Co-ordination group for Human Use
EMEA/H/A-31/1400
EMA/CMDh/191907/2015

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,

Medicinal products:

Invented names:	see Annex I
Active substance:	hydroxyzine
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, Hungary initiated a procedure on 25 April 2014 based on concerns resulting from the evaluation of data from pharmacovigilance activities. The notification for the procedure is appended to this agreement.

The evaluation procedure started on 08 May 2014.

The Pharmacovigilance Risk Assessment Committee (PRAC) recommendation was adopted on 12 February 2015 and is appended to this agreement.

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

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 PRAC recommendation, agreed by consensus that the marketing authorisations for hydroxyzine-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 PRAC recommendation are set out in Annex II.

3. The amendments to be introduced to the product information of hydroxyzine-containing medicinal products are set out in Annex III.

4. The timetable for the implementation of the agreement is set out in Annex IV.

To the extent that other medicinal products containing hydroxyzine 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, 25 March 2015

On behalf of the CMDh

Dr Peter Bachmann, Chair