13 June 2013
Patient Health Protection
EMA/PRAC/366917/2013

PRAC List of questions to be addressed by the Stakeholders

For Numeta G13%E and Numeta G16%E emulsions for infusion, and associated names

Article 107i of Directive 2001/83/EC

Procedure number: EMEA/H/A-107i/1373

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On 10 June 2013, the marketing authorisation holder (MAH) for Numeta G13%E informed the European national competent authorities that following reports of hypermagnesaemia in preterm neonates, Numeta G13%E batches had been put on hold at warehouse level. Furthermore, the MAH also outlined a decision to enact a recall of the product from the market to prevent any potential harm to preterm neonates.

On 13 June 2013, considering uncertainties regarding the availability of adequate alternatives across the European Union Member States, the Swedish Competent Authority (MPA – Medical Products Agency) notified the European Medicines Agency, in accordance with Article 107i of Directive 2001/83/EC, of the urgency to undertake a review and agree whether the benefit/risk balance of Numeta G13E% remains positive, and if there is need for additional risk minimisation measures.

Although no reports were received for Numeta G16%E, the Pharmacovigilance Risk Assessment Committee (PRAC) has decided at its June 2013 meeting that this product would also be included in the EMA review because of its magnesium content and of its use in neonates and infants/toddlers up to the age of 2 years, who may also be at risk of developing hypermagnesaemia.

In accordance with Article 107j(1) of the Directive 2001/83/EC, all stakeholders (e.g. healthcare professionals, patients' organisations or the general public) are invited to submit data relevant to the procedure, addressing the below Pharmacovigilance and Risk Assessment Committee (PRAC) list of questions by 1 July 2013:

1. Based on your experience with the use of Numeta G13%E or Numeta G16%E, please provide any relevant information you may have in relation to hypermagnesemia in premature neonates, neonates and infants/toddlers up to the age of 2 years.