Direct Healthcare Professional Communication

Oct 2023

Potential Missing Package Leaflet in Folding Boxes of Perjeta (pertuzumab), Kadcyla (trastuzumab emtansine) 160mg and Phesgo (pertuzumab/trastuzumab) 600 mg.

Dear Healthcare Professional,

Roche in agreement with The General Administration for Pharmaceutical Vigilance of the Central Administration for Pharmaceutical Care at The Egyptian Drug Authority would like to inform you of the following **Potential Missing Package Leaflet in Folding Boxes of Perjeta**:

Summary:

- In April 2023, it was identified during packaging operations that due to an automation issue, a package leaflet was missing from two folding boxes of one of Roche products.
- **Perjeta (pertuzumab), Kadcyla (trastuzumab emtansine) and Phesgo (pertuzumab/trastuzumab)** are additional products packed on the same line.
- Roche cannot fully exclude that a folding box/boxes of the above listed products may have been distributed in the Egyptian market with a missing package leaflet. Any batches manufactured between 15 November 2021 and 24 April 2023 are potentially impacted by this defect. There is no impact on the quality of the medicines.
- Healthcare Professionals should check the folding box prior to dispensing the above medicines. In case of a missing package leaflet, healthcare professionals should refer to the attached package leaflets in the annexes and provide accordingly to patients.
- Healthcare Professionals should report any missing package leaflet via the Company contact point below.

Further information on the safety concern and the recommendations

In April 2023, it was identified during packaging operations that a package leaflet was missing from two folding boxes of one of Roche products. The medicines **Perjeta (pertuzumab),** Kadcyla (trastuzumab emtansine) and Phesgo (pertuzumab/trastuzumab) are packed on the same line and may also be affected.

Roche cannot fully exclude that a folding box/boxes of the above listed products may have been distributed in the Egyptian market with a missing package leaflet.

Any batches manufactured between 15 November 2021 and 24 April 2023 are potentially impacted by this defect. No market complaints for missing package leaflets have been received since the start of commercial packaging on this line on 15 November 2021. There is no impact on the quality of the medicines.

21st Abdel-Aziz Al-Saud, Manial Al-Roda,Cairo
pv.head@edaegypt.gov.eg; pv.safety@edaegypt.gov.eg;
Tel.: 237484988 **Ext.:1470**

The purpose of this communication is to clarify that the products can still be used and to provide copies of the relevant package leaflets.

In terms of preventative action, a balance has been implemented from 24 April 2023 as a mandatory check on all folding boxes on the automated packaging line in question to ensure that the package leaflet is included in every box.

Reference:

EMA: https://www.ema.europa.eu/en/documents/dhpc/potential-missing-package-leafletfolding-boxes-roactemra-tocilizumab-hemlibra-emicizumab-herceptin/trastuzumabtecentriq-atezolizumab_en.pdf

Call for reporting

Healthcare professionals are asked to report any suspected adverse reactions via the Egyptian reporting system:

Name: General Administration for Pharmaceutical Vigilance

Email: pv.followup@edaegypt.gov.eg

Online reporting: https://primaryreporting.who-umc.org/EG
QR Code:

Hotline: 15301

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