MEDIA RELEASE

SAHPRA's position on Semaglutide compounded products

Embargo: Immediate release

Pretoria, 13 December 2023 – The South African Health Products Regulatory Authority (SAHPRA) recently released a media statement on the falsified *Ozempic* products currently being sold on the market and online, specifically unauthorised *Ozempic/semaglutide-containing* products.

SAHPRA has registered one product which contains semaglutide called *Ozempic*. There are two (2) registered presentations of the pre-filled injectable pen for *Ozempic* available in South Africa namely, *Ozempic* 0,25 mg and 0,5 mg/dose pen and *Ozempic* 1 mg/dose pen.

Ozempic (each 1,0 ml solution contains Semaglutide 1,34 mg) 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 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 use in weight-loss.

Compounded medicines

Compounded medicines are not required to be reviewed by SAHPRA for registration *(the physician prescribes medicines for a specific patient use and should only be specified for a*

*short perio*d), and it must be noted that SAHPRA does not verify the safety or efficacy of compounded medicines.

Semaglutide can be compounded as it is included in a medicine that has been registered by SAHPRA. The compounded medicines containing semaglutide must be in accordance with the conditions and requirements contained in the Medicines and Related Substances Act, Act 101 of 1965, and its regulations. A compounded medicine may only contain the active ingredient that is included in a product registered by SAHPRA.

What the public should know

SAHPRA has received reports of compounded medicines claiming to contain semaglutide. Patients are urged to use a SAHPRA approved product if available.

Compounded products may not contain the salt forms of semaglutide (semaglutide acetate, semaglutide sodium or any other form of semaglutide other than semaglutide in the registered product) and those have not been reviewed by SAHPRA for safety or efficacy. It is illegal to compound a medicine using a form of semaglutide that is not in the registered product. Patients should be aware that products claiming to contain semaglutide may not contain the same active ingredient, semaglutide, as the SAHPRA registered product, which has been reviewed for quality, safety, and efficacy.

What healthcare professionals should know

Pharmacists, medical doctors, and other healthcare professionals who are considering the use of compounded medicine providers should be aware that the medicines may contain the salt forms of semaglutide. The use of salt forms of semaglutide is not permissible as per the Medicines Act. These products containing the salts, such as semaglutide sodium and semaglutide acetate, have not been reviewed by SAHPRA for quality, safety, or efficacy.

SAHPRA CEO, Dr Boitumelo Semete-Makokotlela explains that “safeguarding the well-being of South Africans remains a primary concern for the regulatory authority. SAHPRA is monitoring the supply chain as well as the virtual world for unregistered, substandard, and

falsified medicines containing or claiming to contain semaglutide. We are also investigating any contraventions relating to the Medicines Act".

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.**

For more information, we have developed a **useful FAQs** to better understand semaglutide and compounding products from the Regulator's perspective.

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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/