Co-ordination group for Human Use
EMA/CMDh/206590/2015
EMEA/H/A-31/1394

# 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 name(s) | see Annex I |
| Active substance(s) | codeine |
| Pharmaceutical form(s) | see Annex I |
| Strength(s) | see Annex I |
| Route(s) administration | see Annex I |

**Basis for Agreement**

Pursuant to Article 31 of Directive 2001/83/EC, Germany initiated a procedure on 02 April 2014 based on concerns resulting from the evaluation of data from pharmacovigilance activities.

The procedure started on 10 April 2014.

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

The steps taken for the assessment and the notification for the procedure 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 PRAC recommendation, agreed by consensus that the marketing authorisations for codeine containing medicinal products for the treatment of cough and/or cold in paediatric patients should be revoked or varied, as applicable.

   The Icelandic and the Norwegian CMDh member(s) agree(s) 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 revocation or the variation to the terms of the marketing authoristaions applies to the medicinal products referred to in Annex I taken in consideration the amendments to be introduced

to the product information of codeine containing medicinal products for the treatment of cough and/or cold in paediatric patients 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 codeine for the treatment of cough and/or cold in paediatric patients 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 holder(s) for the above mentioned medicinal product(s), together with its annexes and appendices.

London, 22 April 2015

On behalf of the CMDh
Dr Peter Bachmann, Chair