Conditions to the marketing authorisations for Numeta G16%E and associated names

National competent authorities of Member States or reference Member State if applicable, shall ensure that the following conditions are fulfilled by the MAH for Numeta G16%E:

Conditions	Date
The MAH should submit a revised risk management plan including proposals for evaluating the effectiveness of the risk minimisation measures.	Within 3 months after CMDh agreement
The MAH should conduct a prospective non-interventional post-authorisation safety study to further evaluate magnesium levels observed in term newborn infants and children up to two years of age treated with Numeta G16%E in routine clinical practice. The MAH should submit the protocol for the above mentioned study.	By the end of Q3 2015 Within 3 months after CMDh agreement