Meitheal – Recall of glycopyrrolate injection

- On September 3, 2021, Meitheal announced a voluntary, user level recall of four lots of glycopyrrolate injection because of an out of specification result observed for benzaldehyde content during routine quality testing of stability samples at the 18-month timepoint.

- This product was manufactured by Caplin Steriles Limited and distributed by Meitheal Pharmaceuticals from June 19, 2020 through May 24, 2021:

Product Description	NDC #	Lot# (Expiration Date)
Glycopyrrolate injection 4 mg per 20 mL	71288-408-21 71288-408-20	G0010120 (12/2021); G0080520 (4/2022); G0090221 (1/2023); G0100221 (1/2023)

- Glycopyrrolate injection is indicated for use as a preoperative antimuscarinic to reduce salivary, tracheobronchial, and pharyngeal secretions; to reduce the volume and free acidity of gastric secretions; and to block cardiac vagal inhibitory reflexes during induction of anesthesia and intubation; and for use in adults as adjunctive therapy for the treatment of peptic ulcer when rapid anticholinergic effect is desired or when oral medication is not tolerated.

- Benzaldehyde is an aromatic compound and can impact several organs like the brain, liver and kidney. Higher percentages of benzaldehyde concentration observed (up to 1%) is expected to result into negligible health risk. Although the occurrence of serious adverse events could not be ruled out.

- To date, Meitheal has not received reports of any adverse events or identifiable safety concerns attributed to the recalled lots.

- Consumers should contact their physician or healthcare provider if they have experienced any problems that may be related to the recalled glycopyrrolate injection.

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

- Contact Meitheal at **1-844-824-8426** for further information regarding this recall.