

**From the Chief Medical Officer  
Professor Sir Michael McBride**



Department of  
**Health**

An Roinn Sláinte

Máinnstríe O Poustie

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**HSS(MD)3/2023**

**FOR ACTION**

Chief Executives, Public Health Agency/SPPG/HSC Trusts/  
NIAS

GP Medical Advisers, Strategic Planning and Performance  
Group

All General Practitioners and GP Locums (*for onward  
distribution to practice staff*)

OOHs Medical Managers (*for onward distribution to staff*)

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Our Ref: HSS(MD)3/2023

Date: 25 January 2023

**PLEASE SEE ATTACHED FULL CIRCULATION LIST**

Dear Colleague

**SUPPLY OF LICENSED AND UNLICENSED EPIDURAL BAGS – NATIONAL  
PATIENT SAFETY ALERT**

**Actions required by HSC Trusts and any other organisations providing  
procedures that require epidural infusions:**

1. Review products in use and current stock holding, to establish the impact of the supply shortage.
2. Where necessary, agree a Trust-wide action plan to temporarily use alternative product(s) taking into consideration the need to:
  - a. review and update local guidelines, protocols, and epidural charts to reflect agreed changes at Trust level;
  - b. work with Trust medicines governance leads and Medical Device Liaison Officer to review the infusion pumps used and whether there is a need to change drug library settings where alternative products are utilised; and
  - c. review products already being made in pharmacy aseptic units to release capacity if necessary.
3. If the products listed below are not considered appropriate, seek advice from lead anaesthetist on alternative management options, such as epidural bolus administration, regional blocks and patient-controlled analgesia.
4. If actions 2 and 3 are deemed unsuitable, a decision to prepare alternative infusions in-house must include a comprehensive risk assessment noting that:

- a. **Preparing infusions in pharmacy aseptic facilities should be considered as 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 has been approved by Chief Pharmacist and Medical Director, and subsequently reported through a board-reporting committee.**

## **Summary**

There are supply issues impacting Fresenius Kabi (FK) unlicensed epidural bags containing bupivacaine only and levobupivacaine with fentanyl. These are also impacting Sintetica's licensed epidural bags containing bupivacaine only and bupivacaine with fentanyl (see Additional Information section below).

A range of alternative licensed and unlicensed bags is available during the affected period (see Additional Information section), 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 from microbial contamination. **Preparation in clinical areas should only be considered if all other options have been exhausted.**

To mitigate and manage patient safety risks, Trusts should use alternative pre-prepared (licensed or unlicensed) epidural infusion bags as first line options.

FK should have new stock available week commencing 30 January 2023, pending QA approval. Sintetica products should be available from mid-late February 2023.

## **Additional Information**

### **Epidural Infusion Bags now out of stock**

#### **Sintetica (licensed) products**

Bupivacaine 250mg/250ml (0.1%) / Fentanyl 500micrograms/250ml infusion bags

Bupivacaine 250mg/250ml (0.1%) infusion bags

Bupivacaine 312.5mg/250ml (0.125%) infusion bags

### **Fresenius Kabi (unlicensed) products**

Levobupivacaine 250mg/250ml / Fentanyl 1.25mg/250ml infusion bags  
Levobupivacaine 250mg/250ml / Fentanyl 500micrograms/250ml infusion bags  
Levobupivacaine 500mg/500ml / Fentanyl 1mg/500ml infusion bags  
Levobupivacaine 500mg/500ml / Fentanyl 2mg/500ml infusion bags  
Levobupivacaine hydrochloride 625mg/500ml / Fentanyl 2mg/500ml infusion bags  
Levobupivacaine 100mg/100ml / Fentanyl 200micrograms/100ml infusion bags  
Levobupivacaine 125mg/100ml / Fentanyl 200micrograms/100ml infusion bags

### **Stock currently available now**

#### **Sintetica (licensed) epidural infusions available to order now from Mawdsley's**

Bupivacaine 312.5mg/250ml (0.125%) / Fentanyl 500micrograms/250ml infusion bags  
Bupivacaine 625mg/500ml (0.125%) / Fentanyl 1mg/500ml infusion bags

#### **Limited stock of:**

Bupivacaine 500mg/500ml (0.1%) / Fentanyl 1mg/500ml infusion bags

#### **Fresenius Kabi (unlicensed) epidural infusions available to order now directly from Fresenius Kabi**

Bupivacaine 500mg/500ml (0.1%) / Fentanyl 1mg/500ml infusion bags

#### **Limited stock of:**

Bupivacaine 750mg/500ml (0.15%) infusion bags  
Bupivacaine 250mg/250ml (0.1%) / Fentanyl 500micrograms/250ml infusion bags  
Bupivacaine 100mg/100ml (0.1%) / Fentanyl 200micrograms/100ml infusion bags  
Bupivacaine 625mg/500ml (0.125%) / Fentanyl 1mg/500ml infusion bags  
Levobupivacaine hydrochloride 625mg/500ml / Fentanyl 1mg/500ml infusion bags

#### **Fresenius Kabi (licensed) epidural infusions available to order now directly from Fresenius Kabi**

Levobupivacaine 125mg/100ml infusion bags

#### **Ethypharm (licensed) epidural infusions available to order now from Alliance and Mawdsley's**

Levobupivacaine 250mg/200ml infusion bags (licensed)

### **Guidance on ordering and prescribing unlicensed medicines**

Any decision to prescribe an unlicensed medicine must be supported by relevant guidance and HSC Trust medicines governance policy and procedures for the use of unlicensed medicines, or equivalent in other organisations. Please see the links below for further information:

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

## **Implementation**

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 and critical care, Medicines Governance leads and Medical Device Liaison Officer (MDLO).

Yours sincerely



**PROFESSOR SIR MICHAEL McBRIDE**  
Chief Medical Officer



**MRS CATHY HARRISON**  
Chief Pharmaceutical Officer

## Circulation List

Director of Public Health/Medical Director, Public Health Agency (*for onward distribution to all relevant health protection staff*)  
Assistant Director Public Health (Health Protection), Public Health Agency  
Director of Nursing, Public Health Agency  
Assistant Director of Pharmacy and Medicines Management, SPPG (*for onward distribution to Community Pharmacies*)  
Directors of Pharmacy HSC Trusts  
Director of Social Care and Children, SPPG  
Family Practitioner Service Leads, SPPG (*for cascade to GP Out of Hours services*)  
Medical Directors, HSC Trusts (*for onward distribution to all Consultants, Occupational Health Physicians and School Medical Leads*)  
Nursing Directors, HSC Trusts (*for onward distribution to all Community Nurses, and Midwives*)  
Directors of Children's Services, HSC Trusts  
RQIA (*for onward transmission to all independent providers including independent hospitals*)  
Medicines Management Pharmacists, SPPG (*for cascade to prescribing advisers*)  
Regional Medicines Information Service, Belfast HSC Trust  
Regional Pharmaceutical Procurement Service, Northern HSC Trust  
Professor Donna Fitzsimons, Head of School of Nursing and Midwifery QUB  
Professor Sonja McIlfrack, Head of School of Nursing, University of Ulster  
Heather Finlay, CEC  
Donna Gallagher, Open University  
Professor Paul McCarron, Head of School of Pharmacy and Pharmaceutical Sciences, UU  
Professor Colin McCoy, Head of School, School of Pharmacy, QUB  
Professor Colin Adair, Postgraduate Pharmacy Dean, NI Centre for Pharmacy Learning and Development, QUB  
Joe Brogan, Assistant Director of Integrated Care, SPPG  
Michael Donaldson, SPPG (*for distribution to all General Dental Practitioners*)  
Raymond Curran, Head of Ophthalmic Services, SPPG (*for distribution to Community Optometrists*)  
Trade Union Side  
Clinical Advisory Team  
Louise McMahan, Director of Integrated Care, SPPG

This letter is available on the Department of Health website at  
<https://www.health-ni.gov.uk/topics/professional-medical-and-environmental-health-advice/hssmd-letters-and-urgent-communications>