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Public statement on *Chelidonium majus* L., herba

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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, isochelidonine), 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In some European countries all marketing authorizations for medicinal products were withdrawn, which lead to a daily intake of more then 2.5 mg alkaloids from *Chelidonium majus* according to the posology of the SPC.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.

http://www.emea.europa.eu/htms/human/hmpc/hmpcmonographs.htm