MEDIA RELEASE

Public urged to use registered *Ozempic* products

Embargo: Immediate release

Pretoria, 11 December 2023 – The South African Health Products Regulatory Authority (SAHPRA) is aware of the falsified *Ozempic* products currently being sold on the market and online.

SAHPRA has been informed of advertisements regarding unauthorised *Ozempic/semaglutide-containing* products that are being disseminated through radio stations and social media platforms.

The Regulator is warning the public to be wary of products claiming to be *Ozempic (semaglutide)* which are not approved by SAHPRA.

Ozempic is a Schedule 4, prescription-only medicine, authorised by SAHPRA only for the treatment of type 2 diabetes mellitus in adults. SAHPRA has **not** authorised/registered *Ozempic* for weight-loss, therefore, use in that regard would be off-label. It must be noted that only a healthcare practitioner can make a Schedule 4 product available off-label as they would provide the requisite guidance and support to the patient/individual.

Novo Nordisk South Africa, who is the Holder of Certificate of Registration (HCR) has confirmed a national shortage of *Ozempic* stock; this resulted in limited access to treatment for diabetic patients. This may have created an opportunity for falsified/counterfeit products flooding the market claiming to be *Ozempic* and being used off-label for weight loss. Consumers should be wary of online offers for products claiming to be *Ozempic* or *semaglutide*.

Currently, there are no generic versions of this medicine being lawfully manufactured. Therefore, any product not manufactured by Novo Nordisk claiming to contain *semaglutide* is likely to be fake or counterfeit. The public is being exposed to many different types of unregistered/unauthorised products that are either substandard or falsified thereby putting their health at risk. **See examples of registered vs counterfeit products**.

Registered products safe to use

Ozempic solution for injection is a registered product by SAHPRA belonging to the HCR, Novo Nordisk South Africa.

There are only two (2) registered presentations of the pre-filled pen for *Ozempic* available in South Africa namely, ***Ozempic* 0,25 mg and 0,5 mg/dose pen and *Ozempic* 1 mg/dose pen**.

What the public should know

- Using unregistered *semaglutide* products claiming to have the effects of *Ozempic* bought from unverified/illegally trading suppliers could be detrimental to your health as these have not been evaluated by SAHPRA for safety, quality, and efficacy.
- These falsified/fake *Ozempic* products may contain certain active ingredients found in the registered *Ozempic* products; however, the formulations or manufacturing processes may be different. These formulations have not been evaluated by SAHPRA.
- SAHPRA urges the public to first consult their medical professionals for their health treatment and prescriptions, and only purchase or use SAHPRA registered/authorised products sold at registered pharmacies.
- Any medicines that are bought outside of the legal supply chain:
    - May not contain any active ingredient.
    - May contain dangerous levels of the active ingredient.
    - May contain another active ingredient such as insulin instead of *semaglutide*.
    - May contain harmful inactive ingredients.
    - May be nonsterile and contaminated with microbes, therefore not suitable for injection.

“Protecting the health of South Africans is top of mind for the regulator. The scourge of unregistered, substandard, and falsified medicines on the market is a serious health risk for the public. SAHPRA is listening to the public concerns, and we have an ongoing investigation into these falsified *Ozempic* and unregistered *semaglutide*-containing products”, indicates SAHPRA CEO, Dr Boitumelo Semete-Makokotlela.

Public are urged to report any suspected products that are falsely claiming to work like Ozempic. **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.**

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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.

Notes to Editors:

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

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

Should you request an interview for television, please send your request to media@sahpra.org.za and copy melanie.govindasamy@sahpra.org.za. Include your discussion points in your request.

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/