

SAHPRA AND THE SAPC CRACK DOWN ON UNLAWFUL MANUFACTURING OF UNREGISTERED GLP-1 MEDICINES

The South African Health Products Regulatory Authority (SAHPRA), in collaboration with the South African Pharmacy Council (SAPC), has intensified enforcement action against the unlawful manufacturing and distribution of unregistered GLP-1 medicines promoted for weight loss. This follows an inspection conducted at iDexis Compounding (Pty) Ltd, trading as Sentra Pharmacy, in Silverton, Pretoria, during which significant regulatory non-compliance was identified, and multiple injectable products were seized.

The investigation revealed that the company was producing and supplying medicines under the pretext of “compounding”, but outside the legal framework permitted under South African law. While compounding is strictly limited to the preparation of medicines for individual patients based on a valid prescription, the facility was found to be manufacturing and marketing GLP-1-based products, including semaglutide, tirzepatide, and combination formulations, for broader commercial distribution, particularly for weight management purposes.

Further inspection findings revealed serious deficiencies in quality, safety, and regulatory compliance. These included the illegal importation of semaglutide and tirzepatide active pharmaceutical ingredients (APIs), the absence of analytical testing to confirm identity, potency and purity, and inadequate sterile manufacturing conditions, including dust contamination, unsuitable equipment, and the lack of a validated HVAC system. In addition, no pharmacovigilance system was in place to monitor or respond to adverse drug reactions. SAHPRA has also noted reports of adverse events, including hospitalisations, linked to the use of these products, as well as concerns regarding possible illegal importation of APIs and promotional activities targeting healthcare providers and consumers.

As part of its enforcement action, SAHPRA has seized all finished products containing semaglutide, tirzepatide, and related combinations found on site. The company has been instructed to initiate a full Recall of affected products distributed through healthcare providers, pharmacies, and other channels.

According to the Medicines and Related Substances Act, 101 of 1965, as amended, compounding must remain strictly within the applicable parameters of the law and cannot be used as a mechanism for large-scale manufacture, advertising, or distribution of unregistered medicines.

“SAHPRA will continue to take decisive regulatory and enforcement action against any entity that contravenes the Medicines and Related Substances Act. The unlawful manufacture, importation, advertising, and distribution of unregistered medicines pose a serious risk to public health. We will not hesitate to act to protect patients and safeguard the integrity of South Africa’s regulatory system,” said SAHPRA CEO, Dr Boitumelo Semete-Makokotlela.

The South African Pharmacy Council will be taking further action against pharmacy professional involved in illegal manufacturing practices. “Unlawful manufacturing, promotion and distribution of unregistered GLP-1 medicines for weight loss is a serious violation of the law and a direct threat to public safety. Following the inspection conducted at Sentra Pharmacy, the SAPC will pursue decisive regulatory action against those involved.

Pharmacists and pharmacy support personnel found selling, compounding or distributing these unregistered medicines risk severe disciplinary action. Including possible removal from the register. Council will not tolerate any conduct that compromises patient safety or the integrity of the pharmacy profession,” said Vincent Tlala, CEO of South African Pharmacy Council.

Members of the public are encouraged to consult healthcare professionals for guidance relating to weight management or diabetes treatment options, and to report any suspected adverse reactions or suspicious products to SAHPRA.

ENDS

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