**Direct healthcare professional communication (DHPC)**
**Date: July 2022**

**Erelzi▼ (etanercept) – Temporary supply of Erelzi 25mg pre-filled syringe in foreign packaging**

Dear Healthcare Professional / Homecare company / Wholesaler

This letter is sent in agreement with the Medicines and Healthcare Products Regulatory Agency (MHRA). We would like to inform you about the following:

**Summary**

- **There is a current interruption the UK supply of Erelzi 25mg pre-filled syringe, due to a manufacturing issue at Sandoz.**
- **To resolve this temporary issue a number of Erelzi 25mg pre-filled syringe packs originally destined for Slovakia (batch number and expiry date shown below), have been repurposed for the UK.**
- **The only difference between the UK and Slovakian product is the packaging (outer paper box, label on the syringe and patient information leaflet).**
- **If a patient or caregiver contacts you with concerns about seeing a different packaging for Erelzi 25mg pre-filled syringe, carefully check the differences and the batch numbers and expiry dates below, and if they match, please reassure patients that this product is the same as their usual UK product.**

**Background**

There is a current interruption in the UK supply of Erelzi 25mg pre-filled syringe, due to a manufacturing issue at Sandoz. This interruption is temporary with re-supply of UK stock anticipated for w/c August 22nd 2022.

The MHRA have agreed that a limited number of Erelzi 25mg pre-filled syringe packs originally produced for use in Slovakia can be repurposed for use in the UK. The only difference between the UK and Slovakian product is the packaging (outer paper box, label on the syringe and patient information leaflet). To ensure the correct patient information leaflet (PIL) is available for UK patients, the Slovakian packs are individually placed in plastic bags with a UK patient information leaflet and a copy of this letter inserted. This letter is intended to provide you with information to answer any questions and must be removed from the bag before it is given to the patient. The plastic bag will also contain a letter intended for patients to explain the difference in packaging.

**The batch numbers and expiry dates of the Slovakian packs are as follows:**

| **Product Strength** | **Batch Numbers** | **Expiry** |
|---|---|---|
| 25mg pre-filled syringe Erelzi | KZ5367 | 31st December 2022 |

The MHRA has agreed that Sandoz make Wholesale companies, Homecare companies and Hospital Pharmacies who are likely to dispense the product aware of this in case a patient or carer is concerned by this difference.

If a patient or caregiver contacts you with concerns about seeing a different packaging for the Erelzi 25mg pre-filled syringe, carefully check the differences and the batch numbers and expiry dates below, and if they match, please reassure patients that this product is the same as their usual UK product.

If you require additional copies of this letter please contact Sandozgb@EU.propharmagroup.com.

***Adverse Event Reporting***

Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard

Healthcare professionals are asked to report any suspected adverse reactions to the Yellow Card Scheme electronically. Report via the website https://www.gov.uk/yellowcard, the free Yellow Card app available from the Apple App Store or Google Play Store, and some clinical IT systems (EMIS, SystmOne, Vision, MiDatabank) for healthcare professionals. Suspected side effect can also be reported by calling 0800 731 6789 for free.

When reporting please provide as much information as possible, including information about medical history, any concomitant medication, onset timing, treatment dates, and product brand name.

Adverse events should also be reported to Sandoz via uk.patientsafety@novartis.com or online through the pharmacovigilance intake (PVI) tool at www.report.novartis.com

If you have a question about the product, please contact us on 01276 698607 or Medical Information on 01276 698101 or by email. Medical information email: Sandozgb@EU.propharmagroup.com

▼The medicine referred to in this material is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. Please see www.mhra.gov.uk/yellowcard for instructions on how to report side effects.

The non-identical nature of biological medicines and vaccines means it is very important that safety surveillance is carried out on a brand/product-specific basis. When reporting a suspected adverse event to a biological medicine (such as blood products, antibodies and advanced therapies [such as gene and tissue therapy]) or vaccine, please ensure that you provide the brand name (or product licence number and manufacturer), and the specific batch-number. Additionally, when providing patients with details of the vaccine or biological medicine administered, it is good practice to give them details of the brand and batch number. This will allow patients and carers to more accurately report suspected adverse events to the Yellow Card Scheme.

***Company contact points***

If you have any questions, or if you require any further information, please contact the Sandoz Medical Information Team e-mail*:* Sandozgb@EU.propharmagroup.com Tel: +44 (0)1276 698 101

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Medical Director

July 2022 | 225585