For the attention of the Chief Pharmacist

28 July 2020

RoActemra® (tocilizumab) 162 mg Solution for Injection in Pre-filled Syringe
Interim supply of Irish livery stock to mitigate supply disruption

Dear Pharmacist

Summary: Roche is mitigating supply disruption for RoActemra® (tocilizumab) 162 mg Solution for Injection in Pre-filled Syringe in the UK.

To ensure continuity of supply during the current Covid-19 situation, Roche Products Limited has obtained approval from the MHRA to supply RoActemra (tocilizumab) 162 mg Solution for Injection in Pre-filled Syringe in Irish pack livery. The first packs are expected to be on the UK market from 23 June 2020, with GTIN (Global Trade Identification Number) 05000471007275 printed on the box.

Please note the following:

- This product is considered licensed in the UK.
- The packs supplied in Irish livery have the same formulation as the UK product packs and are manufactured according to the same manufacturing process and quality controls as the UK product.
- The differences in the packs are as follows;
    - Carton
        - Inside the blue box states Ireland / Malta instead of United Kingdom
        - Barcode (GTIN) number differs

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- Label and Carton
  - No Chugai logo on IE packs
  - Individual component number is different and states IE instead of GB-CHU

- PIL
  - Section 4: Reporting of side effects. UK refers to MHRA Yellow Card Scheme website and app. IE pack refers to HPRA website for Ireland and ADR portal website for Malta.
  - Section 6: Contents of the pack and other information. Marketing Authorisation holder to contact for more information, contact telephone numbers are different.

- Please ensure the UK Summary of Product Characteristics (SPC) and Patient Information Leaflet (PIL) are followed, available at https://www.medicines.org.uk/emc/.
- The MHRA has agreed to an exemption according to Article 63(3) of Council Directive 2001/83/EC, granted in accordance with regulation 266(4)(a) of the Human Medicines Regulations (HMR) 2012, from the obligation that certain particulars should appear on the outer and immediate packaging of RoActemra (tocilizumab) 162 mg Solution for Injection in Pre-filled Syringe.
- Please ensure that the GTIN for the Irish livery packs is set up in your pharmacy systems to enable electronic ordering and dispensing.

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

Call for reporting
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, treatment dates, and product brand name.

Company contact point
If you have any questions about this letter or wish more information about RoActemra (tocilizumab), please contact our Medical Information team on 0800 328 1629 or email medinfo.uk@roche.com.

With many thanks in advance for your understanding and cooperation.

Yours sincerely

Roche Products Limited

Jane Millward
Head of Supply Chain, UK