

All correspondence should be
addressed to the Director General

In reply, please quote



ZAMBIA MEDICINES REGULATORY AUTHORITY

PUBLIC NOTICE

Date: 16th May, 2025

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

MEDICAL PRODUCT ALERT NO. 3/2025: FALSIFIED IMFINZI (DURVALUMAB) INJECTION 500MG/10ML IDENTIFIED IN THE WHO EASTERN MEDITERRANEAN 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 three batches of falsified **IMFINZI (durvalumab)** injection 500mg/10ml. The falsified products have been detected in the Islamic Republic of Iran and Türkiye.

These falsified products were first reported to WHO in March 2025. WHO previously issued Medical Product Alert N°5/2024 regarding another falsified batch of IMFINZI that was detected in Armenia, Lebanon, and Türkiye.

IMFINZI is a sterile concentrate for infusion. It contains the active pharmaceutical ingredient **durvalumab**, which is a monoclonal antibody. As monotherapy, it is used for the treatment of Non-Small Cell Lung Cancer (NSCLC) in adults.

How to identify these falsified products

These products are falsified as they deliberately misrepresent their identity, composition, and source. The genuine manufacturer, AstraZeneca, has identified multiple visual discrepancies in the falsified products. AstraZeneca has confirmed that the products mentioned in this alert are indeed falsified.

- Lot BAZR – This is a genuine lot number for distribution only in India. The falsified product shows discrepancies in the packaging artwork and text placement, with some text missing.
- Lot BBEG – This is a genuine lot number for distribution only in Egypt. The falsified product shows discrepancies in the packaging artwork and text placement, with some text missing. The product price (in Egyptian Pounds) is also missing.
- Lot AVZT – This lot number is not recognised by the genuine manufacturer. Any IMFINZI product with this lot number is considered falsified.

Risks

These falsified products should be considered unsafe, and their use may be life-threatening in some circumstances. The use of these falsified **IMFINZI** injections may lead to ineffective or delayed treatment. It is important to detect and remove any falsified **IMFINZI (durvalumab)** injections from circulation to prevent harm to patients.

ZAMRA wishes to notify healthcare professionals and members of the public that, while this product is not registered in Zambia and has not authorised its importation, the ZAMRA has intensified surveillance of the product on the Zambian market as it may be imported through illegal means.

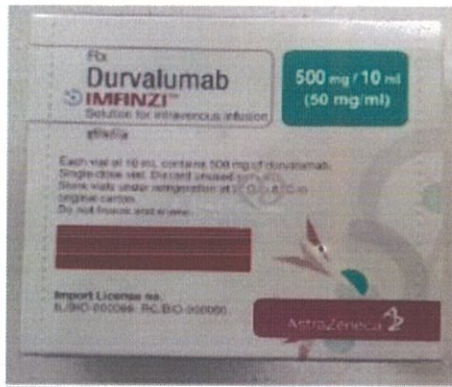

In the unlikely event that you are in possession of this product, do not use it. If you suffer any adverse drug reaction/event having used this product, you are advised to seek immediate medical advice and report the incident to the National Pharmacovigilance Unit at Zambia Medicines Regulatory Authority 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

Annex: Products subject of WHO Medical Product Alert N°3 /2025

| Product Name | IMFINZI (durvalumab) injection 500mg/10ml | | |
|-----------------------|--|--------------------------|---------|
| Stated manufacturer | AstraZeneca | | |
| Identified in | Islamic Republic of Iran | Islamic Republic of Iran | Türkiye |
| Lot | BAZR | BBEG | AVZT |
| Expiry date | 03-2025 | 12-2025 | 12-2026 |
| Available Photographs | | | |
| Lot BAZR |  | | |
| Lot BBEG |  | | |