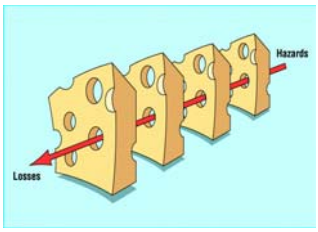

Northern Ireland
Medicines Governance Team

SAFETY MEMO 10

From: Medicines Governance Pharmacists,
Linden Ashfield Daryl Connolly
Sharon O'Donnell Jillian Redpath

To:
Directors of Pharmaceutical Services / Trust Pharmacy Managers
Dr N Morrow, Chief Pharmacist, DHSSPSNI } For information
Directors of Pharmacy, HSS Boards

20th March 2006

RE: Withdrawal of Konakion® Neonatal (phytomenadione)

As you may be aware, Konakion® Neonatal will be discontinued on 31st March 2006. Konakion® Neonatal will be replaced by Konakion® MM Paediatric. Konakion® MM Paediatric was previously only licensed to be given by mouth or as an injection to premature babies/babies at special risk. It has now been approved for use as an intramuscular injection in healthy babies of 36 weeks gestation and older. There are potential risks of overdose associated with the calculation and preparation of doses.

Where Konakion® MM Paediatric (2mg/0.2ml) will now be used in place of Konakion® Neonatal (1mg/0.5ml), there is a **change to the volume previously administered.**

The volume for a 1mg intramuscular dose in healthy babies of 36 weeks gestation and older:

- was 0.5ml of Konakion® Neonatal (almost the entire contents of the ampoule)
- will now be 0.1ml of Konakion® MM Paediatric (approximately half the contents of the ampoule)

When doses are based on a babies weight (pre-term babies) Roche advise caution as there is the potential for ten fold dosing **errors when calculating and measuring the dose based on the baby's weight**. Further information is contained within the healthcare professional letter and the press release available on the MHRA website www.mhra.gov.uk .

To assist with the changeover and minimise the risk of medication incidents associated with the change, the following steps are recommended:

- Identify wards and departments using Konakion® Neonatal.
- Ensure that all relevant staff are aware of the changeover. Posters advising on the calculation and measurement of doses of Konakion® MM Paediatric for wards and departments are available from Roche (Telephone 0800 3281629).
- Agree a timetable for removal of Konakion® Neonatal from stock lists and ensure adequate supplies of Konakion® MM Paediatric are available.
- Ensure that appropriate syringes are available for the measurement of doses.
- Confirm that Konakion® MM Adult is not stocked or issued to areas using Konakion® MM Paediatric.

Many Trusts may also be aware of and have dealt with this issue. If you have any further questions about this memo, please contact your Medicines Governance pharmacist.