

**Article 31 of Directive 2001/83/EC resulting from pharmacovigilance data**

Procedure No: EMEA/H/A-31/1397

**Ambroxol- and bromhexine-containing medicinal products**

**Divergent statement**

We support the revised CMDh position, but only for the following indications

- Bromhexine: Secretolytic indication for adults and children >2 years
- Ambroxol: Pain relief of mild to moderate symptoms of acute sore throat

The benefit/risk balance for these indications remains favourable provided that the SmPC will be updated according to the conditions set out in Annex III of the recommendation.

The benefit/risk balance is considered negative for all other indications and all bromhexine-combination as well as ambroxol-combination products.

**CMDh member expressing a divergent opinion:**

Kora Doorduyn (NL)	18 November 2015	Signature: .....
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