Department of Health & Social Care

NHS

UPDATE:

Update to communications issued 21 October 2020

Material updates in BOLD

Medicine Supply Notification

MSN/2020/019-U2

Konakion MM® Paediatric (phytomenadione) 2mg/0.2ml ampoules

Tier 2 – medium impact*

Date of issue: 11/1/2021

Summary

- **UK licensed Konakion MM® Paediatric 2mg/0.2ml injection will be out of stock until w/c 25 January 2021.**
- Unlicensed supplies of Konakion MM® Paediatric 2mg/0.2ml injection are available to support during this time.
- **From w/c 25 January onwards, UK licensed generic phytomenadione 2mg/0.2ml injection will be available.**
- **Neokay® 1mg capsules (phytomenadione) also remain available (only licensed for the prevention of vitamin K deficiency bleeding in babies).**

Actions Required

- **Until the resupply date, where Neokay® 1mg capsules are not considered appropriate, clinicians should consider prescribing unlicensed Konakion MM® Paediatric 2mg/0.2ml injection** (see supporting information for ordering advice).
- Trusts should consider their position regarding the use of unlicensed Konakion MM® Paediatric 2mg/0.2ml injection that may be supplied against a Midwives Exemption (see supporting information below for further information).

Supporting Information

Guidance on ordering and prescribing unlicensed imports:

- **The following specialist importers have currently confirmed they can source unlicensed imports of phytomenadine 2mg/0.2ml injection with variable lead times (please note, there may be other companies that can also source supplies):**
  - **Smartway Pharma**
  - **UL Global Pharma**
- Until UK licensed supplies of generic phytomenadione 2mg/0.2ml injection are available at the end of January, Cheplapharm have also sourced unlicensed stock of Konakion MM® Paediatric 2mg/0.2ml injection in EFA (English – French – Arabic) layout. SPS Quality Assurance colleagues have established the similarities between this and the UK licensed product.

*Classification of Tiers can be found at the following link: https://www.england.nhs.uk/publication/a-guide-to-managing-medicines-supply-and-shortages/

Ordering information for unlicensed Cheplapharm's Konakion MM® Paediatric 2mg/0.2ml injection:

- Alliance Healthcare Specials (Alcura) - PIP code: 8021677
    - Description: KONAKION PAED AMP 2MG/0.2ML
    - Email: specials.orders@alliance-healthcare.co.uk
    - Tel: 0344 8544 998/Fax: 08450 518 779

Any decision to prescribe an unlicensed medicine must consider the relevant guidance and NHS Trust or local governance procedures. 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)

When prescribing a product that is not licensed in the UK due to a supply issue with the licensed alternative prescribers must indicate on the FP10 prescription that an unlicensed product is required. This can be done by annotating the prescription with the following wording: "special order".

Midwives Exemptions:

We have discussed with our own internal legal team, who have advised that unlicensed medicines may be supplied against a Midwives Exemption.

The following represents DHSC's view of the exemptions that might be applicable to the circumstances as described to us, but it should not replace the need for the Trust to consider its own position and take its own legal advice if necessary:

"There are two kinds of exemptions for midwives in the Human Medicines Regulations (HMRs). One relates to the need for a prescription and that is set out in regulation 235 and Part 1 of Schedule 17 HMRs. These provide that the requirement in regulation 220 that POMs are supplied against a prescription does not apply to the sale or supply by midwives of POMs containing phytomenadione in the course of their professional practice. As this product is a product for parenteral administration, it is a POM by virtue of Part 1, Sch. 1 HMRs, i.e. whether it has a licence or not. Therefore, nothing can be seen in the HMRs that would limit the midwives' *prescription* exemption to licensed phytomenadione (given by any route).

As to the relevance of a licence for the *assembly or supply* of the product, regulations 3 and 4 HMRs may be applicable, as well as the specials exemption, depending on how the product is sourced and what the midwife does. If the midwife assembles the product into a syringe for injection, this activity would be covered by regulation 3 HMRs as it exempts the midwife from the need for a manufacturing licence for that activity. Again, this assembly could be of a licensed or unlicensed product.

As to how the product is supplied, it might be supplied to the hospital as an unlicensed special if the conditions for such supply are met, or it could be prepared in a hospital pharmacy under regulation 4 HMRs/section 10 of the Medicines Act 1968. Both of those provide potentially lawful supply routes for unlicensed products."

Enquiries

If you have any queries, please contact DHSCmedicinesupplyteam@dhsc.gov.uk

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