All correspondence should be addressed to the Director General

In reply, please quote
LET_LSE/PMS/0006/06/26

ZAMBIA MEDICINES REGULATORY AUTHORITY

PUBLIC NOTICE

Date: 9th June 2026

To: Pharmaceutical outlets, Health Facilities, Healthcare Professionals, Public

URGENT PUBLIC ALERT:

FALSIFIED OPDIVO (NIVOLUMAB) 100MG/10ML INJECTION LOT NO. ASW3556 EXPIRY DATE 10. 2027 ON THE ZAMBIAN MARKET

FOR IMMEDIATE RELEASE – 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 ensure the quality, safety and efficacy of medicines and allied substances for human and animal health protection.

The Authority wishes to notify healthcare professionals **(oncologists & pharmacists)**, health facilities, pharmaceutical outlets and the public that it is investigating the presence of falsified **OPDIVO (NIVOLUMAB) 100MG/10ML INJECTION** on the market. The product under investigation was procured for a patient undergoing chemotherapy at a private health facility by a named pharmaceutical outlet in Lusaka.

The stated manufacturer and brand owner Bristol-Myers Squibb (BMS) has confirmed that they did not manufacture the product and that Lot **ASW3556** is not a valid Lot for BMS.

Product details:

S/N	Name of Product	Stated Manufacturer	Batch/Lot Number	Expiry Date
1.	Opdivo (Nivolumab) 100mg/10ml Injection	Bristol-Myers Squibb	ASW3556	10. 2027

What is Opdivo (Nivolumab)?

Opdivo (generic name: nivolumab) is a prescription immunotherapy treatment used to treat cancers such as melanoma, lung, colorectal, malignant pleural mesothelioma, urinary tract, gastric, liver, Hodgkin lymphoma, and head and neck cancers. It is administered as an intravenous infusion every 2 to 4 weeks, depending on the type of cancer.

Dangers of using falsified Opdivo (Nivolumab)

Falsified medicines deliberately or fraudulently misrepresent their identity, composition or source. Use of falsified anticancer medication (including Opdivo) may lead to ineffective dosing, disease progression and direct toxicity.

Pharmaceutical outlets, health facilities and other cancer treatment centers that may have the impacted product **(Lot No. ASW3556)** are advised to refrain from using the medication and immediately report to ZAMRA.

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

suppliers. Falsified and substandard anticancer drugs represent a rapidly growing global pharmaceutical crime crisis that severely compromises patient safety.

The Authority has continued investigating the incident in collaboration with the genuine manufacturer and other international partners in order to establish the source of the falsified product.

If you suffer any adverse drug reaction 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 you need further clarification, please do not hesitate to contact our Secretariat.

Makomani Siyanga (Mr.)
DIRECTOR-GENERAL

ANNEXURE: Secondary packaging of the falsified Opdivo (Nivolumab) injection