COMESA Competition Commission
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Common Market for Eastern and Southern Africa

Ref: CCC/CP/CA/04/2024

3 July 2024

CONSUMER ALERT

FALSIFIED OZEMPIC (SEMAGLUTIDE) IDENTIFIED IN THE REGIONS OF AMERICAS AND EUROPE BY WORLD HEALTH ORGANISATION

The COMESA Competition Commission (the Commission) has become aware through the alert ***Medical Product Alert N°2/2024: Falsified OZEMPIC (semaglutide)*** published by the World Health Organisation (WHO) 19 June 2024 that three falsified batches of OZEMPIC (semaglutide) have been detected in a number of countries.

The WHO alerts states that OZEMPIC (semaglutide) is from a group of medicines called glucagon-like peptide-1 (GLP-1) inhibitors that are indicated for the treatment of hyperglycemia in type 2 diabetes mellitus in adults, adolescents, and children over 12 years of age. The genuine manufacturer of OZEMPIC has confirmed that the three products referenced in this Alert are falsified: the products misrepresent their identify and source as they were not manufactured by Novo Nordisk:

- batch number LP6F832 is not recognized.
- the combination of batch number NAR0074 with serial number 430834149057 does not correspond to genuine manufacturing records.
- batch number MP5E511 is genuine, but the product is falsified.

Further the alert indicates that the falsified products have been detected in Brazil (October 2023), the United Kingdom of Great Britain and Northern Ireland (October 2023), and the United States of America (December 2023), and were supplied in the regulated supply chain.

The WHO has stated that the use of falsified OZEMPIC may result in the ineffective treatment of patients due to incorrect dosage, contamination with harmful substances, or use of unknown or substituted ingredients. It may pose other serious risks to health because of its subcutaneous injection administration that could be life-threatening. The WHO has advised Healthcare professionals to report any incident of adverse effects,

lack of effectiveness and suspected falsification to the National Regulatory Authorities/National Pharmacovigilance Centre.

The WHO has called on National regulatory/health authorities to contact their marketing authorization holders for advice on identification of falsification, increase monitoring of informal including online sale of products; and are advised to immediately notify WHO if they identify these falsified products.

The WHO has urged anyone who has any of the affected products, to not use them and if someone has or may have used the affected product or suffered an adverse reaction or unexpected side-effect after use, are advised to seek immediate medical advice from a healthcare professional. The WHO statement is hereto attached as Annex 1.

The WHO has outlined ways to identify falsified medical products as follows:

1. Check the Lot Number and Serial Number: WHO advises not to distribute, use, or sell products labelled with batch numbers listed in Annex 1.
2. Examine the Pen: Falsified Ozempic pens may have a scale extending out from the pen when setting the dose.
3. Assess the Label Quality: The label might be of poor quality and may not adhere well to the pen.
4. Look for Spelling Mistakes: The carton may have spelling mistakes on the front of the box.

The COMESA Competition Commission observes that WHO has included in the alert a reference to its fact sheet which indicates that such falsified products can be marketed through unregulated websites to pharmacies, clinics and hospitals and that they are distributed prominently in low- and middle-income countries.

In this regard, pursuant to Article 30(1)(b) of the COMESA Competition Regulations, the Commission wishes to alert consumer in the Common Market of the development.

The Commission further requests any person who establishes that the said drug is being sold in COMESA Member States, to avoid its purchase or use, and to report the matter to the Commission by contacting **Mr. Steven Kamukama, Director Consumer Welfare and Advocacy Division** on +265 (0) 111 772466 or by email on: skamukama@comesacompetition.org

Affected persons within the Common Market may also contact their national consumer institutions or any other body with the mandate on consumer protection in their countries.

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World Health Organization

Medical Product Alert N°2/2024: Falsified OZEMPIC (semaglutide)

Falsified OZEMPIC (semaglutide) identified in the WHO Regions of Americas and Europe

19 June 2024 | Medical product alert | Geneva | Reading time: 2 min (492 words)

العربية | 中文 | Français | Русский | Español

Alert Summary

This WHO Medical Product Alert refers to three falsified batches of OZEMPIC (semaglutide). This falsified product has been detected in Brazil (October 2023), the United Kingdom of Great Britain and Northern Ireland (October 2023), and the United States of America (December 2023), and was supplied in the regulated supply chain.

OZEMPIC (semaglutide) is from a group of medicines called glucagon-like peptide-1 (GLP-1) inhibitors that are indicated for the treatment of hyperglycemia in type 2 diabetes mellitus in adults, adolescents, and children over 12 years of age.

The genuine manufacturer of OZEMPIC has confirmed that the three products referenced in this Alert are falsified: the products misrepresent their identify and source as they were not manufactured by Novo Nordisk:

- **batch number LP6F832 is not recognized.**

- the combination of batch number NAR0074 with serial number 430834149057 does not correspond to genuine manufacturing records.
- batch number MP5E511 is genuine, but the product is falsified.

WHO has previously communicated the need for diligence by national regulators on some of these batches and similar GLP-1 agonist products in general.

Please refer to the Annex of this Alert for full details of the affected products.

Risks

The use of falsified OZEMPIC may result in the ineffective treatment of patients due to incorrect dosage, contamination with harmful substances, or use of unknown or substituted ingredients. It may pose other serious risks to health because of its subcutaneous injection administration that could be life-threatening.

Advice to healthcare professionals, regulatory authorities and the public

Healthcare professionals should report any incident of adverse effects, lack of effectiveness and suspected falsification to the National Regulatory Authorities/National Pharmacovigilance Centre.

National regulatory/health authorities are encouraged to contact their marketing authorization holders for advice on identification of falsification, increase monitoring of informal including online sale of products; and are advised to immediately notify WHO if they identify these falsified products.

If you have any of the affected products, WHO recommends that you do not use them. If you, or someone you know, has or may have used the affected product, or suffered an adverse reaction or unexpected side-effect after use, you are advised to seek immediate medical advice from a healthcare professional.

All medical products must be obtained from authorized/licensed suppliers. If you have any information about the manufacture or supply of these falsified products, please contact WHO via rapidalert@who.int.

Ways to identify falsified products

1. Check the Lot Number and Serial Number: WHO advises not to distribute, use, or sell products labelled with batch numbers listed in Annex.

2. **Examine the Pen: Falsified Ozempic pens may have a scale extending out from the pen when setting the dose.**
3. **Assess the Label Quality: The label might be of poor quality and may not adhere well to the pen.**
4. **Look for Spelling Mistakes: The carton may have spelling mistakes on the front of the box.**

WHO Global Surveillance and Monitoring System

for Substandard and Falsified Medical Products

For more information, please visit our website

Email: rapidalert@who.int

19 June 2024

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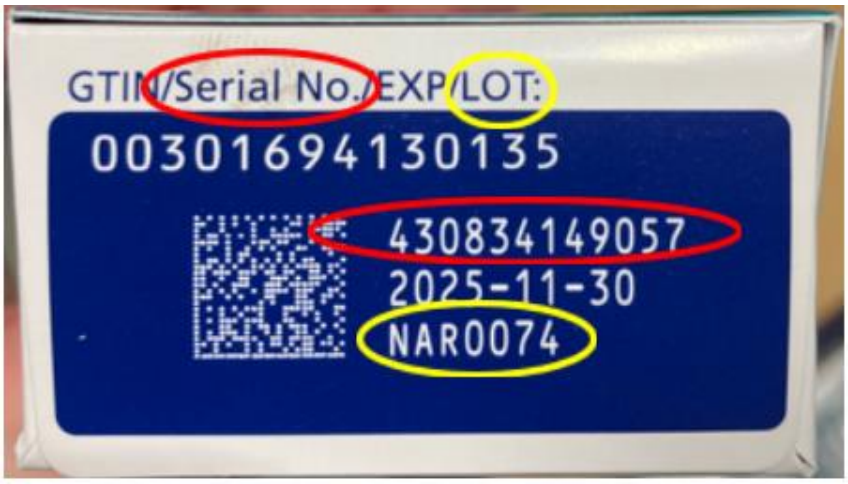
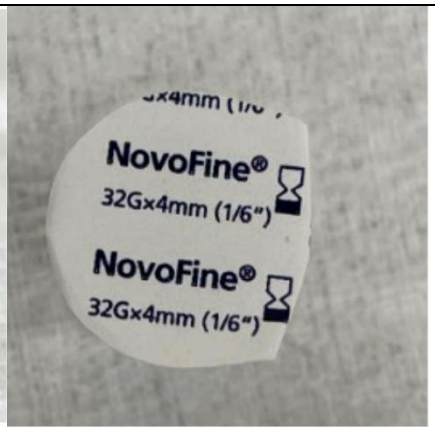
Annex: Products subject of WHO Medical Product Alert No. 2/2024

Product Name	OZEMPIC
Stated manufacturer	Novo Nordisk Farmaceutica do Brasil Ltda
Packaging	Portuguese
Lot	LP6F832
Expiry date	11 / 2025
Identified in	Brazil
Available photos*	N/A

Product Name	OZEMPIC
Stated manufacturer	Novo Nordisk
Packaging	German
Lot	MP5E511
Expiry date	07 / 2025
Identified in	United Kingdom of Great Britain and Northern Ireland
Available photos*	

	 **Photos of product detected in United Kingdom of Great Britain and Northern Ireland*

Product Name	OZEMPIC
Stated manufacturer	Novo Nordisk
Packaging	English
Lot	NAR0074
Expiry date	2025-11-30
Identified in	United States of America
Available photos*	 *Photos continued on next page*

	  **Photos of product detected in United States of America*