SAHPRA
South African
Health Products
Regulatory Authority

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COMMUNICATION TO STAKEHOLDERS

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INTENTION TO DECLARE MEDICINES COMPOUNDED IN TERMS OF SECTION 14(4) CONTAINING GLP-1 OR GLP-1/GIP AGONISTS UNDESIRABLE IN TERMS OF SECTION 23 OF THE MEDICINES AND RELATED SUBSTANCES ACT, ACT 101 OF 1965, AS AMENDED

INTRODUCTION

In terms of Section 23 of the Medicines and Related Substances Act, Act 101 of 1965, as amended (the Medicines Act), the South African Health Products Regulatory Authority (SAHPRA) may declare a medicine as undesirable if it is of the opinion that it is not in the public interest that such a medicine be made available to the public.

SAHPRA intends to declare medicines compounded in terms of Section 14(4) of the Medicines Act containing Glucagon-Like Peptide-1 (GLP-1) Active Components or a combination of Glucagon-Like Peptide-1 (GLP-1) and Gastric Inhibitory Polypeptide agonist (GIP) Active Components undesirable in in terms of Section 23 of the Medicines Act.

No person may sell any medicine declared as undesirable in terms of Section 23 of the Medicines Act.

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RATIONALE

Compounding medicines using GLP1 or GLP1/GIP agonist active components are not in the public interest due to several critical factors. Firstly, biological medicines (GLP1 or GLP1/GIP agonists) are inherently complex and sensitive to variations in manufacturing processes. Unlike chemical drugs, biologicals are produced using living organisms, making their composition and behaviour less predictable. **This complexity increases the risk of batch-to-batch variability, which can compromise the safety and efficacy of compounded medicines.**

Secondly, SAHPRA's requirements in terms of biosimilars emphasises the importance of demonstration of similar quality, safety and efficacy in relation to the original registered product. SAHPRA requires that biosimilar medicines undergo comprehensive head-to-head comparative testing to demonstrate that they are highly similar to the reference product, with no clinically meaningful differences in terms of safety, purity, and potency. **Compounding GLP1 or GLP1/GIP agonists of a biological nature outside of the SAHPRA biosimilar framework undermines these requirements creating the potential for substandard or unsafe products.**

The lack of standardised protocols in compounding GLP1 or GLP1/GIP agonists can lead to inconsistent dosing and therapeutic outcomes. This inconsistency poses a significant risk to patients who rely on precise dosages for effective treatment. **Additionally, compounded GLP1 or GLP1/GIP agonist medicines may not undergo the stringent quality control testing procedures before their release for patient usage, as are required for registered biological medicines. This increases the risk of patients being exposed to substandard, counterfeit or falsified products.** Furthermore, as these products will be distributed outside the conventional and highly regulated supply chain, it is unlikely that they will be subject to post-marketing surveillance and pharmacovigilance monitoring by healthcare workers. **This increases the risk of serious and life-threatening adverse events going undetected in patients who use them.** Finally, the risk to patients using compounded GLP-1 or GLP-1/GIP agonist medications is heightened because these products are administered via injection and must therefore be sterile. If

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proper sterilisation protocols are not followed, patients may be at risk of developing septicaemia, which can lead to organ failure and potentially be fatal.

In conclusion, compounding medicines using GLP1 or GLP1/GIP agonist active ingredients are not in the public interest due to the inherent variability, lack of regulatory oversight, and potential safety risks associated with such practices. Subjecting GLP1 or GLP1/GIP agonists to the requirements of Section 14(1) of the Medicines Act, i.e., registration, ensures that patients receive safe, effective, and consistent treatments.

COMMENT PERIOD

The public is requested to provide comment on this intention within one (1) month of the date of publication.

Comments may be submitted to the Senior Manager: Inspectorate and Regulatory Compliance, and Office of the Chief Regulatory Officer to the following email addresses:

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