REPUBLIC OF KENYA

MINISTRY OF HEALTH

PHARMACY AND POISONS BOARD

PUBLIC ALERT

FALSIFIED DARZALEX (DARATUMUMAB) INJECTION BATCH MYS7381 AND STV1K01, DETECTED IN MALDIVES AND MEXICO

The Pharmacy and Poisons Board ("the Board") is mandated by Cap 244 of the Laws of Kenya to protect and promote public health by regulating the pharmacy profession and ensuring access to quality, safe, and effective health products and technologies ("HPTs").

In furtherance of this mandate, the Board undertakes post-marketing surveillance activities to monitor HPTs circulating in the market and to take appropriate regulatory actions in safeguarding public health.

During the course of these surveillance activities, **the Board received an alert from the World Health Organization, regarding falsified Darzalex (Daratumumab) injection detected in the Maldives and Mexico**. These falsified product batches were supplied or offered by non-authorized distributors.

The legitimate manufacturer confirmed that batch numbers MYS7381 and STV1K01 are not genuine. Visible particulate matter was found in at least one falsified batch, STV1K01. Accordingly, any Darzalex (Daratumumab) Injection bearing either of these batch numbers should be considered falsified and must not be used.

The falsified batches may contain incorrect, insufficient, or harmful ingredients, and its quality, safety, and efficacy cannot be guaranteed. Use of this product poses a serious risk to patient safety and public health.

PUBLIC ADVISORY

To date, the Board has not detected or confirmed the presence of the falsified Darzalex (Daratumumab) Injection Batch MYS7381 and STV1K01 within the Kenyan market.

This alert is therefore issued as a precautionary measure to enhance vigilance, prevent potential entry into the supply chain, and safeguard public health. In light of the above, the Board advises as follows:

1. Procurement agencies, hospitals, distributors, pharmacists, pharmaceutical technologists, and members of the public are urged to remain vigilant and report immediately any encounter with the falsified product batches.
2. All stakeholders within the supply chain to procure HPTs exclusively from licensed manufacturers, importers, distributors, and retailers. Procuring from unlicensed sources endangers patients and constitutes a violation of the Pharmacy and Poisons Act, Cap 244 of the Laws of Kenya.

The Board, together with relevant Government investigative agencies, will take firm regulatory and legal action against any individual or entity involved in the distribution of this and any other falsified batches of HPTs.

HOW TO REPORT

Any suspected falsified or substandard medicine, should be reported through the following official channels:

- Online portal: https://pv.pharmacyboardkenya.org/users/mpublic
- USSD Code: *271#
- Mobile App: mPvERS (Android & iOS)
- Email: pv@ppb.go.ke | pms@ppb.go.ke
- Telephone: 0795743049

The Pharmacy and Poisons Board remains committed to protecting and safeguarding public health. Your cooperation is essential in ensuring the quality, safety and efficacy of Health Products and Technologies in Kenya.

Dr. Ahmed I. Mohamed
CHIEF EXECUTIVE OFFICER

11th August 2026