SOUTH AFRICAN HEALTH PRODUCTS REGULATORY AUTHORITY (SAHPRA)

STRATEGIC PLAN

FOR THE FISCAL YEARS

2018/19 – 2022/23

DATE OF TABLING:

MARCH 2018

FOREWORD BY MINISTER OF HEALTH

The Strategic Plan for the years 2018 to 2023 has been developed by the South African Health Products Regulatory Authority (SAHPRA). It represents the strategies and planned actions of the Board of SAHPRA to ensure that through their considered and responsible actions, they can, together with the Staff at the Authority, assure and guide the Authority to grow into maturity; and reach its full potential to provide for the monitoring, evaluation, regulation, investigation, inspection, registration and control of medicines, scheduled substances, clinical trials, medical devices, radiation emitting devices and radioactive nucleides and related matters in the public interest. In doing so the expectations are to positively shift the provision of healthcare services towards justifiable expectations of quality, safe and efficacious health products.

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

DR A. MOTSOALEDI (MP)
MINISTER OF HEALTH

STATEMENT BY THE CHAIRPERSON

As the Chairperson of the Board of the newly appointed South African Health Products Regulatory Authority (SAHPRA), I am excited to be able to share the first SAHPRA Strategic Plan with all the Authority's stakeholders.

The Authority came into being on February 1st 2018 when the Medicines Control Council (MCC) was dissolved. The MCC was established under the Medicines and Related Substances Act, 1965 (Act No. 101 of 1965) as amended, and has done extraordinary work for many years to ensure that South Africa's medicines are safe, effective and of good quality.

I would like to sincerely thank the dedicated staff, external experts and academics who collectively enabled the MCC to be recognized as a world class African drug regulatory authority which has set the platform for SAHPRA. But since 1994 successive Health Ministers have recognized that the legislative framework governing the MCC, and the functionality and mandate that this gave the Council, was no longer fit for purpose. Under the leadership of Minister Dr Aaron Motsoaledi, the new SAHPRA legislation has now been enacted. This allows SAHPRA to comprehensively regulate all medicines, medical devices and radiation emitting devices.

The legislation supports a new approach to medicines regulation in South Africa that permits appropriate regulatory models to be applied to different categories of products. These changes reflect new global thinking about medicines regulation worldwide, in which greater transparency, information sharing and collective review is used to enhance the quality and speed of approving clinical trials and the registration of new health products. By using these new approaches, SAHPRA will be able to boldly tackle its greatest initial challenge, which is the backlog of products awaiting regulatory decisions.

A priority action for the SAHPRA Board is to address this enormous task, not by tweaking traditional methods for dossier review, but by implementing a fundamentally different regulatory approach that incorporates contemporary thinking including reliance arrangements between national regulatory authorities worldwide. With the numbers of new products, new technologies and new manufacturers continuously expanding, SAHPRA will also be focusing on a strengthened approach to post-marketing surveillance and vigilance to ensure that South Africa's medicines and medical devices are safe and of good quality once introduced into the market place. Linked to this is the need for a different approach to communication. In the days of social media and of consumer demands for information, SAHPRA will prioritize a new communications strategy that allows greater transparency about the way the Authority operates and more open dialogue with all its constituencies. This five-year strategic plan (2018/19-2022/23) outlines the approach that SAHPRA will be taking to fulfill its renewed mandate by setting ambitious yet realistic goals and targets aimed at transforming the medicines regulatory landscape in South Africa.

PROF. HELEN REES

CHAIRPERSON: SAHPRA

STATEMENT BY THE ACTING CHIEF EXECUTIVE OFFICER (CEO)

This is the first Strategic Plan of the South African Health Products Regulatory Authority (SAHPRA). The Plan sets out nine (9) strategic outcome oriented goals, a number of strategic objectives and targets necessary to achieve the Authority's mission of safeguarding the health and wellbeing of all who live in South Africa and to support human and animal health through scientific and ethical regulation of medicines, medical devices, radiation emitting devices and radioactive nucleides. It also sets out key performance indicators as measurements that will test the degree to which the objectives and targets will be achieved.

To achieve SAHPRA Vision and Mission, special attention will be given to the following strategic outcome oriented goals:

Goal 1: Publicly demonstrate responsiveness and accountability as an effective and efficient high performance organisation.

Goal 2: Timeous regulatory decision taken on medicines and medical device applications to ensure compliance to defined standards of quality, safety, efficacy and performance.

Goal 3: Re-evaluate and monitor medicines, medical devices periodically.

Goal 4: Investigate, monitor, analyse, solicit and act upon existing and new adverse events, interactions, information with regard to post-marketing surveillance and vigilance.

Goal 5: Ensure regulatory compliance through a process of active Inspections and investigations.

Goal 6: Evaluate clinical trial protocols in accordance with defined standards.

Goal 7: Evaluate the applications for sale of unregistered health products in accordance with defined standards.

Goal 8: Establish and strengthen collaborative initiatives with any other regulatory authority or institutions in order to achieve the objects of the Medicines Act.

Goal 9: SAHPRA is capacitated by adequate, competent and motivated Human Capital.

Achievement of these goals is of paramount importance for SAHPRA to meet and, where possible, exceed expectations of its stakeholders and the public at large. In this regard, the Management team with the support of the Board are committed to the successful implementation of this Strategic Plan. Monitoring and evaluation of the plan will be done to ensure that anticipated performance results are achieved.

I feel indebted to members of Management team, employees and National Department of Health colleagues who contributed ideas, suggestions, experiences, expertise and time in the development of this Plan. In a special way, I thank the SAHPRA Board Chairperson and members of the Board for their guidance and support and all stakeholders for their support and cooperation towards achieving the SAHPRA's Mission and Vision.

MS P NKAMBULE

ACTING CEO: SAHPRA

OFFICIAL SIGN OFF

It is hereby certified that this Strategic 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 strategic outcome oriented goals and objectives which SAHPRA will endeavour to achieve over the period 2018/19–2022/23.

MR IAN VAN DER MERWE **DATE**

CHIEF FINANCIAL OFFICER (NDOH)

MS PORTIA NKAMBULE **DATE**

ACTING CHIEF EXECUTIVE OFFICER

PROF HELEN REES **DATE**

CHAIRPERSON: SAHPRA BOARD

APPROVED BY:

DR A. MOTSOALEDI (MP) **DATE**

MINISTER OF HEALTH

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ACRONYMS AND ABBREVIATIONS

ADR	Adverse Drug Reaction
APP	Annual Performance Plan
API	Active Pharmaceutical Ingredient
ATM	African Traditional Medicines
CEO	Chief Executive Officer
CMs	Complementary Medicines
CTC	Clinical Trials Committee
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
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	Medical and Health Products Regulatory Agency, United Kingdom
MOU	Memorandum of Understanding
MRA	Medicines Regulatory Authority
MTEF	Medium Term Expenditure Framework
MTSF	Medium Term Strategic Framework

NCE	New Chemical Entity
NDoH	National Department of Health
NHI	National Health Insurance
NRA	National Regulatory Authority
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
TB	Tuberculosis
TGA	Therapeutic Goods Administration, Australia
WHO	World Health Organization

DEFINITIONS

Medical Devices	**"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;
Medicine	**"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;
Health Product	As is contained within the ambit of this document only, means medicines, medical devices, radiation emitting devices and radioactive nucleides, complementary medicines, veterinary medicines, biological and biosimilars.

PART A:
STRATEGIC OVERVIEW

1 VISION

To strive towards excellence in health product regulation with the aim of promoting and protecting human and animal health in South Africa, being recognised and respected both nationally and globally as a leading and exemplary health product regulator.

2 MISSION

To safeguard the health and wellbeing of all who live in South Africa and to support human and animal health through scientific and ethical regulation of medicines, medical devices, radiation emitting devices and radioactive nucleides.

3 VALUES

SAHPRA has identified the following values as the principles that will underpin the policies, procedures, code of conduct and culture of the organisation:

Table 1: Values and Principles Governing SAHPRA

#	Value	Description
1	**Care**	• Caring about society and the environment: For humans and animals, this involves consideration of our impact on individuals, local communities and on the environment, acting with diligence and sensitivity.
2	**Ethical Conduct**	• Commitment to ethical conduct by promoting and protecting the health of all who live in South Africa and of its animals through relevant, scientifically sound and ethical regulatory practices.
3	**Unity of Purpose**	• Ensuring that all policies, guidelines and procedures are underpinned by the core principles and values of the organization that are known to all staff of the Authority, Board members and stakeholders, united by a common vision, facilitating collaboration and support, thereby contributing to a beneficial, safe and effective working environment. • Teamwork and cohesion are key and collaboration should include pooling of resources, work-sharing and effective communication. • Fostering professionalism, trust and honesty in interactions with colleagues and stakeholders. • Cultivating an environment where all contributions are valued; everyone is treated consistently and fairly; diverse viewpoints are heard and capitalised on and conflicts are resolved effectively. • Making SAHPRA goals a priority, by targeting and carefully using SAHPRA resources to ensure effective delivery of our work.
4	**Service Excellence**	• Valuing good work ethics and striving towards service excellence and extroversion. This represents being committed to working with stakeholders and building good relationships with them by understanding them, their needs, responding quickly and providing appropriate solutions that are underpinned by the core mission and values of the organization.

#	Value	Description
		• Treating stakeholders with respect at all times; being helpful, courteous, accessible, responsible and knowledgeable in our interactions; ensuring that all communication is clear, effective and tailored to the needs of the audience. • Developing robust performance measures, allowing for benchmarking and monitoring challenges and opportunities for growth. • Ensuring that the Board, Authority and relevant stakeholders have clarity on the mandate of the organization, policies and procedures that underpin their work and clarity of the roles they perform.
5	**Transformation**	• Investing in professional growth of staff by sharing knowledge and experience, peer networking, education through training and creating opportunities to develop. This includes creative problem solving, informed risk-taking, learning from our mistakes and experiences and behaving professionally. • Career pathing, skills development and performance in the workplace to be managed with the aim of introducing greater diversity. • Work with academic and training agencies to identify and develop new opportunities for regulatory science training. • Leaders should develop innovative approaches and drive continuous improvement as well as effective and smooth organisational change initiatives. • Influence and support the global regulatory network in which we operate, promoting harmonisation, whilst ensuring local responsiveness to the evolving needs of our country.
6	**Innovation**	• Promote ideas sharing and support innovation, research and development that is in the public's interest. • Identifying needs to broad challenges present in society. • Creating an enabling environment for sound, ethical research and backing new ideas by bringing them to the market. • Pursuing cost-effective solutions in operations research and training. • Monitoring and evaluating the impact of interventions on the challenges faced. • Applying new ways of doing things at all levels of the Authority • Encouraging out-of-the box thinking and rewarding groundbreaking initiatives.
7	**Integrity**	• Working with integrity and responsibility: Setting and achieving goals, consistently delivering business results while complying with standards and meeting deadlines. • Ensuring efficiency in the best use of public resources. • A work environment underpinned by a culture of fairness, impartiality, independence, accountability and transparency. • Alignment of the Authority's operational ethos with the principles set out in the WHO Good Regulatory Practice Guideline.

4 LEGISLATIVE AND OTHER MANDATES

4.1 SAHPRA Mandate Obligations and Functions

The South African Health Products Authority (SAHPRA) is the Regulatory Authority of South Africa, which is responsible for the regulation of health products intended for human and animal use; the licensing of manufacturers, wholesalers and distributors of medicines, medical devices, radiation emitting devices and radioactive nucleides; and the conduct of clinical trials.

The legislative mandates of SAHPRA are derived from the Constitution; the National Health Act, 2003 (Act No. 61 of 2003); the Medicines and Related Substances Act, 1965 (Act No. 101 of 1965), as amended (herein after referred to as “the Medicines Act”); and other relevant legislation, regulations and policies.

Further, SAHPRA’s mandate has expanded to include the regulation and control of radiation emitting devices and radioactive nucleides under the Medicines Act and the Hazardous Substances Act, 1973 (Act No. 15 of 1973).

4.1.1 The Constitution of the Republic of South Africa, 1996

In terms of the Constitutional provisions, the Authority is, amongst others, guided by the following sections and schedules:

The Constitution of the Republic of South Africa, 1996, places obligations on the state to progressively realize socio-economic rights, including access to health care.

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

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

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

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.

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

The Medicines and Related Substances Act, 1965 (Act No. 101 of 1965), which was 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, amongst others, the establishment of SAHPRA, the licensing of manufacturers and importers of Active Pharmaceutical Ingredients, 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 nucleides that meet the defined standards of quality, safety, efficacy and performance, where applicable;
- Ensure that the process of evaluating or assessing and registering of medicines, medical devices, radiation emitting devices and radioactive nucleides is transparent, fair, objective and concluded timeously;
- Ensure the periodic re-evaluation or re-assessment and ongoing monitoring of medicines, medical devices, radiation emitting devices and radioactive nucleides;
- Ensure 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;
- Ensure that compliance with existing legislation is promoted and achieved through a process of active inspection and investigation; and
- Ensure 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.

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

Within the Medicines Act, “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) (herein after referred to as “the Hazardous Substances Act”).

The Hazardous Substances Act provides for the efficient, effective and ethical evaluation and registration of non-ionizing radiation emitting devices and radioactive nucleides.

It also prohibits and controls the importation, manufacture, sale, use, operation, application, modification, disposal or dumping of substances and (electronic) products that may cause injury or death due to their detrimental direct or indirect effects. The Hazardous Substances Act classifies such substances and products in groups according to the risk associated with them.

Group I, Group II, Group Ill or Group IV hazardous substance means a substance, mixture of substances, product or material declared in terms of section 2 (1) of the Hazardous Substances Act to be a Group I, Group II, Group III or Group IV hazardous substance, respectively;

a) any substance or mixture of substances which, in the course of customary or reasonable handling or use, including ingestion, might, by reason of *its* toxic, corrosive, irritant, strongly sensitizing or flammable nature or because it generates pressure through decomposition, heat or other means, cause injury, ill-health or death to human beings, to be a Group I or a Group II hazardous substance;

b) any electronic product to be a Group III hazardous substance; and

c) subject to the approval of the Minister of Mines, any radio-active material to be a Group IV hazardous substance.

4.1.5 Related legislation impacting on and influencing the functioning of SAHPRA

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

  Provides for the registration of fertilizers, farm feeds, agricultural remedies, stock remedies, sterilizing plants and pest control operators. To regulate or prohibit the importation, sale, acquisition, disposal or use of fertilizers, 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 Control 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)**

  To 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 co-ordinating 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.

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

  Provides for the requirements that employers must comply with in order to create a safe working environment for employees in the workplace.

- **Child Care Act, 1983 (Act No. 74 of 1983)**

  Provides for the protection of the rights and well-being of children.

- **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.

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

  To ensure that all South African institutions conduct themselves in a responsible manner when collecting, processing, storing, sharing another entity's personal information

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

  Amplifies the constitutional provision pertaining to accessing information under the control of various bodies.

- **Promotion of Administrative Justice Act, 2000 (PAJA) (Act No. 3 of 2000)**

  Amplifies the constitutional provisions pertaining to administrative law by codifying it.

- **Public Finance Management Act, 1999 (Act No. 29 of 1999)**

  Regulates financial management in the national government and provincial governments. Further it ensures that all revenue, expenditure, assets and liabilities of all levels of governments are managed efficiently and effectively and provides for the responsibilities of persons entrusted with financial management to support, among others, sustainable access to health care and medicines.

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

  Provides for the minimum conditions of employment that employers must comply with in their workplaces.

- **State Information Technology Act, 1998 (Act No. 88 of 1998)**

  Provides for the creation and administration of an institution responsible for the State's information technology system.

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

  Establishes a framework to regulate key aspects of the relationship between employer and employee at individual and collective levels.

- **The Division of Revenue Act, 2003 (Act No. 7 of 2003)**

  Provides for the manner in which revenue generated may be disbursed.

- **Skills Development Act, 1998 (Act No. 97 of 1998)**

  Provides for the measures that employers are required to take to improve the levels of skills of employees in workplaces.

- **Preferential Procurement Policy Framework Act, 2000 (Act No. 5 of 2000)**

  To give effect to section 217 (3) of the Constitution by providing a framework for the implementation of the procurement policy contemplated in section 217 (2) of the Constitution; and to provide for matters connected therewith

- **Employment Equity Act, 1998 (Act No. 55 of 1998)**

  Provides for the measures that must be put into operation in the workplace in order to eliminate discrimination and promote affirmative action.

- **The Copyright Act, 1998 (Act No. 98 of 1998)**

  To regulate copyright and to provide for matters incidental thereto.

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

  Provides for the promotion of black economic empowerment in the manner that the state awards contracts for services to be rendered, and incidental matters.

- **State Information Technology Agency Amendment Act, 2002 (Act No. 38 of 2002)**

  To provide for the establishment of a company that will provide information technology, information systems and related services to, or on behalf of, participating departments and in regard to these services, act as an agent of the South African Government; and to provide for matters connected therewith.

- **Electronic Communication and Transaction Act, 2002, (Act No. 25 of 2002)**

  To provide for the facilitation and regulation of electronic communications and transactions; to provide for the development of a national e-strategy for the Republic; to promote universal access to electronic communications and transactions and the use of electronic transactions by SMMEs; to provide for human resource development in electronic transactions; to prevent abuse of information systems; to encourage the use of e-government services; and to provide for matters connected therewith.

- **Competitions Act, 1989 (Act No. 89 of 1998)**

  To provide for the establishment of a Competition Commission responsible for the investigation, control and evaluation of restrictive practices, abuse of dominant position, and mergers; and for the establishment of a Competition Tribunal responsible to adjudicate such matters; and for the establishment of a Competition Appeal Court; and for related matters.

- **Consumer Protection Act, 2008 (Act No. 68 of 2008)**

  To promote a fair, accessible and sustainable marketplace for consumer products and services and for that purpose to establish national norms and standards relating to consumer protection, to provide for improved standards of consumer information, to prohibit certain unfair marketing and business practices, to promote responsible consumer behaviour, to promote a consistent legislative and enforcement framework relating to consumer transactions and agreements.

4.2 Policy Mandates

The Authority, as an organ of the state, is obliged to discharge its policy mandate in a coherent manner, which is consistent with the National Development Plan (NDP) Vision 2030, Medium Term Strategic Framework (MTSF) Priorities and the policy of the National Department of Health (NDoH).

The following table reflects NDP goals, MTSF Priorities and NDoH strategic goals that are aligned with the SAHPRA strategic goals.

Table 2: Health strategic issues and priorities

NDP Goals 2030	MTSF Priorities	NDoH strategic goals 2014 - 2019
Average male and female life expectancy at birth increased to 70 years	HIV&AIDS and TB prevented and successfully managed Maternal, infant and child mortality reduced	Prevent disease and reduce its burden and promote health
Tuberculosis (TB)prevention and cure progressively improved		
Maternal, infant and child mortality reduced		
Prevalence of non-communicable diseases reduced		
Health System reforms completed	Health care costs reduced	Improve financial management by improving capacity, contract management, revenue collection and supply chain management
	Efficient health management information system for improved decision making	Develop an efficient health management information system for improved decision making
	Improved quality of health care	Improve the quality of care by setting an monitoring national norms and standards, improving systems for user feedback, increasing safety in health care and by improving clinical governance
Primary health care teams deployed to provide care to families and communities	Re-engineering of Primary health care	Re-engineer primary healthcare by: increasing the number of ward base outreach teams, contracting general practitioners, and district specialist teams and expanding school health services
Universal Health coverage achieved	Universal health coverage achieved through implementation of National Health Insurance	Make progress towards universal health coverage through the development of the National Health Insurance scheme, and improve the readiness of health facilities for its implementation.

The following SAHPRA goals will contribute to the above priorities outlined in table 2.

Goal 1: Publicly demonstrate responsiveness and accountability as an effective and efficient high performance organisation.

Goal 2: Timeous regulatory decision taken on medicines and medical device applications to ensure compliance to defined standards of quality, safety, efficacy and performance.

Goal 3: Re-evaluate and monitor medicines and medical devices periodically.

Goal 4: Investigate, monitor, analyse, solicit and act upon existing and new adverse events, interactions, information with regard to post-marketing surveillance and vigilance.

Goal 5: Ensure regulatory compliance through a process of active Inspections and investigations.

Goal 6: Evaluate clinical trial protocols in accordance with defined standards.

Goal 7: Evaluate the applications for sale of unregistered health products in accordance with defined standards.

Goal 8: Establish and strengthen collaborative initiatives with any other regulatory authority or institutions in order to achieve the objects of the Medicines Act.

Goal 9: SAHPRA is capacitated by adequate, competent and motivated Human Capital.

4.2.1 Antimicrobial Resistance National Strategy Framework 2014 – 2024

The National Department of Health Antimicrobial Resistance (AMR) National Strategy Framework 2014 – 2024 includes *Sub-objective 4.1: Ensures access to safe, effective and affordable antimicrobials*

The availability of antimicrobials according to the national standard treatment guidelines and essential medicine list needs to be sustainable. Robust regulatory and medicine management systems, including procurement, distribution and dispensing systems are needed to support regulated access to safe, effective and affordable antimicrobials.

AMR is a global challenge and a threat to public health and safety. Through its mandate, SAHPRA will support the national AMR strategic framework through ensuring availability of safe, efficacious and good quality antimicrobial medicines; promoting their rational use; and implementing appropriate post-marketing surveillance mechanisms, including use of laboratory testing systems to monitor quality and vigilance reporting systems.

SAHPRA will be working with key stakeholders, including the Department of Agriculture, Forestry and Fisheries (DAFF), to ensure improved controls and appropriate use of antimicrobials. In this regard, SAHPRA has already begun engaging these stakeholders to preserve key antimicrobials such as colistin through stricter controls to mitigate the development of resistance.

Further, there are gaps and overlaps between the mandates of DAFF under Act 36 and the mandate of SAHPRA under the Medicines Act. SAHPRA will continue to dialogue with DAFF and the NDoH in this regard.

4.2.2 National Health Insurance

The government has tabled the National Health Insurance (NHI) in a bid to expand accessible healthcare to all South Africans and to provide universal coverage of health services, while controlling costs. The Authority must streamline operations and optimize output as a key role player in addressing public health priorities. This will necessitate urgent attention to optimize processes and mechanisms that enhance efficiency in the registration of health products and ensure their quality, safety, efficacy and appropriate use.

It remains important for the Authority to entrench a regulatory role in contributing to significant improvements in health outcomes, patient safety and cost saving in the overall care of patients.

The Authority therefore remains an asset and a key role player within the National Health framework.

4.2.3 The National Drug Policy (1996)

Health objectives of the National Drug Policy are to ensure the availability and accessibility of essential drugs to all citizens, to ensure the safety, efficacy and quality of drugs, to promote the rational use of drugs by prescribers, dispensers and patients through provision of the necessary training, education and information and to promote the concept of individual responsibility for health, preventive care and informed decision making.

SAHPRA has a longstanding partnership with the NDoH for the delivery of mandates on National Drug Policy. The Authority sees its role as critical in partnering with the Department to achieve the vision for a long and healthy life for all South Africans, and will continue to actively engage and work collaboratively with the Department and other stakeholders to ensure synergy.

4.3 Relevant court rulings

Court rulings currently relevant to SAHPRA are operational and not strategically relevant.

4.4 Planned Policy Initiatives

The Medicines Act will be reviewed and proposed amendments submitted for consideration in order to align with the current legislative dispensation and clarify areas of overlap with other legislation.

5 SITUATIONAL ANALYSIS

5.1 Performance Environment

5.1.1 Background

The South African Health Products Authority (SAHPRA) is the Authority of South Africa, which is responsible for the regulation of health products intended for human and animal use, the licensing of manufacturers, wholesalers and distributors of medicines and medical devices, radiation emitting devices and radioactive nucleides; and the conduct of clinical trials.

The legislative mandates of SAHPRA are derived from the Constitution; the National Health Act, 2003 (Act No. 61 of 2003); the Medicines and Related Substances Act, 1965 (Act No. 101 of 1965), as amended (herein after referred to as "the Medicines Act"), and other relevant legislation, regulations and policies.

Further, SAHPRA's mandate has expanded to include the regulation and control of radiation emitting devices and radioactive nucleides into the scope of the Authority which appears in the Medicines Act and the Hazardous Substances Act, 1973 (Act No. 15 of 1973); both of which provides for the regulation and control radiation emitting devices and radioactive nucleides.

5.1.2 Analysis of Key Regulatory Technical Areas and Capacity

A high level analysis was undertaken of work conducted by various technical task teams and project teams involved in reviewing key legislative, programmatic, infrastructural, structural and operational aspects required to amend relevant legislation and consider transitional measures from the MCC to SAHPRA over the last decade. This analysis generated a number of key areas requiring consideration for the establishment of the new entity. The most recent and relevant issues, identified by the Health Products Technical Task Team (HPTTT) in 2014[1], are discussed broadly in the next sections and were considered in developing the Annual Performance Plan (2018/19) and organisational structure for SAHPRA.

a) Medicine Registration Applications

Whilst the Authority has established target time lines internally for the evaluation of generic medicines and new chemical entities (NCEs), the historical policy framework and constraints in the MCC's registration process has resulted in these timelines not being met on a continuous basis, with the consequent development of a significant backlog in the processing of applications for medicine registration and for amendments to dossiers. These delays could have an impact on the availability of medicines in the country with potentially adverse consequences for public health as well as an impact on the pharmaceutical industry.

[1] Health Products Technical Task Team HPTTT Report, 11 June 2014

A change in the approach to the registration of medicines is required through streamlining procedures and processes, adopting project management systems as well as engagements and information sharing with other NRAs. This approach, together with improved information management systems and an appropriate strategy for staff capacity building, will contribute to the attainment of a long term and sustainable solution and will facilitate timely access to much needed medicines.

b) Increasing Post-Registration Amendment Workload

A significant backlog of work currently exists in the assessment of post-registration amendment applications with the result that products often cannot be marketed until these have been addressed.

The Post-Registration Units are challenged by an ever-increasing workload due to the larger number of products registered, which are continuously being amended. A significant factor in the workload of these unit is that applicants tend to submit a large number of amendments immediately after registration of their products. This is often caused by the major delays in the time from first application to the time of final registration.

A large number of these amendments relates to the sourcing of Active Pharmaceutical Ingredients (APIs) from a cheaper supplier in Industry's endeavour to drive down the cost of medicine production. These require a significant additional amount of work and, in some instances, the final dossier resulting from these amendments is profoundly different from the original application approved by SAHPRA.

The number of package insert amendment applications and post-registration quality amendment applications has also increased significantly and are required to be reviewed by the same pool of evaluators for registration assessments, resulting in a further exacerbation of the workload. More technical evaluators are required to handle the increased amendment requests timeously so as to ensure that required medicines are available on the market.

Many applicants who apply for state tenders often make changes to their dossiers to facilitate better pricing and submit these requests at short notice, placing additional pressure on the Post-Registration Unit. These changes relate to manufacturing sites, packaging materials and additional/alternate sources of APIs and are often submitted in respect of priority public health products required including antiretroviral and TB medications. As a result, staff are constantly under pressure to expedite these reviews which constitute a significant technical and administrative workload. Furthermore, fast-tracking of these applications often disadvantages other applicants in the queue and makes the interpretation of the backlog challenging.

c) Backlog Project

The analysis of the performance environment outlines some of the constraints that have contributed to inefficiencies in the current system with specific recommendations to address each one. In addition, the Board will establish the Technical Operations and Regulatory Strategy (TORS) Committee whose mandate is to develop an integrated plan to address the backlog with approaches that will

allow regulatory assessment of all products in a defined, achievable but ambitious timeline.

This will be financed from the envisaged increase in revenue generated through increased fees. The new fee structure will be a departure from the historical fees charged in the MCC era, nevertheless this can be justified by the establishment of a bold, refocused operational framework including the measurement of outcomes.

d) Skilled and Suitably Qualified In-House Employees

Whilst the regulatory workload has rapidly increased over the years, this has not resulted in a comparable increase in suitably qualified external evaluators or experienced in-house technical and administrative staff. The pool of external evaluators, with the range of expertise required, are almost all part-time evaluators, concurrently holding full-time positions at universities and other scientific and educational institutions. Many are also appointed as members of the Authority itself and/or one or more of its committees.

The pool of qualified and trained evaluators without industry conflict of interest, willing to do this work, has been decreasing and those remaining have become burdened with an increasing workload.

In addition, few full-time in-house staff work as evaluators currently. External reviewers are currently not being engaged through formal systems of performance agreements and as a result, productivity and the quality of evaluation reports are not routinely monitored and managed, resulting in variable performance outcomes. Further, transfer of skills to in-house evaluators to support in-house capacity strengthening is inadequate. In addition, SAHPRA will conclude performance agreements with all the Authority external evaluators to enable performance appraisal, and this should include the transfer of critical evaluation skills to in house staff and the use of external evaluators to undertake peer review of dossiers regarded as best practice by WHO.

Furthermore, to ensure consistency of standards in respect of technical evaluations and report-writing, a system of quality assurance will be implemented similar to that adopted by other national medicines regulators. Using best practice examples from other regulatory authorities, new strategies for the optimisation of the work of external evaluators will be considered including asking evaluators to join staff for a designated time period to undertake a predetermined work agenda.

There remains a need to expedite the appointment and train a pool of competent, full-time in-house evaluators to improve efficiencies and turn-around times of review work. Besides the evaluation of applications, there are many technical tasks that are required, prior to allocation for evaluation, supporting the evaluation process, preparation of minutes of meetings, and technical engagement with applicants and evaluators. The shortage of technical staff with pharmaceutical regulatory knowledge and experience is also a contributing factor to the current delays being experienced hence the urgent need to expand this pool of personnel. Additional technical staff will be appointed to address the regulatory workload, supported by appropriate training and capacity building.

e) Case Management in the Evaluation Process

Streamlining evaluation procedures and processes through a case management approach is a cornerstone of Good Regulatory Practice and will contribute to improving the efficiency of regulatory functions and activities in a predictable, transparent and decisive manner. In this framework, applications received are allocated to case managers who oversee the evaluation process and ensure all applications are evaluated within prescribed time lines. Case or portfolio managers are responsible for managing resources, planning and scheduling of reviews and case team meetings, and communication with applicants. They are aware of the status of each application at any point in time. The case managers are also the first point of call for responding to external queries related to the applications. There is a need to adopt case management systems used by similar organisations elsewhere, such as the approach implemented by the regulatory authority of Switzerland i.e. SwissMedic and others.

f) Economic Implications

The global economic downturn over the last few years has resulted in many applicants exploring cheaper sources of materials and labour. This has had a significant impact on amendment applications especially since APIs are the most expensive component in a product. Cheaper manufacturers, packaging material, etc., all result in major changes to the dossier initially registered, yet the staff complement has not been adjusted to compensate for this. This will be addressed in the framework for the backlog project.

g) Consultants and Contract Staff

Several attempts to alleviate the backlog have been made. These included the use of short-term consultants or contract staff. In all instances these contract personnel have required training, mentoring and orientation by internal staff on evaluation and reporting procedures, often compromising productivity of experienced staff. A further concern is the short-term nature of these contracts since many of these personnel only develop the required proficiency with the work towards the end of their contracts. In addition, the consultants claim more hours and higher rates for doing submissions, when compared to internal staff. This capacity building initiative will be better invested in full time staff who are retained and whose professional development progresses with the Authority's needs.

h) Regulation and Control of Active Pharmaceutical Ingredients

The adoption of a regulatory framework and inspection system for Active Pharmaceutical Ingredients (APIs) on a global level has laid the basis for harmonization and/or mutual recognition of API requirements. In South Africa, production of APIs is very limited currently and, as a result, experience in the inspection of API facilities is, likewise, limited. There is a need for strengthening the capacity of inspectors to support inspections and assessment of API sources. There is also a need for the Authority to participate in international networks to ensure harmonization of API requirements.

i) Clinical Trials

Currently all Phase 1 - 3 clinical trials require regulatory approval by SAHPRA. These include studies with new chemical entities as well as those for new indications, dosages and formulations of currently registered products. Generally, Phase 4 trials, in line with approved indications and dosages, do not require formal approval but are required to be notified to the Authority. However, more rigorous Phase 4 studies may be required in future as approaches to registration change in response to the need to get selected products urgently from Phase 3 studies out into the marketplace, and SAHPRA must be prepared to respond to these changing demands. In addition, in-house capacity must be strengthened to review applications for bioavailability studies for generic medicines.

Applications to conduct a clinical trial are reviewed by the Clinical Trials Committee (CTC) and recommendations are made for approval. The CTC meets on a 6-weekly basis and typically reviews approximately between 20 – 40 studies during each cycle (approximately 240 per annum).

All applications for clinical trial amendments currently require formal approval and are either handled within the Unit (e.g. investigator and site changes, minor administrative amendments) or forwarded to a CTC evaluator for review (e.g. major protocol amendments). There are challenges in that the Unit is heavily reliant on the external reviewers who have their primary jobs elsewhere. In addition, there is lack of information management systems and human capacity. There is a need to strengthen internal capacity with more full time internal professional staff and to also participate in international networks to ensure harmonization of clinical trials requirement

j) Vigilance

Much work has already been undertaken by the Authority in identifying gaps in the current vigilance framework and the additional strategies needed under SAHPRA. New strategies will include implementation of Good Vigilance Practice standards and a Quality Management System (QMS) for vigilance activities; implementing risk management strategies (plans) in regulatory decision-making (product registration); strengthening oversight of therapeutic effectiveness, misuse, abuse, overdosing, off-label use and quality issues; developing a framework for feedback and communication of vigilance-related matters to stakeholders. Efforts will be made to enhance capacity of the pharmacovigilance system including improving the quality of reports and increasing reporting rates. In addition, there should be stronger linkages made with programmatic vigilance activities such as the EPI programme for Adverse Events following Immunisation (AEFI) monitoring and the ARV programme monitoring, and linkages to the National Health Laboratory Service for antimicrobial resistance (AMR) monitoring.

Following the need for a reappraisal of the old Paradox database system being used for the management of Adverse Drug Reaction (ADR) reports, relative to other vigilance databases with higher levels of functionality, the WHO VigiFlow system was procured using WHO funding. This allows direct reporting from the Authority's VigiFlow system into the WHO database (Vigibase) in Uppsala, Sweden and will also facilitate a switch from onerous paper-based reporting to electronic reporting of ADR reports by manufacturers and health professionals. However, additional formal systems to strengthen the vigilance of complementary, veterinary medicines and

medical devices will be required as the regulatory frameworks for these products are being implemented. Additional software will be required for reporting of veterinary ADR reports as the current software is incapable of reading veterinary terminology.

In light of the above, minimum functions and standards have been established in anticipation of the start of the Authority. Under SAHPRA more work will be done to further strengthen this system including enhancing stakeholder and public communication in response to identified safety-related issues.

k) Regulation of Biological Products

The number of biological products requiring regulation has expanded rapidly as a result of the remarkable growth of research in biotechnology and related scientific advances. The regulation of biological products relies on complex regulatory decision-making through a wide range of activities that begin with premarket product review, continue throughout all aspects of product production, and extend to post-market review and follow-up.

Increasingly, the effective regulation of newer emerging technologies in this area, such as biosimilars, will require the development of innovative regulatory strategies and standards as well as coordinated partnerships with other NRAs and agencies. There is a need for substantial skills development within the Authority in strengthening both evaluation capacity and inspections in this area.

l) Complementary Medicines

Draft regulations for Complementary Medicines (CMs) were initially published in July 2011 for comment by the industry and other relevant stakeholders. Following this process, an amendment to the General Regulations to the Medicines and Related Substances Act, 1965 (Act No. 101 of 1965) was published in November 2013 and in August 2017 to enable implementation of a regulatory framework for CMs. These regulations require all companies selling complementary medicines to register their products with the regulator following a phased approach as per the various call-up time lines as identified. The General Regulations to the Medicines Act were published on 25 August 2017 to allow for an amendment to the CMs definition and to identify “Health Supplements” as an additional group of products to be regarded falling within the CMs definition. These products will be called up over time and regulatory oversight over these type of medicines will be established.

Guidelines on application procedures and requirements were developed by the MRA and approved by SAHPRA to assist applicants submitting applications for registration. These guidelines have been published on the SAHPRA website. Furthermore, the procedures and systems other NRAs with experience in regulating CMs have been assessed to determine optimum models/ regulation and best practice.

Administrative procedures for the receipt of these applications have been established and will follow the same pathway as that of all other medicines.

A dedicated information management system for the regulation of these CMs products is required and will need to be integrated into the proposed IT framework.

Specific regulatory expertise for CMs is currently limited within SAHPRA. There is a need to expedite the training of both existing in-house staff as well as new staff

planned for the unit. This could be achieved by formal training programmes on dossier evaluation, supported by mentoring from committee experts. To date the CMs unit together with the chair of the Complementary Medicines Committee have undertaken study visits to identified NRAs i.e. TGA (Australia) and Health Canada to collect information on the regulatory oversight of CMs by these 2 NRAs (TGA and Health Canada are regarded as the leaders in overseeing the regulation of CMs).

There is a need to strengthen the understanding and culture for regulation within the CMs industry to ensure compliance, since this is a previously unregulated industry. In this regard, a forum under the Industry Task Group (ITG) has been set up to engage industry on dossier compilation, and related regulatory requirements. To this end SAHPRA has set up a number of workshops to engage the CMs Industry and explain regulatory requirements.

m) African Traditional Medicines

The MCC at its meeting of 29-30 September 2016 established a Working Group to investigate its role in the regulation of African Traditional Medicines (ATMs) produced for bulk sale (i.e. not ATMs compounded by an individual healer for a specific patient). This followed recommendations of the Complementary Medicines Committee (CMC) to Council to consider provision for regulation of ATMs. A draft framework for the control and regulation of ATMs was developed by the Working Group and presented to Council for consideration. Work on the draft framework is still ongoing and includes dialogue with the African National Healers Association.

n) Veterinary medicines

In South Africa, three pieces of legislation govern the registration and evaluation of veterinary medicines, namely:

- the Medicines and Related Substances Act, 1965 (Act No. 101 of 1965) as amended,
- the Fertilizers, Farm Feeds, Agricultural and Stock Remedies Act, 1947 (Act No. 36 of 1947) administered by the Department of Agriculture
- the Foodstuffs, Cosmetics and Disinfectants Act, 1972 (Act No. 54 of 1972) that governs the maximum limits for veterinary medicines & stock remedies present in foodstuffs.

There is concern that the different set of control systems under the dual system for registration of veterinary medicines poses a challenge to public health and has an impact on the outcomes of the Animal Diseases Act, 1984 (Act No. 35 of 1984) and the Meat Safety Act, 2000 (Act No. 40 of 2000).

A number of medicines gazetted in the schedules and utilised as veterinary medicines are exempted from scheduling under Act 101, 1965 and registered under Act No. 36 of 1947. Some of these veterinary medicines have active ingredients that are also used for human purposes.

Discussions between the NDoH and Department of Agriculture, Forestry and Fisheries (DAFF) are underway to propose harmonisation and the way forward to the best interest of the public and animals. The importance of these discussions have been highlighted by the need to protect antibiotic use in animals and humans against the backdrop of growing antimicrobial resistance. Colistin was the first antibiotic discussed by the MCC and DAFF and the Ministerial Advisory Committee on AMR.

New regulatory requirements were established for colistin use in animals as a result. This approach will be used as the basis for future attempts to preserve antibiotics for appropriate human and animal use.

o) Medical Devices

Regulations were published on 22 April 2014 as an amendment to the General Regulations to the Medicines and Related Substances Act, 1965 (Act No. 101 of 1965) for a comment period of 3 months. These regulations provide for a regulatory framework for medical devices based on risk. On the 9th December 2016, Government Gazette No. 1515 relating to the Medical Devices was published. A phased approach to implement this area of regulation included first to roll out establishment licensing and to subsequently phase in product registration once collaborative agreements were finalised with the national conformity assessment body (SANAS) and other similar globally recognised programmes.

The model being proposed for regulating medical devices follows recommendations made by the International Medical Device Regulatory Forum (IMDRF) previously known as Global Harmonisation Task Force (GHTF). In line with this framework, IMDRF guidelines are being adapted and adopted. These guidelines have been published for Stakeholder comment and implemented in 2017. There is a need, however, to expedite engagements with other NRAs to examine procedures and systems as well as explore information sharing mechanisms. Two of the leading NRAs in this area are the MHRA in the UK and the Japan regulatory authority.

A fee structure for Medical Devices has been developed and is awaiting discussion, after which it will be published for public comment and then submitted to the Minister of Finance for approval and implementation.

There are currently no formal systems, with the exception of radiation control, for monitoring the safety quality and performance of medical device products in the marketplace. There is a need for a vigilance system in line with the proposed regulatory framework and benchmarking systems for reporting and assessment reports with identified reference NRAs.

The Inspectorate Unit has been exposed to requirements and procedures for inspecting manufacturing sites through engagement with the WHO Pre-Qualification Programme (PQP). There is a need for additional capacity building of inspectorate Unit staff through formal training programmes (e.g. NRAs and GHTF), and co-inspections. Having said that, it is the intention that inspections of these facilities and registration of these products would likely be conducted by identified conformity assessment bodies accredited by SANAS. In addition, SAHPRA will acknowledge and accept accreditation received by international conformity assessment bodies from the IMDRF member countries including the WHO.

SAHPRA will be required to perform *ad hoc* inspections as the regulator to ensure compliance by SANAS, and any other conformity assessment body with standards i.e. ISO 13485 as well as performing *ad hoc* inspections at manufacturing sites to verify compliance with standards.

A dedicated information management system for the regulation of these products is required and will need to be integrated into the EDMS and the proposed related IT framework. Human resources to support the regulatory requirements will need to be appointed and the unit strengthened to allow for the necessary oversight. To date

the unit has received in excess of 1 000 applications for an establishment licence indicating the size of the Industry.

Specific regulatory expertise for medical devices is currently limited within SAHPRA and this will require an expanded workforce capacitated to undertake this work. To date the Authority has engaged extensively with industry, WHO and the IMDRF on the proposed regulatory framework and related compliance. This engagement will need to continue in the future.

p) Benchmarking of Good Practices

In line with its mandate to engage key regulatory stakeholders, the HPTTT met with representatives of the FDA during 2013 and 2014 and undertook visits to MHRA, EMA and SwissMedic to examine and benchmark procedures in identified technical and operational drug regulatory areas as well as to explore mechanisms for capacity building, information sharing and systems to establish mutual recognition for registration requirements and product approvals.

The HPTTT has also engaged extensively with WHO to define areas of support for regulatory system strengthening and capacity building in identified technical areas including vigilance systems, medical devices, quality management systems (QMS), and the training of inspectors in APIs, Biologicals and blood products regulation.

The WHO Good Regulatory Practices (GRP) has been accepted as the benchmark towards which to model the regulatory system strengthening of the Authority to ensure its effective contribution to public health. In addition, the MCC and SAHPRA have had workshops with the Centre for International Regulatory Science (CIRS) to explore new regulatory approaches that involve reliance on other NRA evaluations and which assign different levels of review for different categories of submission.

The discussions and visits to NRAs and alignment to WHO GRP were aimed at maximizing the regulatory capacity and operations needed by the Authority, through understanding the structure and functioning of these agencies, in conformance with international regulatory best practice standards. This will ensure that once established, the Authority will fulfil its mandate of delivering safe and efficacious products that are of good quality, in a timely manner whilst recognising the current limitations of skills and resources.

These visits focused on various aspects of the structure and functioning of these agencies and allowed a comparative assessment of the organizational structure and scope of work, human and other resource allocation, fees and budget, and international collaboration and market authorisation procedures of these agencies with that proposed for the Authority.

It was clear from these visits that SwissMedic, as a similar sized agency to that proposed for SAHPRA and which has also recently undergone a transition, would be a useful benchmark for the transition to the Authority. The visit to SwissMedic highlighted the need to prioritise resource planning which is deemed to be a critical success factor to meeting regulatory obligations and timelines. SAHPRA must ensure that issues relating to infrastructure, processes and systems and availability of internal skilled evaluators are adequately addressed.

For the NRAs visited, information technology plays a critical role in all regulatory processes. For the Authority, improving the current IT infrastructure will significantly

enhance operational efficiencies in all areas and also contribute to reducing delays in the regulatory workload.

The current application evaluation process in the Authority will benefit from a case management or project management approach which co-ordinates the overall application process including resources, allows the status of an application to be known at any point in time, and improves registration timelines. This approach has been cited by both EMA and SwissMedic as a critical success factor in meeting their regulatory time lines. Implementation of this approach should be expedited.

A standardised framework, supported by a quality management system (QMS), for producing evaluation reports will be adopted to ensure the consistency of technical reviews, improve the quality of evaluation reports, as well as facilitate information exchange and sharing with other NRAs.

As described in the proposed new SAHPRA communication strategy, regular and consistent communication with key stakeholders is necessary to communicate the value of the regulator as well as create a culture of transparency.

q) Quality Management Systems

A competent regulatory authority needs to ensure transparency, consistency and efficiency in the implementation of its procedures, processes and systems in accordance with established Quality Management (QM) principles. Moreover, resources made available to the authority either through industry fees or fiscal contributions must demonstrate effective, efficient, prudent and transparent use. For the Authority, a QM framework which drives the identification of needs, consideration of performance indicators and comparison of best practice procedures will enable the development of an integrated business management system and control of processes to ensure Good Regulatory Practices in line with international standards. This is also important in the context of increased cooperation with key international regulatory partners.

Recently (September 2017) the WHO has amended the definition of “Stringent Regulatory Authority” to reflect the requirements as “A NRA listed by the WHO”. In order to be listed as a stringent authority by the WHO, the NRA needs to establish a QMS and apply to WHO for assessment. A Quality Management Systems (QMS) approach needs to be implemented across all the Authority functions from the date of its commencement. This is one of the critical requirements for the Authority to focus on seeing that the Directorate: Inspectorate has a well-established (albeit outdated) QMS, the Authority can build on the existing framework to develop an overarching QMS.

r) Capacity Building for Regulatory Sciences

The constrained human resources environment for qualified regulatory personnel both in South Africa and in the region highlights the need for a comprehensive strategy to build capacity and develop the scarce skills required to ensure strong regulatory systems for all health products to be covered under the Authority. It is clear that the regulatory workload proposed for the Authority needs to be supported by attracting more technical evaluators as well as building this capacity amongst in-house personnel. There is an immediate need to increase the number and capacity of regulatory staff, including developing a sustainable pool of experts to evaluate

dossiers for health products. Concomitant with this, as an independent structure the Authority should review evaluators salaries and consider competitive rates for payment.

Currently the Authority implemented a pilot training programme in collaboration with local universities targeting young MSc and PhD graduates in the pharmaceutical, clinical and biological sciences. In the short term, it is anticipated that this framework will produce a new pool of graduates who are able to evaluate dossiers and other regulatory applications, as well as having required insights to work within the new SAHPRA framework. While it is estimated that it takes approximately two years to train a competent evaluator, with ongoing mentorship, this cohort will address the pressing need to increase the pool of evaluators and that of other key regulatory personnel within the Authority.

The CEO of the Authority will be tasked with developing short- and medium-term strategies to expedite the training and capacity-building required for regulatory staff. Should additional funds be required for this purpose, the Board will support the CEO in identifying these funds.

s) Information Technology Assessment

Information technology (IT) plays a significant role in all regulatory processes. This is witnessed in other comparable regulators from other countries. To date the MCC did not benefit from appropriate information management utilisation. The MCC and now SAHPRA still receives a substantial proportion of paper-based submissions resulting in the accumulation of large volumes of paper which then has to be triaged, filed and stored. The MCC struggled to stay abreast of managing the paper trail while also trying to cope with growing numbers of applications that need to be processed within reasonable timelines.

The paper-based and legacy IT systems are completely inadequate for the task of expanded health product regulation and there is widespread agreement that a seamless, paperless electronic submission and management system, engineered to offer high levels of security and user-friendliness, are essential pre-requisites for the establishment of the Authority.

A well-functioning IT system is a key support component in resolving the current delays in regulatory decision-making and will contribute to improving the delivery of quality services. A functional, end-to-end electronic document management system will allow for tracking the status of applications throughout the review cycle.

The Authority has initiated a project to improve its current paper-based regulatory processes by deploying an electronic document management system (EDMS), including use of the electronic Common Technical Document (eCTD) format to support application and registration procedures for new products and amendments, as well as manage all related documentation and regulated products, including medical devices.

The current IT system will support SAHPRA's expanded mandate and be designed to regulate a comprehensive array of health products. This is a huge expansion in the scope of regulation within an environment of an increasingly dynamic industry, higher ethical and public expectations and a demonstrable need for improved efficiency and effectiveness. These pose a very significant IT challenge. Done correctly it will provide opportunities to generate the income needed from the various

sectors it plans to regulate. Done incorrectly, it may lead to increasing delays in registration and regulatory decision-making, and the resentment of both industry and the public.

The proposed IT system should have a variety of seamlessly integrated sub-systems that combine functionality, efficiency and effectiveness with ultra-high security.

Related to the need for the implementation of a fit for purpose IT system will be in the medium term, consideration for the Authority to move to new premises where a custom made IT system and the interface with the public more broadly can be enhanced.

t) Communication Strategy

It is recognised that the resource constraints experienced by the MCC previously had prevented the development of an effective communication strategy. It was noted that when critical new strategies have been introduced, the Authority has lacked capacity to effectively communicate with the public leading to distrust and confusion, as was shown with the recent implementation of the new CMs regulations.

The Authority will need to implement a carefully developed, adequately funded communication strategy led by a Communications Officer. In this regard it endeavours to:

- Implement an ongoing and comprehensive effort to ensure that all its stakeholders understand the roles and values of the regulator.
- Work in a transparent manner and timeously explain future plans and strategies, and explains all its decisions and the reasons that support those decisions.
- Develop mechanisms to allow all stakeholders to communicate easily with the regulator including being able to lodge queries and complaints.
- Develop innovative strategies to gauge feedback from stakeholders including consideration of patient groups, journalist briefings and a hotline for applicants.
- Have a public engagement strategy utilising a multimedia approach that addresses the different categories of stakeholders including the lay public, health professionals and the pharmaceutical industry.
- Have a proactive relationship with the media and that selected categories of staff are trained to respond to the media.

u) Radiation Control

A new mandate for SAHPRA is the regulation of all electromedical devices and radioactive isotopes for medical use. These products are categorised into two groups, namely Group III and Group IV as defined in the Hazardous Substances Act. SAHPRA will pursue product registration for Group III and IV hazardous substances and will implement appropriate post-marketing surveillance to monitor product performance and safety. NDoH staff in the Radiation Control Unit responsible for this expanded mandate of the Authority will be transferred to SAHPRA.

Further, it is envisaged that Group I and Group II hazardous substances under this Act will be regulated by the National Nuclear Regulator. As this is a new portfolio for SAHPRA, there will be an immediate need for the Authority to dialogue with the relevant stakeholders including affected staff in this regard, and to review current strategies and amend these as required.

5.2 Organizational Environment

SAHPRA was established as a Schedule 3A public entity with operational autonomy and accountability and with responsibility for regulation of all medicines including complementary medicines, medical devices and *in vitro* diagnostics, and for radiation emitting devices and nucleides. This includes the regulatory compliance functions and oversight of clinical research and vigilance. The MCC largely focused on the regulation of medicine and therefore SAHPRA is a completely different entity in terms of breadth of function and potential size.

SAHPRA is accountable to the Minister of Health through a Board. The SAHPRA Board is responsible for appointing the Chief Executive Officer (CEO) after consultation with the Minister and for overseeing the performance of the CEO and the Executive Management of SAHPRA. The Board was appointed by the Minister on 2nd October 2017. The MRA and the MCC dissolved on the 31st January 2018, the day preceding the first meeting of the Board. The functions were absorbed into the Authority and restructured to best meet the required regulatory objectives.

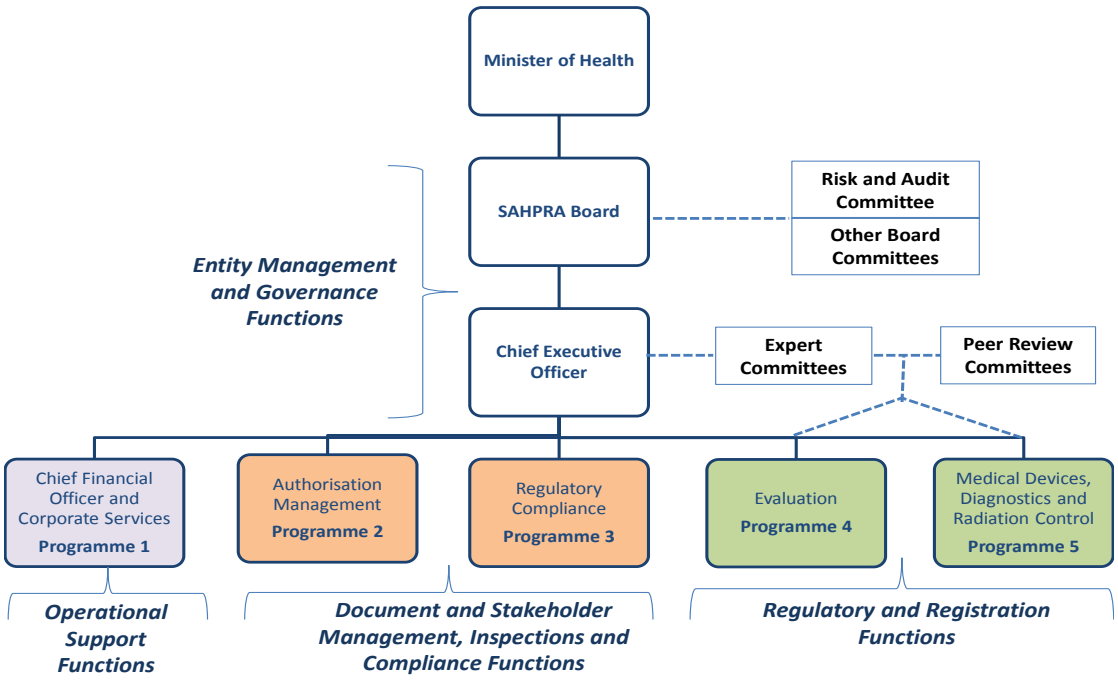
The Board has appointed committees to assist with performance of its functions. The Acting CEO was appointed by the Board following consultation with the Minister of Health. The Authority's functions, staff and assets will be transferred from the NDoH pending agreement with the Bargaining Council.

Full implementation is being phased in, taking into consideration the need to minimise disruption of existing regulatory processes and retention of existing scarce skills and capacity including external evaluators and technical committee members, and the financial constrains at the time. The appointment of new senior staff in SAHPRA will be treated as a priority for action by the Authority.

5.2.1 SAHPRA Organizational structure

The Authority will position itself as a professional, technically competent regulatory organisation. The Authority is an independent entity and will operate on sound business principles. Once fully established, SAHPRA will be comparable to other relevant international regulatory authorities. The macro structure of SAHPRA is provided in Figure 1:

Figure 1: MACRO ORGANISATIONAL STRUCTURE OF SAHPRA



SAHPRA is a Schedule 3A Public Entity. The Authority reports to the Minister of Health via a Board. The Executive Authority (Minister) appoints the Board (Accounting Authority). The Board appoints, from amongst its members, committees to support the work of the Board. The Authority's CEO is appointed by the Board, after consultation with the Minister and the CEO reports to the Board.

The Authority has 5 programmes to support its functions, namely;

- Programme 1: Administration
- Programme 2: Authorisation Management
- Programme 3: Inspectorate and Regulatory Compliance
- Programme 4: Medicines Evaluations and Registration
- Programme 5: Medical Devices Diagnostics and Radiation Control

The SAHPRA CEO appoints peer review and other committee/s to provide support to the regulatory duties. The Authority's CEO and executive committee are responsible for the management of the Authority.

In addition, the following technical committees reporting to the Acting CEO are being retained for a period of 6 months and will be subject to review:

- Names and Scheduling Committee
- GXP Committee
- Clinical Committee
- Clinical Trials Committee
- Biological Medicines Committee
- Pharmaceutical and Analytical Committee
- Complementary Medicines Committee
- Pharmacovigilance Committee
- Veterinary Medicines Committee
- Medical Devices Committee

- Legal Committee

5.2.2 Organizational Culture

The Authority's new public entity status, evolved operational model and wider ambit of regulation in varied sectors of science and technology is vulnerable to inadequate change management manifesting as poor staff morale and an entropic organizational culture, which have an impact on stability and skills retention. SAHPRA's set of values are aligned to the mission and vision of the organization and include recognition of active change management initiatives to succeed in establishing the Authority's own organizational identity.

The leadership of the organization has undertaken to build a common culture that is aligned with the organizational strategy and values. Management will over 2018-2020 be focusing on capacity building, providing staff with adequate support while measuring staff outputs and ensuring accountability. This intention is to ensure that the espoused values of the organisation's objectives and values are "lived" in an exemplary manner, and to ensure that exemplary staff is recognized.

Many of these initiatives have commenced with the roll-out of the newly adopted values through the introduction of the Authority, launching an improved automated performance management system and linkage of the recently-initiated values to the Key Performance Areas (KPAs). Non-cash incentive programmes are being explored to reward exemplary performance. These include recognition, flexi-time schedules, one-on–one coaching and mentoring, training over and above work skills plan aligned to the candidates' choice, opportunities for work-related travel, opportunities for team leadership, theme contests and team building events, stress management and wellness services and opportunities to work on challenging or opportunity creating projects. The objective is that the staff will integrate and operate cohesively to build the organization into the "employer of choice".

6 DESCRIPTION OF THE STRATEGIC PLANNING PROCESS

The process of developing this strategic plan was informed by:

- Review and analysis of key strategic documents, i.e. Policies and Strategic Plans of the Department of Health; National Treasury Framework and Guidelines; Medium Term Strategic Framework (MTSF) 2014- 2019: Outcome 2: A Long and healthy life for all South Africans; the National Development Plan (NDP): Vision 2030.
- The management team for each functional area of work participated in the compilation of this strategic plan.

This Strategic Plan, therefore, reflects the strategic goals and objectives which the Authority will endeavour to achieve over the 5-year period.

7 STRATEGIC OUTCOME ORIENTED GOALS

Goal 1:	**Publicly demonstrate responsiveness and accountability as an effective and efficient high performance organisation**
Goal Statement :	SAHPRA is an effective and efficient high performing organisation that is responsive and publicly accountable.
Indicator :	Audit Outcome

Goal 2:	**Timeous regulatory decision taken on medicines and medical device applications to ensure compliance to defined standards of quality, safety, efficacy and performance**
Goal Statement:	The Authority makes timeous regulatory decisions based on defined standards for Quality, Safety, Efficacy and Performance.
Indicator:	Regulatory decision taken within a specified timeline

Goal 3:	**Re-evaluate and monitor medicines and medical devices periodically.**
Goal Statement:	Establish a framework to ensure that registered products are periodically re-evaluated in accordance with the defined standards of Quality, Safety, Efficacy and Performance
Indicator:	Framework finalised and approved within a specified timeline

Goal 4:	**Investigate, monitor, analyse, solicit and act upon *existing* and new adverse events, interactions, information with regard to post-marketing surveillance and vigilance**.
Goal Statement:	Ensure that evidence of existing and new adverse events, interactions, signals emerging from post-marketing surveillance and vigilance is being solicited, investigated, monitored, analysed and acted upon; and establish supportive national and global partnerships.
Indicator:	Published quarterly reports of new adverse events and signals that have been assessed, actioned and concluded.

Goal 5:	**Ensure regulatory compliance through a process of active Inspections and investigations.**
Goal Statement:	Inspect and Investigate Establishments and permit holders in accordance with the defined guidelines and standards
Indicator:	% of Establishments inspected within specified timelines
	% of permits issued within specified timelines.

Goal 6:	**Evaluate clinical trial protocols in accordance with defined standards**
Goal Statement:	Clinical trial protocols are evaluated in accordance with the defined standards to ensure participant safety and data integrity.
Indicator:	% of clinical trial protocols evaluated within a specified timeline

Goal 7:	**Evaluate the applications for sale of unregistered health products in accordance with defined standards.**
Goal Statement:	Ensure that unregistered health product applications are evaluated in accordance with defined standards to ensure access only to safe, efficacious and quality unregistered health products.
Indicator:	% of applications for the sale of an unregistered health product evaluated within a specified timeline.

Goal 8:	**Establish and strengthen collaborative initiatives with any other regulatory authority or institutions in order to achieve the objects of the Medicines Act.**
Goal Statement:	Liaise with any other regulatory authority or institution with a view to exchange information with and receive information from any such authority or institution in respect of— (i) matters of common interest; or(ii) a specific investigation; and enter into agreements of collaboration with any regulatory authority or other relevant organisations.
Indicator:	Establish at least 9 collaborative relationships to support the functions of SAHPRA

Goal 9:	**SAHPRA is capacitated by adequate, competent and motivated human capital**
Goal Statement:	A functional SAHPRA with a budget and personnel to implement the Authority's mandate effectively is phased in and fully operational by 2023.
Indicator:	% of funded positions filled

PART B:
Strategic Objectives

8 PROGRAMME 1: ADMINISTRATION

8.1 Programme Purpose

To provide leadership and administration support necessary for SAHPRA to deliver on its mandate and comply with the relevant legislative requirements.

The Administration Programme plays a crucial role in the delivery of the SAHPRA services through the provision of a range of support services, such as organisational development, HR and labour relations, information technology, property management, security services, legal, communication and the integrated planning function. SAHPRA depends highly on the effective management of financial resources and procurement process as administered within the financial department. Generating sufficient revenue remains a critical focus area for SAHPRA to ensure financial viability and sustainability.

There are four sub-programmes, namely:

- **Sub-Programme 1: Financial and Supply Chain Management**

  The purpose of the sub-programme is 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. The Internal Finance unit also serves the Audit and Risk Committee, Internal Auditors, Finance Committee and National Department of Health, National Treasury and Auditor-General by making available to them information and reports that allow them to carry out their statutory responsibilities. Further, this sub-programme must seek to improve cash flow position of SAHPRA.

- **Sub-Programme 2: Governance and Compliance**

  The purpose of this sub-programme is 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.

  This sub-programme is supported by 3 functional work programmes residing within SHAPRA's corporate services. They comprise the functions found within the Office of the Board Secretary and Legal Services; the Office of Strategic Planning and Monitoring; and the Office of Quality Management.

  The purpose of the each of these programmes and their corresponding contribution to Governance and Compliance are as follows:

  - **Board Secretary and Legal Services**: To manage the corporate governance framework and legal risk of the Authority and be held legally accountable to the Authority.
  - **Strategic Planning and Monitoring**: To review existing operational processes and recommend new or changed processes and work methods to ensure optimal organisational effectiveness and to measure and monitor the Authority's performance.

- **Quality Management Systems:** To ensure SAHPRA has effective, efficient and transparent quality management policies, programmes and systems in support of achieving the Authority's objectives.

- **Sub-Programme 3: Information Technology and Communication**

  The purpose of this sub-programme is 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**

  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.

8.2 Strategic Objectives

Strategic Objective 1.1	**Establish, in a phased approach, a fully functional Authority suitably staffed to execute the mandate and goals of SAHPRA.**
Objective Statement	A functional SAHPRA with a budget and personnel to implement the SAHPRA mandate effectively is established and operationally maintained.
Indicator	% of funded positions filled
	% of Staff trained as per annual training plan
Baseline	New Indicator
	New Indicator
Target	90 %
	100 %

Strategic Objective 1.2	**Maximise performance to improve organisational efficiency**
Objective Statement	Performance agreements with employees are signed to ensure commitment to organisational efficiency and maximal performance
Indicator	% Employee performance agreements signed no later than 31 May of each financial year
Baseline	New Indicator
Target	100 %

Strategic Objective 1.3	**Develop a communication strategy to support improved external stakeholder interactions and relations**
Objective Statement	Availability of SAHPRA communication systems
Indicator	Communication strategy developed, approved and published
Baseline	New Indicator
Target	Approved communication strategy published on the website in year one

Strategic Objective 1.4	**Create public and stakeholder awareness about the mandate of SAHPRA**
Objective Statement	Ensure public and stakeholders are kept timeously updated on the relevant information relating to public safety and authority performance as it relates
Indicator	Number of media and communication events and stakeholder meetings
Baseline	New Indicator
Target	4

Strategic Objective 1.5	**Implement good governance, oversight and accountability through appropriate delegation, including financial management and compliance with PFMA requirements.**
Objective Statement	To ensure good governance, oversight and accountability through appropriate delegations to Board and management governance structures and legislative compliance.
Indicator	Audit Outcome
Baseline	New Indicator
Target	Unqualified audit report

Strategic Objective 1.6	**Ensure that the monitoring and inspection of information stored on SAHPRA Information and Communication Technology (ICT) facilities and services is done in an appropriate and responsible manner**
Objective Statement	Availability of SAHPRA IT systems
Indicator	ICT Policy developed and approved
Baseline	New Indicator
Target	Approved ICT Policy

Strategic Objective 1.7	**Ensure comprehensive plan that outlines how technology should be used to meet IT and SAHPRA goals is in place**
Objective Statement	Availability of SAHPRA IT systems
Indicator	ICT Strategy developed and approved
Baseline	New Indicator
Target	Approved ICT Strategy

Strategic Objective 1.8	**Share, cooperate and strengthen collaborative initiatives with relevant stakeholders to support mandate of SAHPRA.**
Objective Statement	Collaborative Initiatives with relevant regulators/other organizations to further the mandate and objectives of SAHPRA
Indicator	Number of collaborative relationships strengthened.
Baseline	New Indicator
Target	9

Strategic Objective 1.9	**Enter into agreements with contract laboratories to support quality assurance and control function of the Regulator**
Objective Statement	Availability of quality assurance and quality control laboratory services to support mandate of SAHPRA
Indicator	Number of service level agreements in place
Baseline	1
Target	2

Strategic Objective 1.10	**Maintain medicine and medical device registers**
Objective Statement	Mandated publication of health products registers on Authority website for Public Information
Indicator	Updated Medicine and medical device registers published on the regulators website quarterly
Baseline	New Indicator
Target	Quarterly update reports

8.3 Resource Consideration

In order for the Authority to successfully achieve the strategic goals 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.

8.4 Expenditure Trends

8.4.1 Programme 1: Administration Budget

Resource considerations (R'000)

2015/16	2016/17	2017/18	2018/19	2019/20	2020/21
Budget Estimates	**Budget Estimates**	**Budget Estimates**	**Budget Estimates**	**Budget Estimates**	**Budget Estimates**
No historical data - New public entity			**65 100**	**90 355**	**103 319**
Economic Classification of Budget			**65 100**	**90 355**	**103 319**
Compensation of Employees			26 892	34 468	41 320
Goods and Services			38 208	55 887	61 999

8.4.2 Risk Management

Risk management is imperative during the implementation of the strategic priorities in order to mitigate non-performance and ensure success of the programmes. The table below outlines the key risks that have been identified, their likelihood of materializing and the potential impact on strategic execution, as well as the proposed solutions to mitigate the perceived risks.

Table 3: Programme 1 - Key Implementation Risks and Mitigation Strategies

Strategic objective	Risk Description	Potential Consequences	Mitigating Strategies
• Effective financial management	• Liquidity of SAHPRA • Insufficient capacity	• Service delivery will be affected and compromised mandate.	• Increased stakeholder awareness (Internal/external) on compliance • Implement revised fee structure • Capacitate the finance division
• Implement good governance, oversight and accountability through appropriate delegation, including financial management and compliance with PFMA requirements.	• Non-compliance with the PFMA, Treasury Regulations, GRAP standards, etc	• Negative Audit Findings and Opinions	• Internal audit function • Increased internal stakeholder awareness on compliance
• Efficient and Effective Processes and Systems	• Inadequate Technology infrastructure	• Negative impact on quality of service rendered. • Disruptions to business process and potential loss of information	• Define the business processes • Implementation of the EDMS
• Share, cooperate and strengthen collaborative initiatives with relevant stakeholders to support mandate of SAHPRA.	• Non-compliance with legislation and regulations	• Negative impact on the Authority's revenue • Reputational damage • Inability to deliver on the mandate	• Intensify stakeholder awareness

9 PROGRAMME 2: AUTHORISATION MANAGEMENT

9.1 Programme Purpose

To provide administration support necessary for SAHPRA to deliver on its mandate and comply with the relevant legislative requirements.

The purpose of this programme is to co-ordinate 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, to manage and maintain SAHPRA's main Registry.

There are five sub-programmes, namely:

Sub-Programme 1: Document Reception and Helpdesk

The purpose of this sub-programme is to receive, record and / or direct all documents submitted to SAHPRA.

Sub-Programme 2: Records Management

The purpose of this sub-programme 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

The purpose of this sub-programme is to co-ordinate the process of the making of a regulatory decision of medicines (screening, dispatch to evaluators, co-ordinating reports, recommendations, responses; arranging peer review 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 product. 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

The purpose of this sub-programme is to co-ordinate 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.

Sub-Programme 5: Licensing, Permits and Certificates Portfolio Management

The purpose of this sub-programme is to manage and co-ordinate 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.

9.2 Strategic Objectives

Strategic Objective 2.1	Take regulatory decision on all Backlog Applications
Objective Statement	Focused and innovative approach to reduce medicine application backlog and register compliant health products, increasing public medicine access
Indicator	% of Backlog applications with regulatory decisions taken
Baseline	All applications received prior to 01 February 2018
Target	All applications prior to 1st February 2018 with regulatory decisions taken

Strategic Objective 2.2	**Issue of licence, permits, registration certificates, certificates of establishments and health products for applications received for Medicines, medical devices and radiation nucleides within a specified timeline after regulatory decision taken**
Objective Statement	Establishment licence / registration certificates / licence for product use for radiation emitting devices and nucleides / lot release certificates issued within predefined timelines
Indicator	% of licence/permits/certificates issued within predefined timelines on quarterly basis
Baseline	40 %
Target	85 %

9.3 Resource Consideration

In order for the Authority to successfully achieve the strategic goals 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 registration process.
- Resource Capacity: The Authority needs additional human capacity to strengthen its core business activities and expansion programmes in areas such as Project managers and ICT analysts with skills and understanding of the regulatory environment.
- Skilled Human Capital is critical to sustain ongoing progressive trends to fulfilling mandates and focused and intensified training programmes must be developed and implemented.

9.4 Expenditure Trends

9.4.1 Programme 2: Authorisation Management Budget

Resource considerations (R'000)

2015/16	2016/17	2017/18	2018/19	2019/20	2020/21
Budget Estimates	**Budget Estimates**	**Budget Estimates**	**Budget Estimates**	**Budget Estimates**	**Budget Estimates**

No historical data - New public entity	**30 555**	**34 963**	**48 461**
Economic Classification of Budget	**30 555**	**34 963**	**48 461**
Compensation of Employees	26 985	30 194	43 410
Goods and Services	3 570	4 770	5 051

9.4.2 Risk Management

Risk management is imperative during the implementation of the strategic priorities in order to mitigate non-performance and ensure success of the programmes. The table below outlines the key risks that have been identified, their likelihood of materializing and the potential impact on strategic execution, as well as the proposed solutions to mitigate the perceived risks.

Table 4: Programme 2 - Key Implementation Risks and Mitigation Strategies

Strategic objective	Risk Description	Potential Consequences	Mitigating Strategies
• Take regulatory decision on all Backlog Applications • Issue of licences, permits, registration certificates, certificates of establishments and health products for applications received for Medicines and Medical Devices within a specified timeline after regulatory decision taken	• Non-compliance with targets set for Programme	• Negative Audit Findings and Opinions	• Internal audit function • Increased internal stakeholder awareness on compliance
	• Inadequate Technology infrastructure	• Negative impact on quality of service rendered. • Disruptions to business process and potential loss of information	• Define the business processes • Implementation of the EDMS
	• Non-compliance with legislation and regulations	• Negative impact on the Authority's revenue • Reputational damage • Inability to deliver on the mandate	• Intensify stakeholder awareness

10 PROGRAMME 3: INSPECTORATE AND REGULATORY COMPLIANCE

10.1 Programme Purpose

The main purpose of this programme is 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)

Through conducting of inspections at Active Pharmaceutical Ingredient (API) and medicine and medical device manufacturers, wholesalers, laboratories and clinical trial sites, located both locally and internationally;

as well as inspection and monitoring of compliance with applicable legislation as mandated (Medicines and Related Substances Act, 1965, Hazardous Substances Act, 1973).

There are three sub-programmes, namely:

Sub-Programme 1: Inspections

The purpose of this sub-programme is 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

To ensure public access to safe medicines through regulatory compliance and monitoring of compliance with applicable legislation as mandated.

Sub-Programme 3: Laboratory Services

To oversee the quality control testing of medicines including biological medicines and vaccines for compliance with predefined quality standards.

10.2 Strategic Objectives

Strategic Objective 3.1	**Inspect establishments to ensure compliance with relevant GXP and established standards within pre-defined timelines.**
Objective Statement	To run an effective and efficient GXP and Vigilance programme with defined timelines
Indicator	% of establishments due for inspection inspected annually
Baseline	40 % annually
Target	60 %

Strategic Objective 3.2	**Inspect permit holders/establishments of narcotic and psychotropic substances to ensure compliance with established standards within pre-defined timelines.**
Objective Statement	To run an effective and efficient Inspection and Vigilance programme with defined timelines
Indicator	% of permit holders/establishments/sites of narcotic and psychotropic substances inspected annually
Baseline	20 % annually [1]
Target	20 % annually [1]
[1] These sites are already regulated within the Inspectorate Framework. This sampling set is to ensure oversight only. The limited risk does not warrant a greater percentage sampling target per year	

10.3 Resource Consideration

Inspectorate and Regulatory Compliance is a programme that must be adequately resourced to ensure effective service delivery. The capacity to administer the required functions will be phased in to avoid a situation where the programme is compromised as a result of overload. A training process will be established through which all post holders are trained in all operational process and specific technical components. Training will be required in the period April 2017 onwards and there will be a need for on-going training, including updating and training of new personnel as required.

10.4 Expenditure Trends

10.4.1 Programme 3: Inspectorate and Regulatory Compliance Budget

Resource considerations (R'000)

2015/16	2016/17	2017/18	2018/19	2019/20	2020/21
Budget Estimates	**Budget Estimates**	**Budget Estimates**	**Budget Estimates**	**Budget Estimates**	**Budget Estimates**
Economic Classification of Budget			**34 826**	**38 844**	**49 341**
Compensation of Employees			27 723	30 427	40 427
Goods and Services			7 103	8 417	8 913

10.4.2 Risk Management

Risk management is imperative during the implementation of the strategic priorities in order to mitigate non-performance and ensure success of the programmes. The table below outlines the key risks that have been identified, their likelihood of materializing and the potential impact on strategic execution, as well as the proposed solutions to mitigate the perceived risks.

Table 5: Programme 3 - Key Implementation Risks and Mitigation Strategies

Strategic objective	Risk Description	Potential Consequences	Mitigating Strategies
• Inspect establishments to ensure compliance with relevant GXP and established standards within pre-defined timelines.	• Non-compliance with targets set for Programme • Laboratory infrastructure	• Negative Audit Findings and Opinions	• Internal audit function • Increased internal stakeholder awareness on compliance • Development of a priority capital expenditure plan
• Inspect permit holders / establishments of narcotic and psychotropic substances to ensure compliance with established standards within pre-defined timelines.	• Adequate funding to meet mandates • Attracting and retaining qualified and experienced staff	• Negative impact on quality of service rendered. • Disruptions to business process and potential loss of information	• Continue efforts to increase revenue generation to supplement funding from National Treasury • Implementation of a well-designed rewards and remuneration strategy
	• Non-compliance with legislation and regulations	• Negative impact on the Authority's revenue • Reputational damage • Inability to deliver on the mandate	• Intensify stakeholder awareness

11 PROGRAMME 4: MEDICINES EVALUATION AND REGISTRATION

11.1 Programme 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.

Functions

- Management of the evaluation of applications to ensure safety, quality and efficacy of products.
- Management of the registration and control of medicines.
- Management of regulations pertaining to the sales of medicines.
- Establishment of surveillance mechanisms to detect, assess and prevent adverse reactions to health products.
- Management of the authorisation of sale of unregistered medicine for specified purposes in terms of relevant legislation.

There are seven sub-programmes, namely:

Sub-Programme 1: Clinical Evaluation

The purpose is to evaluate the safety and efficacy of orthodox medicines.

The functions include:

- Evaluation of new chemical entities and generic medicines with respect to safety and efficacy;
- Evaluation of post-registration amendments;
- Safety updates (USRNs, SR-PINs, PSURs and other major safety amendments;
- Evaluation new indications package inserts and PIL updates;
- Preparation of reports on clinical evaluations;
- Preparation of peer review committee recommendations on applications;
- Ensure the safety and efficacy of new products;
- Ensure the safety and efficacy of marketed products.
- Handling of technical/ scientific queries referred by Authorisation Management;
- Evaluation of applicant responses (both pre- and post);
- Development and/or updating of relevant guidelines;
- Interaction with industry representatives, department of health, international agencies and other relevant stakeholders to establish co-operative agreements, disseminate and exchange information.

Sub-Programme 2: Clinical Trials

The purpose is 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.

The functions include:

- Evaluation of new clinical trials applications of orthodox medicines, complementary medicines and medical devices including bioequivalence studies; evaluation of safety reports and line listings;
- Updating policy documents on the conduct of clinical trials;

- Evaluation of study documentation updates (Informed Consent documents, Investigator brochures, certificate of analysis, study insurance, shelf life extensions, etc.);
- Evaluation of completed study reports and synopsis; evaluation of additional site, site staff and investigator applications;
- Evaluation of protocol amendments applications of approved protocols;
- Evaluation of progress reports of on-going clinical trials, protocol deviations, protocol violations and waiver;
- Evaluation of Data Safety Monitoring Board (DSMB) reports on clinical trials and make recommendations;
- Preparation of reports on completed evaluations;
- Preparation of peer review committee recommendations on applications;
- Promotion of vigilance by collecting, managing and assessing serious adverse events reports in clinical trials.

Sub-Programme 3: Pharmaceutical Evaluation

The purpose is to perform pharmaceutical and analytical evaluations of new and registered medicines inclusive of clinical aspects of veterinary medicines and biological.

The functions include:

- Oversee and direct evaluation of data sets submitted by applications in the pharmaceutical industry for the registration and amendments of medicines to ensure quality, safety and efficacy;
- Preparation of reports on biological and veterinary clinical evaluations for submission to Expert Committees;
- Handling of technical/ scientific queries referred by Authorisation Management;
- Interaction with industry representatives, department of health, international agencies and other relevant stakeholders to establish co-operative agreements, disseminate and exchange information;
- Development and updating of relevant guidelines.

Sub-Programme 4: Vigilance and Post-Marketing Surveillance

The purpose is 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.

The functions include:

- Creating awareness amongst healthcare professionals regarding the significance / importance of reporting ADRs;
- Monitoring benefit-risk profiles of medicines and medical devices
- Generating of independent, evidence-based recommendations regarding the safety, efficacy and quality of medicines and medical devices;
- Promoting vigilance by collecting, managing and assessing adverse reaction and medication error reports; including post-marketing surveillance and research data;
- Collaborate and harmonize with local and international cohorts monitoring ADRs;
- Implementing of post-market surveillance for adverse events related to medical devices and complementary medicines and develop and/or update relevant guidelines;
- Handling of technical / scientific queries referred by Authorisation Management;
- Investigation of adverse events related to medicines and medical devices; and

- Evaluation of vigilance reports and enforce corrective actions where applicable.
- Providing of relevant and user friendly feedback to stakeholders particularly health professionals and the public.

Sub-Programme 5: Complementary and Alternative Medicines (CMs)

The purpose is 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.

The functions include:

- Evaluation of data sets submitted by applicants for the registration of complementary medicines to ensure safety, quality and efficacy;
- Preparation of reports on evaluations for submission to the Expert Committee;
- Interaction with industry representatives, Department of Health, international agencies and other relevant stakeholders to establish co-operative agreements, disseminate and exchange information;
- Development and/or updating of relevant guidelines.

Sub-Programme 6: Veterinary Medicines

The purpose is to evaluate the safety, efficacy and quality of veterinary medicines.

The functions include:

- Evaluation of all applications for registration of veterinary medicines, including new chemical entities and generic veterinary medicines, with respect to safety, efficacy and quality;
- Evaluation of post-registration amendments; safety updates; package insert amendments and updates;
- Preparation of reports on clinical and quality evaluations;
- Preparation of peer review committee recommendations on applications;
- Handling of technical/scientific queries referred by Authorisation Management;
- Evaluation of applicant responses (both pre- and post-registration);
- Development and/or updating of relevant guidelines;
- Interaction with industry representatives, department of health, international agencies and other relevant stakeholders to establish co-operative agreements, disseminate and exchange information

Sub-Programme 7: Laboratory Services

Access to international standard quality control (QC) laboratory services is essential for post-marketing surveillance of medicines via pharmaceutical analysis. Under the current provisions of the Medicines and Related Substances Act, SAHPRA is obliged to test all biological medicines and vaccines for batch release purposes. Under the MCC, pharmaceutical samples were submitted on an *ad hoc* basis to contract laboratories, while biological (batch release) samples are submitted to the contract laboratory, with which the MCC has a contract under the NDOH tender.

Given the current resource constraints, the creation of in-house analytical laboratory facilities, however desirable, would not be feasible and therefore, the short-medium term approach would be to continue the outsourcing of pharmaceutical and biological analysis and all laboratory service. A contract would need to be drafted with a suitable institution through an open tender process.

11.2 Strategic Objectives

Strategic Objective 4.1	**Evaluate clinical trial protocols in accordance with defined standards**
Objective Statement	Clinical trials applications received are evaluated in accordance with the defined standards to ensure participant safety and data integrity
Indicator	% of clinical trial applications evaluated within an evaluation cycle
Baseline	80 %
Target	95 %

Strategic Objective 4.2	**Evaluate Clinical trial protocol amendments in accordance with defined standards**
Objective Statement	Clinical trial protocol amendments received are evaluated in accordance with defined standards to ensure participant safety and data integrity
Indicator	% of Clinical trial protocol amendments evaluated within pre-defined timelines
Baseline	70 %
Target	75 %

Strategic Objective 4.3	**Evaluate the applications for sale of unregistered health products in accordance with defined standards**
Objective Statement	Ensure that unregistered health product applications received are evaluated in accordance with defined standards to ensure access only to safe, efficacious and quality unregistered health products.
Indicator	% of applications for the sale of an unregistered health product evaluated within a specified timeline.
Baseline	70 %
Target	85 %

Strategic Objective 4.4	**Scientific Evaluation of all NCE / Biological applications submitted for regulatory decision**
Objective Statement	To ensure that regulatory decisions taken on NCE / Biological application evaluations are taken within globally acceptable timelines
Indicator	% of NCE / Biological application evaluations concluded with a regulatory decision taken within 275 working days (time spent at regulator)
Baseline	30 %
Target	80 %

Strategic Objective 4.5	**Scientific evaluation of New Health Product amendments submitted for regulatory decision**
Objective Statement	To ensure that regulatory decisions taken on all new health product amendments are taken within globally acceptable timelines
Indicator	% of NCE / Biological amendments evaluations concluded with a regulatory decision within 120 working days (time spent at regulator)
Baseline	30 %
Target	80 %

Strategic Objective 4.6	**Scientific evaluation of all Generic / Biosimilar applications submitted for regulatory decision**
Objective Statement	To ensure that regulatory decisions taken on Generics / Biosimilar application evaluations are taken within globally acceptable timelines
Indicator	% of Generics / Biosimilar application evaluations concluded with a regulatory decision taken within 180 working days (time spent at regulator)
Baseline	30 %
Target	80 %

Strategic Objective 4.7	**Scientific evaluation of Generic / Biosimilar amendments submitted for regulatory decision**
Objective Statement	To ensure that regulatory decisions taken on all Generic / Biosimilar amendments are taken within globally acceptable timelines
Indicator	% of Generic / Biosimilar amendments evaluations concluded with a regulatory decision within 120 working days (time spent at regulator)
Baseline	30 %
Target	80 %

Strategic Objective 4.8	**Investigate, monitor, analyze, solicit and act upon existing and new adverse events, interactions and signals emerging from post-marketing surveillance and vigilance.**
Objective Statement	Ensure that evidence of existing and new adverse events, interactions, and signals emerging from post-marketing surveillance and vigilance are being investigated, monitored, analysed and acted upon.
Indicator	Published quarterly reports of new adverse events and signals that have been assessed, actioned and concluded
	An inclusive vigilance framework for all health products developed and approved
Baseline	New indicator
	New indicator
Target	4
	Approved vigilance framework for all health products

11.3 Resource Consideration

Availability of regulatory expertise and resources, especially in evaluating complex biotechnology product submissions, is an issue for clinical and P&A committees especially considering that the Biosimilar Quality and Clinical dossier cannot be reviewed separately/independently or away from each other as there is close relation in Quality and Clinical evidence in support of approval for registration. Increased regulatory cooperation between the relevant committees is essential.

New staff required to capacitate the vigilance programme including doctors, pharmaco-epidemiologists, data managers and pharmacologists. Advanced and ongoing training for vigilance staff in line with continuing development is essential given the expanded mandate.

11.4 Expenditure Trends

11.4.1 Programme 4: Medicines Evaluation and Research Budget

Resource considerations (R'000)

2015/16	2016/17	2017/18	2018/19	2019/20	2020/21
Budget Estimates	**Budget Estimates**	**Budget Estimates**	**Budget Estimates**	**Budget Estimates**	**Budget Estimates**
No historical data - New public entity			**67 158**	**82 537**	**93 239**
Economic Classification of Budget			**67 158**	**82 537**	**93 239**
Compensation of Employees			57 088	69 767	79 716
Goods and Services			10 070	12 770	13 523

11.4.2 Risk Management

Risk management is imperative during the implementation of the strategic priorities in order to mitigate the non- performance and ensure success of the programmes. The table below outlines the key risks that have been identified, their likelihood of materializing and the potential impact on strategic execution, as well as the proposed solutions to mitigate the perceived risks.

Table 6: Programme 4 - Key Implementation Risks and Mitigation Strategies

Strategic objective	Risk Description	Potential Consequences	Mitigating Strategies
• Scientific evaluation of all NCE / Biological applications submitted for regulatory decision • Scientific evaluation of New Health Product amendments submitted for regulatory decision • Scientific evaluation of all Generic / Biosimilar applications submitted for regulatory decision • Scientific evaluation of Generic / Biosimilar amendments submitted for regulatory decision	• Inadequate Technology infrastructure	• Negative impact on quality of service rendered. • Disruptions to business process and potential loss of information	• Define the business processes • Implementation of the EDMS
	• Non-compliance with legislation and regulations	• Negative impact on the Authority's revenue • Reputational damage • Inability to deliver on the mandate	• Intensify stakeholder awareness

12 PROGRAMME 5: MEDICAL DEVICES, DIAGNOSTICS AND RADIATION CONTROL

12.1 Programme Purpose

The main purpose of Programme 5: Medical Devices, Diagnostics and Radiation Control, is to develop and maintain regulations and guidelines pertaining to the regulatory oversight of medical devices, ionizing and non-ionizing radiation emitting devices; and radioactive nucleides. Core functions for this programme include:

- Licensing of medical device establishments;
- Registration of medical devices and radiation emitting devices and radioactive nucleides;
- Designation and supervision of conformity assessment bodies;
- Conducting inspections of medical device establishments;
- Post-marketing surveillance and vigilance; and
- Approval of clinical trials.

Medical Devices and Radiation Control currently exist within Programme 5 of this transition phase of SAHPRA's operational structure. The magnitude and immaturity of the medical device framework and uncertainty of the transition of the radiation control component at the time of MCC's transition to SAHPRA; necessitated this partition in this initial phase; to help operationalize the framework with minimal disruption to the MCCs current functioning. It is currently being reconsidered for inclusion in the other programmes as all of the functions can be met in Programme 2, 3 and 4. This re-engineering proposal is underway and will be submitted by the Board in the adjustments budget in September 2018 to help streamline and reposition the programmes. Nevertheless, for this Strategic Plan, the Programme functions and objectives appear below to conform to the current business case and organogram

There are two sub-programmes, namely:

Sub-programme 1: – Medical Devices : The purpose of this sub-programme is 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: The purpose of this sub-programme is to efficiently, effectively and ethically evaluate and register non-ionizing radiation emitting devices and radioactive nucleides.

12.2 Strategic Objectives

Strategic Objective 5.1	**Licence Medical Device Establishments that are compliant with prescribed reference standards**
Objective Statement	To licence and monitor medical device establishments for compliance with prescribed reference standards.
Indicator	% of licence applications finalised within defined timelines
Baseline	New indicator
Target	80 %

Strategic Objective 5.2	**Implement a system to register Medical Devices**
Objective Statement	A functioning and capacitated system by which medical devices are registered is in place and operational.
Indicator	A system to register medical devices developed and implemented
	% of regulatory decisions taken on medical device applications within predefined timeline
Baseline	New Indicator
Target	A system to register medical devices implemented
	50 %

Strategic Objective 5.3	**Evaluate radiation emitting devices and radioactive nucleides for regulatory decision**
Objective Statement	Evaluate applications for registration of radiation emitting devices and radioactive nucleides, in terms of the Hazardous Substances Act
Indicator	% regulatory decisions taken on radiation emitting devices and radioactive nucleides applications within predefined timeline
Baseline	New Indicator
Target	50 **%**

12.3 Resource Consideration

Human resources and training are two key resources required for the Medical Device Unit as it is a fledgling Unit. The Medical Device Unit has made inroads in implementing the framework for regulatory oversight of medical devices in South Africa. The Unit has directed current, limited resources, into training stakeholders on the statutory requirements for medical device establishment licence holders, and the licence application process. As the roadmap for the implementation of the regulatory framework for medical devices progresses, increased resources will be required to train stakeholders on matters relating to registration of medical devices, regulatory compliance, medical device clinical trials, vigilance and post-marketing surveillance of medical devices, access to medical devices and Section 21 authorisation of medical devices.

The Unit has started with the evaluation and processing of medical device establishment licences. The volumes of in-coming applications are large and there are not enough resources to efficiently perform the necessary activities. A severe restraint has been recognised as there are not sufficient human and IT resources available to adequately perform technical and administration functions to facilitate the licensing procedure. Financial resources must be made available to attract suitably qualified and experienced personnel.

A memorandum of understanding must be signed with SANAS to provide for the accreditation of conformity assessment bodies (CAB) that will perform inspections of medical device establishments, against ISO 13485, on behalf of the regulator. Human, financial and ITC resources must be made available in the Medical Device Unit to allow for the development of the documented framework for this procedure, effective engagement with SANAS and appropriate validation of CABs.

There are a number of vacancies in the Radiation Control Unit in the present organisational structure which needs to be prioritised.

12.4 Expenditure Trends

12.4.1 Programme 5: Medical Devices and Radiation Control Budget

Resource considerations (R'000)

2015/16	2016/17	2017/18	2018/19	2019/20	2020/21
Budget Estimates	**Budget Estimates**	**Budget Estimates**	**Budget Estimates**	**Budget Estimates**	**Budget Estimates**
No historical data - New public entity			**18 231**	**21 733**	**22 708**
Economic Classification of Budget			**18 231**	**21 733**	**22 708**
Compensation of Employees			10 457	12 575	12 996
Goods and Services			7 774	9 158	9 712

12.4.2 Risk Management

Risk management is imperative during the implementation of the strategic priorities in order to mitigate non-performance and ensure success of the programmes. The table below outlines the key risks that have been identified, their likelihood of materializing and the potential impact on strategic execution, as well as the proposed solutions to mitigate the perceived risks.

Table 7: Programme 5 - Key Implementation Risks and Mitigation Strategies

Strategic objective	Risk Description	Potential Consequences	Mitigating Strategies
• License Medical Device Establishments that are compliant with prescribed reference standards • Implement a system to register Medical Devices • Register radiation emitting devices and radioactive nucleides	• Non-compliance with targets set for Programme	• Negative Audit Findings and Opinions	• Internal audit function • Increased internal stakeholder awareness on compliance
	• Adequate funding to meet mandates • Attracting and retaining qualified and experienced staff	• Negative impact on quality of service rendered. • Disruptions to business process and potential loss of information	• Continue efforts to increase revenue generation to supplement funding from National Treasury • Implementation of a well-designed rewards and remuneration strategy
	• Non-compliance with legislation and regulations	• Negative impact on the Authority's revenue • Reputational damage • Inability to deliver on the mandate	• Intensify stakeholder awareness

PART C:
LINK TO OTHER PLANS

The capital budget responds to the Authority's operational requirements. The capital budget of SAHPRA as detailed below requires further investigations to assess the ITC environment and the depth of capital expenditure required to support SAHPRA to evolve into a fully functioning regulatory authority.

The Capital expenditure budget will be funded from the revenue generated.

2015/16	**2016/17**	**2017/18**	**2018/19**	**2019/20**	**2020/21**
Budget Estimates	**Budget Estimates**	**Budget Estimates**	**Budget Estimates**	**Budget Estimates**	**Budget Estimates**
No historical data - New public entity			**5 943**	**5 709**	**6 027**
Total Payments for Capital Assets			**5 943**	**5 709**	**6 027**
Machinery and Equipment			4 884	4 587	4 839
Software			1 059	1 122	1 188

PART D:
ANNEXURES

ANNEXURE A: TECHNICAL INDICATOR DESCRIPTION

Indicator Name	Short Definition	Purpose / Importance	Source	Calculation Method	Data Limitations	Type of Indicator	Calculation Type	Reporting Cycle	Baseline	Desired Performance	Responsibility
Programme 1: Administration											
% of funded positions filled	Positions on organogram for which funding exits in the annual budget are filled by the end of that year	Where funding is available, SAHPRA must ensure it is fully utilized and critical positions for operational functionality are filled	Register/ Master file of appointed staff Annual staffing plan	Numerator: Number of staff appointed in each financial year Denominator: Total number of funded vacant posts for that financial year	Outlook for a single month may not reflect the situation during the remainder of the year	Output	% cumulative	Quarterly	New Indicator	90%	Director HR
% of staff trained as per annual training plan	Percentage of staff prioritized for upskilling programme as per training plan	To ensure staff at SAHPRA are capacitated with skills to enhance organization performance	Skills development plan; and Training records	Numerator: Number of staff trained Denominator: Total number of staff identified for upskilling in training plan	Supplier dependent	Output	% Cumulative	Quarterly	New indicator	100 %	Director HR
% Employee performance agreements signed no later than 31 May each financial year	Performance agreements are negotiated and signed with every staff member each year	Signed performance agreements with staff members has a direct operational performance	Signed performance agreements Total number of staff	Numerator: Number of signed agreements by or before 31st May Denominator: Total number of staff	N/A	Output	% Cumulative	Annual	New Indicator	100 %	Director HR
Communication strategy developed, approved and published	Communication strategy is developed to support improved external stakeholder interactions and relations	Communication and interaction with external stakeholders is key to building strategic relationships	Approved communication strategy document	N/A	N/A	Output	N/A	Annual	New Indicator	Approved communication strategy published on the website in year one	Director ICT
Number of media and communication events and stakeholder meetings	Media and communication events and stakeholder meetings are held regularly to ensure stakeholders are aware of SAHPRA mandates/ policies / guidelines	Communication and interaction with external stakeholders is key to building transparent relationships	ITG Meeting Minutes	N/A	N/A	Output	N/A	Quarterly	New Indicator	4 meetings annually	CEO

Indicator Name	Short Definition	Purpose / Importance	Source	Calculation Method	Data Limitations	Type of Indicator	Calculation Type	Reporting Cycle	Baseline	Desired Performance	Responsibility
Audit Outcome	Annual audit by Auditor General is unqualified	As a regulator, it is critical that SAHPRA should set an example	Auditor General Report	N/A	N/A	Output	N/A	Annual	New Indicator	Unqualified audit without findings	CFO
ICT Policy Developed and approved	ICT policy is developed to support improved internal and external stakeholder interactions and relations	To ensure the monitoring and inspection of information stored on SAHPRA's ICT facilities and services are performed in an appropriate and responsible manner	Approved ICT policy	N/A	N/A	Output	N/A	Bi-Annual	New Indicator	Approved ICT policy	Director ICT
ICT Strategy developed and approved	ICT strategy is developed to improved internal stakeholder interface	To ensure that a comprehensive plan is developed and implemented with regards to the Authority's mandate and ICT goals	Approved ICT strategy	N/A	N/A	Output	N/A	Bi-Annual	New Indicator	Approved ICT strategy	Director ICT
Number of collaborative relationships strengthened	Relationships with relevant stakeholders to strengthen collaborative initiatives	Build collaborative initiatives to ensure SAHPRA's mandate is strengthened	Signed MOUs	N/A	N/A	Output	N/A	Annual	New Indicator	9 signed MOUs	CEO
Number of service level agreements in place	Enter into Agreements with Contract Laboratories to support Quality Assurance and Control function of Regulator	To ensure Quality Assurance mandate of Inspection and regulatory compliance mandate is autonomous and rigorous	Signed SLAs	N/A	Will require annual review and ratification to verify	Output	Number	Annual	1	2	Inspection and Regulatory Compliance Director
Updated medicine and medical device registers published on the regulators website quarterly	Updated List of registered health products are available on website for public information	To ensure the external stakeholders have access to list of medicine registered	Published quarterly update reports on the website	Count	n/a	Output	Cumulative	Quarterly	New Indicator	Quarterly updates	Authorisation Management Director
Programme 2: Authorisation Management											
% of Backlog Applications with regulatory decisions taken	Cumulative measure of impact of focused framework to register health products in backlog	To ensure medicines in backlog are expedited for registration and available for public use	Siamed database	Numerator: Number of backlog applications with regulatory decisions	n/a	Output	% Cumulative	Quarterly	All applications prior to 1st February 2018	All applications prior to 1st February 2018 with regulatory decisions taken	Authorisation Director Authorisation Management Director

Indicator Name	Short Definition	Purpose / Importance	Source	Calculation Method	Data Limitations	Type of Indicator	Calculation Type	Reporting Cycle	Baseline	Desired Performance	Responsibility
				Denominator: All backlog applications prior to 1st February 2018							

Indicator Name	Short Definition	Purpose / Importance	Source	Calculation Method	Data Limitations	Type of Indicator	Calculation Type	Reporting Cycle	Baseline	Desired Performance	Responsibility
% of licence/permits/certificates issued within predefined timelines on quarterly basis	Aggregated % of all licences, permits and registrations of establishments for Medicines, Medical Devices and IVDs issued as measure of organisational performance	End of line outcome of applications made by external industry stakeholders and demonstrates organisational performance	Report from server infrastructure	Numerator: Number of licenses issued following an inspection visit Denominator: Total number of establishments inspected annually Numerator: Number of permits issued following an application Denominator: Total number of permit applications received. Numerator: Number of certificates issued following dispatch of an application Denominator: Total number of dossiers dispatched	Denominator is supplier driven, dependent on number of applications made in year	Output	% cumulative	Quarterly	40%	85%	Authorisation Management Director
Programme 3: Inspectorate and Regulatory compliance											
% of establishments due for inspection inspected annually	Aggregate of all inspections completed for establishments liable for inspection in that year	To ensure compliance with GXP standards	Report from Server Infrastructure	Numerator: Number of inspection reports completed with regulatory decision Denominator: Total number of inspection establishments liable for inspection for year	Some inspections may be completed but reports are outstanding by end of reporting cycle	Output	Cumulative	Quarterly	40 %	60 %	Inspectorate and Regulatory compliance Director
% of permit holders/ establishments/ sites of narcotic and psychotropic substances	Aggregate of all inspections completed for permit holders holders/ sites of narcotic and psychotropic	To ensure compliance with NCIB standards and control of narcotics and psychotropic	Psychotropic register Report from Server	Numerator: Number of inspection reports completed with regulatory decision	Some inspections may be completed but reports are	Output	Cumulative	Quarterly	20 %	20 %	Inspectorate and Regulatory compliance Director

Indicator Name	Short Definition	Purpose / Importance	Source	Calculation Method	Data Limitations	Type of Indicator	Calculation Type	Reporting Cycle	Baseline	Desired Performance	Responsibility
inspected annually	substances completed in that year	substances	Infrastructure	Denominator: Total number of inspections allocated per year	outstanding by end of reporting cycle						
Programme 4: Medicines Evaluation and Registration											
% of clinical trial applications evaluated within an evaluation cycle	Clinical trial protocols are evaluated for compliance to GCP in a 6 week cycle	To ensure clinical trials are conducted strictly according to GCP standards to ensure patient safety and data integrity	Clinical Trial Register Report from Server Infrastructure	Numerator: Number of clinical trial evaluation reports completed within a 6 week cycle Denominator: Total number of clinical trial applications received within a 6 week cycle	Denominator is supply dependent	Output	Cumulative	Quarterly	80 %	95 %	Medicine Evaluation and Registration Directors
% of clinical trial protocol amendment evaluated within pre-defined timelines	Clinical trial protocol amendments are evaluated for compliance to GCP in a 6 week cycle	To ensure clinical trials are conducted strictly according to GCP standards to ensure patient safety and data integrity	Clinical Trial Register Report from Server Infrastructure	Numerator: Number of clinical trial protocol amendment evaluation reports completed within a 6 week cycle Denominator: Total number of clinical trial protocol amendment applications received	Denominator is supply dependent	Output	Cumulative	Quarterly	70 %	75 %	Medicine Evaluation and Registration Directors
% of applications for the sale of an unregistered health product evaluated within a specified timeline	Sale of unregistered health product applications are evaluated for a regulatory decision in a 48 hour period cycle	To ensure applications for sale of unregistered product are evaluated to ensure patient safety	Section 21 Spreadsheet Report from Server Infrastructure	Numerator: Number of sale of unregistered health product applications reports completed with regulatory decision within 48 hours Denominator: Total Number of sale of unregistered health product applications received	Denominator is supply dependent	Output	Cumulative	Quarterly	80 %	85 %	Medicine Evaluation and Registration Directors
% of NCE/Biological applications evaluations	NCE/ Biological applications are evaluated against	NCE/ Biological applications are evaluated against	Report from Server Infrastructure	Numerator: Number of NCE/Biological	Denominator is supply dependent	Output	Cumulative	Quarterly	30 %	80 %	Medicine Evaluation and Registration

Indicator Name	Short Definition	Purpose / Importance	Source	Calculation Method	Data Limitations	Type of Indicator	Calculation Type	Reporting Cycle	Baseline	Desired Performance	Responsibility
concluded with a regulatory decision taken within 275 working days (time spent at regulator)	established standards and concluded within globally benchmarked timeline	established standards and concluded within globally benchmarked timeline to ensure public access to medication		evaluation reports completed with regulatory decision Denominator: Total Number of reports received NCE/Biological applications received							Directors
% of NCE/Biological amendments evaluations concluded with a regulatory decision within 120 working days (time spent at regulator)	New Health Product amendments evaluated against established standards and concluded within globally benchmarked timeline	New Health Product amendments are evaluated against established standards and concluded within globally benchmarked timeline to ensure public access to medication	Report from Server Infrastructure	Numerator: Number of new health product amendment reports completed with regulatory decision Denominator: Total number of reports received new health product amendments received	Denominator is supply dependent	Output	Cumulative	Quarterly	30 %	80 %	Medicine Evaluation and Registration Directors
% of Generic / Biosimilar application evaluations concluded with a regulatory decision within 180 working days (time spent at regulator)	Generic / Biosimilars applications are evaluated against established standards and concluded within globally benchmarked timeline	Generic / Biosimilar applications are evaluated against established standards and concluded within globally benchmarked timeline to ensure public access to medication	Report from Server Infrastructure	Numerator: Number of Generic / Biosimilars evaluation reports completed with regulatory decision Denominator: Total number of Generic / Biosimilars applications received	Denominator is supply dependent	Output	Cumulative	Quarterly	30 %	80 %	Medicine Evaluation and Registration Directors
% of Generic / Biosimilar amendment evaluations concluded with a regulatory decision within 120 working days (time spent at regulator)	Generic / Biosimilars amendment applications are evaluated against established standards and concluded within globally benchmarked timeline	Generic / Biosimilars amendment applications are evaluated against established standards and concluded within globally benchmarked timeline to ensure public access to medication	Report from Server Infrastructure	Numerator: Number of Generic / Biosimilar amendment evaluation reports completed with regulatory decision Denominator: Total number of Generic / Biosimilar amendment applications received	Denominator is supply dependent	Output	Cumulative	Quarterly	30 %	80 %	Medicine Evaluation and Registration Directors
Published quarterly reports of new adverse events and signals that have	New adverse event and signals are successfully investigated for publication of regulatory	Quality, Safety and efficacy information relating to a registered product is investigated	Report from Server Infrastructure (Vigibase)	Number of adverse event reports	Number is supply dependent	Measures Activities	Non-cumulative	Quarterly	0	4	Medicine Evaluation and Registration Directors

Indicator Name	Short Definition	Purpose / Importance	Source	Calculation Method	Data Limitations	Type of Indicator	Calculation Type	Reporting Cycle	Baseline	Desired Performance	Responsibility
been assessed, actioned and concluded	decision for public information	from adverse event reports and signals to ensure use of health product is still in public best interest									
An inclusive vigilance framework for all health products developed and approved	New adverse event and signals are successfully investigated for all health products not currently measured for publication of regulatory decision for public information	Quality, Safety and efficacy information relating to a registered product is investigated from adverse event reports and signals to ensure use of health product is still in public best interest	Approved framework	none	Denominator is supply dependent Unavailability of quality reports		none	Annual	New Indicator	Approved vigilance framework for all health products	Medicine Evaluation and Registration Directors
Programme 5: Medical devices, diagnostics and radiation control											
% of licence applications finalised within defined timelines	% of Medical Device establishment inspections completed in that year	To ensure compliance with GXP standards	Report from Server Infra structure	Numerator: Number of medical device establishment inspection reports completed with regulatory decision Denominator: Total number of medical device establishments liable for inspection per year	Some inspections may be completed but reports are outstanding by end of reporting cycle	Output	Cumulative	Quarterly	New Indicator	80 %	Medical Device and Radiation Control Directors
A system to register medical devices developed and implemented	A system to regulate medical devices implemented	To ensure compliance of medical device products to established standards of quality and performance and safety	A functional system	N/A	N/A	Output	N/A	Bi-Annual	New Indicator	Approved system to register medical devices implemented	Medical Device and Radiation Control Directors
% Regulatory decisions taken on Medical Device applications within predefined timeline	Medical Device applications are completed with a regulatory decision within a predefined timeline	To ensure compliance of medical device products to established standards of quality and performance and safety	Register of medical devices	Numerator: Number of medical device application evaluation reports completed with regulatory decision Denominator: Total number of medical device applications	Denominator is supply dependent Unavailability of quality reports	n/a	Cumulative	Quarterly	New Indicator	50 %	Medical Device and Radiation Control Directors

Indicator Name	Short Definition	Purpose / Importance	Source	Calculation Method	Data Limitations	Type of Indicator	Calculation Type	Reporting Cycle	Baseline	Desired Performance	Responsibility
				received							
% Regulatory decisions taken on radiation emitting devices and radioactive nucleides applications within predefined timeline	Radiation emitting devices and radioactive nucleides applications are evaluated and concluded with a regulatory decision within a predefined timeline	To ensure compliance of radiation emitting devices and radioactive nucleides to established standards of quality and performance and safety	Radiation Control database	Numerator: Number of radiation emitting devices and radioactive nucleides applications completed with regulatory decision Denominator: Total number of radiation emitting devices and radioactive nucleides applications received per year	Denominator is supply dependent	output	% cumulative	Quarterly	New Indicator	50 %	Medical Device and Radiation Control Directors