

Date: 1st June 2020

DIRECT HEALTHCARE PROFESSIONAL COMMUNICATION

**Semglee® ▼ 100 units/ ml x 3ml prefilled pens (Insulin glargine):
Interim Supply of Polish Stock to Mitigate Supply Disruption**

Dear Healthcare Professional,

**Summary: Mylan is currently experiencing supply disruption with Semglee®
100 units/ ml x 3ml prefilled pens (Insulin glargine) in the UK.**

Due to unavoidable circumstances related to the current Covid-19 situation, we have experienced an increased demand of Semglee and anticipating a temporary supply constraint. To ensure continuity in supply during this period of disruption, Mylan has obtained approval from the MHRA to supply Polish product:

Batch Number	Quantity (no. of packs)	Expiry	Origin
BF19003212	5,000	31/01/2021	Poland

Please note the following:

- This product is considered licensed in the UK.
- The product from Poland has the same formulation as the UK product
- The product from Poland is manufactured according to the same manufacturing process and quality controls as the UK product.
- There are differences between the Polish and UK product information. The language is different.
- Please ensure the UK Summary of Product Characteristics (SPC) and Patient Information Leaflet (PIL) are followed.
- Please refer to the UK approved SPC supplied electronically and PIL enclosed in a plastic bag attached to the carton of Polish packs with patient letter. Discard the Polish leaflet in the pack.
- For additional copies of the leaflet, please refer to <https://www.medicines.org.uk/emc/product/9815> or contact the company contact point (see below).
- The MHRA has approved this product under a batch specific variation to the marketing authorisation in accordance with regulation 266(4)(a) and 266(4)(b) of the Human Medicines Regulations (HMR) 2012, from the obligation that certain particulars should appear on the outer and immediate packaging of Semglee and that certain aspects of the labelling do not appear 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.

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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, SystemOne, Vision, MiDatabank) for healthcare professionals. Suspected side effect can also be reported by calling 0800 731 6789 for free. Adverse events should also be reported to Mylan via ukpharmacovigilance@mylan.com

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 Semglee, please contact Julian De Gabriele, Mylan UK Healthcare Limited info.uk@mylan.co.uk