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Agonists and APIs: High Court Injects Clarity into Compounding Debate

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The practice of compounding (that is, the preparation, mixing, combining, packaging and labelling of a medicine by, amongst others, a pharmacist)[1] has attracted renewed attention and regulatory scrutiny, in light of the recent proliferation of compounded medicines containing GLP-1[2] agonist active components in the South African market. GLP-1 agonists are a class of medicines directed at the treatment of type 2 diabetes and related cardiovascular conditions, as well as chronic weight management and obesity.[3]

The compounding of particular medicines for individual patients by a pharmacist is expressly contemplated in the Medicines and Related Substances Act[4] ("Medicines Act"), which regulates the manufacturing and supply of medicines in South Africa. Compounding is generally used in circumstances where mass-produced formulations of medicines are either unavailable or unsuitable for a particular patient.

In terms of section 14(1) of the Medicines Act, all medicines that are subject to registration, as determined by the South African Health Products Regulatory Authority ("SAHPRA"), are required to be registered in order to be lawfully imported, offered, advertised or sold in South Africa.

As a legal prerequisite to the registration of any medicine, SAHPRA must be satisfied that the medicine in question is, *inter alia*, suitable for the purpose for which it is intended, and is safe, efficacious and of good quality.[5]

Notably, the registration requirements in the Medicines Act include an explicit carve-out for compounded medicines in terms of section 14(4) of the Medicines Act. Four principal requirements, for the lawful sale of an (unregistered) compounded medicine emerge from section 14(4) of the Medicines Act, namely that –

- the medicine must be compounded for a particular patient in the specific quantity required for the treatment of that patient;
- the medicine must not contain any component which has been prohibited for sale in terms of the Medicines Act, or which SAHPRA has declined to register;
- the medicine must not be advertised; and
- the active components of the medicine must appear in another medicine which has been registered under the Medicines Act.

It is this last-mentioned requirement that the High Court, Pretoria, was called upon to interrogate and clarify in the recent decision of *Novo Nordisk (Pty) Ltd v iDexis Compounding Specialists (Pty) Ltd t/a Sentra Pharmacy and Others*,[6] which was handed down on 22 June 2026 ("the *iDexis* decision"). The *iDexis* decision concerned the extent to which compounded medicines containing GLP-1 agonist active components may lawfully be advertised, offered and sold in South Africa.

The prevalence of these medicines in the South African market has not gone unnoticed by SAHPRA and the South African Pharmacy Council ("SAPC"), who, on 23 May 2026, announced that they would pursue "intensified enforcement action against the unlawful manufacturing and distribution of unregistered GLP-1 and [gastric inhibitory polypeptide] medicines".[7]

It is against this background that Novo Nordisk Proprietary Limited ("Novo Nordisk"), being the authorised South African importer and distributor of registered medicines containing semaglutide (a GLP-1 agonist and Scheduled substance), branded as Ozempic and Wegovy, launched an application for an urgent interdict against iDexis Compounding Specialists Proprietary Limited ("iDexis"), and its sole shareholder and director.

Novo Nordisk sought to prevent iDexis and its shareholder/director from manufacturing and selling (unregistered) medicines containing semaglutide, on the basis that doing so contravened the Medicines Act, pending the outcome of an investigation by SAHPRA and the SAPC into their alleged illegal manufacture and sale of these medicines. iDexis, in turn, sought to argue that the compounding of medicines containing semaglutide is lawful, as Ozempic, which contains semaglutide, is a registered medicine in South Africa.

In deciding whether or not to grant the interim interdict, the court focused on what it regarded as the definitive issue in so far as the legality of iDexis' activities was concerned, namely whether the active pharmaceutical ingredients ("APIs") in Novo Nordisk's and iDexis' respective products were of such a nature that iDexis was lawfully permitted to compound its product by virtue of section 14(4) of the Medicines Act.

In doing so, Van Niekerk J undertook a detailed factual analysis of the API in Ozempic and Wegovy, as contrasted with the API in iDexis' product, which originated from a source undisclosed by iDexis. Taking into account that the semaglutide developed and manufactured by Novo Nordisk Denmark is a biological product extracted from yeast, whilst the API in iDexis' product is a synthetic peptide with a molecular structure similar (but not identical) to the Ozempic API, the court concluded that section 14(4) did not permit iDexis to compound medicines containing a synthetically produced semaglutide that had not been approved and registered with SAHPRA.

Interpreting section 14(4) in light of the purpose of the Medicines Act (being the regulation of medicines in the public interest), the court held that –

"... it is a matter of logic and common sense that the active component of a scheduled medicine, which requires a stringent registration process, can never be allowed into a medicine without the scrutiny of SAHPRA, and without the proper stringent screening process envisaged in terms of the Medicines Act and regulations, by relying on *"similarity"* subjectively determined, under the guise of compounding in terms of section 14(4)".[8]

iDexis' compounding of medicine containing synthetically produced semaglutide was, therefore, found to be unlawful. Turning to the relief sought, the court found that the requirements for an interim interdict had been met, holding in particular that, where it appears conduct may be contrary to the Medicines Act, such conduct should not be permitted to continue unabated, particularly where the ongoing illegality is also a criminal offence (as in this case).

The *iDexis* decision now provides helpful legal clarity on the interpretation of section 14(4) of the Medicines Act and the ambit of lawful compounding, as contemplated in this section.

Pharmacists and licensed pharmacies would be well advised to take note of the decision and seek the appropriate legal advice to ensure that their compounding activities align with the applicable statutory framework. The interim nature of the relief granted in the *iDexis* decision, the court's limited focus in deciding the matter, and the far-reaching impact of the matters canvassed in the judgment, however, signal that the debate surrounding lawful compounding, particularly in so far as it pertains to medicines containing GLP-1 agonists, is far from settled.

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[1] The General Regulations published in terms of the Medicines Act, under GN 859 in *GG* 41064 of 25 August 2017, define "compound" as "the preparation, mixing, combining, packaging and labelling of a medicine (a) by a pharmacist practising in accordance with the Pharmacy Act, 1974; (b) by a veterinarian practising in accordance with the Veterinary and Para-Veterinary Professions Act, 1982 (Act 19 of 1982); or (c) by a person licensed in terms of section 22C(1)(a) of the Act and practising in accordance with their scope of practice".

[2] Glucagon-like peptide-1.

[3] See paragraph 13 of the *iDexis* decision.

[4] No. 101 of 1965.

[5] Section 15(3) of the Medicines Act.

[6] Case number 2024-130119.

[7] Media Release published by SAHPRA and the SAPC, entitled "SAHPRA and the SAPC Crack Down on Unlawful Manufacturing of Unregistered GLP-1/GIP Medicines" and dated 23 May 2026.

[8] Paragraph 64 of the *iDexis* decision.

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