



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Committee on Herbal Medicinal Products (HMPC)

Opinion of the HMPC on a European Union herbal monograph on *Ginkgo biloba* L., folium

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 *Ginkgo biloba* L., folium 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.

London, 28 January 2015

On behalf of the HMPC

Prof. Dr Werner Knöss, Chair



Annex I: European Union herbal monograph (EMA/HMPC/321097/2012)

Appendix I: Assessment report (EMA/HMPC/321095/2012)

Appendix II : Divergent positions

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

As delegate of AEMPS (Agencia Española de Medicamentos y Productos Sanitarios) in the HMPC, I express a divergent opinion to the well-established use monograph on *Ginkgo folium*:

The evidence does not support the position of *Ginkgo biloba* L. as having well-established use and recognised efficacy as required by Article 10a of Directive 2001/83/EC in the improvement of quality of life in mild dementia.

Given the discrepancy between the available clinical studies we are of the opinion that the robustness of the results is not sufficient to support the indication of dementia. In addition, the lack of sound data on the effect of *Ginkgo biloba* on the quality of life in these patients does not allow reaching a valid conclusion on it.

The following wording could be acceptable: "Herbal medicinal product for the improvement of (age-associated) mild cognitive impairment."

Adela Núñez, HMPC member from Spain

London, 28 January 2015

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

The indications for well-established use in the monograph are not supported by scientific efficacy data. It has not been demonstrated that the products in the monograph are effective for the improvement of (age-associated) cognitive impairment and of quality of life in mild dementia.

Eeva Sofia Leinonen, HMPC member from Finland

London, 28 January 2015

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

We recognised the well-established use status but considering the clinical data available to demonstrate improvement in quality of life in mild dementia, we are not in favour of the wording laid down in the indication well-established use section 4.1 of the monograph.

An Lé, HMPC member from France

London, 28 January 2015

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

I do not support the proposed European Union herbal monograph on *Ginkgo biloba* L., folium based on the consideration reported below.

The evidence does not support the position of *Ginkgo biloba* L., folium as having well-established medicinal use and recognised efficacy as required by Article 10a of Directive 2001/83/EC.

The data are insufficient to support a well-established use indication in accordance with Annex 1 of 2001/83/EC, as amended. The efficacy of *Ginkgo biloba* has not been sufficiently and consistently proven.

Ioanna Chinou, HMPC member from Greece

London, 28 January 2015

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

I do not support the proposed European Union herbal monograph on *Ginkgo biloba* L., folium based on the consideration reported below.

The evidence does not support the position of *Ginkgo biloba* L., folium as having well-established medicinal use and recognised efficacy as required by Article 10a of Directive 2001/83/EC.

The data are insufficient to support a well-established use indication in accordance with Annex 1 of 2001/83/EC, as amended. The efficacy of *Ginkgo biloba* has not been sufficiently and consistently proven.

Marisa Delbò, HMPC member from Italy

London, 28 January 2015

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 *Ginkgo biloba* L., folium for "the improvement of (age-associated) cognitive impairment and of quality of life in mild dementia." Our view is that the data available are insufficient to support a well-established use indication in accordance with Annex 1 of 2001/83/EC, as amended. The efficacy of *Ginkgo biloba* has not been sufficiently and consistently proven.

Una Mockler HMPC member from Ireland

London, 28 January 2015

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

Related to the indication, established based on Well-established use (art. 10a Directive 2001/83),

The indication stated as "Herbal medicinal product for the improvement of (age-associated) cognitive impairment." would be preferable from a Dutch point of view.

I have to express also a divergent opinion related to the indication, established based on Traditional use (art. 16d (1) of Directive 2001/83/EC).

This indication should be restricted to "Traditional herbal medicinal product for the relief of heaviness of legs. Traditional herbal medicinal product for use in specified indications exclusively based upon long standing use."

Emiel van Galen HMPC member from The Netherlands

London, 28 January 2015

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

The Community herbal monograph on *Ginkgo biloba* L., folium is based on 'well-established medicinal use' and has the following indication:

"Herbal medicinal product for the improvement of (age-associated) cognitive impairment and of quality of life in mild dementia".

All *Ginkgo* products are classified as traditional herbal medicinal products in Sweden. These products are traditionally used for symptomatic self-medication in patients with age-related memory problems.

The evidence of clinical efficacy presented in the assessment report pertaining to the Community monograph on *Ginkgo biloba* L., folium are considered not to fulfil the requirements set out in directive 2001/83/EC for a product with a well-established medicinal use for the following reasons:

- The results of the clinical trials do not fulfil the requirement of 'coherence of scientific assessments' to demonstrate a well-established medicinal use. Studies included in the assessment report display conflicting results regarding therapeutic efficacy. The two largest RCT:s failed to demonstrate efficacy regarding progression to dementia and Alzheimer's disease (DeKosky ST et al. JAMA 2008 and Vellas B et al. Lancet Neurology 2012).
- The 2009 Cochrane review (Birks and Grimley Evans) concluded that the evidence supporting the claim that *Ginkgo biloba* extract has a predictable and clinically significant benefit in patients with dementia or cognitive impairment is inconsistent and unreliable.

The data on clinical efficacy of *Ginkgo biloba* extracts have been assessed nationally. Current Swedish national guidelines on dementia do not include *Ginkgo biloba* extracts as a treatment option (The National Board of Health and Welfare 2010: National guidelines for Care in cases of Dementia). Furthermore, treatment with *Ginkgo biloba* extract is listed as "NOT recommended" in patients with mild/moderate Alzheimer's disease.

Comment on the proposed indication

The proposed indication wording has a promotional character, which is not acceptable.

Per Claeson, HMPC member from Sweden

London, 28 January 2015

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

I do not support the proposed European Union herbal monograph on *Ginkgo biloba* L., folium based on the consideration reported below.

The evidence does not support the position of *Ginkgo biloba* L., folium as having well-established medicinal use and recognised efficacy as required by Article 10a of Directive 2001/83/EC.

The data are insufficient to support a well-established use indication in accordance with Annex 1 of 2001/83/EC, as amended. The efficacy of *Ginkgo biloba* has not been sufficiently and consistently proven.

Linda Anderson, HMPC member from United Kingdom

London, 28 January 2015