Public statement on *Chelidonium majus* L., *herba*

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<th>Event</th>
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<td>Discussion in Working Party on Community Monographs and Community List (MLWP)</td>
<td>July 2010 November 2010</td>
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<td>Adoption by HMPC for release for consultation</td>
<td>25 November 2010</td>
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<td>End of consultation (deadline for comments). Comments should be provided using this template. The completed comments form should be sent to <a href="mailto:hmpc.secretariat@ema.europa.eu">hmpc.secretariat@ema.europa.eu</a></td>
<td>15 April 2011</td>
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<td>Agreed by HMPC Working Party on Community Monographs and Community List (MLWP)</td>
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**Keywords**

Herbal medicinal products; HMPC; Community herbal monographs; Community list entries; Public statements; *Chelidonium majus* L., *herba*; Chelidonii herba; greater celandine herb
Public statement on *Chelidonium majus* L., herba

**Problem statement**

The HMPC has discussed the Community herbal monograph on *Chelidonium majus* L., herba (greater celandine herb). The HMPC concurrently assessed the toxicological and safety aspects and its conclusions can be found in the assessment report on *Chelidonium majus* L., herba.

There are over 20 different *Chelidonium* alkaloids identified, among them alkaloids belonging to the benzylisoquinoline type (0.01-1%): more particularly benzophenanthridines (chelerythrine, chelidonine, sanguinarine, isocheledonine), protoberberines (berberine, coptisine, dihydrocoptisine, stylopine) and protopine. Among others chelidonine and sanguinarine have been tested for their antitumoral activity *in vitro*.

In some European countries all marketing authorizations for medicinal products were withdrawn, which lead to a daily intake of more then 2.5 mg alkaloids from *Chelidonium majus* according to the posology of the SPC. This restriction is based upon the repeatedly reported hepatotoxic reactions after oral intake of *Chelidonium majus* preparations. Most (65%) of the spontaneously reported adverse drug reactions in the World Health Organisation data base in Uppsala are related to liver and biliary conditions. Hepatotoxicity was not dose-dependent and an idiosyncratic mechanism has been put forward.

Two possible therapeutic indications were suggested:

- **Traditional herbal medicinal product for symptomatic relief of digestive disorders such as dyspepsia and flatulence (oral use)**
- **Herbal preparations for treatment of warts, callus and corns (cutaneous use).**

For the first indication safer herbal and conventional medication is available. The second indication is not sustained by detailed clear information about traditional use.

**Conclusions**

Under the regulatory framework applicable to traditional herbal medicinal products laid down in Chapter 2a of Directive 2001/83/EC as amended and in particular Article 16a(1)(a) on their use in minor indications that do not require supervision of a medical practitioner, the findings from the assessment imply that the benefit-risk analysis of *Chelidonium majus* L., herba is negative.

The extent and the quality of the available scientific data have not been sufficient to come to a positive benefit-risk assessment for oral treatment, taken into account the expected benefit from the herbal medicinal products. As no data were retrieved for more serious conditions that could alter the benefit/risk assessment, the HMPC has therefore concluded that the benefits of *Chelidonium majus* L., herba do not outweigh its possible risks.

The cutaneous use is not sufficiently supported by market information on monotherapy.

If new information on clinical safety and efficacy of *Chelidonium majus* L., herba as a single ingredient were to be made available, such documentation may be re-assessed by the HMPC. The currently available clinical and toxicological data on *Chelidonium majus* L., herba cannot be considered adequate to fulfill the criteria required for developing a Community herbal monograph.
To read more about the toxicological aspects of *Chelidonium majus*, a link to the page where access to the assessment report on greater celandine herb (*Chelidonium majus* L, herba) is provided.