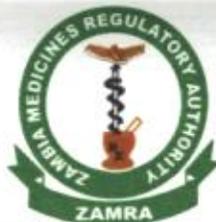


All correspondence should be addressed to the Director General



In reply, please quote
LET_LSE/PMS/0016/12/25

ZAMBIA MEDICINES REGULATORY AUTHORITY

PUBLIC NOTICE

Date: 30th December 2025

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

MEDICAL PRODUCT ALERT NO. 7/2025: FALSIFIED IBRANCE (PALBOCICLIB) IDENTIFIED IN THE WHO AFRICAN, 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 inform all healthcare professionals, pharmaceutical outlets and members of the public that it has been notified by the World Health Organisation (WHO) of the circulation of nine (9) batches of falsified **IBRANCE (PALBOCICLIB)**. These falsified products have been detected in Cote d'Ivoire, Egypt, Lebanon, Libya and Türkiye.

IBRANCE (PALBOCICLIB) is a medicine used to treat some types of advanced breast cancer. Genuine IBRANCE is prepared as capsules for oral use. The falsified products have been offered directly to consumers via online platforms and have been found at pharmacy level.

The genuine manufacturer has confirmed that the products listed in this alert are falsified. Samples of the falsified products have been tested by the genuine manufacturer and were found to contain **no active pharmaceutical ingredient**.

How to identify the falsified products

The falsified products have several visual discrepancies on the packaging. Some of the falsified products carry genuine lot numbers but display packaging, serialization, and capsule printing anomalies (see product details below):

Falsified lot numbers: The following lot numbers are **NOT valid for genuine IBRANCE** and any **IBRANCE** product with these lot numbers should be treated as falsified: FS5173, GS4328, LV1850, and TS2190.

Suspicious lot numbers: (likely to be falsified if combined with any indicator below): GK2981, GR6491, GT5817, HJ8710, and HJ8715.

Indicators of falsification include:

- Label states: "Manufactured by: Pfizer, PO Box 29387, Mission, KS 66201".
- Label contains spelling errors or poor-quality printing.
- Security foil on the bottle shows the Pfizer logo in black ink.
- Capsules marked with black ink "PBC 125" or have no markings.
- Capsules are an unusual color (e.g., bright orange).

Risks

These falsified medicines did not contain any active pharmaceutical ingredient and should therefore be considered unsafe. Their use could result in treatment failure, uncontrolled cancer progression, and a higher risk of death due to lack of therapeutic effect.

It is important to detect and remove any falsified from circulation to prevent harm to patients.

Advise to healthcare providers, pharmaceutical outlets and members of the public

ZAMRA wishes to notify healthcare professionals and members of the public that, although this product is not registered in Zambia and no special import permits have been issued, ZAMRA has heightened its surveillance as the product is being sold online, and may be imported through illegal routes.

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



Annex: Products subject of WHO Medical Product Alert N°7/2025

| Product name | IBRANCE (palbociclib) | |
|---------------------|-----------------------|-------------------------------|
| Stated manufacturer | PFIZER | |
| Lot number | Expiry Date | Identified In |
| FS5173 | 271126 | Côte d'Ivoire, Lebanon, Libya |
| GK2981 | 250630 | Lebanon |
| GR6491 | 250630 | Côte d'Ivoire, Türkiye |
| GS4328 | 260131 | Côte d'Ivoire |
| GT5817 | 250630 | Egypt |
| HJ8710 | 260228 | Egypt |
| HJ8715 | 04/2028 | Türkiye |
| LV1850 | 311028 | Libya |
| TS2190 | 200529 | Libya |

| Lot: FS5173 | Lot: FS5173 | Lot: GR6491 | Lot: HJ8710 | Lot: GT5817 | Lot: LV1850 |
|--|--|--|---|--|--|
| Lebanon | Côte d'Ivoire | Türkiye | Egypt | Egypt | Libya |
|  |  |  |  |  |  |