Co-ordination group for Human Use
EMA/H/A-31/1342
EMA/CMDh/376357/2013

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 product

Medicinal products

Names:	see Annex I
International non-proprietary name:	codeine
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 resulting from the evaluation of data relating to pharmacovigilance of an authorised medicinal product, the United Kingdom initiated a procedure on 03 October 2012. A revised notification enlarging the scope of the procedure was received on 22 October and is appended to this agreement.

The procedure started on 03 October 2012.

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 13 June 2013 and is appended to this agreement.

The CMDh has considered the PRAC recommendation 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, the CMDh, having considered the matter and the appended PRAC recommendation, is of the opinion by consensus that the marketing authorisations should be revoked or varied, as applicable.

The agreement reached by the Member States represented within the CMDh differs from the recommendation of the PRAC. The detailed explanation for the differences from the PRAC recommendation is set out in the Annex II.

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

2. The Scientific conclusions and grounds for revocation or variation to the terms of the marketing authorisations and detailed explanation for the differences from the PRAC recommendation are set out in the Annex II.

3. The revocation or the variation to the terms of the marketing authorisations applies to the medicinal products referred to in Annex I. The relevant sections of the summary of product characteristics and package leaflet are set out in Annex III.

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

To the extent that other medicinal products containing codeine-containing medicinal products indicated in the management of pain in children 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 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 product, together with its annexes and appendices.

London, 26 June 2013

On behalf of the CMDh
Dr Peter Bachmann, Chairman