



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

EMA/HMPC/712219/2014  
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Committee on Herbal Medicinal Products (HMPC)

## Opinion of the HMPC on a European Union herbal monograph on *Echinacea purpurea* (L.) Moench, herba recens

### Opinion

The HMPC, in accordance with Article 16h(3) of Directive 2001/83/EC, as amended, and as set out in the appended assessment report, establishes by a majority of 21 out of 29 votes a European Union herbal monograph on *Echinacea purpurea* (L.) Moench, herba recens which is set out in Annex I.

The divergent positions are appended to this opinion.

The Norwegian HMPC member agrees with the above-mentioned recommendation of the HMPC.

This opinion is forwarded to Member States, to Iceland and Norway, together with its Annex I and appendices .

The European Union herbal monograph and assessment report will be published on the European Medicines Agency website. They replace those adopted on 6 March 2008.

London, 24 November 2014

On behalf of the HMPC

Prof. Dr Werner Knöss, Chair



## **Annex I: European Union herbal monograph (EMA/HMPC/48704/2014)**

## Appendix I: Assessment report (EMA/HMPC/557979/2013)

## Appendix II : Divergent positions

The member of the HMPC mentioned below did not agree with the HMPC's opinion for the following reason:

We do not support the Well Established Use indication for *Echinacea purpurea* (L.) Moench, herba recens for "the short-term prevention and treatment of common cold". In our view the data provided are insufficient to support a Well Established Use indication in accordance with Annex 1 of Directive 2001/83/EC, as amended. The efficacy of *Echinacea purpurea* (L.) herba recens has not been sufficiently proven. We would however support a traditional use indication for the treatment of symptoms of the common cold.

Anna Cunney HMPC member from Ireland

London, 24 November 2014

The member of the HMPC mentioned below did not agree with the HMPC's opinion for the following reason:

In „Monograph“ and in „Community list entry“ elaborated for *Echinacea purpurea* herba recens is used for this fresh (= recens) herbal substance an english term „purple coneflower herb“ in parentheses as an equivalent one through both texts. But „purple coneflower herb“ term is valid as the english title of the herbal drug monograph 01/2008:1823 describing dried herbal substance in Ph. Eur. 8.2 only, with a latin equivalent title „*Echinacea purpurea* herba“.

Reading both „Monograph“ and „Community list entry“ one can understand there is no difference between „*Echinacea purpurea* herba recens“ and „*Echinacea purpurea* herba“ with the same english term „purple coneflower herb“. If there would be no difference in the meaning of both latin terms (and the same english term used for both latin ones) then a footnote at Section 2 title „Qualitative and quantitative composition“ shall be present describing „The dried material complies with Ph.Eur. (ref. 01/2008:1823)“ – and it would be wrong.

This confusion could be prevented by adding word „fresh“ in the front of all english terms „purple coneflower herb“, e.g. „fresh purple coneflower herb“ in „Monograph“ and in „Community list entry“. This corrected term is equivalent with „*Echinacea purpurea* herba recens“.

As this recommendation was not accepted a nonsens from pharmacognostical point of view was adopted by voting.

I have no other objections to scientific evaluated data from articles mentioned in LoR and other texts in „Monograph“ and in „Community list entry“ elaborated for *Echinacea purpurea* herba recens.

Milan Nagy HMPC member from Slovakia

London, 24 November 2014

The member of the HMPC mentioned below did not agree with the HMPC's opinion for the following reason:

The evidence does not support the indication for *Echinacea purpurea* recens, herba, based on well-established use including recognised efficacy as required by article 10a of Directive 2001/83/EU.

The data presented as evidence for the indication 'Herbal medicinal product for the short-term prevention and treatment of common cold', are not considered conclusive and are insufficient to demonstrate recognized efficacy.

Emiel van Galen HMPC member from The Netherlands

London, 24 November 2014

The member of the HMPC mentioned below did not agree with the HMPC's opinion for the following reason:

Regarding the European Union monograph on *Echinacea Purpurea* L., Herba Recens, the divergent position as expressed in March 2008 is still valid because no new clinical data to support a well-established used indication for *Echinacea* as a "Herbal medicinal product for short-term prevention and treatment of common cold" have been provided.

Adela Núñez, HMPC member from Spain

London, 24 November 2014



Four members of the HMPC mentioned below did not agree with the HMPC's opinion for the following reason:

Do not support the well-established use indication for *Echinacea purpurea* L., herba recens as a 'short-term prevention and treatment of common cold'.

The data provided to support this indication do not fulfil the requirements for well-established use and recognised efficacy in accordance with Annex 1 of 2001/83/EC, as amended. Specifically, the clinical data presented for this indication are insufficient to support the proposed well-established use indication.

Linda Anderson, HMPC member from United Kingdom

Marisa Delbò, HMPC member from Italy

Silvia Giroto, Co-opted HMPC member

Gioacchino Calapai, Co-opted HMPC member

London, 24 November 2014