SANDOZ

Date: May 2025

DIRECT HEALTHCARE PROFESSIONAL COMMUNICATION

Erelzi (etanercept) 50 mg solution for injection in pre-filled pen
Interim Supply of Irish Stock

Dear Healthcare Professional / Homecare Company / Wholesaler

Summary: Sandoz is currently experiencing supply constraints with Erelzi (etanercept) 50 mg solution for injection in pre-filled pen

To ensure continuity in supply, Sandoz has obtained approval from the MHRA to supply the Irish product (Batch Numbers PC6179, PC3034) which is expected to be on the UK market from May 2025.

Please note the following:

- **This product is considered licensed in UK.**
- **The product from Ireland has the same formulation as the UK product.**
- **The product from Ireland is manufactured according to the same manufacturing process and quality controls as the UK product.**
- **There is a current interruption in the UK supply of Erelzi 50 mg solution for injection in pre-filled pen due to manufacturing constraints at Sandoz.**
- **To resolve this temporary issue a number of Erelzi 50 mg solution for injection in pre-filled pen packs originally destined for Ireland (batch numbers and expiry dates shown below), have been supplied to the UK.**
- **The only difference between the UK and Irish product is the Product Licence Number on the Carton and reference in the Irish Leaflet to report side effects to Irish Regulator and contact Irish Marketing Authorisation Holder for further information.**
- **Please refer Patients to the MHRA Yellow Card Scheme and UK Marketing Authorisation Holder Contact Details which is also included below in Call for Reporting Section**
- **If a patient or caregiver contacts you with concerns about different packaging for Erelzi 50 mg solution for injection in pre-filled pen, 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 the numbers do not match, please follow your medicines falsification protocol.**
- **The MHRA has approved this product under a batch specific variation to the marketing authorisation.**

Please ensure all relevant staff are made aware of the content of this letter and that the information is communicated to the patients.

Background
There is a current interruption in the UK supply of Erelzi 50 mg solution for injection in pre-filled pen, due to a manufacturing constraint at Sandoz. This interruption is temporary with re-supply of UK stock anticipated in next few months.

The MHRA have agreed that a number of Erelzi 50 mg solution for injection in pre-filled pen packs originally produced for use in Ireland can be supplied for use in the UK. The only difference between the UK and Irish product is the Product Licence Number on the Carton and reference in the Irish Leaflet to report side effects to Irish Regulator and contact Irish Marketing Authorisation Holder for further information.

The batch number and expiry date of the Irish packs are as follows:

Product Strength	**Batch Number(s)**	**Expiry**
Erelzi 50 mg solution for injection in pre-filled pen	PC6179	31-July-2027
Erelzi 50 mg solution for injection in pre-filled pen	PC3034	31-July-2027

The MHRA has agreed that Sandoz make Healthcare Professionals, who are likely to dispense the product aware of this in case a patient or carer is concerned by this difference. We will also notify the NHS Commercial Medicines Unit and share a copy of this letter with them electronically for distribution.

If a patient or caregiver contacts you with concerns about seeing different packaging for Erelzi 50 mg solution for injection in pre-filled pen, carefully check the differences and the batch numbers and expiry dates above, 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 mi.uk@sandoz.com.

Call for reporting

Please continue to report suspected adverse drug reactions (ADRs) to the MHRA through the Yellow Card scheme.

Please report:

- all suspected ADRs that are serious or result in harm. Serious reactions are those that are fatal, life-threatening, disabling or incapacitating, those that cause a congenital abnormality or result in hospitalisation, and those that are considered medically significant for any other reason
- all suspected ADRs associated with new drugs and vaccines identified by the black triangle ▼

You can report via:

- the Yellow Card website
- the free Yellow Card app available from the Apple App Store or Google Play Store
- some clinical IT systems (EMIS/SystmOne/Vision/MiDatabank) for healthcare professionals

Alternatively, you can report a suspected side effect to the Yellow Card scheme by calling 0800 731 6789 for free, Monday to Friday between 9am and 5pm.

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

Company Contact Points

Adverse events should also be reported to Sandoz via adverse.event.uk@sandoz.com or online through the pharmacovigilance intake (PVI) tool at https://pvi1j.solutions.iqvia.com/

If you have a question about the product, please contact Medical Information on 01276 698101 or via email at mi.uk@sandoz.com

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

Yours faithfully,

Hannah Stevenson

Sandoz UK,

Medical Director