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F.5 Phytomenadione mixed micelle solution

MSF supports the inclusion of phytomenadione (vitamin K1) mixed micelle (MM) solution (paediatric, 2 mg/0.2 ml and 10 mg/1 ml) in the WHO Model List of Essential Medicines (EML) and in the WHO Model List of Essential Medicines for Children (EMLc), for the prophylaxis and treatment of haemorrhagic disease of the newborn and for haemorrhage or risk of haemorrhage in adults, as a result of severe "hypoprothrombinaemia" (i.e. deficiency of clotting factors II, VII, IX and X) of various aetiologias, including overdosage of coumarin-type anticoagulants, their combination with phenylbutazone and other forms of hypovitaminoses K.

Currently, phytomenadione 10 mg tablet and 1 mg/ml and 10 mg/ml solution in ampoules are included in both EMLs.

MSF has been using phytomenadione mixed micelle solutions in its programs since 2003.

MSF acknowledges the critical role of phytomenadione in preventing haemorrhagic disease of newborns and emphasizes the value of the mixed micelle formulation, which facilitates both oral and parenteral administration and may offer improved bioavailability and safety over older Cremophor-based formulations. Based on its experience and clinical realities in humanitarian and resource-limited settings, MSF emphasizes the need for maintaining the IM administration as a priority in these settings. While oral administration is effective under ideal conditions, the required multi-dose regimen (doses at birth, 4–7 days, and day 30) presents serious implementation challenges in settings where reliable follow-up - especially at 30 days - is often not possible. Incomplete dosing of orally administered vitamin K significantly compromises its efficacy, particularly against late-onset vitamin K deficiency bleeding.

MSF will continue to implement and strongly supports the use of the phytomenadione MM formulation as a single-dose IM injection at birth. This approach aligns with MSF clinical protocols and ensures high coverage and protection in newborns, regardless of follow-up capacity.

MSF urges WHO to publish guidance to clearly differentiate between the ideal use of the MM formulation as oral, in settings with robust follow-up systems and as single-dose IM in humanitarian and low-resource settings.

Finally, MSF requests the 25th Expert Committee on the Selection and Use of Essential Medicines to evaluate the need to maintain the current phytomenadione formulations listed in the EML, especially if the MM formulation is approved by the Expert Committee.

Considering all these elements, MSF urges the 25th Expert Committee on the Selection and Use of Essential Medicines to include phytomenadione mixed micelle solution in the WHO Model List of Essential Medicines and in the WHO Model List of Essential Medicines for Children for the prophylaxis and treatment of haemorrhagic disease of the newborn and for the treatment of haemorrhage or risk of haemorrhage in adults, as a result of severe "hypoprothrombinaemia" (i.e.

deficiency of clotting factors II, VII, IX and X) of various aetiologias, including overdosage of coumarin-type anticoagulants, their combination with phenylbutazone and other forms of hypovitaminoses K.

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