PECFENT RECALL

Kyowa Kirin International PLC ("KKI") confirms that, following discussions with the European Medicines Agency, it is undertaking the recall of a batch of bottles of its PecFent fentanyl nasal spray due to a packaging manufacturing defect at its third party supplier.

This recall, which extends to patients, pharmacies and wholesale suppliers in a number of European countries, is a precautionary measure and KKI does not believe there is any significant risk to patients.

The recall is of bottles of 400 microgram (8 sprays) of PecFent. The seal between the pump and some of the bottles from this batch did not function correctly, leading to evaporation and/or leakage of the solution. Currently, there have been reports of defects affecting 0.17% of the bottles from the bulk batch.

The countries and batch numbers affected by this recall are as follows:

PRODUCT	BATCH	COUNTRY
PECFENT 400 4 mg/mL 4 Bottles 1,55 mL ES	54301 17	Spain
PECFENT 400 4 mg/mL 4 Bottles 1,55 mL ES	54303 17	Spain
PECFENT 400 4 mg/mL 1 Bottle 1,55 mL PL	54304 17	Poland
PECFENT 400 4 mg/mL 1 Bottle 1,55 mL NL	54305 17	Netherlands
PECFENT 400 4 mg/mL 1 Bottle 1,55 mL FR	54307 17	France
PECFENT 400 mcg/erogazione Spray Nasale 4 Flaconi 1,55 mL CP	54309 17	Italy

All other supplies of PecFent are unaffected by this recall.

PecFent is a medicine used to treat breakthrough pain in adult patients with cancer. Breakthrough pain is when a patient experiences additional, sudden pain in spite of ongoing treatment with painkillers. PecFent is used in patients who are already using opioids (a group of painkillers that includes morphine and fentanyl) to control long-term cancer pain.