SAHPRA
South African Health Products Regulatory Authority

SERVICE DELIVERY CHARTER

Policy Number	**:**	**SBP-CHT-05**
Revision	**:**	**1.0**

Contents

1. OVERVIEW

1.1 The White Paper on Transforming Public Service Delivery (*Batho Pele* White Paper, 1997) centres on how public services are provided, specifically focusing on improving the efficiency and effectiveness of how services are delivered. *Batho Pele*, a Sesotho word which means "People First", and the *Batho Pele* Principles are embodied in SAHPRA's Service Delivery Charter, which are (Abridged Batho Pele Programme, 2014):

a. Consultation
b. Service Standards
c. Access
d. Courtesy
e. Information
f. Openness and Transparency
g. Redress
h. Value for Money

1.12 Other pieces of legislation relevant for the development of the Service Delivery Charter are:

a. Constitution of the Republic of South Africa (1996) – one of the nine principles governing public administration provided in Section 195 of the Constitution insists that services must be provided impartially, fairly, equitably and without bias.
b. Promotion of Administrative Justice Act (PAJA), 2000 (Act No. 3 of 2000) - confirms the right of service beneficiaries to consultation and redress if their rights are adversely affected by an administrative action.
c. Promotion of Access to Information Act (PAIA), 2000 (Act No. 2 of 2000) - gives effect to the constitutional right of access to any information held by the State and any information that is held by another person which may be required for the exercise or protection of any rights.

2 PURPOSE

2.1 A "Service Delivery Charter is a statement of commitment that the organisation makes towards service delivery" as per the Public Entities Guide on Developing a Service Delivery Charter. Summary of the charter is highlighted on Appendix A below.

2.2 The South African Health Products Regulatory Authority's (SAHPRA)'s Service Delivery Charter serves as a public pledge to uphold excellence, accountability, and transparency in fulfilling its mandate. Specifically, this Charter aims to:

a. state its services, to clearly outline SAHPRA's scope of services to stakeholders, including industry, healthcare providers, and the public.
b. set out the service standards that the service recipients can expect.
c. publicly commit to continuously improving services; and
d. ensure transparency and accountability on service commitment.

3 SCOPE

3.1 Legislative Mandate

3.1.1 Constitutional Mandate

The Constitution of the Republic of South Africa, 1996, places an obligation on the state to progressively realise socio-economic rights, including access to healthcare. Section 27 of Chapter 2 of the Bill of Rights of the Constitution states the following about healthcare, food, water and social security:

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

3.1.2 Legislative Mandate

- SAHPRA's objective is to provide for the monitoring, evaluation, regulation, investigation, inspection, registration and control of medicines, scheduled substances, clinical trials and medical devices, in vitro diagnostics and further matters related to the public interest.
- Since its establishment in February 2018, as a Schedule 3A entity of the National Department of Health (NDoH), there has been no updates to its legislative and policy mandates. The cornerstone legislative mandates of SAHPRA are derived

from the national Constitution, the National Health Act, 2003 (Act No. 61 of 2003) and the Medicines and Related Substances Act, 1965 (Act No. 101 of 1965), as amended (herein after referred to as "the Medicines Act"); and

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

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

This Act provides a framework for a structured uniform health system within the Republic, considering the obligations imposed by the Constitution and other laws of national, provincial and local government regarding health services. The objectives of the National Health Act, as understood alongside other laws and policies that relate to health, are to:

- Unite the various elements of the national health system into a common goal to actively promote and improve the national health system in South Africa.
- Provide a system of co-operative governance and management of health services within national guidelines, norms and standards, in which each province, municipality and health district must address questions of health policy and delivery of quality healthcare services.
- Establish a health system based on decentralised management, principles of equity, efficiency, sound governance, internationally recognised standards of research and a spirit of enquiry and advocacy which encourage participation.
- Promote a spirit of 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; and
- Create the foundations of the healthcare system.

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

- Amended by the Amendment Act, 2008 (Act No. 72 of 2008) and Amendment Act, 2015 (Act No. 14 of 2015) and enacted in May 2017, the Act enabled, among others, the establishment of SAHPRA, the licensing of manufacturers

and importers of active pharmaceutical ingredients and the regulation of medical devices.

- In terms of the Medicines Act, the objects of the Authority are to provide for the monitoring, evaluation, regulation, investigation, inspection, registration and control of medicines, scheduled substances, medical devices, radiation control, clinical trials and further matters related to the public interest.
- The Act also provides for registration and control of veterinary medicines in such a way as to ensure that they are produced, distributed and used without compromising human and animal health. Antimicrobials intended for use in animals and registered under the Medicines Act can only be administered or prescribed by a veterinarian.
- As per section 2b (1) of the Medicines Act, the Authority must, to achieve its objects, ensure:
  - The efficient, effective and ethical evaluation or assessment and regulation of medicines, medical devices, radiation-emitting devices and radioactive nuclides that meet the defined standards of quality, safety, efficacy and performance, where applicable.
  - That the process of evaluating or assessing and registering of medicines, medical devices, radiation emitting devices and radioactive nuclides is transparent, fair, objective and concluded timeously.
  - The periodic re-evaluation or re-assessment and ongoing monitoring of medicines, medical devices, radiation-emitting devices and radionuclides.
  - The investigation, monitoring and analysis of evidence of existing and new adverse events as well as reactions, interactions and signals emerging from post-marketing surveillance and vigilance activities, while ensuring that these are acted upon.
  - That compliance with existing legislation is promoted and achieved through a process of active inspection and investigation; and
  - That clinical trial or clinical performance study protocols are assessed according to prescribed scientific, ethical and professional criteria and defined standards.
- In executing its functions, the Authority may:
  - Liaise with any other regulatory authority or institution and may, without limiting the generality of this power, require the necessary information

from, exchange information with and receive information from any such authority or institution in respect of:

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

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

- The Hazardous Substances Act provides for the efficient, effective and ethical evaluation and licensing of radionuclides (Group IV hazardous substances) and listed electronic products (Group III hazardous substances – including but not limited to electronic generators of ionising or non-ionising radiation).
- SAHPRA is only responsible for the regulation of Group III and Group IV hazardous substances.
- Section 3 of the Act refers to regulation of Group III hazardous substances, that is, listed electronic products, and section 3A refers to Group IV hazardous substances, that is, radionuclides.

3.1.6 Other Related Legislations

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

- Fertilisers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act No. 36 of 1947)
- Animal Diseases Act, 1984 (Act No. 35 of 1984)
- Veterinary and Para-Veterinary Professions Act, 1982 (Act No. 19 of 1982)
- Drugs and Drug Trafficking Act, 1992 (Act No. 140 of 1992)
- Foodstuffs, Cosmetics and Disinfectants Act, 1972 (Act No. 54 of 1972) as Amended
- Environmental Management Act: Waste Management Act, 1998 (Act No. 107 of 1998)
- Health Professions Act, 1974 (Act No. 56 of 1974)
- Nursing Act, 1978 (Act No. 50 of 1978)

- Pharmacy Act, 1974 (Act No. 53 of 1974)
- Customs and Excise Act, 1964 (Act No. 91 of 1964)

3.2 Rights of SAHPRA staff

You have a RIGHT to:	You have an OBLIGATION to:
Certainty (to be informed) of obligations to SAHPRA • Be informed as a stakeholder • Receive support • Have access to products (digital)	**Timeously engage, register and comply with legal obligations** • Be informed and adhere to due dates • Find out the minimum requirements • Make required payments to SAHPRA on time as per gazetted fees
Excellent service irrespective of the method of engagement with SAHPRA • Experience high-quality service • SAHPRA to meet expectations • Consistent service when engaging SAHPRA • Service renewal on matters raised with SAHPRA	**Fully cooperate and provide accurate information through efficient and timeous engagement via appropriate channels.**
Be heard, complain and lodge disputes that are resolved timeously • When not satisfied with our service, engage the immediate supervisor/manager • Escalate through SAHPRA processes • Request for reasons if clarity is required on an outcome • Lodge an appeal within prescribed timelines • Escalate to the Office of the CEO if exhausted SAHPRA processes in disagreement with SAHPRA on administrative matters	**Provide all supporting documentation and information within the required timeframes** • Familiarise yourself with SAHPRA notifications/letters issued on requested information • Observe timelines • Update SAHPRA with current contact details and Responsible Pharmacists/persons
Be treated without fear or favour by SAHPRA in a confidential manner, within the relevant legislative framework • All are equal before the law • No intimidation or harassment • No unfair treatment • No unlawful actions/activities • Be treated professionally by SAHPRA	**Act honestly and have respect for the Regulatory system** • Honour your obligations • Assist in deterring non-compliance by reporting fraud and non-compliance with legislation • Refuse to collude or conceal criminality • Report any fraud or criminality you are aware of
Be represented by a professional	**Accept personal responsibility for all SAHPRA affairs and not avoid accountability**

• Ethically qualified certified and or accredited legal practitioner can be authorised to handle your matters with SAHPRA	• Your information and your portal credentials remain your identity and will be safely stored. • Representation does not delegate accountability • Anything your representative is authorised to do, it is on your behalf.
Respect by all SAHPRA staff • Courteous behaviour at all times • Respect is mutual • Considered honest unless proven otherwise • Pleasant service experience by all SAHPRA staff	**Respect for the legislative work performed by all SAHPRA staff** • Accept an enquiry/transaction outcome to have been performed faithfully • Will be factual in all transactions

3.3 Who are we?

3.3.1 SAHPRA is a Schedule 3A public entity of the National Department of Health, created by the South African government to ensure that the health and well-being of humans and animal are at its core. SAHPRA is constituted as an independent entity that reports to the Minister of Health through its Board.

3.3.2 SAHPRA is tasked with regulating (monitoring, evaluating, investigating, inspecting and registering) all health products. This includes clinical trials, complementary medicines, medical devices and *in vitro* diagnostics (IVDs). Furthermore, SAHPRA has the added responsibility of overseeing radiation control in South Africa. SAHPRA's mandate is outlined in the Medicines and Related Substances Act (Act No 101 of 1965 as amended) as well as the Hazardous Substances Act (Act No 15 of 1973).

3.3.3 SAHPRA has the following three pillars to ensure that medicines, medical devices and IVDs meet the requisite standards to protect the health and well-being of South Africans:

a. Safety
b. Efficacy
c. Quality

It is these three pillars that also define SAHPRA's ethos.

3.4 Strategic Focus

3.4.1 Vision

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

3.4.2 Mission

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

3.4.3 Values

- Ubuntu - To promote compassion, respect and in all actions and decisions.
- Responsiveness - Implement clear service timelines for applications, queries, and complaints.
- Integrity - Ensure impartiality and fairness in decision-making processes.
- Transparency - Provide open access to regulatory information, decisions, and guidelines
- Efficiency - Streamline processes to minimise delays and maximise service quality.
- Excellence - Strive for continuous improvement and adopt global best practices.
- Collaboration – Break silos, build bridges, and value every contribution toward common goals.

3.5 Who benefits from this Service Charter

This Charter sets out the standard of service you can expect from the staff of SAHPRA in the offices of the various SAHPRA Buildings (Gauteng, Western Cape and KwaZulu-Natal). SAHPRA recognises the following groups as its key stakeholders:

a. General Public
b. Health Products Industry

c. Minister of Health
d. Director-General of Health
e. Parliament
f. Government (National and Provincial)
g. Health Professionals and Health Professional Organisations
h. Academia and Research Institutions
i. Media
j. International Organisations
k. Donors
l. Other Partners

3.6 What you can generally expect at service points

Batho Pele: We are committed to providing quality services to both our internal and external stakeholders by meeting and exceeding their expectations and needs. We commit to all Batho Pele principles:

a. **Consultation** – SAHPRA is committed to maintaining regular consultation with relevant stakeholders to ensure continuous improvement in the quality of service provided by the Entity. This engagement allows SAHPRA to address concerns, understand stakeholder needs and make informed adjustments to enhance service delivery.
b. **Service Standards** – SAHPRA is committed to setting clear service standards that define the quality of services stakeholders can expect.
c. **Access** – Increasing access to services.
d. **Courtesy** – Ensuring ubuntu while dealing with stakeholders.
e. **Information** – SAHPRA is dedicated to providing stakeholders with comprehensive, clear, and relevant information to help them make informed decisions. This includes detailed guidance on regulatory processes and compliance, as well as updates on policies and standards.
f. **Openness & Transparency** - Increasing openness and transparency about how services are delivered.
g. **Redress** – Proactively addressing and resolving issues as well as addressing failures and mistakes so that problems are resolved or dealt with positively.
h. **Value for Money** – Rendering our services to the satisfaction of our stakeholders.

Regulatory principles: these pillars that define the culture of SAHPRA to achieve safety, efficacy and quality.

a. **Shared Values** – Improve SAHPRA's professional culture and adopt professionalism as one of SAHPRA's core values.
b. **Operational effectiveness and efficiencies** – Reducing bureaucracy.
c. **Agility and Urgency** – In regulatory processes to accommodate the rapid pace of change.
d. **Harmonisation of legislative framework** – Enhancing partnership and collaborations with strategic partners.
e. **Regulation** – Continuous efficient monitoring, evaluating, investigating, inspecting and registering all health products.
f. **Reliance** – Implementation

3.7 Key service standards of services we provide

3.7.1 A service standard is a "reasonable and measurable expectation from the side of the service beneficiary and an honest commitment by the service provider to meet or exceed that expectation" (Operations Management Framework, 2016: 134).

3.7.2 SAHPRA's definition of service as per the Medicines and Related Substances Act (Act No 101 of 1965 as amended) and the Hazardous Substances Act (Act No 15 of 1973) is:

a. the regulation of health products intended for human and animal use.
b. the licensing of manufacturers, wholesalers, and distributors of medicines and medical devices; radiation-emitting devices and radioactive nuclides.
c. the conduct of clinical trials in a manner that is compatible with the national medicines policy

3.7.3 SAHPRA strives to inform stakeholders on service expectations through a commitment to deliver on the service standards shown below.

a. **Support Services**

Services	Current Standard of Service	Desired Standard of Service
Payment of SAHPRA Service Providers	Within 30 days of receipt of an invoice	Within 30 days of receipt of an invoice
Handling of Complaints/Queries	Resolved complaints/queries resolved within 30 business days	60% of complaints/queries resolved within 30 business days

Engagement with SAHPRA	Stakeholder satisfaction with SAHPRA communication and engagement efforts	70% of stakeholder satisfaction with SAHPRA communication and engagement efforts obtained
Refunds	Within 2 to 3 months due to non-compliance to refund guideline	Within 30 days of receipt of a refund request with completed required documents
Payment for SAHPRA services	– On application for services – Within 30 days of receipt of an invoice	– On application for services – Within 30 days of receipt of an invoice
Debt collection	2-3 months after service delivery or regulated fee	Within 30 days after receipt of an invoice

b. Core Business Services

Services	Current Standard of Service	Desired Standard of Service
GENERAL HEALTH PRODUCT AUTHORISATION		
Health Product Application Status Checker	Updated as and when the Unit trackers are updated	Availability of a real-time status checker
Registered Health Products	Medicines register updated weekly	Availability of a real-time register
Registration of NCEs	80% finalised within 360 WD	60 registered annually
Registration of Generics	75% registered within 250 WD	420 Generic Master applications finalised annually
Processed applications for renewals applications	Applications for renewals of certificates of registration finalised within 120 working days (screening and evaluation timeline)	60% of received applications for renewals of certificates of registration finalised within 120 working days (screening and evaluation timeline)
Quality Variations	Type II finalised within 200 WD	60% Type II finalised within 200 WD
Clinical Variations	Type II finalised within 200 WD	60% Type II finalised within 200 WD
Certificate Variations	Certification process completed within 25 WD	Certification process completed within 20 WD
Priority Request Reviews Process	Applications finalised within 180 working days (evaluation timeline) for priority review pathways post screening	80% of applications finalised within 180 working days (evaluation timeline) for priority review pathways post screening
Marketing Authorisation approvals for priority review pathways.	Marketing Authorisation approvals granted within 180 working days (evaluation timeline) for priority review pathways	75 % of Marketing Authorisation approvals granted within 180 working days (evaluation timeline) for priority review pathways
INSPECTORATE AND REGULATORY COMPLIANCE		
Licensing	New GMP related licenses issued within 125 working days	60% of New GMP related licenses are issued within 125 working days

Services	Current Standard of Service	Desired Standard of Service
	New GWP related licenses issued within 125 working days	70% of New GWP related licenses are issued within 125 working days
Permits	85% Permits issued within 20 working days	
Notification of recalls and alerts	80% of recalls and related alerts published within 7 working days	
Regulatory Compliance Investigation Reports	80% regulatory compliance investigation reports produced within 30 working days	85% of regulatory compliance investigation reports produced within 30 working days
SECTION 21 APPLICATIONS		
Online Submission Portal for Section 21 Applications	95% Section 21 applications for category A medicines processed with a decision within 3 working days from date of receipt of complete application	95% Section 21 applications for category A medicines processed with a decision within 3 working days from date of receipt of complete application
CLINICAL TRIALS		
Human clinical trial applications finalised	Clinical Trials safety signal detected and mitigated within 80 working days	70% within 80 days
PHARMACOVIGILANCE		
Health product safety signals issued	All high public health impact safety signals detected and mitigated within 40 working days	60% within 40 working days
Reports on health product safety signals assessed	Reports on health product significant safety issues assessed within 60 working days	70% within 60 working days
Safety communications published	Safety communications published within 10 working days	90% within 10 working days
ADRs/ AEFIs reports which are shared with the WHO global database of ICSR (VigiBase)	ADRs/ AEFIs reports which are shared with the WHO global database of ICSR (VigiBase) received within each quarter	70% within each quarter
COMPLEMENTARY MEDICINES		
Complementary (Category D) Medicines Licensing	License applications finalised within 90 working days	80% within 90 WD
Complementary Medicines Section 21	Applications for the use of unregistered Category D (CMs) medicines finalised within five (5) working days	80% within 5 working days
BIOLOGICAL MEDICINES		
Lot Release of Human Vaccine	50* working days	90% in 50 WD

Services	Current Standard of Service	Desired Standard of Service
	*Excludes vaccines that require longer incubation times for testing	
VETERINARY MEDICINES		
Veterinary Section 21	24 working hours	80% within 24 working hours (Category C)
Veterinary Clinical Trials	120working days	120 working days
MEDICAL DEVICES		
Medical device establishment license applications finalised	Application finalised within 90 working days	80% application finalised within 90 working days
Medical device Clinical trials	Medical device clinical trials applications finalised within 60 working days	70% of medical device clinical trials applications within 60 working days
Medical device section 36 applications finalised	Medical device section 36 applications finalised within 30 working days	70% medical device section 36 applications finalised within 30 working days
RADIATION CONTROL		
License applications for Radionuclide authorities	Applications for Radionuclides authority licenses finalised within 60 working days	70% applications for Radionuclides authority licenses finalised within 60 working days
License applications for listed- electronic products	Applications for listed-electronic products licenses within 50 working days	90% of applications for listed-electronic products licenses within 50 working days
Dental X-ray license applications finalised	Licence applications for dental X-rays finalised within 30 working days	70% licence applications for dental X-rays finalised within 30 working days
Radiation Protection and Safety	Radiation over-exposures investigations completed within 60 working days	70% radiation over-exposures investigations completed within 60 working days
Radiation Incidents Investigations	Radiation incident investigations completed within 90 working days	70% radiation incident investigations completed within 90 working days

Fees are levied for certain services rendered and are subject to change. The latest fees for SAHPRA services are available on SAHPRA's website (www.sahpra.org.za).

3.8 Service rights of applicants and stakeholders

SAHPRA values the services provided to applicants and stakeholders, and therefore ensures the following rights to applicants and stakeholders:

a. Privacy and confidentiality
b. Professionalism and ethical behaviour
c. Prompt and efficient services
d. Consultations on the needs and expectations of services
e. Communication on services standards to expect
f. Be treated with ubuntu
g. Equal access to services to which they are entitled
h. Given full and accurate information
i. Transparency on regulatory decisions
j. Who is in charge
k. Mechanism for reporting complaints and dispute resolution

3.9 Expectations from applicants and stakeholders

Service delivery is two-way system and for SAHPRA to realise its service commitments, it is depended on partnerships. SAHPRA therefore expects the following from applicants and stakeholders:

a. Provide accurate and complete information
b. Provide all supporting documentation and information within the required timeframes
c. Act with integrity
d. Be respectful
e. Provide feedback on services provided
f. Fees for services

3.10 Service commitment to applicants and stakeholders

SAHPRA is committed to providing quality services to applicants and stakeholders by committing to:

a. Privacy and confidentiality
b. Having regular consultations with relevant stakeholders on the quality of services
c. Setting service standards specifying the quality of services to be expected
d. Ensuring higher levels of courtesy
e. Providing relevant information and advice about services
f. Increasing openness and transparency on decisions
g. Addressing complaints or disagreements timeously
h. Services provided in a fair manner

i. Rendering our services to the satisfaction of our stakeholders
j. Access to information

3.11 Customer's Obligation

We rely on a strong partnership with you for the realisation of the promises in this Charter. We also count on you to be courteous towards our staff and treat them with respect.

3.12 If you phone us, you can expect personnel to:

a. answer the phone courteously, identify the centre and provide their names and designation
b. be helpful and deal with your inquiries promptly
c. transfer your call to the appropriate area/person, where necessary

3.13 Compliments and Complaints

3.13.1 Procedure to Submit Compliments and Complaints:

- Submit your complaint or compliment via our website: https://www.sahpra.org.za/ , click **contact us**, **general enquiries** and choose an option in a tabulate box: complaint, compliment, feedback or enquiry, an alternative option, you could submit your complaint to our customer care e-mail address on enquiries@sahpra.org.za.

3.13.2 When you lodge a complaint, you can expect:

a. Access to information and an impartial, speedy and effective complaints handling procedure.
b. an apology and appropriate redress when you are not treated well, or standards have not been met.

3.13.3 Procedure for Appeals:

- Procedure for Appeals in Terms of Section 24A of the Medicines Act, and
- The Procedure for Appeals in terms of Section 24A applies to SAHPRA's administrative decisions on requests. Refer to the table below on instances that can be considered.

Table 1: Instances that can be considered under section 24A

Authority's decision relating to	Appealable	Not Appealable
Decision on standard of quality, safety and efficacy		X
Contravention of the Medicines Act		X
Non-compliance with timeframes	Depending on the circumstances such appeal maybe considered	
Submission of incomplete dossier		X
Failure or delay in respond to a query	X	
Failure to submit a required report	X	

3.13.4 Any entity or person who is aggrieved by SAHPRA's decision or lack of decision may lodge an appeal as follows:

a. All appeals should be submitted to the Chief Executive Officer's (CEO's) office.
b. The applicant/aggrieved person must file an appeal within 30 days of receiving the decision of SAHPRA.
c. The CEO must in 30 days of receipt of the appeal meet and hear the applicant's grievance or complaint.
d. The CEO shall inform the applicant of the outcome of the appeal.
e. The CEO may reject an appeal, and in the event the appeal is rejected, the CEO must provide written reasons thereof.
f. If the matter remains unresolved, the applicant has 30 days of being informed of the CEO's decision, to request the Minister to constitute an Appeal Committee.
g. In the event the appellant refers an appeal to the Minister, the appellant shall pay the prescribed fee.
h. The Appeal Committee shall hear and make its decision within 30 days of its first meeting to hear the appeal.
i. Should any party feel aggrieved by the decision of the Appeal Committee, such party may approach the High Court for a judicial review.

3.13.5 Reporting Fraud and Corruption

- Report any incidents of fraud, corruption or unethical behaviour to the anonymous SAHPRA 24-hour hotline: 0800 204 307.

- Whistleblower and medical Product Complaints through the following link on our website: https://www.sahpra.org.za/complaints-relating-to-medicine-and-medical-devices/.

4 OUR PLEDGE

We, the leadership and staff at SAHPRA, solemnly pledge and commit ourselves jointly and individually to:

a. Abide by the basic values and principles governing public administration as enshrined in Section 195 of the Constitution of the Republic of South Africa of 1996, and other laws and government policies that give effect to such values and principles.

b. Abide by the values and principles as stipulated in the White Paper on Transforming Public Service Delivery (Batho Pele White Paper).

c. Promote and live by the value statement of SAHPRA as it relates to:

- **Transparency** - Provide open access to regulatory information, decisions, and guidelines.
- **Responsiveness** - Implement clear service timelines for applications, queries, and complaints.
- **Ubuntu** - To promote compassion, respect and in all actions and decisions
- **Efficiency** - Streamline processes to minimise delays and maximise service quality.
- **Integrity** - Ensure impartiality and fairness in decision-making processes.
- **Collaboration** – Break silos, build bridges, and value every contribution toward common goals.
- **Excellence** - Strive for continuous improvement and adopt global best practices.

5 MONITORING PROGRESS

SAHPRA's progress on the implementation of its service standards is reported in the entity's quarterly and annual reports. Where service standards have not been met, corrective actions will be identified and implemented.

6 REVIEW OF THE SERVICE DELIVERY CHARTER

The Service Delivery Charter will be reviewed every three years.

7 CONTACT SAHPRA

7.1 General Enquiries

📞 Tel: (012) 501 0300

📧 Email: enquiries@sahpra.org.za

7.2 Hours of Operation

Hours of business are Monday to Friday: 08:00 – 17:00 (excludes public holidays).

7.3 We can be found at the following Offices:

Head Office (Pretoria)

Building A

Loftus Park

402 Kirkness Street

Arcadia

Pretoria

📌 **Coordinates**

-25.75103123371855, 28.2230970376626

Postal Address:

South African Health Products

Regulatory Authority

Private Bag X828

Pretoria

0001

Cape Town Office (Radiation Control)

Avanti Office Park North

35 Carl Cronje drive

Tygervalley

Bellville

7530

📌 **Coordinates**

-33.86885582264172, 18.63123976615851

Durban Office

Suite 10, 4 The Crescent

Westway Office Park

Westville

Durban

3629

📌 **Coordinates**

29.85050521636615, 30.9285920601322

8 DEFINITIONS

8.1 The following terms are used in this document:

Abbreviations/ Terms	Meaning
Business Day	Any day in the Republic of South Africa according to the Calendar year which is not a Saturday, Sunday or official public holiday within the meaning of the Public Holidays Act, 1994 and all references in this Agreement to days shall be deemed calendar days, unless specifically stipulated as being Business Days
CEO	SAHPRA Chief Executive Officer
CFO	Chief Financial Officer
CRO	Chief Regulatory Officer
HR	Human Resources
Medicines Act	Medicines and Related Substance Act, 1965 (Act No. 101 of 1965) as amended
Month	Calendar Month;
Regulations	General Regulations in terms of the Medicines and Related Substance Act, 1965 (Act No. 101 of 1965) as amended
SAHPRA	South African Health Products Regulatory Authority