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Public statement on *Chelidonium majus* L., herba

Final

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Public statement on *Chelidonium majus* L., herba

PROBLEM STATEMENT

The HMPC has discussed the possibility of developing a Community herbal monograph on *Chelidonium majus* L., herba (Greater Celandine).

Chelidonium majus L., herba contains over 20 different alkaloids, among them alkaloids belonging to the benzylisoquinoline type (0.01-1%) including benzophenanthridines (chelerythrine, chelidonine, sanguinarine, isochelidonine), protoberberines (berberine, coptisine, dihydrocoptisine, stylopine) and protopine.

In the Vigisearch database of WHO, there are 124 reported adverse drug reactions (derived from 56 spontaneous case reports) affecting the liver-biliary system after intake of medicinal products containing *Chelidonium majus* (up to 4 May 2011). The absolute majority of the cases has been reported from Germany, whereas some single cases have been reported from Austria and Belgium.

In some European countries marketing authorisations for medicinal products containing *Chelidonium majus* have been withdrawn because of concerns with reported adverse effects, particularly liver toxicity. The products withdrawn to date have been those which would lead to a daily intake of more then 2.5 mg alkaloids from *Chelidonium majus,* according to the posology of the SPC.

Two possible therapeutic indications were proposed for the monograph:

Traditional herbal medicinal product:

1) for symptomatic relief of digestive disorders such as dyspepsia and flatulence (oral intake)
2) for treatment of warts, callus and corns (cutaneous use).

CONCLUSIONS

The HMPC has reviewed the toxicological and safety aspects of *Chelidonium majus* and the detailed conclusions can be found in the assessment report.

The HMPC considered the evidence to support a safe oral daily dose limit of not more than 2.5 mg alkaloids, but was not reassured by the scientific rationale or the information available.

The HMPC concluded that evidence of clinical efficacy was lacking for monotherapy and thus a well established use indication was not supported.

The HMPC considered the documented traditional uses for *Chelidonium majus,* but concluded that in the presence of a high number of spontaneously reported liver-biliary adverse drug reactions and the withdrawal of products in Member States due to safety concerns, the benefit-risk assessment of oral use of *Chelidonium majus* is considered negative with respect to the establishment of a community monograph.

Safer herbal medicinal products are available in the indication in question.

If new information on clinical safety and efficacy of *Chelidonium majus* L., herba as a single ingredient for oral use were to be made available, such documentation may be re-assessed by the HMPC.

With regard to cutaneous use, the HMPC considered that the indication was not sufficiently supported by market information on monotherapy.

To read more about the toxicological aspects of *Chelidonium majus* L., herba a link is provided to the page where to access the assessment report on greater celandine herb (*Chelidonium majus* L., herba) and its list of references.

http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/herbal/medicines/herbal_med_000051.jsp&mid=WC0b01ac058001fa1d