Issue date
13 May 2022

Distributed to:
Chief Executives
Directors of Clinical Governance

Action required by:
Directors of Clinical Governance

We recommend you also inform:
Directors of:
- Anaesthetics
- Intensive Care Units
- Medical Services
- Nursing and Midwifery
- Pharmacy

Operating Theatre staff
Medical staff
Nursing staff
Pharmacists
Drug and Therapeutics Committees

Expert Reference Group

Content reviewed by:
Clinical Excellence Commission
Medication Safety Expert Advisory Committee
ACI Surgical Services Taskforce

Clinical Excellence Commission
Tel: 02 9269 5500

Email
Internet Website
Intranet Website

Review date
December 2022

'Sterile Theatre Pack' formulations of lignocaine (lidocaine) with adrenaline (epinephrine) and bupivacaine with adrenaline (epinephrine) injection disruption to supply

Situation

Due to supply disruptions to 'Sterile Theatre Pack' formulations of lignocaine (lidocaine) with adrenaline (epinephrine) and bupivacaine with adrenaline (epinephrine) injections, alternative versions of these products will be made available. These products are non-autoclaved, will not be individually wrapped in secondary packaging, and should not be placed directly into the sterile field in theatre.

Background

There is a current disruption to the following products:

Bupivacaine with adrenaline (epinephrine)

- Marcain 0.25% with adrenaline 1:400,000 injection vial 20 mL 'Sterile Theatre Pack' – ARTG 125178

Lignocaine (lidocaine) with adrenaline (epinephrine)

- Xylocaine 2% with adrenaline 1:200,000 injection vial 20 mL 'Sterile Theatre Pack' – ARTG 12020
- Xylocaine 1% with adrenaline 1:200,000 injection vial 20 mL 'Sterile Theatre Pack' – ARTG 12015
- Xylocaine 0.5% with adrenaline 1:200,000 injection vial 20 mL 'Sterile Theatre Pack' – ARTG 12008

The disruption is due to a change in the local autoclaving site for these products. The location of the new site, and anticipated return to normal supply for the above mentioned products, has been delayed until at least **September 2022.** In the interim, the drug sponsor has gained TGA approval to supply a non-autoclaved version of these products. These products will not be individually wrapped in secondary packaging and will not be termed 'Sterile Theatre Pack' however the contents of the vials are sterile.

Alternative products may also be available under section 19A of the Therapeutic Goods Act 1989 – see database. **The safety concerns on the next page apply to any product that has not undergone the autoclaving process (i.e. not in secondary packaging).**

Available alternative without individual secondary packaging	'Sterile Theatre Pack' – currently subject to disruption to supply
	

Safety concerns

The alternative non-autoclaved products will not be individually wrapped in secondary packaging and **should not be** placed directly into the sterile field in theatre. Exisiting procedures for handling and administering of non-autoclaved products are to be used when handling these alternative products. Please ensure all staff are aware of this practice change for these alternative products prior to use.

Note – the autoclaving process is designed to sterilise the external surfaces of the vial but has no impact on the solution inside the vial, which is already sterile.

Required actions for the Local Health Districts/Networks

1. Forward this Safety Notice to relevant clinicians, clinical departments and Drug and Therapeutics/Medication Safety Committees for action.
2. Undertake a local risk assessment and develop strategies to mitigate the risks associated with the use of the non-autoclaved alternatives e.g., through the application of cautionary labels on product packaging, use of shelf talkers.
3. Ensure staff members in clinical areas administering these products are made aware of these risks
4. Ensure a system is in place to document and review actions taken in response to this Safety Notice and any incidents involving these products.
5. Confirm receipt and distribution of this notice to CEC-MedicationSafety@health.nsw.gov.au by **COB Monday 16 May 2022.**