## Sagent – Recall of docetaxel injection

- On May 29, 2024, the FDA announced a user-level recall of two lots of Sagent Pharmaceutical's docetaxel injection because of a customer complaint due to potential presence of particulate matter from the stopper in the drug product.

- The recalled products were distributed nationwide from October 11, 2023 to April 11, 2024.

| Product Description | NDC number | Lot number (Exp Date) |
|---|---|---|
| Docetaxel injection 160 mg/16 mL (10 mg/mL) | 25021-254-16 | F1030001 (12/2024) |
| Docetaxel injection 80 mg/8 mL (10 mg/mL) | 25021-254-08 | F1040001 (12/2024) |

- Docetaxel is indicated for the treatment of breast cancer, non-small cell lung cancer, prostate cancer, gastric adenocarcinoma, and head and neck cancer.

- Intravenous administration of an injectable product that contains particulate matter may result in serious adverse events. Potential complications related to injection of particles include inflammation of a vein, granuloma, and blockage of blood vessels in the heart, lungs or brain which can cause stroke or life-threatening blood clot events.

- The frequency and severity of these adverse events could vary depending upon a variety of factors including the size and number of particles in the drug product, patient comorbidities (such as age, compromised organ function), and presence or absence of vascular anomalies.

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

- Anyone with an existing inventory of the product being recalled should discontinue use, stop distribution, and return recalled product.

- Contact Sagent customer call center at **1-866-625-1618, option 1** for questions regarding this recall. Healthcare workers with questions about the recall may contact Sagent Medical Affairs at **1-866-625-1618, option 3**.