London, 20 May 2014
Co-ordination group for Human Use
EMA/CMDh/292841/2015
EMEA/H/A-31/1401

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
International non-proprietary names	ibuprofen dexibuprofen
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 09 June 2014 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 13 June 2014.

The Pharmacovigilance Risk Assessment Committee (PRAC) recommendation was adopted on 10 April 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 medicinal products containing ibuprofen or dexibuprofen (systemic formulations) should be varied.

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

2. The scientific conclusions and grounds for variation to the terms of the marketing authorisations are set out in Annex II.

3. The amendments to be introduced to the product information of medicinal products containing ibuprofen or dexibuprofen (systemic formulations) 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 ibuprofen or dexibuprofen (systemic formulations) 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.