Date: 24th January 2023

DIRECT HEALTHCARE PROFESSIONAL COMMUNICATION

Kevzara▼ 200 mg solution for injection in pre-filled syringe (sarilumab):
Interim Supply of German Stock to Mitigate Supply Disruption

Dear Healthcare Professional,

Summary: Sanofi is currently experiencing supply disruption with Kevzara 200 mg solution for injection in pre-filled syringe (sarilumab) in the UK (Northern Ireland).

To ensure continuity in supply, Sanofi has obtained approval from the Medicines and Healthcare products Regulatory Agency (MHRA) to supply German product (batch number 0L789J; 1,700 packs) instead of the UK (Great Britain) packs, which are currently supplied. The packs from Germany are expected to be on the UK (Northern Ireland) market from January 2023 to March 2023.

Please note the following:

- This product is considered licensed in the UK (Northern Ireland).
- The product from Germany has the same formulation as the UK (Northern Ireland) product.
- The product from Germany is manufactured according to the same manufacturing process and quality controls as the UK (Northern Ireland) product.
- There are minor differences between the German and UK (Northern Ireland) product information, where the carton, leaflet and pre-filled syringe labelling are presented in German language. A comparison between the outer cartons can be found in Annex 1 and Annex 2 of this letter. Please ensure the UK Patient Information Leaflet (PIL) is followed.
- Please discard the German leaflet in the pack and refer to the UK approved PIL, which can be found at https://www.medicines.org.uk/emc/product/8144/pil. A copy of the UK approved PIL should be printed and supplied to the patient with their medicine.
- For additional copies of the leaflet, please refer to the link above or contact the company contact point (see next page).
- The MHRA has agreed to an exemption granted in accordance with Article 63.3 of Directive 2001/83/EC, from the obligation that certain particulars should appear on the outer and immediate packaging of Kevzara 200 mg solution for injection in pre-filled syringe and that the information must be given in English.

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

Call for reporting
Kevzara▼ is subject to additional monitoring. This will allow quick identification of new safety information. Please report ANY suspected adverse drug reactions (ADRs) to new drugs and vaccines identified by the black triangle▼ to the MHRA through the Yellow Card Scheme.

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 ADRs to 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▼

It is easiest and quickest to report ADRs online via the Yellow Card website - https://yellowcard.mhra.gov.uk/ or via the Yellow Card app available from the Apple App Store or Google Play Store.

Alternatively, prepaid Yellow Cards for reporting are available:

- by writing to FREEPOST YELLOW CARD (no other address details necessary)
- by emailing yellowcard@mhra.gov.uk
- at the back of the British National Formulary (BNF)
- by telephoning the Commission on Human Medicines (CHM) free phone line: 0800-731-6789
- by downloading and printing a form from the Yellow Card website (see link above) When reporting please provide as much information as possible, including information about medical history, any concomitant medication, onset, treatment dates, and product brand name

Suspected adverse reactions should also be reported to Sanofi: Tel: 0800 0902314. Email: UK-drugsafety@sanofi.com.

Company contact point
If you have any questions about this letter or require more information about Kevzara 200 mg solution for injection in pre-filled syringe, please contact Sanofi Medical Information at 410 Thames Valley Park Drive, Reading, Berkshire, RG6 1PT, UK or telephone 0800 035 2525 or email uk-medicalinformation@sanofi.com

Yours faithfully,

John Forni
Medical Head Specialty Care UK & Ireland

Felicia Pinto
Head of Regulatory Affairs UK & Ireland

Aventis Pharma Limited (trading as Sanofi Genzyme)

Annex 1 – Current Approved UK (Great Britain) Carton

Annex 2 – German Carton