All correspondence should be addressed to the Director General

LET_LSE/PMS/0008/12/25

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# ZAMBIA MEDICINES REGULATORY AUTHORITY

## PUBLIC NOTICE

Date: 10th December, 2025

To: Distributors, Wholesalers, Retailers, Healthcare Professionals, General Public

### MEDICAL PRODUCT ALERT NO. 6/2025: FALSIFIED SIMULECT (BASILIXIMAB) FOR INJECTION IDENTIFIED IN THE WHO AFRICAN AND EUROPEAN REGIONS

The Zambia Medicines Regulatory Authority (ZAMRA) is a statutory body established under an Act of Parliament, the Medicines and Allied Substances Act No. 3 of 2013 of the laws of Zambia. The main mandate of ZAMRA is to regulate, and control the manufacture, importation, storage, distribution, supply, sale and use of medicines and allied substances for human and animal use for public health protection.

Based on the above, ZAMRA wishes to alert healthcare professionals, pharmaceutical outlets and members of the public that it has been notified by the World Health Organisation (WHO) of the circulation of falsified **SIMULECT (BASILIXIMAB)** for injection. The falsified product has been detected in Rwanda, Bulgaria, and Türkiye.

**SIMULECT (BASILIXIMAB)** is an immunosuppressant medicine classified as a monoclonal antibody. It is used for the prevention of acute organ rejection in adults and children undergoing kidney transplantation. SIMULECT is supplied as powder in a vial with or without water for injection (solvent) for reconstitution and is administered either as an intravenous infusion or as an injection, usually in a hospital setting.

This product is falsified because it deliberately misrepresents its identity, composition, and source. The genuine manufacturer has confirmed that the product listed in this alert is falsified. A sample of the falsified product was forensically tested by the genuine manufacturer and found to contain **no active pharmaceutical ingredients**; instead, it contained ascorbic acid.

**How to identify the falsified product**

The genuine manufacturer has identified several visual discrepancies on the packaging:

**Batch number**: The falsified product shows batch number **SFYD2**, which is not a valid batch number for SIMULECT. Any SIMULECT product with batch number **SFYD2** should be considered falsified.

**Folding box and label information**: The falsified product label displays the National Drug Code NDC 0078-0331-84. While the National Drug Code (NDC) is a unique identifier for medicines marketed in the United States of America, the label contains other discrepancies compared to genuine SIMULECT packaging:

- The genuine product lists the ingredient dose in milligrams using "mg," while the falsified product uses "MG".
- The genuine product lists the country of manufacture as "Product of France" while the falsified product lists the country of manufacture as "Product of Switzerland or France".

**Head Office**
Plot No: 2350/M
Off Kenneth Kaunda International Airport Road.
P.O. Box 31890, Lusaka, ZAMBIA
Tel: +260 211 432 350 /432 351
E-mail: pharmacy@zamra.co.zm

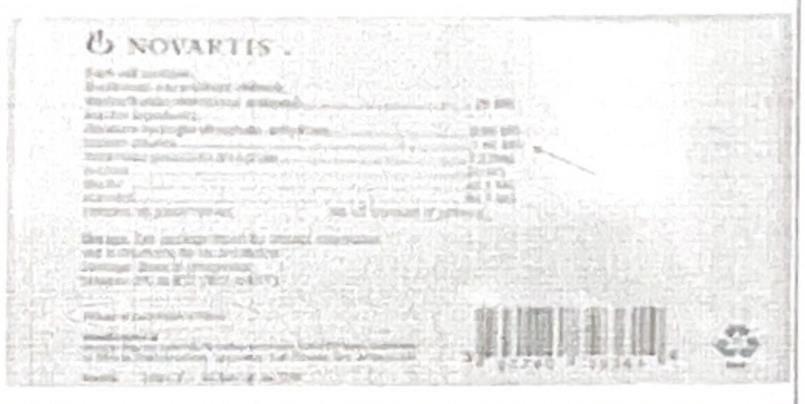
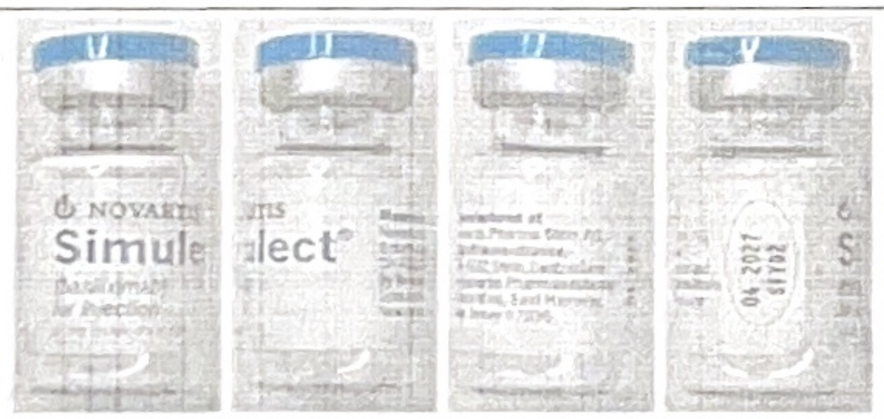
**Report Adverse Reactions to:**
Pharmacovigilance Unit, Lusaka
Tel: +260 211 432 356
E-mail: npvu@zamra.co.zm
**Website: www.zamra.co.zm**

## Risks

This falsified product should be considered unsafe, and its use poses severe and potentially life-threatening risks to patients, including: treatment failure leading to organ rejection, inadequate or excessive immune suppression, increasing vulnerability to opportunistic infections, life-threatening allergic or toxic reactions from unknown or harmful ingredients, risk of infection from unsterile injections.

## Product details

Annex: Product subject of WHO Medical Product Alert N°6/2025

| | | | |
|---|---|---|---|
| **Product Name** | SIMULECT (basiliximab) for injection | | |
| **Stated manufacturer** | NOVARTIS | | |
| **Identified in** | Bulgaria | Rwanda | Türkiye |
| **Batch number** | SFYD2 | | |
| **Expiry date** | 04 2027 | | |
| **Available Photographs** | | | |
|   |   | | |
| **Falsified SIMULECT vials** | | | |
|   | | | |

## Advise to healthcare providers, pharmaceutical outlets and public

It is important to detect and remove substandard or falsified medical products, including falsified SIMULECT from circulation to prevent harm to patients.

ZAMRA wishes to notify healthcare professionals and members of the public that, although this product is not registered in Zambia and no special import permit has been issued, it may be imported through illegal means (including online).

In the unlikely event that you are in possession of this product, do not use it. If you suffer any adverse drug reaction/event having used any of this product, you are advised to seek immediate medical advice and report the incident to the National Pharmacovigilance Unit at Zambia Medicines Regulatory Authority by phone: +260 211 432 356/+260/956 521 094 or email address at: npvu@zamra.co.zm or pharmacy@zamra.co.zm.

Should the public need further clarification, please do not hesitate to contact the Secretariat.

Makomani Siyanga (Mr)
**DIRECTOR-GENERAL**