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South Africa

Compounded GLP-1 medicines under sustained scrutiny in South Africa as SAHPRA and SAPC take enforcement action

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South Africa's regulatory stance on compounded Glucagon-like peptide 1 (GLP-1) medicines has moved from warning signals to visible enforcement. On 23 May 2026, the South African Health Products Regulatory Authority (SAHPRA), together with the South African Pharmacy Council (SAPC), announced intensified enforcement action against the unlawful manufacturing and distribution of unregistered GLP-1 and glucose-dependent insulinotropic polypeptide (GIP) medicines containing semaglutide, tirzepatide or a combination of both, promoted for weight loss.

This latest action follows the trajectory we identified in our earlier alert of 18 March 2026 which can be accessed here. In that alert, we noted that SAHPRA had already expressed concern in 2024 about falsified, compounded and substandard GLP-1 products, and that its 5 March 2025 communication signalling an intention to declare compounded GLP-1 and GLP-1/GIP agonist medicines *"undesirable"* suggested a tightening regulatory environment.

We observed at the time that, although a formal prohibition had not yet been implemented, SAHPRA's interventions pointed to increasing scrutiny and the likelihood of stricter enforcement. The latest enforcement action taken by SAHPRA and SAPC on 11 May 2026 confirms that this prediction has materialised.

SAHPRA and SAPC's latest enforcement action

SAHPRA and SAPC conducted a joint inspection at iDexis (Pty) Ltd, trading as Sentra Pharmacy, in Silverton, Pretoria on 11 May 2026. According to SAHPRA's media release dated 23 May 2026, the inspection revealed that the company was producing and supplying semaglutide, tirzepatide and combination GLP-1/GIP injectable products under the pretext of *"compounding"*, but outside the legal framework permitted under South African law. SAHPRA seized all GLP-1/GIP injectable products found onsite and instructed the company to initiate a full recall of affected products distributed through healthcare providers, pharmacies and other channels.

SAHPRA expressly reiterated that, under the Medicines and Related Substances Act 101 of 1965 (Medicines Act), compounding must remain strictly within the applicable legal parameters and cannot be used as a mechanism for large-scale manufacture, advertising or distribution of unregistered medicines. For stakeholders in the healthcare, pharmacy, wellness and weight-management sectors, the message is clear: compounded GLP-1 products are under increasing scrutiny, and any activity that resembles commercial-scale production or promotion of unregistered injectable products is likely to attract regulatory attention.

What is compounding?

The Medicines and Related Substances Act 101 of 1965 (Medicines Act) defines compounding as the preparation, mixing, combining, packaging and labelling of a medicine by a pharmacist, veterinarian or person licensed under section 22C(1)(a) of the Medicines Act to dispense and compound, while acting within their scope of practice. Crucially, it is not an unrestricted activity.

For a compounded medicine to be lawful it must, among other things, not contain a prohibited substance, must not contain a component for which registration has been rejected, must not be advertised, and must use an active pharmaceutical ingredient (API) that is already included in a SAHPRA-registered medicine.

The point of lawful compounding is to permit limited, patient-specific preparation within a regulated clinical and pharmacy context and not to bypass registration requirements or replicate pharmaceutical manufacturing at scale. It is therefore no surprise that SAHPRA stated in its media release that compounding is strictly limited to the preparation of medicines for individual patients based on a valid prescription. The authority found that the pharmacy in question had moved beyond those bounds and was instead manufacturing and marketing semaglutide-, tirzepatide- and combination-based products for broader commercial distribution, especially for weight management purposes. It seems in this instance the API was not identical to the formula which was registered with SAHPRA for semaglutide and tirzepatide.

Conclusion

Compounded GLP-1 medicines are now under sustained scrutiny in South Africa. The latest crackdown serves as a timely reminder that compounding must remain exactly that: a narrow, lawful and controlled process carried out within statutory limits. It cannot be used as a mechanism for large-scale manufacturing, advertising or distribution of unregistered medicines. What was previously an emerging regulatory trend has become an enforcement reality. Businesses and practitioners operating in this space should urgently review their sourcing, dispensing, advertising and distribution practices to ensure that they remain within the narrow legal boundaries of compounding under South African law.

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