Pharmacy Month 2026

Ask Your Pharmacist

Your Pharmacist, Your Partner in Health

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Opening & Introduction of Pharmacy Month

Ms Mojo Mokoena
Chief Operating Officer (COO)
South African Pharmacy Council

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Services Pharmacists can provide, PIMART update, Family Planning update and Role of PSPs

Ms Raesibe Madigoe

South African Pharmacy Council

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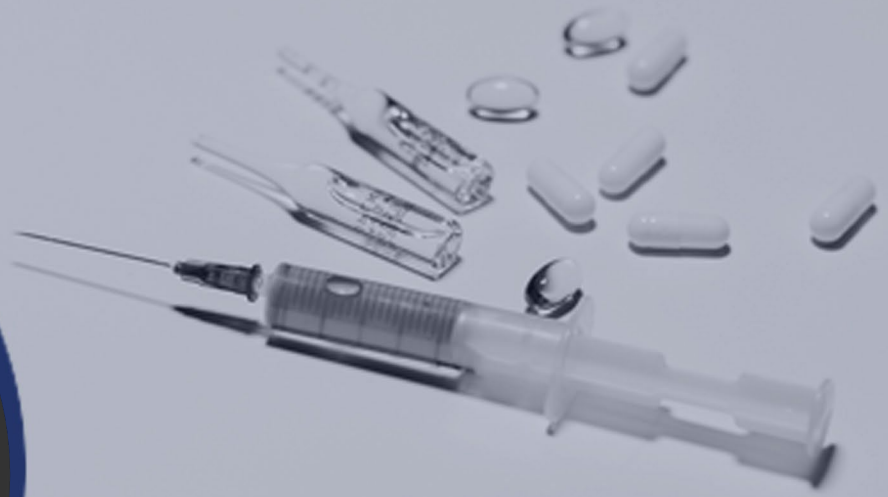

Raesibe Madigoe

South African Pharmacy Council

12 August 2026

South African Pharmacy Council
www.sapc.za.org

Overview

- Legislation
- Expanding Access to Pharmaceutical Care
- Council decisions
- Section 22A(15) Permits Holders
  - PIMART
  - PCDT
  - Immunisation and Injection Services
  - Family Planning

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Legislation

- BN868 of 2025: Services for which a pharmacist can levy a fee_2026
- SECTION 22A (15) permits for pharmacists (Act 101, of 1965)
- Board Notice 101 of 2021: Pharmacists who provide PIMART services
- BN241 of 2022: Immunisation and Injection Technique
- BN384 of 2023: PCDT, scope of practice, competency standards and criteria for curriculum
- BN314 of 2022: Family planning services

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Introduction

The South African Pharmacy Council (Council) is a statutory body established in terms of Section 2 of the Pharmacy Act, 53 of 1974 (the Act). The objectives of Council are found in Section 3 of the Act.

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Expanding Access To Pharmaceutical Care

Council Resolution May 2025

Council resolved that pharmacists may provide professional services within their scope of practice outside the physical premises of a pharmacy, provided that medicines are not sold outside a pharmacy.

- Increased access to pharmacist-initiated therapy
- Supports patient-centred care
- Increases service delivery to underserved communities

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Expanding Access To Pharmaceutical Services cont...

- Medicine therapy management
- Immunisation services
- Chronic disease management
- Family planning services
- Minor ailment management
- Screening and early detection
- Palliative and supportive care
- Health promotion and health education

Good Pharmacy Practice

Section 22A(15) Permit Holders

- Scope of Practice
  - Diagnose approved conditions
  - Prescribe medicines within permit conditions
  - Administer Schedule 1 to Schedule 4 medicines
  - Manage patients in accordance with the list of conditions published by the National Department of Health.

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Permit Application Process & Issuance

- Online application
  - Payment of application fee (BN Fees_supplementary training)
  - Competence certificate from the Provider
- SAPC
  - Officer checks documents
  - Manager evaluation –Recommendation to DG
  - DG –Issues Permit
  - Notification to Applicant to view
  - Notification to SAPC
- SAPC – receives issued permit for recording purposes
  - Issue registration certificate and
  - Permit (link to medicines list STG & EML)

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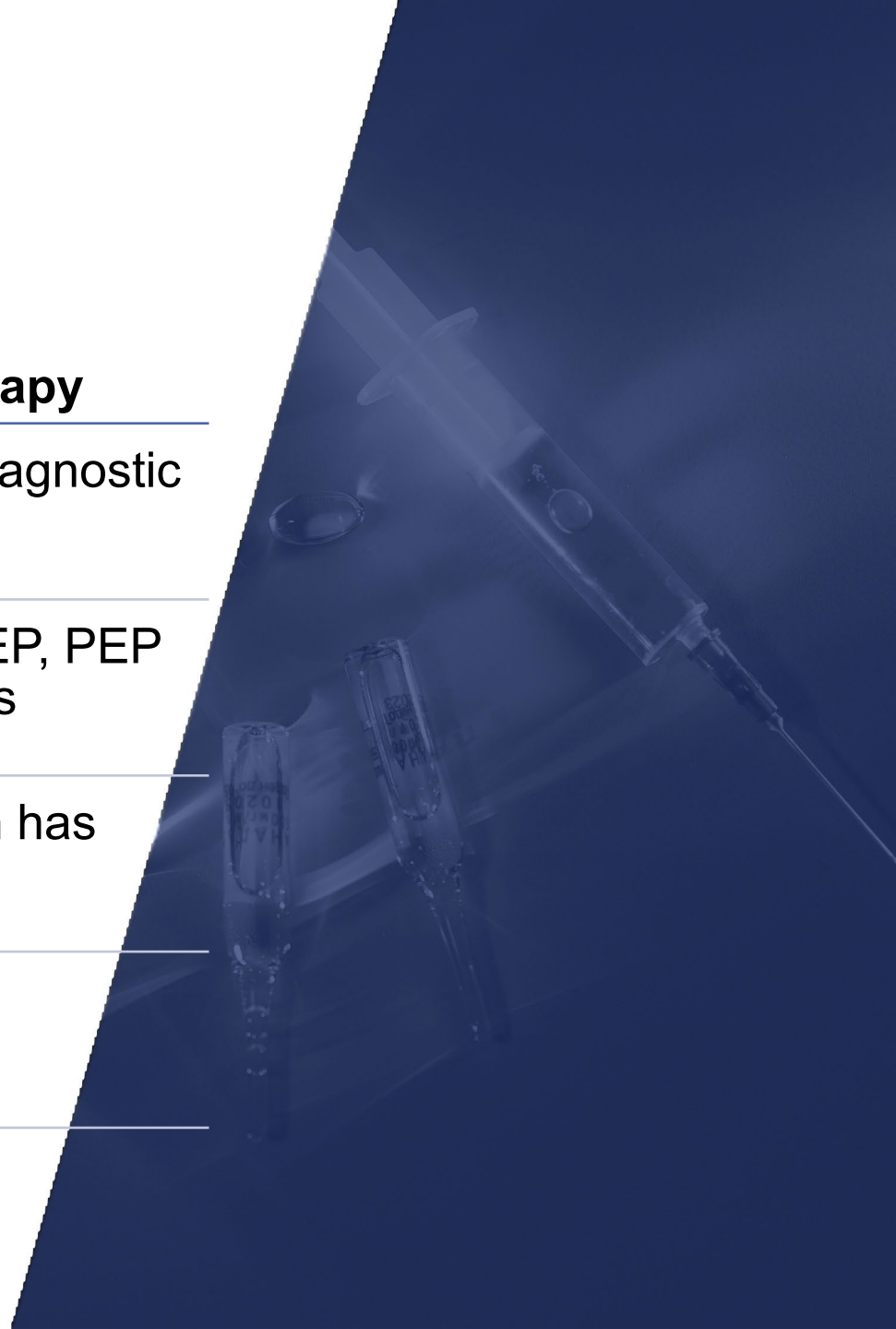
PIMART Services

Pharmacist-Initiated Management of Antiretroviral Therapy

Scope	Ordering, conducting and interpretation of diagnostic and laboratory tests
	Initiate anti-retroviral treatment limited to PrEP, PEP and 1st line Antiretroviral Therapy (ART) plus initiation of TB-Preventative Therapy (TPT)
	Adjustment of ART (where necessary) which has been prescribed previously
	Monitoring of the outcomes of therapy



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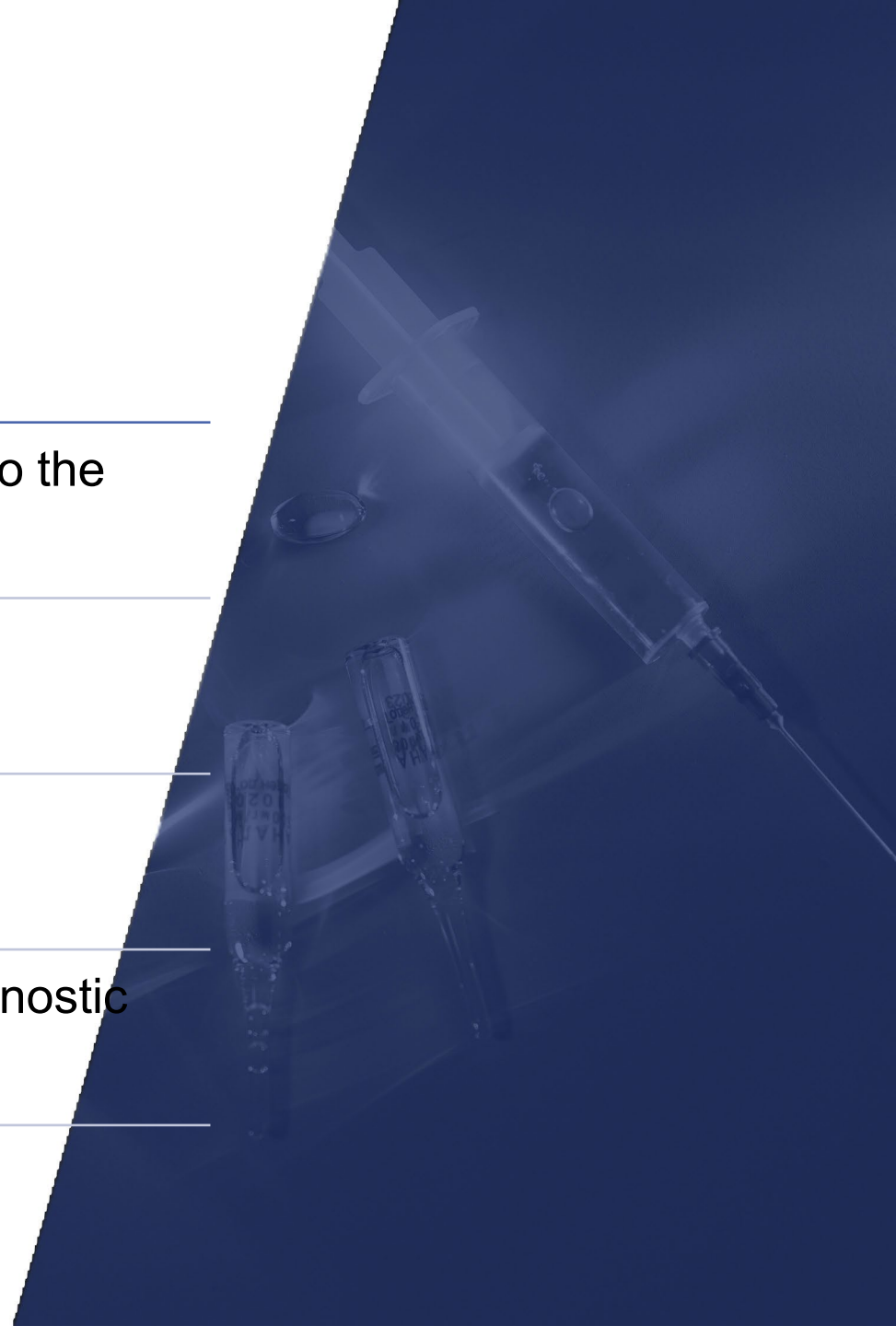
PCDT Services

Primary Care Drug Therapy (PCDT)

Scope	Assess and diagnose conditions according to the PCDT list
	Prescribe according to PHC,STGs and EML
	Provide follow-up care
	Ordering, conducting, and interpreting diagnostic and laboratory tests



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PCDT Services cont....

Council in 2026 resolved that:

PCDT Pharmacist Prescriptions

- May be dispensed by any other pharmacist or pharmacy support personnel, within their scope of practice
- Are repeatable in accordance with the NDoH's latest Primary Health Care Standard Treatment Guidelines and Essential Medicines List (PHC STG and EML)
- May be dispensed at any other pharmacy provided it is validated and authenticated

Medical Certificate

- A PCDT Pharmacist may declare a patient unfit for work for a maximum of three (3) days

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Family Planning Services

Reproductive Health Services

Scope

- Family Planning counselling
- Contraceptive initiation and management
- Reproductive health education
- Ongoing follow-up and support

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Immunisation Services

Pharmacists Offering Immunisation Services

Scope	Administering of vaccines according to (EPI_SA)
	Monitoring, measuring and reporting of outcomes
	Reporting of immunisation adverse events
	Referral to other healthcare providers

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Any questions?

Identifying and Reporting Substandard and Falsified Medicines, Including The Process After Reports are Received

Ms Daphney Mokgadi Fafudi

South African Health Products Regulatory Authority

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Identifying & Reporting Substandard and Falsified Medicines

Protecting patient safety — one report at a time

DAPHNEY FAFUDI
MANAGER: REGULATORY COMPLIANCE


PANELISTS
1

What we'll cover

A practical path from spotting a problem to closing the loop

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South African Health Products Regulatory Authority

01

The scale of the problem

Why this matters now, in South Africa

02

Substandard vs. falsified

Getting the definitions right

03

Spotting the red flags

Visual, packaging and performance clues

04

Your duty to report

Who must report, and why it's protected

05

How to report to SAHPRA

Channels, forms and what to include

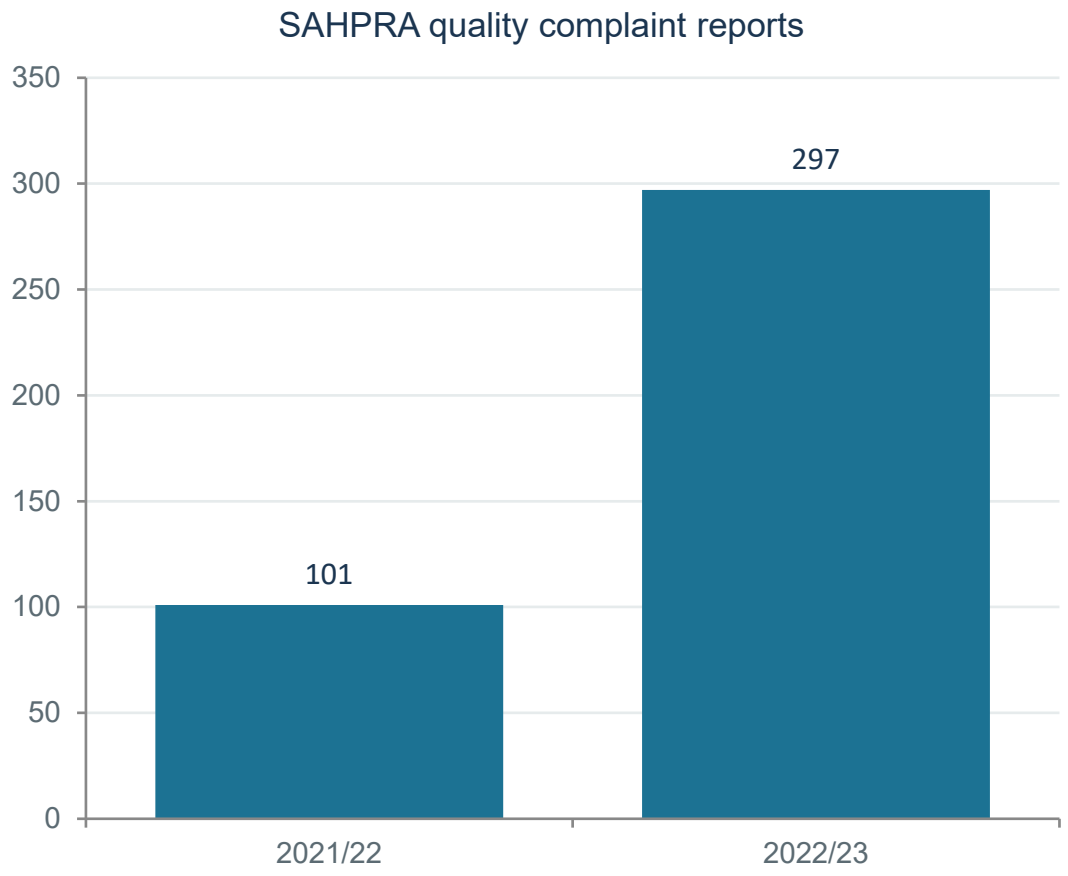
06

What happens next

SAHPRA's investigation process, step by step

A growing threat to patient safety

Health product quality complaints reported to SAHPRA are rising sharply



1 in 10

medicines in low- and middle-income countries is estimated by WHO to be substandard or falsified

588

reports of possible non-compliant products received by SAHPRA in 2025/26

Most affected categories: lifestyle medicines: painkillers, weight-loss, performance-enhancement products, skin-lightening products, anxiolytics, antibiotics and chronic medicines.

Know the terms before you flag a product

SAHPRA and WHO use precise definitions — "counterfeit" is no longer the correct term

SUBSTANDARD

Authorised medicines that fail to meet quality standards, specifications, or both — usually from poor manufacturing or storage, not intent to deceive.

e.g. degraded active ingredient, incorrect dissolution, contamination

FALSIFIED

Medicines that deliberately misrepresent their identity, composition, or source — including fake packaging, wrong or no active ingredient, or unauthorised manufacturers.

e.g. fake weight-loss injections, diverted or cloned packaging

NOT THE SAME AS: GENERIC

Registered generics are tested and SAHPRA-approved as safe and effective substitutes — they are not substandard by definition.

Don't confuse a legitimate generic with a quality problem

Why this is a patient-safety emergency

The consequences reach far beyond the individual patient

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South African Health Products Regulatory Authority

Treatment failure & direct harm

Sub-potent or wrong ingredients can mean a disease goes untreated, or a toxic ingredient causes injury or death.

Antimicrobial resistance

Substandard antibiotics with too little active ingredient are a documented driver of resistance, worsening a global crisis.

Strain on the health system

Failed first-line treatment forces costlier second- and third-line care, and erodes trust in legitimate medicines.

Erosion of public trust

Every undetected incident makes patients more likely to seek medicines outside regulated, safe channels — deepening the problem.

Red flags: packaging & appearance

What to check at receiving, dispensing, and on the shelf

- Packaging, box or blister print quality lower than usual — blurred text, colour shifts, cheap card stock
- Spelling errors, inconsistent fonts, or a batch number / expiry date that is smudged, altered, or missing
- No SAHPRA registration number, or a registration number that doesn't match the product on search
- Security features absent or tampered — holograms, seals, tamper bands, or serialisation codes
- Product supplied outside the normal, authorised supply chain (unfamiliar wholesaler, cash-only, no invoice)
- Pack size, leaflet, or language variant that doesn't match what SAHPRA has approved for this market

Red flags: product & patient signals

Sometimes the medicine looks right — but behaves wrong

Unusual physical properties

Abnormal colour, smell, texture, taste, or particles/discolouration in liquids and injectables.

Unexpected lack of effect

A patient reports the medicine “isn't working” the way an established product usually does.

Unexpected adverse reaction

New or unusually severe side effects, especially clustered around a specific batch or supplier.

Price or source anomalies

Prices well below market rate, unofficial online sellers, or informal/street purchase of scheduled medicines.

If in doubt — report it. SAHPRA does not require certainty, only reasonable suspicion.

Reporting is a professional duty, not optional

Under the Medicines and Related Substances Act, 1965 (as amended)

Who must report

- Pharmacists and pharmacy support staff
- Doctors, nurses and other healthcare professionals
- Certificate of Registration holders (manufacturers, importers)
- Wholesalers and distributors
- Members of the public and patients

You are protected

No blame on the reporter

Reporting an adverse event or quality concern does not assign fault to the person reporting it.

Confidential handling

Reports are treated confidentially and personal information is processed under POPIA.

Whistleblower channel available

Anonymous reporting is supported for suspected substandard or falsified products.

How to report to SAHPRA

Choose the channel that fits the situation — all reach the Pharmacovigilance and Regulatory compliance teams

Med Safety App

Free mobile app for ADRs and product quality problems, incl. offline capture. Search “Medsafety” and select South Africa.

eReporting (VigiFlow®)

Online submission portal on the SAHPRA website; report logged and tracked with a unique ID.

ADR / Quality Problem Form

Downloadable form emailed to adr@sahpra.org.za for adverse reactions and quality problems.

Whistleblower / Complaints route

For suspected substandard or falsified products and illegal sales — via SAHPRA's complaints and compliance channel, anonymity supported.

General enquiries: 012 501 0311 · Vigilance: adr@sahpra.org.za · www.sahpra.org.za

What a good report includes

More detail means a faster, more accurate investigation

Product identity

- Brand / generic name & strength
- Batch / lot number and expiry date
- SAHPRA registration number
- Manufacturer / supplier name

The problem observed

- What looks, smells or behaves wrong
- Photos of product & packaging
- Patient impact, if any (ADR)
- Where and how it was obtained

Reporter & context

- Your name, role and contact details (or anonymous)
- Facility / pharmacy name and location
- Quantity involved and whether stock is quarantined
- Date first noticed

Keep the physical product and its packaging — do not discard. Quarantine remaining stock pending SAHPRA guidance.

What happens after SAHPRA receives your report

The Regulatory Compliance Unit (RCU) and Vigilance Unit follow a structured process

1

Logged & triaged

Report captured / the complaints register, given a unique ID, and screened for urgency.

2

Preliminary assessment

RCU reviews evidence, checks the registration status, batch and distribution history.

3

Investigation & sampling

Site inspections, supply-chain trace-back, and laboratory testing of retained samples where needed.

4

Risk classification & action

Findings determine action: product recall, suspension, seizure, or referral for prosecution.

5

Closure & feedback

Outcome recorded; reporter receives acknowledgement and, where appropriate, feedback on the result.

Possible regulatory outcomes

The response is proportionate to the risk the product poses

No further action	Investigation finds the product meets requirements; complaint closed with feedback to reporter.
Corrective action by manufacturer	Manufacturing or storage fix required, with monitoring for compliance.
Product recall / withdrawal	Affected batches or the full product are removed from the market and from pharmacy shelves.
Enforcement Actions	Warning letters, licence revocation, Certificate of Registration suspended or withdrawn for serious or repeated non-compliance.
Seizure, destructions & referral for prosecution	Falsified products are seized; matters are referred to SAPS / NPA under the Medicines Act.

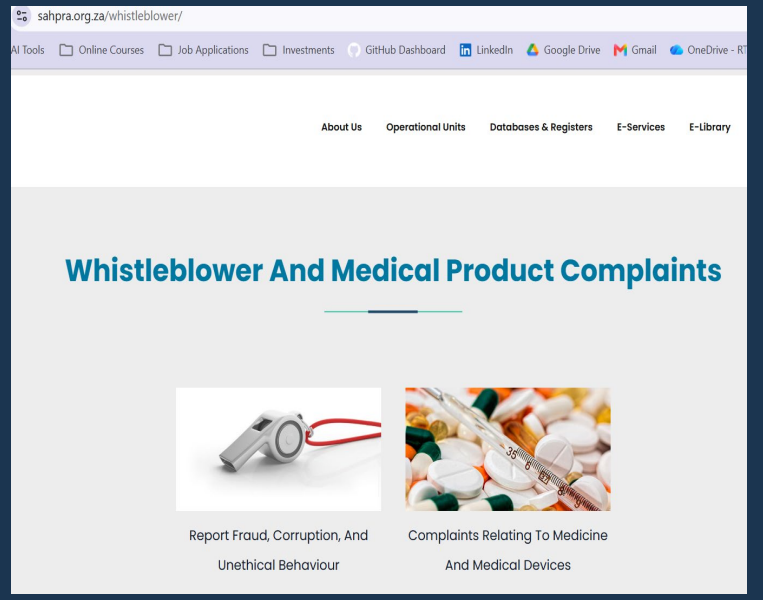
The pharmacy's role in the front line

Five habits that catch problems before patients are harmed

Buy only from authorised suppliers	Verify wholesaler licences and avoid informal or unusually cheap stock.
Inspect at receiving, not just at dispensing	Check packaging, batch numbers and security features on arrival.
Listen to patients	Treat “this doesn't look/work right” comments as a possible signal, not a complaint to dismiss.
Quarantine before you report	Set suspect stock aside immediately to preserve evidence and prevent further dispensing.
Report promptly, every time	Use the Med Safety App, eReporting, or the ADR/Quality form — even when unsure.

Every report protects the next patient

Suspect a substandard or falsified medicine? Don't wait for certainty — quarantine, document, and report.



Med Safety App

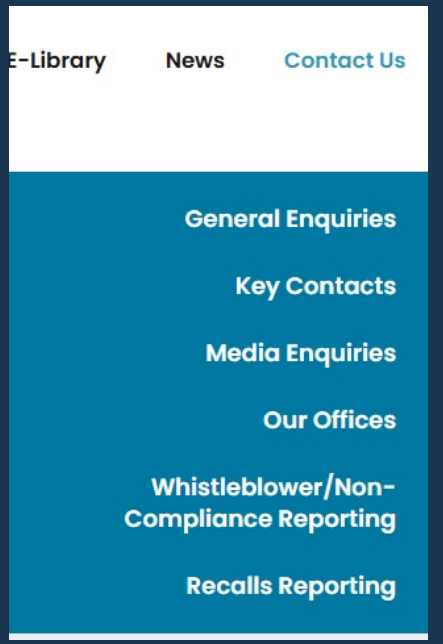
Search “Medsafety” · select South Africa

adr@sahpra.org.za

ADR & Quality Problem Reporting Form

www.sahpra.org.za

eReporting (VigiFlow®) & Whistleblower channel



General enquiries: 012 501 0311

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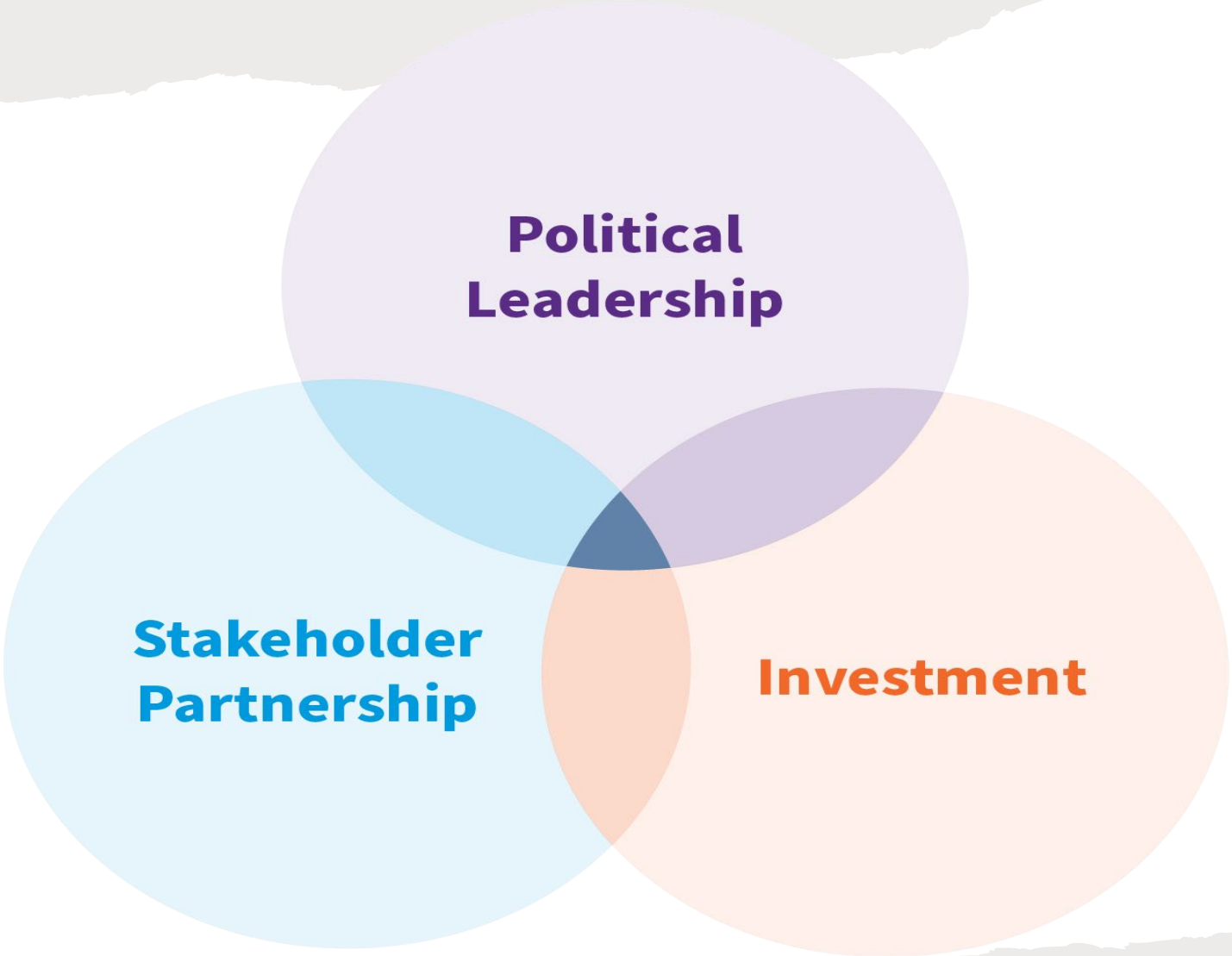
Determinants of success - Overarching and interlinked



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Thank you

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Legislation and Practice Surrounding Compounding of Medicines

Ms Sara Norcross

Industry

health

Department:
Health
REPUBLIC OF SOUTH AFRICA

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Navigating the complexity of the GLP-1RA market

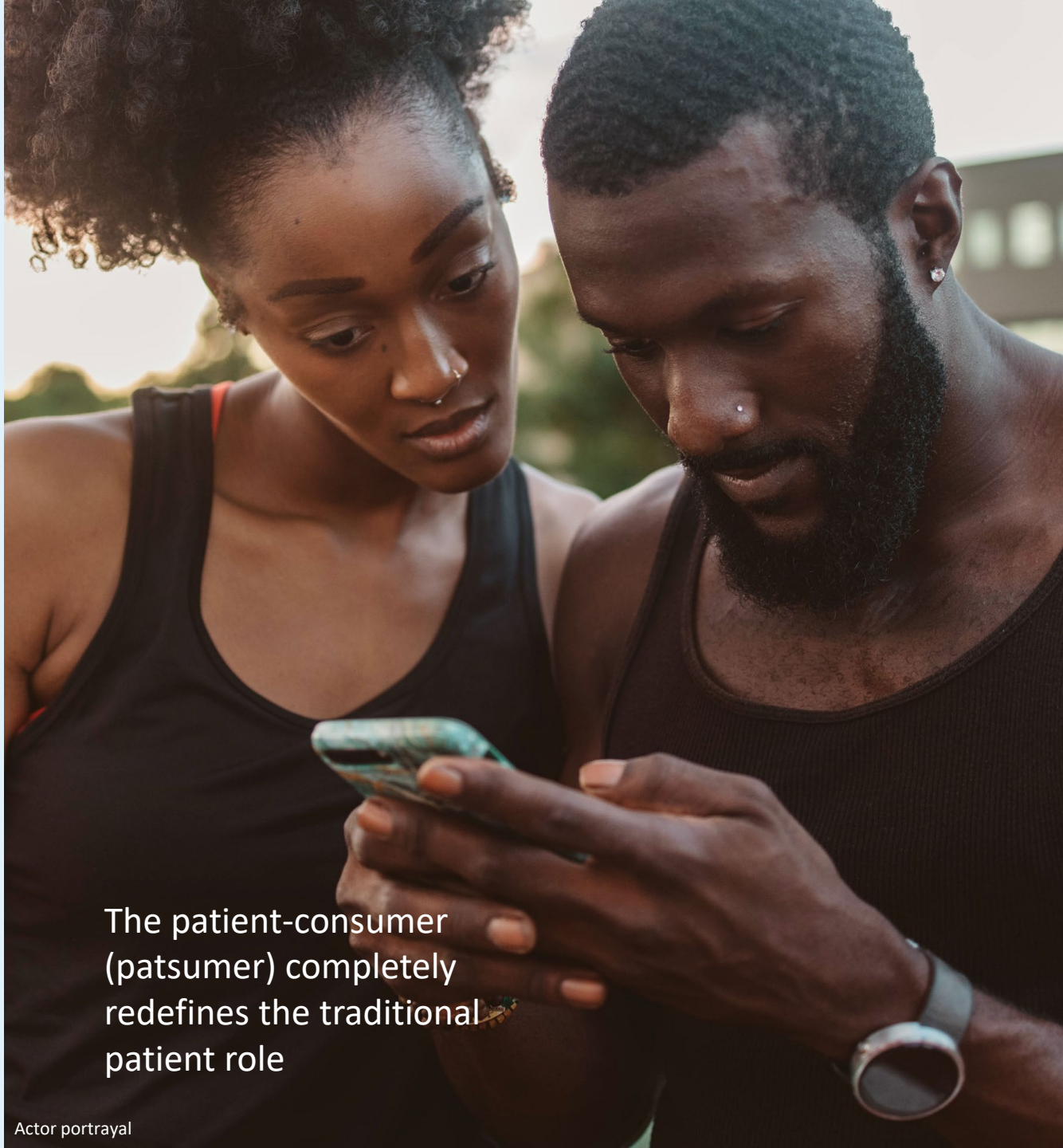
12 August 2026

Sara Norcross
General Manager, Novo Nordisk South Africa

The rise of the ‘patsumer’

Patsumers do not just hand over a prescription; they arrive armed with information gathered from online research or social media:

- They want to explore alternative drug options
- They want to co-design their treatment
- Challenge recommendations
- Hyper-informed (and misinformed) – Dr Google… social media…



Unpacking the differences

	Clone	Generic	Compound	Biosimilar	Falsified medicines
Manufacturing Process Identical	√	x	x	x	x
API Chemically Identical	√	√	√$	x	x
SEQ Similarity	√#	√*	√/x!	√*	x
Substitution at Pharmacy Level	√	√	x	x	x

Key: # 100% similar to originator *At least 85% similarity required $ Registered API required ! Theoretically should be the same, but not tested

Extensior®[1] is the Novo Nordisk clone of Ozempic®[2]

- **Same innovation & manufacturing process from Novo Nordisk**
- **Same high-quality device**
- **Same trusted supply**
- **Different name at a more affordable price**

Extensior®
semaglutide injection

1. Extensior® Professional Information, May 2026
2. Ozempic® Professional Information, May 2026

acino PART OF ARCERA | novo nordisk®

Illicit compounding – Protecting patient safety

High Court rules in favour of Novo Nordisk South Africa, halting illicit compounding with immediate effect

By JNPR - July 6, 2026

High Court rules in favour of Novo Nordisk South Africa, halting illicit compounding with immediate effect. Image source: Pixabay

- Legal win for Novo Nordisk South Africa: Pretoria High Court orders iDexis to halt illicit compounding of unregistered semaglutide with immediate effect
- High Court confirms that only registered APIs, dispensed on prescription, may be used in compounding
- Ruling reinforces SAHPRA and SAPC oversight and protects patients from unsafe GLP-1 medicines

EWN EYEWITNESS NEWS

Weight-loss drugs ruling: It was never about winning a case but about patient safety, says Novo Nordisk

PL Paula Luckhoff
25 June 2026 | 21:58

Novo Nordisk SA's Sara Norcross responds to the claim by iDexis that the interim order barring the compounding pharmacy group from producing these drugs is not in the public interest.

The Money Show | Stephen Grootes | Weight loss | Ozempic

South African Pharmacy Council www.sapc.za.org | SAHPRA South African Health Products Regulatory Authority | HPCSA Health Professions Council of South Africa

JOINT STATEMENT **08 July 2026**

Health regulators warn against the use or dispensing of recalled Semaglutide and Tirzepatide

The South African Pharmacy Council (SAPC), Health Professions Council of South Africa (HPCSA) and the South African Health Products Regulatory Authority (SAHPRA) hereby warn the public, pharmacies and dispensing medical practitioners against any continued use, prescription and/or dispensing of iDEXIS Semaglutide, iDEXIS Tirzepatide, and iDEXIS Semaglutide/Tirzepatide recalled by SAHPRA in June 2026.

The continued use, prescription and dispensing of these products pose a severe risk to patients' safety and/or users. Any healthcare professional found to have dispensed, prescribed or kept stock of the recalled products will face disciplinary action in accordance with applicable legislation, including the Medicines and Related Substances Act, 101 of 1965.

In a Class I, Type A Recall, SAHPRA determined that iDEXIS Semaglutide, iDEXIS Tirzepatide, and iDEXIS Semaglutide/Tirzepatide pose serious safety risk to patients. Thus, any professional found to be prescribing or dispensing them to patients or users will knowingly be endangering the health of the public. The recall notice, which contains a list of the recalled products, may be accessed at: https://www.sahpra.org.za/document/idexis-semaglutide-idexis-tirzepatide-idexissemaglutide-tirzepatide/

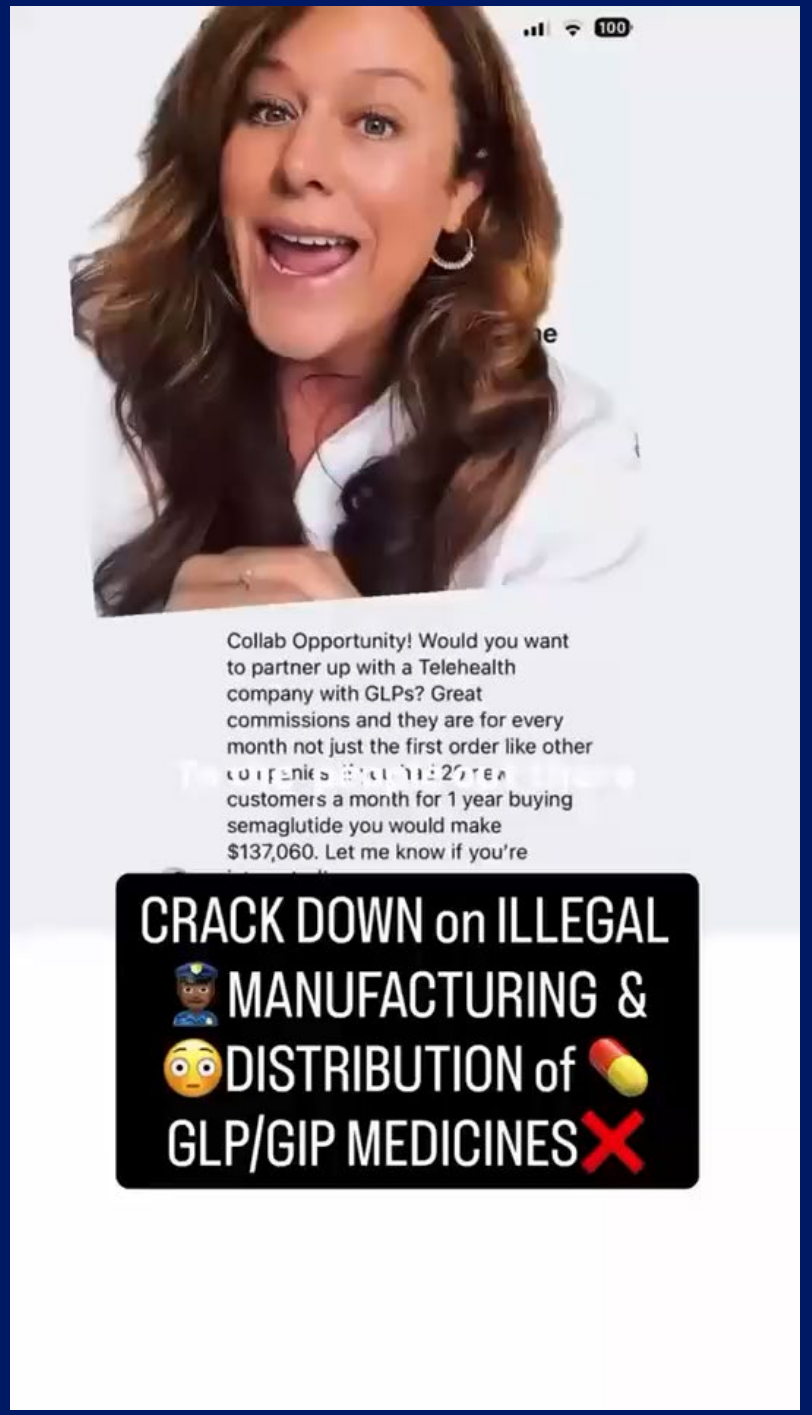
ENDS

Issued by:

1. Mr Vincent Tlala, Registrar/CEO, South African Pharmacy Council
2. Dr Boitumelo Semete-Makokotlela, CEO, South African Health Products Authority
3. Dr Karmani S Chetty, Interim Registrar, Health Professions Council of South Africa

Collab Opportunity! Would you want to partner up with a Telehealth company with GLPs? Great commissions and they are for every month not just the first order like other [illegible] customers a month for 1 year buying semaglutide you would make $137,060. Let me know if you're

CRACK DOWN on ILLEGAL MANUFACTURING & DISTRIBUTION of GLP/GIP MEDICINES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customers a month for 1 year buying semaglutide you would make $137,060. Let me know if you're
CRACK DOWN on ILLEGAL
MANUFACTURING &
DISTRIBUTION of
GLP/GIP MEDICINES

Falsified Medicines misleading the public

Fighting misinformation with trusted truth

Thank you

Scheduling status: **S4** Name of medicine: Extensior® 1,34 mg/mL solution for injection
Qualitative and quantitative composition: Semaglutide 1,34 mg/mL. **Reg. No.:** 61/21.13/0858.
For full prescribing information, refer to the Professional Information approved by the South African Health Products Regulatory Authority (SAHPRA).

Scheduling status: **S4** Name of medicine: Ozempic®
Qualitative and quantitative composition: Semaglutide 1,34 mg/mL. **Reg. No.:** 53/21.13/0497.
For full prescribing information, refer to the Professional Information approved by the South African Health Products Regulatory Authority (SAHPRA).

Scan the QR Code to access Extensior® Abbreviated Professional Information

Scan the QR Code to access Ozempic® Abbreviated Professional Information

2026 Novo Nordisk (Pty) Ltd. Reg. No.: 1959/000833/07. 90 Grayston Drive, Sandown, Sandton, Gauteng, 2031, South Africa. Tel: (011) 202 0500. pro.novonordisk.co.za ZA26SGDI00066 August 2026

Do you have any questions?

Ms Anri Hornsveld

Pharmacy Month Working Group

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