



UPDATE:

Update to communications issued 9 April 2020

Medicine Supply Notification

Phytomenadione (Konakion MM Paediatric) 2mg/0.2ml ampoules (Cheplapharm)

Tier 2 – medium impact*

Date of issue: 21/10/2020

Summary

- **UK licensed Konakion MM Paediatric will be out of stock from the 1st - 30th November 2020.**
- Supplies of Konakion MM Paediatric in tri-lingual packaging (including English; considered unlicensed in the UK) are available to support during this time. See Supporting Information below for further details.

Actions Required

- Where there are insufficient supplies of licensed stock available, clinicians should consider prescribing unlicensed Konakion MM Paediatric.
- Trusts should consider their position regarding the use of unlicensed Konakion MM Paediatric that may be supplied against a Midwives Exemption. See Supporting Information below for further details.
- See Supporting Information for ordering advice.

Supporting Information

- Cheplapharm have sourced sufficient Konakion MM Paediatric in EFA (English – French – Arabic) layout which is manufactured in the same facility and to exactly the same formulation and standards as the UK licenced product.
- Quality Assurance colleagues have approved the *Declaration of Equivalence* document shared with this MSN.
- 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.
 - [Prescribing unlicensed medicines](#), General Medical Council (GMC),
 - [The supply of unlicensed medicinal products](#), Medicines and Healthcare products Regulatory Agency (MHRA)

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

- [Professional Guidance for the Procurement and Supply of Specials](#), Royal Pharmaceutical Society
- 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.”

Ordering information:

- Please also see attached information from Neon Healthcare about how to order unlicensed Konakion MM Paediatric 2mg/0.2ml amps via Alliance and Mawdsleys.
 - 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
 - Mawdsleys Unlicensed - PIP Code: 287334
 - Description: Phytomenadione 2MG/0.2ML AMP
 - Email: unlicensed@mawdsleys.co.uk
 - Tel: 0161 7423304/Fax: 0161 7423444

Enquiries

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