National Patient Safety Alert

Department of Health & Social Care

NHS

Supply of Licensed and Unlicensed Epidural Infusion Bags

Date of issue:	2-Dec-25	Reference no:	NatPSA/2025/007/DHSC

This alert is for action by: acute care hospitals, and any other organisations providing procedures that require epidural infusions.

This is a safety critical and complex National Patient Safety Alert. Implementation should be co-ordinated by an executive lead (or equivalent role in organisations without executive boards) and supported by clinical leaders in pharmacy, theatres, anaesthesia, maternity care and critical care, a Medicine Safety Officer (MSO) and Medicine Device Safety Officer (MDSO).

Explanation of identified safety issue:

There are supply issues affecting epidural bags from Sandoz (licensed) and Fresenius Kabi (unlicensed) containing:

- bupivacaine only
- bupivacaine and fentanyl
- levobupivacine and fentanyl.

A range of alternative licensed and unlicensed bags (including unlicensed imports) are available during the affected period expected to last until at least March 2026, but the use of these products will require a co-ordinated trust wide approach to ensure safe implementation.

Preparing epidural infusions in clinical areas using individual components poses a significant patient safety risk from calculation, measurement and preparation errors, resulting in incorrect dosing and microbial contamination. Preparation in clinical areas should only be considered if all other options, including switching from epidural to other routes of analgesia, have been considered and ruled out.

Actions required

Actions to be completed by 12/12/2025

1. Establish a short life working group chaired by a lead anaesthetist and to include senior representatives from affected clinical areas, a representative from pharmacy to liaise with the medicines procurement team, the Medication Safety Officerand Medical Device Safety Officer to oversee implementation of the following:
2. Review how products are used and confirm/correct current stock holding, ensuring Exend data is up to date to establish the impact of the supply shortage.
3. Where alternative products have been allocated, agree a trust-wide action plan. Taking into consideration the need to:
   a. prioritise available stock for particular procedures or patient groups
   b. review and update local guidelines, protocols, epidural charts and/or ePrescribing order sets
   c. review infusion pumps and the need to change drug library settings where alternative products are utilised
   d. consider where locked boxes are used and risk assess any necessary deviations from standard practice
4. If suitable comparable products are not available, consider alternative management options, such as epidural bolus administration, regional blocks and patient-controlled analgesia.
5. If externally sourced products are unsuitable, a comprehensive risk assessment to prepare infusions in-house must consider:
   a. infusions prepared in pharmacy aseptic facilities should be the first line choice
   b. preparing epidural infusions in clinical areas poses a significant safety risk and should only be undertaken if:
      - All other options have been exhausted;
      - the risk assessment should be approved by Chief Pharmacist and Medical Director and subsequently reported through a board-reporting committee.

   All epidural infusions prepared in pharmacy, or in clinical areas, must be clearly labelled as per guidance – see here.

Failure to take the actions required under this National Patient Safety Alert may lead to CQC taking regulatory action

Additional information:

Epidural Infusion stock availability

Up to date supply information for all affected products is available on the SPS Medicine Supply Tool . Please, note the need to register and log in to view. Regional Pharmacy Procurement Specialist will support the system with regional allocations of all available presentations including unlicensed imports.

Supporting Clinical Information

Additional clinical guidance to support local decision making is currently being drafted by NHSE Clinical Directors and associated clinical specialists. The guidance will be disseminated to all Trusts in the coming week.

Guidance on ordering and prescribing unlicensed medicines

Any decision to prescribe an unlicensed medicine must be supported by relevant guidance and local medicines governance policy and procedures. Please see the links below for further information:

- Medicines and Healthcare products Regulatory Agency The supply of unlicensed medicinal products,
- Royal Pharmaceutical Society Professional Guidance for the Procurement and Supply of Specials,
- General Medical Council Prescribing unlicensed medicines,

Stakeholder engagement

The following stakeholders have been engaged in the management and consulted in the drafting of this alert: NHS Specialist Pharmacy Service, Medicines Shortage Response Group, NHS England National Clinical Director for Critical and Perioperative Care.

Advice for Central Alerting System (CAS) officers and risk managers

This is a safety critical and complex National Patient Safety Alert. In response to CHT/2019/001 your organisation should have developed new processes to ensure appropriate oversight and co-ordination of all National Patient Safety Alerts. CAS officers should send this Alert to the executive lead nominated in their new process to coordinate implementation of safety critical and complex National Patient Safety Alerts, copying in the leads identified on page 1.