Co-ordination group for Human Use
EMA/H/A-107i/1373
EMA/CMDh/552834/2013

Agreement of the Co-ordination group for Mutual Recognition and Decentralised Procedures for human use, pursuant to article 107k(1) and (2) of directive 2001/83/EC, for

Medicinal products

Invented names:	see Annex I
Common name:	parenteral nutrition emulsion for infusion
Pharmaceutical form:	see Annex I
Strengths:	see Annex I
Route of administration:	see Annex I

Basis for Agreement

Pursuant to Article 107i of Directive 2001/83/EC, Sweden initiated a procedure on 13 June 2013. The notification for the procedure is appended to this agreement.

The procedure started on 13 June 2013.

The steps taken for the assessment of the referred matter are detailed in the PRAC assessment report appended to this agreement.

The PRAC recommendation was adopted on 5 September 2013 and is appended to this agreement.

The CMDh has considered the recommendation of PRAC in accordance with Article 107k (1) of Directive 2001/83/EC.

Agreement

1. Pursuant to Article 107k (1) and (2) of Directive 2001/83/EC, and having considered the matter and the appended PRAC recommendation,

   a. the CMDh reached an agreement on the suspension of the marketing authorisations for Numeta G13%E.

   b. the CMDh reached an agreement on the variation to the terms of the Marketing Authorisations for Numeta G16%E for which the relevant sections of Summary of Product Characteristics and package leaflet are set out in Annex IV.

   The agreement reached by the Member States represented within the CMDh relied on the PRAC recommendation. However, the CMDh considered that practical aspects should be taken into account for the implementation of the CMDh opinion at national level.

Iceland and Norway agree with the above-mentioned agreement of the CMDh.

2. The scientific conclusions and grounds for these conclusions are set out in the Annex II.

3. The condition for lifting the suspension of the Marketing Authorisations for Numeta G13%E is set out in Annex III.

4. The conditions affecting the marketing authorisations for Numeta G16%E, as referred to in Article 107i of Directive 2001/83/EC, are set out in Annex V.

5. The timetable for the implementation of the agreement is set out in Annex VI.

This agreement is forwarded to the Member States, to Iceland and Norway and to the marketing authorisation holders for the above mentioned medicinal products, together with its annexes and appendices.

London, 18 September 2013

On behalf of the CMDh
Dr Peter Bachmann, Chair