SAHPRA's has necessary organisational capacity to execute its mandate effectively while also providing sector thought leadership that will ultimately contribute to it asserting its authority as a regulator.

Focused and intensified training programmes must be developed and implemented to ensure not only a capacitated workforce; but a competent one as well.

6.1.1 Resource Considerations

2016/17	2018/19	2018/19	2019/20	2020/21	2021/22	2022/23
Budget Estimates	Budget Estimates	Budget Estimates	Budget Estimates	Budget Estimates	Budget Estimates	Budget Estimates
No historical data - New public entity		65 100	90 355	137 985	148 862	159 629

Economic Classification of Budget	65 100	90 355	137 985	148 862	159 629
Compensation of Employees	26 892	34 468	47 090	50 537	54 260
Goods and Services	38 208	55 887	90 895	98 325	105 369

In order for the Authority to successfully achieve the outcomes as outlined in the Strategic Plan, the following resource requirements are critical:

- Financial Resource: This will enable the Authority to recruit and fill positions essential to the fulfilment our service delivery mandate.
- IT Infrastructure: To support core functions critical to providing impetus to the regulatory process.
- Resource Capacity: The Authority need additional human capacity to strengthen its core business activities and expansion programmes in areas such as finance, supply chain, ICT, human resources and the office of the CEO.
- Skilled Human Capital is critical to sustain ongoing progressive trends to fulfilling mandates and focused and intensified training programmes must be developed and implemented

PART C: MEASURING OUR PERFORMANCE CONTINUED

6.1.2. Updated Risks

KEY RISK	RISK MITIGATION
Inability to attract adequate workforce that is suitably skilled and properly managed due to these factors: ▸ Unfavourable funding model adversely impacting staffing budget ▸ Performance contracts are not in place ▸ Inadequate performance management procedures and guidelines ▸ Insufficient knowledge of the performance management system	▸ Ensure that all employees sign performance management contracts ▸ Align the individual development plan to performance ▸ Develop performance management procedures and guidelines ▸ Conduct training for employees and line Managers on the ▸ performance management system ▸ Consult organised labour on the new performance management system
Ineffective collaboration with ▸ Internal and external stakeholders, due to: ▸ Inadequate stakeholder identification and mapping ▸ Insufficient human resources capacity (communication department) ▸ Communication and stakeholder Management policy is not in place ▸ Failure by labour to use approved communication structures for organisation and mobilisation ▸ Leaking of information to third parties with the aim of tarnishing the SAHPRA's image and reputation	▸ Develop the Stakeholder Management strategy ▸ Recruit qualified and skilled personnel ▸ Ensure that communication and Stakeholder Management policy is approved ▸ Conduct investigations to determine breaches of SAHPRA communication protocols ▸ Institute disciplinary action where SAHPRA communication protocols have been breached ▸ Implement re-screening policy ▸ Block the use of private e-mails and access to the SAHPRA network
Failure to provide appropriate ICT services across SAHPRA business units due to the following factors: ▸ Inadequate IT specialists ▸ Lack of adequate ICT Architecture ▸ Inadequate ICT security governance ▸ Inadequate training for ICT personnel ▸ Ineffective ICT Governance committee	▸ Recruit qualified and skilled personnel ▸ Develop ICT Governance strategy ▸ Develop an ICT network and data security plan ▸ Identify skills shortage and conduct training for ICT personnel ▸ Revive the ICT Governance committee

6.2 HEALTH PRODUCT AUTHORISATION

PROGRAMME 2	HEALTH PRODUCT AUTHORISATION
Purpose	To provide administration support necessary for SAHPRA to deliver on its mandate and comply with the relevant legislative requirements. The specific purpose of this programme is to coordinate the process of registration and/or licensing or amendment of applications in respect of medicines within a legislative framework that defines the requirements necessary for application to the Authority, to receive record and distribute all documents submitted to SAHPRA, and to manage and maintain SAHPRA's main registry.
Sub-Programme 1	**Document reception and helpdesk**
Purpose	The purpose of this sub-programme is to receive, record and/or direct all documents submitted to SAHPRA.
Sub-Programme 2	**Records management**
Purpose	The purpose is to manage SAHPRA's main registry system to ensure the completeness of records, ease of retrieval and compliance with the National Archives Act and relevant organisational policies.
Sub-Programme 3	**Project office – regulatory decision for medicines**
Purpose	The purpose is to coordinate the process of the making of a regulatory decision of medicines (screening, dispatch to evaluators, coordinating reports, recommendations, responses, arranging peer and product review meetings). It is also involved in ensuring that regulatory decisions made at the time of registration are in the public interest throughout the products' lifecycle through post-marketing vigilance of registered products. Vigilance includes the soliciting of data through various approaches, monitoring, analysis and responsive action, including the provision of feedback. In addition, a fully staffed backlog project team led by a senior project manager and linked to this sub-programme will be established.
Sub-Programme 4	**Project office – clinical trials, section 21 portfolio management**
Purpose	The purpose is to coordinate the vigilance process and authorisation of clinical trials and Section 21 applications for medicines and devices within a legislative framework that defines the requirements necessary for application to the Authority. Details on the assessment procedure and the grounds for approval or rejection of the application, and also the circumstances where authorisation already granted may be cancelled, withdrawn, suspended or revoked, are also catered for.
Sub-Programme 5	**Licensing, permits and certificates portfolio management**
Purpose	The purpose is to manage and coordinate the process of licensing and amendments in respect of medicines manufacturers, wholesalers and medical device establishments and the issue of permits and registration certificates within a legislative framework that defines the requirements necessary for application to the Authority. Details on the assessment procedure (based on quality, efficacy and safety criteria) and the grounds for approval or rejection of the application, and also the circumstances where registration/licence/authorisation already granted may be cancelled, withdrawn, suspended or revoked, are also catered for

PART C: MEASURING OUR PERFORMANCE CONTINUED

OUTCOMES, OUTPUTS, PERFORMANCE INDICATORS AND TARGETS									
Strategic Objective/ Outcome	Outputs	Output Indicators	Audited / Actual Performance			Estimated Performance	Medium-Term Targets		
			2016/17	2017/18	2018/19	2019/20	2020/21	2021/22	2022/23
Achieve and maintain high levels of organisational operational efficiency and effectiveness in the regulatory function (5)	Elimination of backlog in medicine registration and variation applications	Percentage of medicines registrations backlog eradicated				Backlog developed and implemented	50% applications for registration cleared 90% variation applications cleared	100% applications for registration cleared 100% variation applications cleared	Zero backlog in medicine registrations
	Finalisation of new licences for local manufacturers, importers and exporters for all Health Products within timelines predefined	Percentage of new licences applications for local manufacturers, importers and exporters finalised within 125 working days			-	New Indicator	50% of new licences issued for new local manufacturer, exporter and importer applications within predetermined timeline	60% of new licences issued for new local manufacturer, exporter and importer applications within predetermined timeline	75 %of new licences issued for new local manufacturer, exporter and importer applications within predetermined timeline

QUARTERLY PERFORMANCE AGAINST OUTCOMES, OUTPUTS, PERFORMANCE INDICATORS AND TARGETS					
Output Indicators	2020/21 Annual Target	Quarterly Targets			
		Q1 Apr - Jun 2020	Q2 Jul - Sep 2020	Q3 Oct - Dec 2020	Q4 Jan - Mar 2021
Percentage of medicines registrations backlog eradicated	40% applications for registration cleared 90% variation applications cleared	10% applications for registration cleared 60% variation applications cleared	20% applications for registration cleared 70% variation applications cleared	30% applications for registration cleared 80% variation applications cleared	50% applications for registration cleared 90% variation applications cleared
Percentage of new GMP licences of local applications finalised within 125 working days	50% licenses issued for new applications within predetermined timeline	n/a	50% of licenses issued for new applications within predetermined timeline	n/a	50% of licenses issued for new applications within predetermined timeline

Explanation of planned performance over the medium term period

Exercise operational control in order to attain and maintain the desired levels of operational co-ordination to ensure the mandate to safeguard the safety of medicines of all those that live in South Africa is efficient and timeous. This is one of the fundamentals necessary for SAHPRA to achieve its organisational impact.

6.2.1 Resource considerations

2016/17 Budget Estimates	2018/19 Budget Estimates	2018/19 Budget Estimates	2019/20 Budget Estimates	2020/21 Budget Estimates	2021/22 Budget Estimates	2022/23 Budget Estimates
No historical data - New public entity		30 555	68 663	69 098	56 311	49 881

Economic Classification of Budget		30 555	68 663	69 098	56 311	49 881
Compensation of Employees		26 985	11 020	35 354	38 183	41 237
Goods and Services		3 570	57 643	33 744	18 128	8 644

In order for the Authority to successfully achieve the outcomes as outlined in the Strategic Plan, the following resource requirements are critical:

- IT Infrastructure: To support core functions critical to providing impetus to the regulatory process.
- Skilled Human Capital is critical to sustain ongoing progressive trends to fulfilling mandates and focused and intensified training programmes must be developed and implemented.
- Quality Management System: to support efficient business change management is critical polices and standardised procedures be developed and implemented to support the re-engineered processes.

KEY RISK	RISK MITIGATION
Inability to secure adequate funding for backlog project	Focused donor funding drives to secure necessary funds
Inadequate local evaluators to support the completion of backlog eradication project	Agility of project to expand net of search for human resources beyond local borders
Failure of reliance model to achieve desired shortened turnaround times	SAHPRA must initiate thought leadership opportunities to ensure all known SMEs within the sphere of reliance models are utilized to ensure effectiveness of the model Agility of backlog project to utilize alternative registration models if necessary
Failure to secure ICT capacity to support Backlog and BAU processes	Focused IT strategy delineating road map for capacitation of all business units including backlog with digital solutions

PART C: MEASURING OUR PERFORMANCE CONTINUED

6.3 INSPECTORATE AND REGULATORY COMPLIANCE

PROGRAMME 3	INSPECTORATE AND REGULATORY COMPLIANCE
Purpose	To ensure public access to safe health products (include disclaimer) through inspections and regulatory compliance. The focus of this programme includes assessment of site compliance, with good regulatory and vigilance practices, including: ▸ Good Manufacturing Practice (GMP); ▸ Good Clinical Practice (GCP); ▸ Good Warehouse Practice (GWP); ▸ Good Distribution Practice (GDP); ▸ Good Laboratory Practice (GLP); ▸ Good Vigilance Practice (GVP)
Sub-Programme 1	**Inspections**
Purpose	To ensure that GxP's inspection activities are actively managed to facilitate the running of an effective inspection programme monitored against pre-defined timelines and commitments communicated to stakeholders.
Sub-Programme 2	**Regulatory Compliance**
Purpose	To ensure public access to safe medicines through regulatory compliance and monitoring of compliance with applicable legislation as mandated.

OUTCOMES, OUTPUTS, PERFORMANCE INDICATORS AND TARGETS

Strategic Objective/ Outcome	Outputs	Output Indicators	Audited / Actual Performance			Estimated Performance	Medium-Term Targets		
			2016/17	2017/18	2018/19	2019/20	2020/21	2021/22	2022/23
Achieve and maintain high levels of organisational operational efficiency and effectiveness in the regulatory function (5)	**Ensure regulatory compliance through a process of active Inspections and investigations.**	**Percentage health product premises/sites inspections finalised with an inspection report submitted to the applicant within 30 working days of conducting a GMP inspection**				New Indicator	60% of GMP inspection completed with report submitted to applicant	80% of GMP inspection completed with report submitted to applicant	90% of GMP inspection completed with report submitted to applicant
		Percentage of investigations completed with decisions in line with predefined standards and timelines of all health product quality complaints reported to the regulator				New Indicator	70% of health product quality complaints investigated	80% of health product quality complaints investigated	90% of health product quality complaints investigated

PART C: MEASURING OUR PERFORMANCE CONTINUED

QUARTERLY PERFORMANCE AGAINST OUTCOMES, OUTPUTS, PERFORMANCE INDICATORS AND TARGETS					
		Quarterly Targets			
Output Indicators	2020/21 Annual Target	Q1 Apr - Jun 2020	Q2 Jul - Sep 2020	Q3 Oct - Dec 2020	Q4 Jan - Mar 2021
Percentage of health product premises/sites inspections finalised with an inspection report submitted to the applicant within 30 working days of conducting a GMP inspection	60% of GMP inspection completed with report submitted to applicant	60% of GMP inspection completed with report submitted to applicant	60% of GMP inspection completed with report submitted to applicant	60% of GMP inspection completed with report submitted to applicant	60% of GMP inspection completed with report submitted to applicant
Percentage of investigations completed with decisions in line with predefined standards and timelines of all health product quality complaints reported to the regulator	70% of health product quality complaints investigated	70% of health product quality complaints investigated	70% of health product quality complaints investigated	70% of health product quality complaints investigated	70% of health product quality complaints investigated

Explanation of planned performance over the medium term period

Exercise industry control in order to attain and maintain the desired levels of industry compliance in the quest to safeguard the safety of medicines of all those that live in South Africa. This is one of the fundamentals necessary for SAHPRA to achieve its organisational impact.

6.3.1 Resource considerations

2016/17	2018/19	2018/19	2019/20	2020/21	2021/22	2022/23
Budget Estimates	Budget Estimates	Budget Estimates	Budget Estimates	Budget Estimates	Budget Estimates	Budget Estimates
No historical data - New public entity		34 826	56 209	38,504	41,174	43,899
Economic Classification of Budget		34 826	56 209	38,504	41,174	43,899
Compensation of Employees		27 723	28 668	24,760	26,741	28,880
Goods and Services		7 103	27 541	13,744	14,433	15,019

6.3.2.Updated Key Risks

KEY RISK	RISK MITIGATION
▸ Inability to timeously recruit and train staff to ensure output target is met	▸ Focused staff recruitment plan to ensure rapid recruitment ▸ Collaboration with recognized collaborative partners to ensure focused outcome training in inspections
▸ Leadership deficits persist if management positions are not prioritized to be filled. ▸ A leadership vacuum leaves the unit vulnerable to risks related to exploitation	▸ Prioritsation of key management positions to ensure unit has strong leadership to keep the unit focused on sound business and governess practices
▸ Slack business process framework not aligned to QMS framework prevents proper monitoring for focused business transformation and re-introduces risk to poor audit outcome for sector	▸ Stringent and focused business process mapping and operational framework to permit rigorous track and trace of all transations
▸ Failure to secure ICT capacity to business processes	▸ Focused IT strategy delineating road map for capacitation of all business units with digital solutions

6.4 MEDICINES EVALUATION AND REGISTRATION

PROGRAMME 4	MEDICINES EVALUATION AND REGISTRATION
Purpose	To evaluate the safety, quality and therapeutic efficacy of medicines and register them for use as per delegated authority in terms of relevant legislation as listed in the legal mandate of part 1a of the strategic plan.
Sub-Programme 1	**Clinical Evaluation**
Purpose	To evaluate the safety and efficacy of orthodox medicines
Sub-Programme 2	**Clinical Trials**
Purpose	To evaluate clinical trial applications of orthodox medicines, complementary medicines and medical devices to ensure that the trial to be conducted is scientifically sound in accordance with the South African Good Clinical Practice guidelines and to ensure safety and protection of rights of patients.
Sub-Programme 3	**Pharmaceutical Evaluations**
Purpose	To perform pharmaceutical and analytical evaluations of new and registered medicines inclusive of clinical aspects of veterinary medicines and biological.
Sub-Programme 4	**Authorisation of the Sale of Unregistered Medicines**
Purpose	To conduct an abbreviated evaluation of applications to authorise the sale of unregistered medicines based on QSE standards
Sub-Programme 5	**Vigilance and Post-Marketing Surveillance**
Purpose	To establish a regimen of vigilance for the collection and evaluation of information relevant to the benefit to risk balance of medicines and medical devices on the South African market, the continuous monitoring of the safety profiles of these products and taking appropriate action where necessary.
Sub-Programme 6	**Complementary and Alternative Medicines**
Purpose	To perform evaluations of new and registered complementary medicines in order to determine their safety, quality and efficacy and to register and/or regulate them for use where applicable.
Sub-Programme 7	**Veterinary Medicines**
Purpose	To evaluate the safety, efficacy and quality of veterinary medicines.

PART C: MEASURING OUR PERFORMANCE CONTINUED

OUTCOMES, OUTPUTS, PERFORMANCE INDICATORS AND TARGETS									
Strategic Objective/ Outcome	Outputs	Output Indicators	Audited / Actual Performance			Estimated Performance	Medium-Term Targets		
			2016/17	2017/18	2018/19	2019/20	2020/21	2021/22	2022/23
Achieve and maintain high levels of organisational operational efficiency and effectiveness in the regulatory function (5)	**Improved turnaround times of medicine registration and regulatory activities**	**Percentage registrations of for New Chemical Entities (NCEs) finalised within predefined timelines**				Average time 1000days	60% in 590 days	80% in 480 days	80% in 350 days
		Percentage registration of generic medicines finalised within predefined number timelines				Average time is 1000 days	60% in 250 days	80% in 180 days	80% in 180 days
		Percentage applications for the sale of unregistered Category A (human) medicines finalised within 24 working hours counting from the time (stamp) when the application was received				80% applications for the sale of unregistered Category A (human) medicines finalised within 24 working hours	85% applications for the sale of unregistered Category A (human) medicines finalised within 24 working hours	85% applications for the sale of unregistered Category A (human) medicines finalised within 24 working hours	85% applications for the sale of unregistered Category A (human) medicines finalised within 24 working hours

OUTCOMES, OUTPUTS, PERFORMANCE INDICATORS AND TARGETS									
Strategic Objective/ Outcome	Outputs	Output Indicators	Audited / Actual Performance			Estimated Performance	Medium-Term Targets		
			2016/17	2017/18	2018/19	2019/20	2020/21	2021/22	2022/23
Achieve and maintain high levels of organisational operational efficiency and effectiveness in the regulatory function (5)	**Improved turnaround times of medicine registration and regulatory activities**	**Percentage of human clinical trial applications finalised within 120 working days, counting from the date the application was received**			New Indicator	New Indicator – new timeline	80% human clinical trial applications finalised within 120 working days	80% human clinical trial applications finalised within 120 working days	80% human clinical trial applications finalised within 120 working days
		Percentage of reports on health product safety signals actioned within 20 working days after receipt				New indicator – new timeline	70% reports on health product safety signals actioned within 20 working days	75% reports on health product safety signals actioned within 20 working days	80% reports on health product safety signals actioned within 20 working days

PART C: MEASURING OUR PERFORMANCE CONTINUED

QUARTERLY PERFORMANCE AGAINST OUTCOMES, OUTPUTS, PERFORMANCE INDICATORS AND TARGETS					
		Quarterly Targets			
Output Indicators	2020/21 Annual Target	Q1 Apr - Jun 2020	Q2 Jul - Sep 2020	Q3 Oct - Dec 2020	Q4 Jan - Mar 2021
Percentage registrations of for New Chemical Entities (NCEs) finalised within predefined timelines	60% in 590 days	20% in 590 days	40% in 590 days	60% in 590 days	80% in 590 days
Percentage registration of generic medicines finalised within predefined timelines	60 % in 250 days	20 % in 250 days	40 % in 250 days	60 % in 250 days	80 % in 250 days
Percentage applications for the sale of unregistered Category A (human) medicines finalised within 24 working hours counting from the time (stamp) when the application was received	85% applications for the sale of unregistered Category A (human) medicines finalised within 24 working hours	85% applications for the sale of unregistered Category A (human) medicines finalised within 24 working hours	85% applications for the sale of unregistered Category A (human) medicines finalised within 24 working hours	85% applications for the sale of unregistered Category A (human) medicines finalised within 24 working hours	85% applications for the sale of unregistered Category A (human) medicines finalised within 24 working hours
% of human clinical trial applications finalised within 120 working days, counting from the date the application was received	80% human clinical trial applications finalised within 120 working days	-	80% human clinical trial applications finalised within 120 working days	-	80% human clinical trial applications finalised within 120 working days
Percentage of reports on health product safety signals actioned within 20 working days after receipt	70% reports on health product safety signals actioned within 20 working days	70% reports on health product safety signals actioned within 20 working days	70% reports on health product safety signals actioned within 20 working days	70% reports on health product safety signals actioned within 20 working days	70% reports on health product safety signals actioned within 20 working days

Explanation of planned performance over the medium-term period

Ensuring that there is a good balance between processing of emergency applications for medicines, medical devices and clinical trials and ensuring that necessary safety precautions are in place.

6.4.1 Resource considerations

2016/17	2018/19	2018/19	2019/20	2020/21	2021/22	2022/23
Budget Estimates	Budget Estimates	Budget Estimates	Budget Estimates	Budget Estimates	Budget Estimates	Budget Estimates
No historical data - New public entity		67 158	65 440	88,217	95,145	101,818

Economic Classification of Budget	67 158	65 440	88,217	95,145	101,818
Compensation of Employees	57 088	53 797	62,353	67,341	72,728
Goods and Services	10 070	11 643	25,864	27,804	29,090

6.4.2.Updated Key Risks

KEY RISK	RISK MITIGATION
▸ Inability to attract adequate workforce that is suitably skilled	▸ Focused prioritized recruitment by unit manager Ensure that all employees sign performance management contracts ▸ Align the individual development plan to performance ▸ Develop performance management procedures and guidelines ▸ Conduct training for employees and line Managers on the core business processes and technical skills
▸ Lack of rigor in newly engineered operational model may not negate new backlog	▸ proper implementation business change management to negate poor implementation causing a new backlog
▸ Failure to provide appropriate ICT services across SAHPRA business units to support evolving processes	▸ Focused digital solutions to support units usiness processes
▸ Inadequate support to align staff to changed processes	▸ Focused business and human resource change management to ensure workforce in this core programme owns and takes responsibility for the evolved framework

6.5 MEDICAL DEVICES, DIAGNOSTICS AND RADIATION CONTROL

PROGRAMME 5	MEDICAL DEVICES, DIAGNOSTICS AND RADIATION CONTROL
Purpose	To develop and maintain regulations and guidelines pertaining to the regulatory oversight of medical devices, ionizing and non-ionizing radiation emitting devices; and radioactive nuclides.
Sub-Programme 1	**Medical Devices**
Purpose	To implement and strengthen the regulatory oversight of medical devices through the development and maintenance of relevant regulations and guidelines.
Sub-Programme 2	**Radiation Control**
Purpose	To efficiently, effectively and ethically evaluate and register non-ionizing radiation emitting devices and radioactive nuclides.

PART C: MEASURING OUR PERFORMANCE CONTINUED

OUTCOMES, OUTPUTS, PERFORMANCE INDICATORS AND TARGETS

Strategic Objective/ Outcome	Outputs	Output Indicators	Audited / Actual Performance			Estimated Performance	Medium-Term Targets		
			2016/17	2017/18	2018/19	2019/20	2020/21	2021/22	2022/23
Achieve and maintain high levels of organisational operational efficiency and effectiveness in the regulatory function (5)	**Finalisation licenses for medical device and radiation control related activities and sites within predefined number of working days (spent at the regulator) counting from the date the application was received**	**Percentage of medical device establishment licence applications finalised within 90 days**				70% of medical device establishment licenced within 90days	70% of medical device establishment licenced within 90days	70% of medical device establishment licenced within 90days	85% of medical device establishment licenced within 90days
		Develop and implement Medical Device Registration Framework				New Indicator	Develop and Implement medical device registration framework	n/a	n/a
		Percentage of medical device applications with regulatory decision finalized within 90 working days				New Indicator	n/a	75% of medical device application finalised within 90 days	80% of medical device application finalised within 90 days
		Percentage of new application licenses for ionizing radiation-emitting devices and radioactive nuclides issued within 30 working days				New Indicator – new timeline	70% new application licenses for ionizing radiation-emitting devices and radioactive nuclides issued within 30 working days	75% new application licenses for ionizing radiation-emitting devices and radioactive nuclides issued within 30 working days	80% new application licenses for ionizing radiation-emitting devices and radioactive nuclides issued within 30 working days

QUARTERLY PERFORMANCE AGAINST OUTCOMES, OUTPUTS, PERFORMANCE INDICATORS AND TARGETS

Output Indicators	2020/21 Annual Target	Quarterly Targets			
		Q1 Apr - Jun 2020	Q2 Jul - Sep 2020	Q3 Oct - Dec 2020	Q4 Jan - Mar 2021
Percentage of medical device establishment licence applications finalised within 90 days	70% medical device establishment licence applications finalised within 90 days	70% medical device establishment licence applications finalised within 90 days	70% medical device establishment licence applications finalised within 90 days	70% medical device establishment licence applications finalised within 90 days	70% medical device establishment licence applications finalised within 90 days
Develop and implement Medical Device registration Framework	Medical device registration framework developed and implemented	Revise roadmap	Draft framework developed	Draft framework approved	Pilot draft framework
Percentage of medical device applications with regulatory decision finalized within 90 days	n/a	n/a	n/a	n/a	n/a
Percentage of new application licenses for ionizing radiation-emitting devices and radioactive nuclides issued within 30 working days	70% of new application licenses for ionizing radiation-emitting devices and radioactive nuclides issued within 30 working days	70% of new application licenses for ionizing radiation-emitting devices and radioactive nuclides issued within 30 working days	70% of new application licenses for ionizing radiation-emitting devices and radioactive nuclides issued within 30 working days	70% of new application licenses for ionizing radiation-emitting devices and radioactive nuclides issued within 30 working days	70% of new application licenses for ionizing radiation-emitting devices and radioactive nuclides issued within 30 working days

Explanation of planned performance over the medium-term period

Ensuring that there is a good balance between processing of emergency applications for medicines, medical devices and clinical trials and ensuring that necessary safety precautions are in place.

6.5.1. Resource considerations

	2016/17 Budget Estimates	2018/19 Budget Estimates	2018/19 Budget Estimates	2019/20 Budget Estimates	2020/21 Budget Estimates	2021/22 Budget Estimates	2022/23 Budget Estimates
No historical data - New public entity			18 231	36 886	53,959	58,295	62,738
Economic Classification of Budget			18 231	36 886	53,959	58,295	62,738
Compensation of Employees			10 457	21 126	46,215	49,912	53,905
Goods and Services			7 774	15 760	7,744	8,383	8,833

PART C: MEASURING OUR PERFORMANCE CONTINUED

6.5.2. Resource considerations

KEY RISK	RISK MITIGATION
Staff capacity to meet current work output is inadequate and at risk to further diminish with 3 senior managers and medical scientists nearing retirement age and the medical device unit being heavily reliant on Community Service Health workers.	▸ Prioritise focused recruitment and create skills transfer programme to ensure no hiatus is created with retirements
Business processes in this unit require review to align to ensure better alignment to mandate	▸ Business process mapping to be completed and updated policy and procedures to be created to
The radiation control unit regulates products with no health focus and which resides under the ambit of the Department of Energy. The risk of inadequate execution of mandate exists if this is not hosted in the correct government department.	▸ High level engagement between department of Energy and Department of Health is necessary to create solution to ensure the sectors are managed in the correct government space.
▸ Failure to provide appropriate ICT services across SAHPRA business units to support evolving processes	▸ Focused digital solutions to support units business processes

7. PUBLIC ENTITIES

NAME OF PUBLIC ENTITY	MANDATE	OUTCOMES	CURRENT ANNUAL BUDGET (R million)
South African Health Products Regulatory Authority	Regulate health products according to quality, safety and efficacy standards	Ensure effective financial management and alignment of budget allocation with strategic priorities (1)	R 308 274 000
		Achieve and maintain financial sustainability through revenue generated and enhanced operational efficiencies (2)	
		Consistently meet the needs and expectations of all SAHPRA's stakeholders (3)	
		Valuing our people (4)	
		Achieve and maintain high levels of organisational operational efficiency and effectiveness (5)	
		Strengthened ICT capacity (6)	
		Attract and retain superior talent (7	
		To promote the observance and upholding of organisational values and culture to advance business objectives and image/reputation (8)	
		To ensure that SAHPRA attains and maintains global best practices (9)	

PART D:
TECHNICAL INDICATOR DESCRIPTIONS (TIDS) - REVIEW

PART D: TECHNICAL INDICATOR DESCRIPTIONS (TIDS) - REVIEW

INDICATOR TITLE	AN UNQUALIFIED OPINION ISSUED BY THE AUDITOR-GENERAL ON THE ANNUAL FINANCIAL STATEMENTS BY 31 JULY EACH YEAR
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 (PDOs) or non-financial performance as prescribed by the PFMA.
Source of data	Availability of the external or Auditor-General's audit opinion available in Quarter 3, based on the previous financial year's performance.
Method of Calculation (Quantitative) / Assessment (Qualitative)	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.
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 possible)	Not applicable
Spatial Transformation (where applicable)	Not applicable
Reporting Cycle	Annual (progress against a 5-year target)
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 3, based on the previous financial year's performance.
Indicator responsibility	Chief Finance Officer (CFO)

INDICATOR TITLE	TOTAL REVENUE GENERATED IN FINANCIAL YEAR
Definition	The total revenue generated from both collection of fees for services rendered and grant received from the fiscus
Source of data	Income statements
Method of Calculation (Quantitative) / Assessment (Qualitative)	Monies received recognized as revenue for services rendered plus the monies received from national treasury as grant received from fiscus
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 regulator is supplier dependant and this in turn is dependent on the economy and state of investment ▸ The assumption of money being available in the fiscus
Disaggregation of Beneficiaries (where possible)	Not applicable
Spatial Transformation (where applicable)	Not applicable
Reporting Cycle	annual
Desired performance	To strive and achieve optimal revenue collection to meet the operational costs and needs of the organisation
Indicator responsibility	CFO

INDICATOR TITLE	TOTAL REVENUE GENERATED FROM FEES IN FINANCIAL YEAR
Definition	The total revenue generated from both collection of fees for services rendered
Source of data	Income statements
Method of Calculation (Quantitative) / Assessment (Qualitative)	Monies received recognized as revenue for services rendered
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 dependant and this in turn is dependent on the economy and state of investment
Disaggregation of Beneficiaries (where possible)	Not applicable
Spatial Transformation (where applicable)	Not applicable
Reporting Cycle	Annual
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	CFO

INDICATOR TITLE	BREAK-EVEN OF EXPENSES AND REVENUE BY 31 JULY EACH YEAR
Definition	A zero balance or surplus at the end of the financial year post reconciling income and expenses
Source of data	Balance sheets and reconciliation statements
Method of Calculation (Quantitative) / Assessment (Qualitative)	Total income less Total expenditure
Assumptions	Rigorous control over budget spending
Disaggregation of Beneficiaries (where possible)	Not applicable
Spatial Transformation (where applicable)	Not applicable
Reporting Cycle	Annual
Desired performance	To achieve a ≥ zero or surplus balance at end of financial year in accordance with the PFMA
Indicator responsibility	CFO

PART D: TECHNICAL INDICATOR DESCRIPTIONS (TIDS) - REVIEW CONTINUED

INDICATOR TITLE	PERCENTAGE POSITIVE RATINGS OF SAHPRA'S EFFECTIVENESS AND EFFICIENCY AS RATED BY PRIVATE AND PUBLIC DIRECT USERS OF SAHPRAS SERVICES
Definition	The undertaking of stakeholder surveys in the industry health product manufacturers, wholesalers, clinical trial applicants, health product holder of registration certificates , and health care providers as applicable on effectiveness and efficiency of SAHPRA s delivery of services as per SAHPRA mandate
Source of data	The stakeholder perception survey findings report produced by Communications every second year, commencing in 2020/21
Method of Calculation (Quantitative) / Assessment (Qualitative)	To be determined by service provider - will be provided in service provider methodology. (quantitative and qualitative methods to be employed)
Assumptions	▸ Services are not as per client's expectations but as per mandate ▸ Client must be a direct recipient of SAHPRA services as charged for ▸ That the targeted respondents will cooperate with the study so that it is concluded successfully with results that are useful
Disaggregation of Beneficiaries (where possible)	Not applicable
Spatial Transformation (where applicable)	Not applicable
Reporting Cycle	Bi-annually
Desired performance	To determine if the operational re-engineering and enhanced stakeholder communication strategy is effective in stimulating confidence in the industry in SAHPRA's mandated output
Indicator responsibility	Senior Manager : Communications

INDICATOR TITLE	PERCENTAGE OF PUBLIC SAMPLED ACCURATELY ENGAGING WITH SAHPRA
Definition	The undertaking of stakeholder surveys in to determine effectiveness of SAHPRAs in executing its mandate by determining the public's awareness and approval of SAHPRAs role towards enabling access to quality, safe and effective health products
Source of data	Survey
Method of Calculation (Quantitative) / Assessment (Qualitative)	To be determined by service provider will be provided in service provider methodology
Assumptions	▸ Services are not as per client's expectations of all public health but as per mandate ▸ Client must be an indirect recipient of SAHPRA services . eg users of health product, advocacy groups ▸ Assumption of participation from public
Disaggregation of Beneficiaries (where possible)	Not applicable
Spatial Transformation (where applicable)	Not applicable
Reporting Cycle	Bi Annual
Desired performance	To ensure the public awareness of the regulator is adequate to ensure public stimulus to improve our service (eg safety reporting) is accounted for
Indicator responsibility	Senior Manager : Communications

INDICATOR TITLE	PERCENTAGE OF POSITIVE RESPONSES OF STAFF CLIMATE SURVEY DIMENSIONS
Definition	SAHPRA employee perceptions of the influences on the job from the physical and organizational structure of the company are surveyed to gage employee well being
Source of data	Climate survey
Method of Calculation (Quantitative) / Assessment (Qualitative)	To be determined by service provider - will be provided in service provider methodology
Assumptions	Employee participation
Disaggregation of Beneficiaries (where possible)	Not applicable
Spatial Transformation (where applicable)	Not applicable
Reporting Cycle	Bi-Annual
Desired performance	To assess employee well being and possible root causes that may affect productivity
Indicator responsibility	Senior Manager Human Resources

INDICATOR TITLE	PERCENTAGE OF SAHPRA BUSINESS PROCESSES DIGITISED
Definition	Convert SAHPRA core business processes from manual or semi-automated functioning to fully digital end to end electronic document and process oversight solution
Source of data	ICT strategic implementation plan
Method of Calculation (Quantitative) / Assessment (Qualitative)	Number of core business processes digitised /number of core business processes
Assumptions	▸ Capital ▸ Business process mapping completed•
Disaggregation of Beneficiaries (where possible)	Not applicable
Spatial Transformation (where applicable)	Not applicable
Reporting Cycle	Quarterly
Desired performance	The core programmes will have a 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

PART D: TECHNICAL INDICATOR DESCRIPTIONS (TIDS) - REVIEW CONTINUED

INDICATOR TITLE	PERCENTAGE OF PRIORITISED POSITIONS FILLED
Definition	Vacant position identified for relevant recruitment phase and with approved budget are filled before commencement of next phase in the next financial year
Source of data	Staff establishment, published advertisements, new contracts dated with date of on boarding
Method of Calculation (Quantitative) / Assessment (Qualitative)	Number of staff recruited in financial year/ number of vacant position illegible for recruitment in financial year
Assumptions	▸ HR Senior Manager will be appointed before commencement of 2020 performance year ▸ Recruitment process is supported by labor ▸ Funds available
Disaggregation of Beneficiaries (where possible)	Targets for female staff must align with targets set as per NDOH HR recruitment policy
Spatial Transformation (where applicable)	Not applicable
Reporting Cycle	Quarterly
Desired performance	SAH{RA establishes a competent workforce through timeous recruitment against the phased plan
Indicator responsibility	Senior Manager: HR

INDICATOR TITLE	PERCENTAGE OF STAFF ESTABLISHMENT POSITIONS FILLED
Definition	SAHPRA is capacitated in incremental phased in approach to reach full staff complement as per approved organogram
Source of data	Staff establishment, SAHPRA approved organogram
Method of Calculation (Quantitative) / Assessment (Qualitative)	Total number of filled position in staff establishment / total number of position on staff establishment as per approved organogram
Assumptions	▸ HR Senior Manager will be appointed before commencement of 2020 performance year ▸ Recruitment process is supported by labor ▸ Funds available
Disaggregation of Beneficiaries (where possible)	Not applicable
Spatial Transformation (where applicable)	Not applicable
Reporting Cycle	Quarterly
Desired performance	SAHPRA establishes a competent workforce through timeous recruitment against the phased plan
Indicator responsibility	Senior Manager: HR

INDICATOR TITLE	PERCENTAGE OF STAFF TRAINED IN KEY CORE BUSINESS FUNCTIONS
Definition	Capacitation od technical staff to align with re-engineered operational framework and renewed business policies in core programmes
Source of data	▸ Training plan for staff related to technical training ▸ Training/workshop/conference/courses records for training completed
Method of Calculation (Quantitative) / Assessment (Qualitative)	Number of technical training/conference/workshops /courses sessions completed X number of people attending ▸ Number of total technical staff earmarked for training in technical training plan residing with CRO
Assumptions	▸ Technical training sessions in specialized areas are available ▸ Travel approved if out of borders ▸ Funding available from SETA
Disaggregation of Beneficiaries (where possible)	Female focused quota for development as per NDOH
Spatial Transformation (where applicable)	Not applicable
Reporting Cycle	Quarterly
Desired performance	Whilst a discreet level of 25% has been set; it is hoped the target can be exceeded based on availability of international resources
Indicator responsibility	Senior Manager:HR

INDICATOR TITLE	PERCENTAGE IMPLEMENTATION OF MEDICINES REGULATORY QUALITY MANAGEMENT SYSTEM
Definition	Assess level of completion and implementation of operational framework against standardised and approved policies, procedures and guidelines for core programmes
Source of data	Site master file for Regulator
Method of Calculation (Quantitative) / Assessment (Qualitative)	Number of policies and procedures developed, approved and implemented for all identified business processes in core programme/number of all identified business processes in core programme
Assumptions	▸ Business process mapping for core programmes is completed ▸ Approval by technical oversight and regulatory strategy committee is regular
Disaggregation of Beneficiaries (where possible)	Not applicable
Spatial Transformation (where applicable)	Not applicable
Reporting Cycle	Quarterly
Desired performance	To ensure benchmarking of
Indicator responsibility	Senior Manager : Strategic Planning, Quality and Business transformation

PART D: TECHNICAL INDICATOR DESCRIPTIONS (TIDS) - REVIEW CONTINUED

INDICATOR TITLE	PERCENTAGE OF SECTOR THOUGHT LEADERSHIP AND REGULATORY SCIENCE PIECES IN MAGAZINES, WEBSITES, JOURNALS AND MEDIA SOURCES
Definition	Determine the effectiveness of SAHPRA with a pool of regulatory experts to influence the sector through published thought leadership pieces in accredited magazines, websites, journals and conferences
Source of data	Publications
Method of Calculation (Quantitative) / Assessment (Qualitative)	Count
Assumptions	▸ Collaborations with key academic /journalistic partners to support publications ▸ Interest expressed by journals, magazines and websites to host the publications ▸ Recruitment of technical staff to permit time resource to support this activity
Disaggregation of Beneficiaries (where possible)	Not applicable
Spatial Transformation (where applicable)	Not applicable
Reporting Cycle	Quarterly
Desired performance	ensure alignment of SAHPRA to international trends by establishing SAHPRA as the thought leader in medicines regulatory space
Indicator responsibility	CEO

INDICATOR TITLE	DETERMINE WHO MATURITY LEVEL
Definition	Maturity level for SAHPRA determined from WHO benchmarking audit
Source of data	WHO audit outcome and report
Method of Calculation (Quantitative) / Assessment (Qualitative)	To be determined by WHO
Assumptions	Preparedness of SAHPRA for audit in 2020
Disaggregation of Beneficiaries (where possible)	Not applicable
Spatial Transformation (where applicable)	Not applicable
Reporting Cycle	annually
Desired performance	Establish Sahpra legitimacy as a key health product regulator in African continent and globally
Indicator responsibility	CEO

INDICATOR TITLE	PERCENTAGE OF 0MEDICINES REGISTRATIONS BACKLOG ERADICATED
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 (Quantitative) / Assessment (Qualitative)	Number of applications finalised from the total number of applications received expressed as a percentage and calculated as follows: ▸ Numerator/Denominator x 100% where the Numerator represents a number of applications finalised over a predefined quarter and the Denominator is a total number of applications drawn from the backlog register
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 possible)	Not applicable
Spatial Transformation (where applicable)	Not applicable
Reporting Cycle	Quarterly
Desired performance	To eradicate the backlog of applications by 2022
Indicator responsibility	Project Manager: Backlog

PART D: TECHNICAL INDICATOR DESCRIPTIONS (TIDS) - REVIEW CONTINUED

INDICATOR TITLE	PERCENTAGE OF NEW GMP LICENCES OF LOCAL MANUFACTURERS, IMPORTERS AND EXPORTERS FINALISED WITHIN PREDEFINED TIMELINE
Definition	Quantification of new licence applications lodged by health product sector manufacturers, that the regulator can process and finalise within a period of 90 working days counting from the day when the applications are deemed to be meeting minimum requirements
Source of data	Licensing Unit that receives applications submitted by abovementioned applicants through SAHPRA reception
Method of Calculation (Quantitative) / Assessment (Qualitative)	Number of applications finalised from the total number of applications received expressed as a percentage and calculated as follows: ▸ Numerator/Denominator x 100% where the Numerator represents a number of applications finalised over a predefined quarter and the Denominator is a total number of applications drawn from the register; regardless of when the application was received
Assumptions	▸ That new applications will continue to be received by the regulator ▸ That the inspections preceding the processing of applications will be undertaken and completed timeously ▸ That sites will be found to be meeting minimum requirements as per applicable guidelines communicated to industry
Disaggregation of Beneficiaries (where possible)	Not applicable
Spatial Transformation (where applicable)	Not applicable
Reporting Cycle	Bi-annually
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: Health Product Authorisation

INDICATOR TITLE	PERCENTAGE OF HEALTH PRODUCT PREMISES/SITES INSPECTIONS FINALISED WITH AN INSPECTION REPORT SUBMITTED TO THE APPLICANT WITHIN 30 DAYS OF CONDUCTING GMP INSPECTIONS
Definition	Quantification of site or premises inspections conducted to support new licence applications lodged by health product sector manufacturers, and holder of registration certificates that the regulator can process and finalise within a period of 30 working days counting from to the day when the applications are deemed to be meeting minimum requirements to the first inspection report submitted to the applicant
Source of data	Signed Inspection reports and signed inspection plans
Method of Calculation (Quantitative) / Assessment (Qualitative)	Number of premises or site inspections finalised with first report submitted to applicant out of the total number of inspections planned per quarterly approved inspection plan expressed as a percentage and calculated as follows: ▸ Numerator / Denominator x 100% where the Numerator represents a number of applications finalised over a predefined quarter and the Denominator is a total number of applications drawn the register; regardless of when the application was received
Assumptions	▸ That the backlog is cleared during the 2019/20 financial year ▸ That new recruits will be successfully onboarded to fill current critical vacancies ▸ Internal business processes are in place and optimized with policies and procedures to support operations ▸ Digitization solution in place
Disaggregation of Beneficiaries (where possible)	Not applicable
Spatial Transformation (where applicable)	Not applicable
Reporting Cycle	Quarterly
Desired performance	To strive to expeditiously process with complete inspection report (without compromising the quality of the application process) ; the highest possible number of licence applications to ensure that site that manufacture health products meet the quality, safety and efficacy (QSE) standards
Indicator responsibility	Senior Manager: Inspectorate and Regulatory Compliance

PART D: TECHNICAL INDICATOR DESCRIPTIONS (TIDS) - REVIEW CONTINUED

INDICATOR TITLE	PERCENTAGE INVESTIGATIONS COMPLETED WITH DECISIONS IN LINE WITH PREDEFINED STANDARDS AND TIMELINES OF ALL HEALTH PRODUCT QUALITY COMPLAINTS REPORTED TO THE REGULATOR
Definition	Quantification of investigations conducted in response to health product quality complaints received by the regulator that the regulator can process and finalise within a period of predefined timeline of when complaint is received to when investigations is either closed, actioned or handed over to alternate authority
Source of data	Signed Investigations reports and complaints received
Method of Calculation (Quantitative) / Assessment (Qualitative)	Number of investigations with a finalised report and recommendation out of the total number of complaints received per quarter expressed as a percentage and calculated as follows:
Assumptions	▸ That new recruits will be successfully on boarded to fill current critical vacancies ▸ Internal business processes are in place and optimized with policies and procedures to support operations ▸ Digitization solution in place
Disaggregation of Beneficiaries (where possible)	Not applicable
Spatial Transformation (where applicable)	Not applicable
Reporting Cycle	Quarterly
Desired performance	To endeavour to conduct the highest possible number of post marketing investigations to keep the public and consumers protected from effects of negative post marketing behaviour, poor product quality and product safety concerns
Indicator responsibility	Senior Manager: Inspectorate and Regulatory Compliance

INDICATOR TITLE	PERCENTAGE OF REGISTRATIONS OF NEW CHEMICAL ENTITIES (NCES) FINALISED WITHIN PREDEFINED TIMELINES
Definition	Quantification of new chemical entities registered within the pre-defined timeline ranging from 275-590 working day-cycles after inclusion in the registration plan for a given financial year, calculated from the day when the applications are deemed to be meeting minimum standards for processing
Source of data	SAHPRA Project Management Office (PMO) generated from Google Sheets
Method of Calculation (Quantitative) / Assessment (Qualitative)	Number of NCE medicines registered compared to the total number of NCE applications in the registration plan, expressed as a percentage, calculated as follows: ▸ Numerator/Denominator x 100%, where Numerator is the total number of NCEs registered within a 275 – 590 day cycle and the Denominator is the total number of NCEs in the registration plan.
Assumptions	▸ That the introduction of the new technology system ▸ will not disrupt the operations and the reporting ability ▸ That suitably qualified staff will be successfully recruited ▸ That the competing priorities for resources with backlog will be resolved ▸ That internal processes such as reliance arrangements and batch processing are in place and work effectively ▸ That the tedious processes currently in terms of new requirements and templates will have been resolved
Disaggregation of Beneficiaries (where possible)	Not applicable
Spatial Transformation (where applicable)	Not applicable
Reporting Cycle	Quarterly
Desired performance	Efficient registration of innovator or novel medication that meets high quality, safety and efficacy standards to enable access to medicines for the benefit of the South African public
Indicator responsibility	Chief Regulatory Officer

PART D: TECHNICAL INDICATOR DESCRIPTIONS (TIDS) - REVIEW CONTINUED

INDICATOR TITLE	PERCENTAGE OF REGISTRATIONS OF GENERIC FINALISED WITHIN THE PREDEFINED TIMELINE
Definition	Quantification of generic medicines registered within 180 -250 working day-cycles after inclusion in the registration plan for a given financial year, calculated from the day when the applications are deemed to be meeting minimum standards for processing
Source of data	SAHPRA Project management Office (PMO) generated from Google Sheets
Method of Calculation (Quantitative) / Assessment (Qualitative)	Number of generic medicines registered compared to the total number of generic medicine applications in the registration plan, expressed as a percentage and calculated as follows: ▸ Numerator/Denominator x 100%, where Numerator is the total number of generic medicines registered within a 180 -250 working day cycle and the Denominator is the total number of generic medicine applications in the registration plan.
Assumptions	▸ That the introduction of the new technology system from around Q2 will not disrupt the operations and the reporting ability ▸ That the regulator will continually receive applications for registration of generic medicines as part of its core business
Disaggregation of Beneficiaries (where possible)	Not applicable
Spatial Transformation (where applicable)	Not applicable
Reporting Cycle	Quarterly
Desired performance	Efficient registration of generic medication that meets high quality, safety and efficacy standards to enable access to medicines for the benefit of the South African public
Indicator responsibility	Chief Registration Officer

INDICATOR TITLE	PERCENTAGE APPLICATIONS FOR THE SALE OF UNREGISTERED CATEGORY A (HUMAN) MEDICINES FINALISED WITHIN 24 WORKING HOURS COUNTING FROM THE TIME WHEN THE APPLICATION WAS RECEIVED
Definition	Timebound indicator reflecting the response to public health needs for unregistered Category A medicines. Unregistered medicines are medicines that do not appear on the SAHPRA medicine register whereas Category A medicines are referred to as orthodox or allopathic medicines.
Source of data	SAHPRA's Section 21 Unit, generated through Google sheets
Method of Calculation (Quantitative) / Assessment (Qualitative)	Number of applications finalised from the total of applications received expressed as a percentage, calculated as follows: ▸ Numerator/Denominator *100% where Numerator is the number of applications finalised within a 24 working-hour timeline and the Denominator is a total number of applications received
Assumptions	▸ That the system is running continually without disruptions ▸ That applicants observe application rules and procedures as communicated to them
Disaggregation of Beneficiaries (where possible)	N/A
Spatial Transformation (where applicable)	N/A
Reporting Cycle	Quarterly
Desired performance	Facilitate the most efficient possible access to unregistered Category A medicines that fulfil a public health mandate of the regulator
Indicator responsibility	Manager: Section 21 Unit

PART D: TECHNICAL INDICATOR DESCRIPTIONS (TIDS) - REVIEW CONTINUED

INDICATOR TITLE	PERCENTAGE OF CLINICAL TRIAL APPLICATIONS FINALIZED WITHIN 120 WORKING DAYS COUNTING FROM THE DATE APPLICATION WAS RECEIVED
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 (Quantitative) / Assessment (Qualitative)	A percentage calculation of total number completed clinical trial applications over a total number of clinical trial applications received, calculated as follows: ▸ Numerator/Denominator X 100%, where the Numerator is the total number clinical trial applications with a final decision issued and the Denominator is the total number of clinical trial applications received within published registration cycles
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 possible)	Not applicable
Spatial Transformation (where applicable)	Not applicable
Reporting Cycle	Bi-Annually
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

INDICATOR TITLE	PERCENTAGE OF REPORTS ON MEDICINE SAFETY COMMUNICATIONS OF NEW ADVERSE EVENTS AND SIGNALS THAT HAVE BEEN ASSESSED AND PREPARED FOR PUBLICATION WITHIN 20 WORKING DAYS AFTER RECEIPT
Definition	Quantification of medicine safety communication alerts relating to new adverse events and signals that have been subjected to necessary assessments after their receipt by the regulator and the decision is reached to publish them to alert the public. Such alerts are handled in the following forms: ▸ Media releases: local safety concerns that warrant immediate public awareness, published safety decisions by other regulatory authorities, safety signals; ▸ Dear healthcare professional letters: safety concern for immediate attention of healthcare professionals from safety notifications, internal reviews; ▸ Medicines safety alerts: educational or informational material for healthcare professionals on health products safety issues from internal reviews; ▸ Safety surveillance: notifications from applicants, internet and media searches; and ▸ Safety signal: Adverse drug reaction reports from Healthcare professionals, consumers and applicants, literature, VigiBase®
Source of data	Manager: Pharmacovigilance
Method of Calculation (Quantitative) / Assessment (Qualitative)	A total number of safety concerns concluded within a period of 20 working days over a total number of safety concerns received, expressed as a percentage and calculated as follows: ▸ Numerator (number of safety concerns concluded within 20 working days of receipt)/ Denominator (total number of safety concerns received within a quarter) x 100%
Assumptions	▸ That the regulator will continually receive ADR reports from applicants, healthcare professionals and consumers ▸ That applicants will notify the Authority of foreign Regulatory Authority decisions which concerns their health products. ▸ That applicants will comply with Authority's recommendations ▸ That necessary resources such as reliable Internet connectivity, Reference material, adequate, competent human resources and ICT support are in place ▸ That active surveillance of medicine safety issues will remain in force ▸ That all information relating to the new safety signal will be available upfront
Disaggregation of Beneficiaries (where possible)	N/A
Spatial Transformation (where applicable)	N/A
Reporting Cycle	Quarterly
Desired performance	Timeous communication of regulatory decisions on the safety of health product, to promote public health of South Africans
Indicator responsibility	Medical Officer

PART D: TECHNICAL INDICATOR DESCRIPTIONS (TIDS) - REVIEW CONTINUED

INDICATOR TITLE	PERCENTAGE OF MEDICAL DEVICES ESTABLISHMENT LICENCE APPLICATIONS FINALISED IN 90 DAYS
Definition	Quantification of the percentage of new medical device establishment applications for licences lodged with the regulator as prescribed by the Medicines and Related Substances Act, 1965 (Act No. 101 of 1965), as amended
Source of data	Medical device applications and licences issued herewith
Method of Calculation (Quantitative) / Assessment (Qualitative)	Number of new licence applications for medical device establishment processed with 30 working days, expressed as a percentage and calculated as follows: ▸ Numerator/Denominator x 100%, where Numerator is the total number of new licences processed with decision issues with 30 working days and the Denominator is the total number of applications in the registration plan
Assumptions	That all tools necessary for processing applications are available and function optimally
Disaggregation of Beneficiaries (where possible)	Not applicable
Spatial Transformation (where applicable)	Not applicable
Reporting Cycle	Quarterly
Desired performance	Maintaining the highest possible levels of quality and safety for medical device establishments manufacturing or importing and exporting of medical devices to ensure the public and the environment
Indicator responsibility	Senior Manager: Medical Devices and Radiation Control

INDICATOR TITLE	DEVELOP AND IMPLEMENT MEDICAL DEVICE REGISTRATION FRAMEWORK
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 CRO and CEO
Method of Calculation (Quantitative) / Assessment (Qualitative)	Count steps in framework completed
Assumptions	Human resource capacity to champion project
Disaggregation of Beneficiaries (where possible)	Not applicable
Spatial Transformation (where applicable)	Not applicable
Reporting Cycle	Quarterly
Desired performance	Framework to register medical devices has commenced by end of quarter 4
Indicator responsibility	Senior Manager: Medical Devices and Radiation Control

INDICATOR TITLE	PERCENTAGE OF NEW LICENCE APPLICATIONS FOR IONISING RADIATION-EMITTING DEVICES AND RADIOACTIVE SOURCES ISSUED WITHIN 30 WORKING DAYS
Definition	Quantification of the percentage of new applications for licences lodged with the regulator by holders of radiation-emitting devices as prescribed by the Hazardous Substances Act, 1973, as amended
Source of data	Various units within programme 5, Radiation Control, have specific elements they are responsible for. The Acting Radiation Control Manager is responsible for coordinating the various areas of operations as a custodian responsible for final outputs
Method of Calculation (Quantitative) / Assessment (Qualitative)	Number processed with 30 working days, expressed as a percentage and calculated as follows: ▸ Numerator/Denominator x 100%, where Numerator is the total number of new licences processed with decision issues with 30 working days and the Denominator is the total number of applications in the registration plan
Assumptions	That all tools necessary for processing applications and measuring performance are available and function optimally
Disaggregation of Beneficiaries (where possible)	N/A
Spatial Transformation (where applicable)	N/A
Reporting Cycle	Quarterly
Desired performance	Maintaining the highest possible levels of protection of radiation workers, patients, public and the environment against the adverse effects of radiation
Indicator responsibility	Acting Radiation Control Manager

ANNEXURE A: MATERIALITY AND SIGNIFICANCE FRAMEWORK

BACKGROUND

In terms of the Treasury Regulation Section 28.3.1 – "For purposes of material [sections 55(2) of the Public Finance Management Act (PFMA)] and significant [section 54(2) of the PFMA], the accounting authority must develop and agree on a framework of acceptable levels of materiality and significance with the relevant executive authority.

The South African Auditing Standard (SAAS 320.03) defines materiality as follows: "Information is material if its omission or misstatement could influence the economic decisions of users taken on the basis of the financial statements. Materiality depends on the size of the item or error judged in the particular circumstances of its omission or misstatement. Thus, materiality provides a threshold or cut-off point, rather than being a primary qualitative characteristic, which information must have if it is to be useful."

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

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

BASIS	ACCEPTABLE PERCENTAGE RANGE
Total assets	1 % - 2 %
Total Revenue	0,5 % - 1 %
Profit after tax	2 % - 5 %

SAHPRA will use 1 % of total revenue to determine materiality. SAHPRA operations are driven mainly by applications received and are therefore essentially revenue-driven.

In determining the materiality value as 1 % we have considered the following factors: a) Nature of the SAHPRA's business In terms of the Medicines Act, the objects of the Authority are to provide for the monitoring,

evaluation, regulation, investigation, inspection, registration and control of medicines, scheduled substances, clinical trials and medical devices, radiation control and related

matters in the public interest. b) The control and inherent risks associated with the SAHPRA. In assessing the control risk of the SAHPRA, and concluding that a materiality level higher than 0,25 % can be used due to a reasonable control environment being present cognizance was given to amongst others:

- Proper and appropriate governance structures have been established;
- An audit and risk committee that closely monitors the control environment of the SAHPRA was established;
- The function of internal audit was partly outsourced to a firm with SAHPRA specific experience; and
- An internal audit plan, based on annual risk assessments being performed, is annually reviewed and agreed by the audit committee.

c) Quantitative Aspects

Materiality Level

The level of materiality for 2020/21 has been set as follows:

Total 2018/19 audited revenue: R 231 280 133 x 1 %= R2 312 013

d) Qualitative Aspects

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

i) New ventures that the SAHPRA has entered into.

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

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

iv) Any fraudulent or dishonest behaviour of an officer or staff of SAHPRA.

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

Registered Office Address CSIR Campus
Reception Building 38a
Meiring Naudé Road,
Brummeria
Pretoria
0002

Postal Address
Private Bag X828
Pretoria
0001

Contact Telephone Numbers
+2712 842 7582/3

Email Address
enquiries@sahpra.org.za

Website Address
www.sahpra.org.za

ISBN
978-1-990951-48-0

SAHPRA
South African
Health Products
Regulatory Authority