**Direct healthcare professional communication (DHPC)**
Date: 15 September 2022

**Rixathon▼ (rituximab) – Temporary supply of Rixathon 500mg vials 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 of the GB supply of Rixathon 500mg vials, due to a manufacturing issue at Sandoz.**
- **To resolve this temporary issue a number of Rixathon 500mg vials originally destined for the Netherlands (batch number and expiry date shown below), have been repurposed for GB.**
- **The only change between the GB and the Dutch product is the language on the packaging (outer paper box, label on the vial and patient information leaflet). The branding, colour and layout is the same.**
- **If a patient or caregiver contacts you with concerns about seeing a different packaging for Rixathon 500mg vial, carefully check the batch numbers and expiry dates below, and if they match, please reassure patients that this product is the same as their usual GB product.**

**Background**
There is a current interruption in the GB supply of Rixathon 500mg vials, due to a manufacturing issue at Sandoz. This interruption is temporary with re-supply of GB stock anticipated for week commencing 3rd October 2022. The MHRA have agreed that a limited number of Rixathon 500mg vials originally produced for use in the Netherlands can be repurposed for use in the GB. The only difference between the GB and the Dutch product is the language on the packaging (outer paper box, label on the vial and patient information leaflet). The branding, colour and layout is the same.

You are receiving this to provide you with additional information and to answer any questions you may have.

To ensure the English patient information leaflet (PIL) is available for GB patients receiving Rixathon, please find enclosed a letter for patients which includes a QR code that can be used to access the PIL online. An image of the QR code is available below. The patient letter will also explain the difference in packaging.

To access the Rixathon Patient Alert Card, please scan the QR code below, which will direct you to the Electronic Medicines Compendium (emc) website where you can print the alert card.

| | English Patient Information Leaflet | Rixathon Patient Alert Card |
|---|---|---|
| QR code | | |
| URL | www.sandozhub.co.uk/sites/sandozhub.co.uk/files/Rixathon-PIL-leaflet.pdf | www.medicines.org.uk/emc/rmm/2149/Document |

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

| **Product Strength** | **Batch Numbers** | **Expiry** |
|---|---|---|
| Rixathon 500mg vials | MJ6414 | 31 May 2025 |

The MHRA has agreed that Sandoz make wholesale companies, compounding companies or hospital pharmacies, who are likely to dispense the product, aware of this in case a patient or caregiver is concerned by this difference.

If a patient or caregiver contacts you with concerns about seeing a different packaging for the Rixathon 500mg vials, carefully check the batch numbers and expiry dates below, and if they match, please reassure patients that this product is the same as their usual GB product.

***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 suspected adverse reactions.

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 via e-mail*:* Sandozgb@EU.propharmagroup.com or telephone: +44 (0)1276 698 101

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