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Co-ordination group for Human Use
EMEA/H/N/PSR/S/0017

# Position of the Co-ordination Group for Mutual Recognition and Decentralised Procedures for human use on non-interventional imposed Post-Authorisation Safety Study (PASS) final report for

**Medicinal product(s)**

| | |
|---|---|
| Invented name(s): | See PRAC assessment report for non-interventional imposed PASS final report appendix |
| Active substance(s): | Alanine, arginine, aspartic acid, cysteine, glucose, glutamic acid, glycine, histidine, isoleucine, leucine, lysine monohydrate, methionine, ornithine hydrochloride, phenylalanine, proline, serine, taurine, threonine, tryptophan, tyrosine, valine, calcium chloride, magnesium acetate, potassium acetate, sodium chloride, sodium glycerophosphate, refined soybean oil, refined olive oil |

**Basis for Position**

Pursuant to Article 107p of Directive 2001/83/EC, the Marketing Authorisation Holder(s) submitted to the European Medicines Agency the final study report for non-interventional imposed post-authorisation safety study (PASS) for the nationally authorised medicinal product(s) mentioned above containing alanine, arginine, aspartic acid, cysteine, glucose, glutamic acid, glycine, histidine, isoleucine, leucine, lysine monohydrate, methionine, ornithine hydrochloride, phenylalanine, proline, serine, taurine, threonine, tryptophan, tyrosine, valine, calcium chloride, magnesium acetate, potassium acetate, sodium chloride, sodium glycerophosphate, refined soybean oil, refined olive oil (for details see PRAC assessment report appendix).

The evaluation procedure started on 16 April 2018.

The steps taken for the assessment of the non-interventional imposed PASS final report are detailed in the appended Pharmacovigilance Risk Assessment Committee (PRAC) assessment report.

The recommendation was adopted by the PRAC on 4 October 2018.

**Position**

1. The CMDh, having considered in accordance with Article 107q(2) of Directive 2001/83/EC the results of the study on the basis of the PRAC recommendation and the PRAC assessment report as

appended, reaches its position by consensus on the variation to the terms of the Marketing Authorisation(s) for the medicinal products mentioned above concerning the following change(s):

The marketing authorisation holder (s) shall remove the below condition:

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.

The Icelandic and the Norwegian CMDh member(s) agree(s) with the above-mentioned position of the CMDh.

2. The scientific conclusions are set out in Annex I.
3. The changes to the conditions to the marketing authorisation(s) of the medicinal products mentioned above are set out in Annex II.
4. The timetable for the implementation of this CMDh position is set out in Annex III.

To the extent that other medicinal products containing Alanine, arginine, aspartic acid, cysteine, glucose, glutamic acid, glycine, histidine, isoleucine, leucine, lysine monohydrate, methionine, ornithine hydrochloride, phenylalanine, proline, serine, taurine, threonine, tryptophan, tyrosine, valine, calcium chloride, magnesium acetate, potassium acetate, sodium chloride, sodium glycerophosphate, refined soybean oil, refined olive oil not listed in the PRAC assessment report are currently authorised in the EU, or are subject to future authorisation procedures by the Member States, the CMDh recommends that the concerned Member States and Marketing Authorisation Holders take due consideration of this CMDh position.

This position is forwarded to Member States, to Iceland and Norway, to the MAHs together with its annexes and appendix(ces).