DRUG REGULATORY AUTHORITY OF PAKISTAN
Division of Quality Assurance and Laboratory Testing

RAPID ALERT

DRAP ALERT No: Nº I/S/05-26-27

FALSIFIED IMFINZI® (Durvalumab) Injection 500mg/10ml & FALSIFIED ENHERTU® 100 mg

Date: 06th May, 2026

Target Audience:

- Regulatory Field Force of DRAP and Provincial Drug Control Departments
- Healthcare Professionals
- Hospitals and Oncology Centers
- Consumers

Problem Statement:

AstraZeneca Pakistan has notified DRAP regarding identification of suspected falsified batches of oncology products namely **IMFINZI® (Durvalumab) Injection 500mg/10ml** and **ENHERTU® 100 mg**, following authenticity queries raised by healthcare professionals from hospitals in Lahore, Pakistan. Investigations conducted by AstraZeneca and the respective manufacturers confirmed that the identified batches were **not manufactured by the genuine manufacturers** and are considered **falsified products**. The affected products and batches are as follows:

S #	Name of Product	Batch	Expiry Date	Purported Manufacturer	Remarks
1	IMFINZI® (Durvalumab) Injection 500mg/10ml	ASCB	08-2028	AstraZeneca, Sweden	Falsified
2	ENHERTU® 100 mg	DK1262	02-2026	Daiichi Sankyo / AstraZeneca	Falsified

Investigation Findings:

IMFINZI® 500mg/10ml

- AstraZeneca Sweden Operations confirmed that batch number **ASCB** was never issued/manufactured by the company.
- Comparative assessment revealed packaging inconsistencies resembling products referenced in **WHO Medical Product Alert No. 5/2024** concerning falsified IMFINZI®.
- The product is intended for intravenous administration and poses a significant risk to patient safety.

ENHERTU® 100 mg

- Manufacturer confirmed that batch number **DK1262** has never been produced.
- Visual examination identified multiple discrepancies in labeling, serial numbering, printing alignment, barcode formatting, and carton artwork compared with genuine packs.
- Packaging characteristics were inconsistent with approved manufacturer specifications.

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Risk Statement:

IMFINZI® (Durvalumab) is an oncology medicine used in treatment of various cancers, while ENHERTU® is indicated for HER2-positive malignancies. Use of falsified oncology products may result in:

- Therapeutic failure
- Disease progression
- Delay in life-saving cancer treatment
- Serious adverse reactions due to unknown composition
- Potential fatal consequences

Since both products are administered intravenously, the public health risk associated with these falsified products is assessed as **critical/high**.

Action Initiated: -

The Regulatory Field Force of DRAP and Provincial Drug Control Departments has been directed to conduct surveillance activities throughout the supply chain to confiscate the falsified products.

Advice for Healthcare Professionals: -

DRAP requests healthcare professionals to have increased vigilance within the supply chains of institutions/pharmacies/healthcare facilities likely to be affected by above mentioned product. Any adverse events or quality problems experienced with the use of these products should be reported to National or Provincial pharmacovigilance centers using Adverse Event Reporting Form or online through this link. Further information on reporting problems to DRAP is available on this link.

Advice for Consumers:

Consumers should not use the mentioned batches of these drug products and should contact their physician or healthcare provider(s) if they have experienced any problem related to taking or using the above mentioned products and should report the incident to the Drug Regulatory Authority of Pakistan / National Pharmacovigilance Centre. All therapeutic goods must be obtained from licensed pharmacies and other authorized/licensed retail outlets. The authenticity and condition of products should be carefully checked. Seek advice from your pharmacists or other healthcare professionals in case of any doubt.

Drug Regulatory Authority of Pakistan

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