

# Healthcare & Pharmaceuticals



18 March 2026

## SOUTH AFRICA

- Global trends around compounded GLP-1 medicines and SAHPRA's emerging response

For more insight into our expertise and services



## Global trends around compounded GLP 1 medicines and SAHPRA's emerging response

**Compounded Glucagon-like peptide 1 (GLP 1) medicines have surged worldwide as demand for weight loss and diabetes treatments continues to outstrip supply. These compounded versions often include modified formulations and added vitamins, or are manufactured outside regulated supply chains, making them significantly different from approved registered products.**

Across the US, compounded GLP 1 weight loss drugs have become the focus of intense regulatory action, litigation and public debate. Reports indicate that the explosion of compounding pharmacies offering low cost versions of semaglutide (found in Ozempic) and tirzepatide (found in Mounjaro) – often without consistent quality oversight – has raised significant safety concerns, including dosing errors and the circulation of active ingredients sourced from unregistered facilities.

The FDA has issued warnings after a rise in overdoses, adverse events and significant quality concerns tied to compounded GLP 1 products, particularly due to unverified active ingredients. Many compounded batches were found to originate from unregistered or uninspected overseas facilities.

The intensity of US litigation, including the high profile dispute between Novo Nordisk and Hims & Hers, alongside class action type consumer actions, has drawn global attention. The scale of the US controversy and regulatory tightening is highly likely to influence peer regulators, including the South African Health Products Regulatory Authority (SAHPRA), which is the regulatory body for overseeing the safety, efficacy and quality of health products in South Africa.

### **SAHPRA's early warning in 2024**

In November 2024, SAHPRA issued a formal public warning highlighting the proliferation of falsified, compounded and substandard GLP 1 products being sold through informal channels, websites and social media platforms in South Africa. SAHPRA emphasised that these products pose health risks, have not undergone quality, safety or efficacy assessments, and may contain active ingredients that were never verified or evaluated by the regulator.

SAHPRA specifically noted the increasing compounding of GLP 1 agonists in the local market and warned healthcare professionals that compounding a medicine using an active ingredient not contained in a SAHPRA registered product is illegal under the Medicines and Related Substances Act 101 of 1965 (Medicines Act).



### SAHPRA's intention to declare compounded GLP 1 medicines undesirable

On 5 March 2025, SAHPRA published an official "Communication to Stakeholders" stating its intention to declare compounded GLP-1 and GLP-1/GIP agonist medicines undesirable under section 23 of the Medicines Act. Once declared undesirable, such products may no longer be sold in South Africa.

SAHPRA justified this intention on several grounds:

- **Biological complexity:** GLP 1/GIP agonists are biological medicines sensitive to manufacturing variability, making compounded versions risky and inconsistent.
- **Biosimilar standards:** Compounding circumvents the required comparative testing necessary to ensure similarity in quality, purity and potency.
- **Lack of quality control:** Compounded sterile injectables risk contamination, inadequate sterility and batch to batch inconsistency.
- **Absence of pharmacovigilance:** Products distributed outside regulated channels evade safety monitoring.

The regulator emphasised that such practices are not in the public interest, and sought public comment for one month on its intention to list these products as undesirable under section 23.

While this 2025 notice shows a clear regulatory shift, the products were never formally declared undesirable. We have, however, seen other countries such as Australia declare that compound medicines containing GLP-1 receptor agonists cannot be prescribed after 1 October 2024.

### A global shift and likely changes ahead for South Africa

International regulatory pressure has placed compounded GLP 1 products under unprecedented scrutiny. Although SAHPRA has progressively moved from warnings to a formal intention to declare these medicines undesirable, these medicines may still currently be prescribed and sold in South Africa since it has not been declared undesirable.

The regulatory direction, both globally and locally, signals a tightening environment for compounded GLP 1 medicines. While these products remain available in South Africa for now, SAHPRA's escalating interventions indicate that prohibition or significant restriction is increasingly likely. Stakeholders operating in the weight loss, compounding and broader pharmaceutical sectors should proactively assess their practices, prepare for stricter regulatory oversight, and remain alert to further announcements from SAHPRA as the regulatory landscape continues to evolve.

**Charles Green and Anneri du Preez**

## OUR TEAM

For more information about our Healthcare & Pharmaceuticals sector and services and services in South Africa, Kenya and Namibia, please contact:



### Roxanna Valayathum

Sector Head:  
Healthcare & Pharmaceuticals  
Director: Corporate & Commercial  
T +27 (0)11 562 1122  
E roxanna.valayathum@cdhlegal.com



### Tim Fletcher

Chairperson  
Director: Dispute Resolution  
T +27 (0)11 562 1061  
E tim.fletcher@cdhlegal.com



### Patrick Kauta

Managing Partner | Namibia  
T +264 833 730 100  
M +264 811 447 777  
E patrick.kauta@cdhlegal.com



### Sammy Ndolo

Managing Partner | Kenya  
T +254 731 086 649  
+254 204 409 918  
+254 710 560 114  
E sammy.ndolo@cdhlegal.com



### Emil Brincker

Practice Head & Director:  
Tax & Exchange Control  
T +27 (0)11 562 1063  
E emil.brincker@cdhlegal.com



### Ian Hayes

Practice Head & Director:  
Corporate & Commercial  
T +27 (0)11 562 1593  
E ian.hayes@cdhlegal.com



### Mashudu Mphafudi

Practice Head & Director:  
Banking, Finance & Projects  
T +27 (0)11 562 1093  
E mashudu.mphafudi@cdhlegal.com



### Aadil Patel

Practice Head & Director:  
Employment Law  
Sector Head:  
Government & State-Owned Entities  
T +27 (0)11 562 1107  
E aadil.patel@cdhlegal.com



### André de Lange

Sector Head:  
Agriculture, Aquaculture & Fishing  
Director: Corporate & Commercial  
T +27 (0)21 405 6165  
E andre.delange@cdhlegal.com



### Magano Erkana

Director | Namibia  
T +264 83 373 0100  
E magano.erkana@cdhlegal.com



### Quintin Honey

Director:  
Corporate & Commercial  
T +27 (0)11 562 1166  
E quintin.honey@cdhlegal.com



### Frieda Kishi

Director | Namibia  
T +264 83 373 0100  
E frieda.kishi@cdhlegal.com



### Mercy Kuzeeko

Director | Namibia  
T +26 (4)83 373 0100  
E mercy.kuzeeko@cdhlegal.com



### Susan Meyer

Director: Competition Law  
T +27 (0)21 481 6469  
E susan.meyer@cdhlegal.com



### Imraan Mahomed

Director:  
Employment Law  
T +27 (0)11 562 1459  
E imraan.mahomed@cdhlegal.com



### Lucinde Rhodie

Director:  
Dispute Resolution  
T +27 (0)21 405 6080  
E lucinde.rhodie@cdhlegal.com



### Njeri Wagacha

Partner | Kenya  
T +254 731 086 649  
+254 710 560 114  
E njeri.wagacha@cdhlegal.com



### Alecia Pienaar

Counsel:  
Environmental Law  
T +27 (0)82 863 6279  
E alecia.pienaar@cdhlegal.com

**BBBEE STATUS:** LEVEL ONE CONTRIBUTOR

Our BBBEE verification is one of several components of our transformation strategy and we continue to seek ways of improving it in a meaningful manner.

**PLEASE NOTE**

This information is published for general information purposes and is not intended to constitute legal advice. Specialist legal advice should always be sought in relation to any particular situation. Cliffe Dekker Hofmeyr will accept no responsibility for any actions taken or not taken on the basis of this publication.

**JOHANNESBURG**

1 Protea Place, Sandton, Johannesburg, 2196. Private Bag X40, Benmore, 2010, South Africa.  
Dx 154 Randburg and Dx 42 Johannesburg.  
T +27 (0)11 562 1000 F +27 (0)11 562 1111 E [jhb@cdhlegal.com](mailto:jhb@cdhlegal.com)

**CAPE TOWN**

11 Buitengracht Street, Cape Town, 8001. PO Box 695, Cape Town, 8000, South Africa. Dx 5 Cape Town.  
T +27 (0)21 481 6300 F +27 (0)21 481 6388 E [ctn@cdhlegal.com](mailto:ctn@cdhlegal.com)

**NAIROBI**

Merchant Square, 3<sup>rd</sup> floor, Block D, Riverside Drive, Nairobi, Kenya. P.O. Box 22602-00505, Nairobi, Kenya.  
T +254 731 086 649 | +254 204 409 918 | +254 710 560 114  
E [cdhkenya@cdhlegal.com](mailto:cdhkenya@cdhlegal.com)

**ONGWEDIVA**

Shop No A7, Oshana Regional Mall, Ongwediva, Namibia.  
T +264 (0) 81 287 8330 E [cdhnamibia@cdhlegal.com](mailto:cdhnamibia@cdhlegal.com)

**STELLENBOSCH**

14 Louw Street, Stellenbosch Central, Stellenbosch, 7600.  
T +27 (0)21 481 6400 E [cdhstellenbosch@cdhlegal.com](mailto:cdhstellenbosch@cdhlegal.com)

**WINDHOEK**

1<sup>st</sup> Floor Maerua Office Tower, Cnr Robert Mugabe Avenue and Jan Jonker Street, Windhoek 10005, Namibia.  
PO Box 97115, Maerua Mall, Windhoek, Namibia, 10020  
T +264 833 730 100 E [cdhnamibia@cdhlegal.com](mailto:cdhnamibia@cdhlegal.com)

©2026 15622/MAR

