NSW Health

Medicine recall: Phytomenadione (Konakion MM) 2 mg/0.2 mL injection

SAFETY ALERT 009/24

Issue Date:	4 June 2024
Distributed to	Chief Executives; Directors of Clinical Governance; Director, Regulation and Compliance Unit
KEY MESSAGE:	NSW Health facilities need to be aware of the medicine recall for phytomenadione (Konakion MM) 2 mg/0.2 mL injection and take appropriate actions as outlined in this Safety Alert.
ACTION REQUIRED BY:	Chief Executives, Directors of Clinical Governance
REQUIRED ACTION:	1. **Immediately upon receipt**, confirm receipt and distribute this Safety Alert to all relevant clinicians, clinical departments, and include it in relevant handovers and safety huddles. 2. **Within 24 hours of receipt**, confirm that required actions (outlined in *Recommendations* section) have been completed or commenced. 3. Escalate any concerns related to this Safety Alert to CEC-MedicationSafety@health.nsw.gov.au. 4. Report any incidents associated with this disruption to supply into the local incident management system e.g., ims⁺.
DEADLINE:	ASAP

We recommend you also inform:	• Directors, Managers and Staff of:
	  ○ Pharmacy
	  ○ Medical Services
	  ○ Paediatrics and Neonatology
	  ○ Nursing/Midwifery Services
	• Drug and Therapeutics Committees
	• All other relevant clinicians, departments and committees.

Website:	https://www.health.nsw.gov.au/sabs/Pages/default.aspx http://internal.health.nsw.gov.au/quality/sabs/index.html
Review date:	31 November 2024

Contact: Clinical Excellence Commission
02 9269 5500
cec-MedicationSafety@health.nsw.gov.au

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Situation

Pharmaco (Australia) Ltd, following agreement with the Therapeutic Goods Administration (TGA), is conducting a Class III hospital level recall of **batch F3160F02** of Konakion MM Paediatric (phytomenadione) 2mg/0.2mL injection (ARTG: 71758).

During the transport of the affected batch to Australia, some units were exposed to a temporary temperature excursion. The affected stock has now entered the distribution chain and is circulating within NSW Health facilities since **5 April 2024**. The affected units cannot be distinguished from the unaffected units of this same batch. As such, a recall of the entire batch is being conducted.

This recall **does not** affect: any other batches of Konakion MM Paediatric 2 mg/0.2 mL injection, Konakion MM 10 mg/1 mL injection, or any other Pharmaco (Australia) products.

Background

Phytomenadione is also known as **Vitamin K_1**.

Konakion MM Paediatric (phytomenadione) 2mg/0.2mL injection is used in the prevention of early and late onset vitamin K deficiency bleeding (VKDB) (previously known as haemorrhagic disease of the newborn) and treatment of neonatal cholestasis.

There are two formulations of phytomenadione marketed in Australia – Konakion MM Paediatric 2 mg/0.2 mL injection ampoule (subject of this Safety Alert) and Konakion MM 10 mg/1 mL injection ampoule (ARTG: 61654).

Assessment

Due to the lack of information about the potential impact of the extreme temperature excursion on the quality of this product, a recall is being conducted.

It is possible that some babies may have received the affected products. As part of an assessment undertaken by a statewide Management Team, it has been confirmed with the drug sponsor that the vitamin K content of the affected products complies with specifications despite the temperature excursion. Therefore, there is no risk to patient safety if the products were used. Based on this, the Management Team has concluded that lookback and open disclosure are **not required**.

The Product Information of Konakion MM 10 mg/1 mL injection ampoule states that the product "*should not be administered intramuscularly as this route of administration exhibits depot characteristics which may cause difficulties in the re-institution of anticoagulant therapy*". However, the drug sponsor Pharmaco have confirmed that both the 2 mg/0.2 mL and 10 mg/mL products are the same formulation (including excipients) and only differ in ampoule volume.

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Recommendations

- Ensure that all affected stock of Konakion MM Paediatric (phytomenadione) 2mg/0.2mL injection is identified, quarantined, and not used for patient care. Please note that when removed from the outer packaging, the full batch number of ampoules is not apparent (see **Figure 1** below). Any ampoules where the full batch number cannot be determined and is not within the original packaging, must also be quarantined, and not used for patient care. Contact DHL Customer Services at d2mcs@dhl.com or d2mcsenquiries@dhl.com to arrange return and replacement of stock.
- Ensure that all potential areas for the storage of the affected stock have been determined and checked including, **but not limited to**; medication rooms, after hours drug cupboards, procedure rooms/trolleys, birth suites, maternity wards, neonatal units, paediatric units, home birth packs, neonatal transport/retrieval packs and pre-prepared take-home packs.
- Ensure that all supply of Konakion MM Paediatric is retained within its **original packaging** until immediately prior to administration. As stated above, the full batch number **does not** appear on individual ampoules. If individually dispensed or pre-packed, the full batch number is to be included on the dispensing label.
- Contact parents who have elected administration of phytomenadione via oral route **in the past 28 days** who have been supplied with or dispensed a take-home pack for administration of the 2nd and/or 3rd doses to check batch numbers and replace stock if required.
- Unaffected stock can continue to be used for patient care. Where available, unaffected batches of Konakion MM Paediatric 2 mg/0.2 mL injection are to be prioritised for:
    - administration via intramuscular injection for the prevention of vitamin K deficiency bleeding
    - discharge supply for parents who have elected administration of phytomenadione via oral route.
- In cases where all supply of Konakion MM Paediatric 2 mg/0.2 mL injection is affected and replacement stock is not immediately available, alternatives for the prevention of vitamin K deficiency bleeding include:
    - Use of the 10 mg/1 mL injection for administration of appropriate dose via the intramuscular route.
    - Use of the 10 mg/1 mL injection for administration of appropriate dose via the oral route. Ensure appropriate follow-up is organised, and parents/carers are adequately educated, as oral administration requires 3 doses (at birth, 3-5 days of age, and during 4th week of life).

  Refer to the Australasian Neonatal Medicines Formulary monograph for dosing information to ensure an appropriate dose is given based on birthweight.
- Ensure ongoing adherence to the '5 Rights' of safe and accurate medication administration as per NSW Health *Medication Handling* Policy Directive (PD2022_032) to minimise the risk of errors.

Figure 1. Images of affected (L) and unaffected (R) batch of Konakion MM Paediatric.

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