Mylan – Recall of Semglee® (insulin glargine injection)

- On January 19, 2022, the FDA announced a consumer-level recall of one batch of Mylan's (a Viatris company) non-interchangeable Semglee (insulin glargine injection) prefilled pens which are packaged in a labeled carton of five pens because of the potential for the label to be missing on some prefilled pens within a labelled carton for this batch.

- This recall does not pertain to the recently launched interchangeable biosimilars, Semglee (insulin glargine-yfgn) injection, a branded product, or insulin glargine (insulin glargine-yfgn) injection, an unbranded product.

- The recalled batch was distributed between May 2021 and November 2021.

Product Description	NDC	Lot # (Expiration Date)
Semglee (insulin glargine injection), 100 units/mL (U-100), 3 mL prefilled pen	49502-196-75	BF20003118 (8/2022)

- Semglee is indicated to improve glycemic control in adults and pediatric patients with type 1 diabetes mellitus and in adults with type 2 diabetes mellitus.

- A missing label on Semglee prefilled pens, for patients receiving treatment with more than one type of insulin (eg, both short and long-acting insulin), could lead to a mix-up of products/strengths, resulting in administration of the wrong insulin. Administration of the wrong insulin could result in less optimal glycemic control (either high or low blood sugar) which could result in serious complications.

- To date, Mylan has not received any reports of adverse events related to this recall.

- The recalled product can be identified by prefilled pens missing a white label with the product name and dosage information affixed around the pen.

- Patients who have the recalled Semglee should contact their physician or health care provider if they have experienced any problems that may be related to using the recalled Semglee.

- Anyone with an existing inventory of the recalled product should stop distribution and quarantine the product immediately.

- Contact Viatris Customer Relations by phone at **1-800-796-9526** or by email at **customer.service@viatris.com** for more information about the recall. Contact Stericycle at **1-888-843-0255** for return information.