Date: 05 April 2022

DIRECT HEALTHCARE PROFESSIONAL COMMUNICATION

Kevzara▼ 200 mg solution for injection in pre-filled pen (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 pen (sarilumab) in the UK (Great Britain).

To ensure continuity in supply, Sanofi has obtained approval from the Medicines and Healthcare products Regulatory Agency (MHRA) to supply German product (batch number 1F157A; 2,415 packs) which is expected to be on the UK (Great Britain) market from April 2022 to June 2022.

Please note the following:

- This product is considered licensed in the UK.
- The product from Germany has the same formulation as the UK (Great Britain) product
- The product from Germany is manufactured according to the same manufacturing process and quality controls as the UK (Great Britain) product.
- There are minor differences between the German and UK product information, where the carton, leaflet and pre-filled pen 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 refer to the UK approved PIL supplied with the German packs. Discard the German leaflet in the pack.
- For additional copies of the leaflet, please refer to https://www.medicines.org.uk/emc/product/8145/pil or contact the company contact point (see next page)
- The MHRA has agreed to an exemption granted in accordance with regulation 266(4)(a) and (b) of the Human Medicines Regulations (HMR) 2012, from the obligation that certain particulars should appear on the outer and immediate packaging of Kevzara 200 mg solution for injection in pre-filled pen 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.

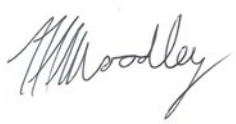
Healthcare professionals are asked to report any suspected adverse reactions to the Yellow Card Scheme electronically. Report via the website https://www.gov.uk/yellowcard, the free Yellow Card app available from the Apple App Store or Google Play Store, and some clinical IT systems (EMIS, SystmOne,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

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

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.

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 pen, 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,



Marc Moodley
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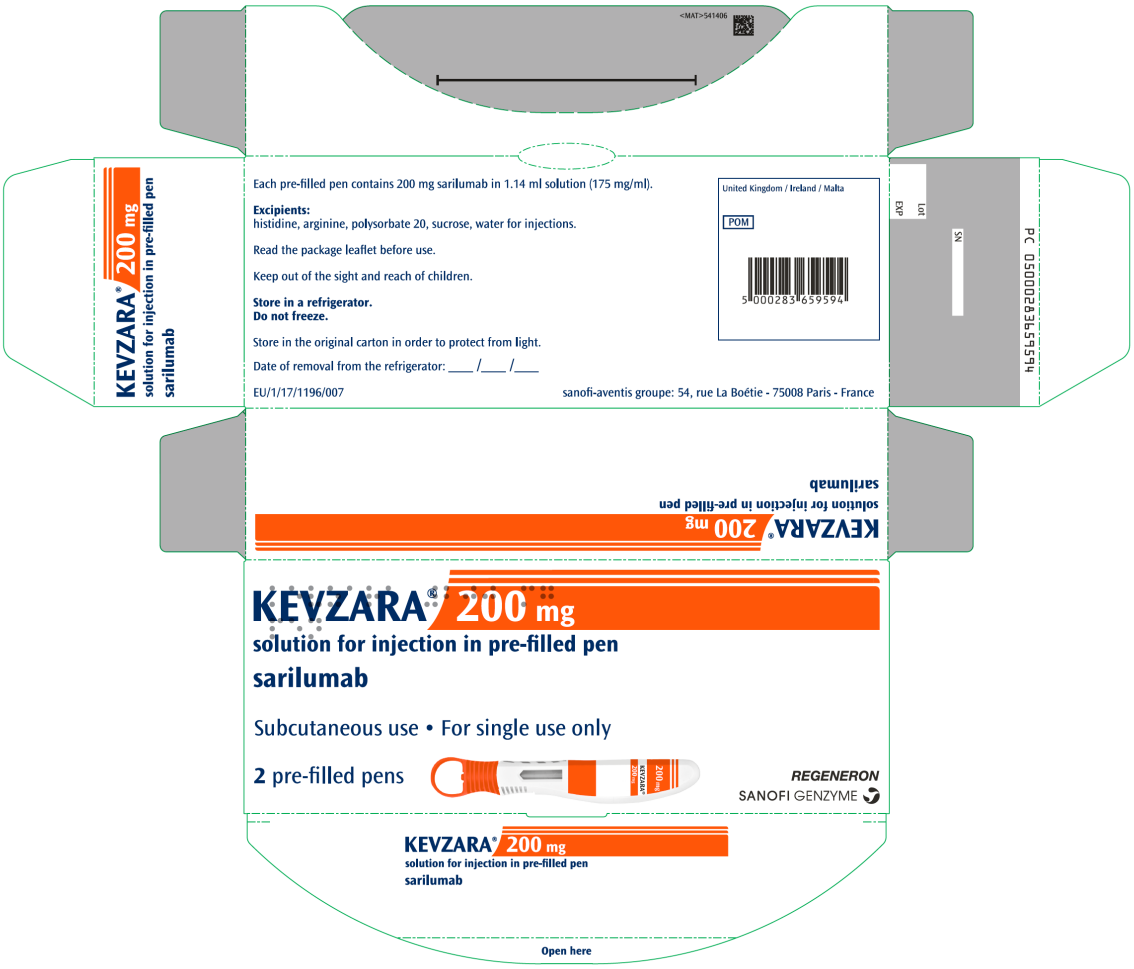
Felicia Pinto
Head of Regulatory Affairs UK & Ireland

Aventis Pharma Limited (trading as Sanofi Genzyme)

Annex 1 – Current Approved UK (Great Britain) Carton



Annex 2 – German Carton