Co-ordination group for Human Use
EMA/CMDh/654826/2014
EMA/H/A-31/1387

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
Active substances	sodium valproate, valproic acid, valproate semisodium, valpromide
Pharmaceutical forms	see Annex I
Strengths	see Annex I
Routes of administration	see Annex I

Basis for Agreement

Pursuant to Article 31 of Directive 2001/83/EC, the United Kingdom initiated a procedure on 7 October 2013 based on concerns resulting from the evaluation of data from pharmacovigilance activities. The notification for the procedure is appended to this agreement.

The procedure started on 10 October 2013.

The Pharmacovigilance Risk Assessment Committee (PRAC) recommendation was adopted on 9 October 2014 and is appended to this agreement.

The steps taken for the assessment are included in the appended PRAC recommendation.

The Co-ordination Group for Mutual Recognition and Decentralised Procedures for human use (CMDh) has considered the recommendation of PRAC in accordance with Article 107k(1) and (2) of Directive 2001/83/EC.

Agreement

1. The CMDh, having considered the final PRAC recommendation, agreed by consensus that the marketing authorisations for valproate and related substances containing medicinal products should be varied.

   The Icelandic and the Norwegian CMDh members agree with the above-mentioned agreement of the CMDh.

2. The scientific conclusions and the detailed explanation of the scientific grounds for the differences from the final PRAC recommendation are set out in Annex II.

3. The amendments to be introduced to the product information of valproate and related substances containing medicinal products are set out in Annex III.

4. The conditions to the marketing authorisations of valproate and related substances containing medicinal products are set out in Annex IV.

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

To the extent that other medicinal products containing valproate and related substances not included in Annex I are currently authorised in the EU, or are subject to future authorisation procedures by the Member States, the CMDh recommends that the Member States concerned take due consideration of the scientific conclusions set out in Annex II.

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, 19 November 2014

On behalf of the CMDh
Dr Peter Bachmann, Chair