



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

EMA/HMPC/244307/2016  
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Committee on Herbal Medicinal Products (HMPC)

## Opinion of the HMPC on a European Union herbal monograph on *Thymus vulgaris* L. or *Thymus zygis* L., herba and *Primula veris* L. or *Primula elatior* (L.) Hill, radix

### 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 23 out of 26 votes a European Union herbal monograph on *Thymus vulgaris* L. or *Thymus zygis* L., herba and *Primula veris* L. or *Primula elatior* (L.) Hill, radix 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 24 September 2012.

London, 5 April 2016



## Annex I: European Union herbal monograph (EMA/HMPC/84990/2015)

## Appendix I: Assessment report EMA/HMPC/85124/2015)

## Appendix II : Divergent positions

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

The bibliographical evidence does not support the position of *Thymi herba* / *Primulae radix* as having well-established medicinal use and recognised efficacy for the use as an expectorant in case of productive cough as required by Article 10a of Directive 2001/83/EC. The data are insufficient to support a well-established use for this indication in accordance with Annex 1 of 2001/83/EC, as amended.

Emiel van Galen, HMPC member from the Netherlands

London, 5 April 2016

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

The UK does not support the proposed European Union herbal monograph for *Thymus vulgaris* L. or *Thymus zygis* L., herba and *Primula veris* L. or *Primula elatior* (L.) Hill, radix:

as a **traditional herbal medicinal product** as an expectorant in case of productive cough in children 4 -12 years, is not considered acceptable.

The data to support the proposed use in this age group are insufficient and it is considered that treatment should be under medical supervision.

and

for the **well-established use** indication as an expectorant in case of productive cough.

In our view the data provided do not fulfil the requirements for well-established medicinal use in accordance with Annex 1 of 2001/83/EC, as amended. The efficacy of *Thymus vulgaris* L. or *Thymus zygis* L., herba and *Primula veris* L. or *Primula elatior* (L.) Hill, radix has not been sufficiently and consistently proven.

Linda Anderson, HMPC member from the United Kingdom

London, 5 April 2016

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 monograph for *Thymus vulgaris* L. or *Thymus zygis* L., herba and *Primula veris* L. or *Primula elatior* (L.) Hill, radix for the well-established use indication as an expectorant in case of productive cough based on the consideration reported below:

In my view the data provided do not fulfil the requirements for well-established medicinal use in accordance with Annex 1 of 2001/83/EC, as amended. The efficacy of *Thymus vulgaris* L. or *Thymus zygis* L., herba and *Primula veris* L. or *Primula elatior* (L.) Hill, radix has not been sufficiently and consistently proven.

Marisa Delbò, HMPC member from Italy

London, 5 April 2016