MEDIA STATEMENT

SAHPRA's position on GLP1 and GIP-GLP1 products that are compounded, substandard and falsified

Embargo: Immediate release

Pretoria, 08 November 2024 – The South African Health Products Regulatory Authority (SAHPRA) is concerned about the proliferation of falsified, compounded and substandard Glucagon-like Peptide (GLP-1)-containing products being made available to the public via websites, social media platforms and other informal channels. These pose a health risk to the public. SAHPRA cautions the public to not purchase and/or consume such products as their safety, efficacy and quality have not been assessed.

Of the registered products that contain GLP-1 agonists, SAHPRA has noted with concern the number of compounded, substandard and/or falsified versions of the following products being sold to the public.

- Ozempic (semaglutide) from Novo Nordisk, which is registered under two (2) presentations of pre-filled injectable pen, namely 0,25 mg and 0,5 mg/dose pen and 1 mg/dose pen. Ozempic is registered in South Africa for the treatment of adults with Type 2 Diabetes to reduce blood sugar levels for the treatment of adults with insufficiently controlled Type 2 Diabetes mellitus as an adjunct to diet and exercise. It is also registered for use in reduction of risk of major adverse cardiovascular events such as heart attack, stroke, or death in adults with Type 2 Diabetes with known heart disease. **Ozempic is NOT registered in South Africa for weight management.**
- Mounjaro (tirzepatide) from Eli Lilly and Company is registered under the following presentations in South Africa: a single dose pre-filled pen containing either 2,5 mg; 5 mg; 7,5 mg; 10 mg; 12,5 mg and 15 mg in 0,5 ml solution for injection. Mounjaro is indicated for the treatment of type 2 diabetes mellitus but has not yet been imported into and placed on the market in South Africa through Eli Lilly and Company distribution channels. **Mounjaro is currently NOT registered in South Africa for weight management**

Compounded medicines containing GLP1 agonists

SAHPRA has noted with concern the increase of compounding of medicines containing GLP1 agonists in the South African market. The complexity of compounding GLP1 agonists, which are sterile medicines containing complex active substances poses a public health and safety risk. The risk associated with compounded medicines containing GLP1 agonists are posed by the absence of the evaluation of these medicines by SAHPRA and the unknown nature and safety of ingredients used in compounding. Compounded products claiming to contain semaglutide have not undergone verification nor evaluation by SAHPRA to assess whether indeed the active pharmaceutical ingredient (API) is identical to the registered one, which is a requirement of the Medicines Act, therefore, may be substandard and pose a risk to those using them. Compounding a medicine using an active ingredient that is not contained in a product registered with SAHPRA is illegal, in terms of the requirements of the Medicines and Related Substances Act. The public is urged to purchase only SAHPRA-registered products containing GLP1-agonists, in light of these risks.

In terms of Section 29 of the Medicines and Related Substances Act, a person who commits an offence shall be held criminally liable, and applicable penalties shall be enforced.

Unauthorised and falsified products containing GLP1 agonists

SAHPRA investigations over the last year have detected a significant number of websites purporting to be online pharmacies that are illegally selling medicines, including falsified and unauthorised versions of semaglutide and/or tirzapetide. The public is advised to not purchase these products.

The following companies/websites have been found to be selling unauthorised or falsified versions of semaglutide and tirzapetide:

Website	Name of falsified / unauthorised product
https://juiceheads.co.za/	Body Pharm Semaglutide 3 Pen Body Pharm Semaglutide 6 Pen Hd Labs Semaglutide 5 Semaglutide 2mg GLP-1 HD Labs Tirzepatide 10 (Tirzepatide) Body Pharm Tirzepatide 30 Pen
https://anabolicsza.com/	Semaglutide 3mg vial from EU Pharmaceuticals Platinum Tirzepatide 30 Lira Tirzapetide 30mg Novo-lela Tirzepatide Body Pharm – Tirzepatide Semaglira – Semaglutide Pharmatech – Ozempic Semaglutide HD Labs – Semaglutide Izempic Novazempic Uzempic Platinum Retatrutide Lira Retatrutide Retatrutide iPharma iPharma Tirzepatide
	Incepta Pharma – Orsema

www.sallyslimming.co.za	Novaglutide
https://slimnburn.co.za/	Novazepatide
https://www.researchpeptides.co.za/	AAP (Anti Appetite Peptide)

The above list is not exhaustive, and the public is urged to report any other websites or retail outlets selling these falsified and unauthorised products.

Pharmacists, medical doctors, and other healthcare professionals who are considering the use of non-registered and falsified products, should be aware that these medicines have not been reviewed by SAHPRA for quality, safety, or efficacy. These companies' unlawful actions put patients at risk. The sale of a registerable medicine without registration is an offence in terms of Section 29 of the Medicines and Related Substances Act. Those who commit an offence in terms of Section 29 of the Medicines Act shall be held criminally liable and applicable penalties shall be enforced.

SAHPRA CEO, Dr Boitumelo Semete-Makokotlela, stressed that safeguarding the well-being of the South African public remains a primary concern for the regulatory authority. "SAHPRA is monitoring the supply chain as well as the online platforms for unregistered, substandard, and falsified medicines containing or claiming to contain semaglutide. We are also investigating any contraventions relating to the Medicines and Related Substances," says Dr Semete-Makokotlela.

The public is urged to report any suspected products that are falsely claiming to be available or sold like Ozempic and/or Mounjaro. You can report through these whistle blower platforms, SAHPRA's 24-hour hotline (0800 204 307) or via our web reporting facility: https://bit.ly/3nrku5t.

Ends

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Notes to Editors:

SAHPRA will post this media release on its website. Navigate to the News section on the website.

A podcast will be recorded and posted on the home page. Scroll down the home page to "**SAHPRA TV and Podcasts**". Podcasts appear on the right-hand side.

Should you wish to request an interview, please send your request to media@sahpra.org.za and Madimetja.Mashishi@sahpra.org.za

Updates on vaccine registration can be accessed here:

Vaccines - News and updates (sahpra.org.za) - https://www.sahpra.org.za/news-and-updates/vaccines-news-and-updates/

About SAHPRA:

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).

SAHPRA has three pillars to ensure that medicines, medical devices and IVDs meet the requisite standards to protect the health and well-being of all who reside in South Africa:

- Safety
- Efficacy
- Quality

It is these three pillars that define the ethos of SAHPRA.