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13 May 2019

The Secretary
Scheduling Secretariat
GPO Box 9848
Canberra ACT 2601

Email to: medicines.scheduling@health.gov.au

Dear Sir or Madam,

Notice inviting public submissions under regulation 42ZCZK of the *Therapeutic Goods Regulations* 1990. Proposed Amendments to the Poisons Standard to be considered at the ACMS Meeting, June 2019

We refer to the notice inviting public comment under Regulation 42ZCZK of the *Therapeutic Goods Regulations* and would like to provide the following comments on the sanguinarine scheduling proposal that will be referred to the June 2019 meeting of the ACMS.

ASMI (Australian Self Medication Industry) is the peak body representing companies involved in the manufacture and distribution of consumer health care products (non-prescription medicines) in Australia. ASMI also represents related businesses providing support services to manufacturers, including advertising, public relations, legal, statistical and regulatory consultants.

ASMI appreciates the opportunity to provide public comment in relation to ACMS agenda.

Please find enclosed, under cover of this letter, ASMI's comments in relation to the sanguinarine scheduling proposal.

As an industry representative, ASMI is a key stakeholder in scheduling matters and we are keen to provide further input as required. We look forward to the Delegate's interim decisions and greater detail on the final scheduling proposals.

Please contact me should you require any further clarification relating to this submission.

Yours sincerely,

Steven Scarff
Regulatory and Legal Director

Sanguinarine

Introduction

While ASMI provides no specific comment on the proposed scheduling of sanguinarine as it relates to black salve, ASMI does hold concerns about the potential unintended impacts that the proposal may have on existing therapeutic goods and their ingredients

The scheduling proposal, or any alternate scheduling decisions, need to avoid unintended impacts.

Context and breadth of consideration

While ASMI understands the risks to consumers posed by black salve, we hold concerns that the scheduling proposal may inadvertently impact therapeutic goods containing sanguinarine and may also inadvertently impact the manufacturers using herbal raw materials to produce these therapeutic goods.

The scheduling proposal has the potential to impact plant species that do not pose a risk to consumers (and the therapeutic goods which include these species) even though the proposal is aimed at black salve.

While medicines scheduling may be an appropriate tool for combatting the manufacture and supply of illegal therapeutic goods (as the black salve products apparently are) the schedule entries need to be carefully drafted so as to avoid unintended effects.

Sanguinarine is an alkaloid that occurs in a number of herbal species, for instance *Chelidonium majus* that is used in a number of listed and registered medicines in the Australian market. (ARTG records indicate that *Chelidonium majus* is an ingredient in seven separate complementary medicines).

Despite the presence of sanguinarine, there is no evidence of *Chelidonium majus* being used in the production of black salve, and no suggestion that it might be.

Published analyses[1] show that the content of sanguinarine in *Chelidonium majus* varies from season to season and from plant part to plant part (with the root containing a higher content that the herb).

Published analyses of *Sanguinaria canadensis* show similar variations[2].

The feedback ASMI has received indicates that the current finished products included on the ARTG are unlikely to be impacted by a Schedule 10 entry for sanguinarine (with a cut-off of 0.1%). However, we have not been able to draw the same conclusions in relation to the raw materials used to produce these products, or in relation to other herbal species.

There are concerns a Schedule 10 entry could present significant and unreasonable barriers in the production and distribution of the herbal material for legitimate uses, if concentrations in the dried material have potential to exceed a scheduled limit that prohibits sale or supply of the material for

[1] Bogucka-Kocka A and Zalewski D. Qualitative and Quantitative Determination of Main Alkaloids of *Chelidonium majus* L. Using Thin-Layer Chromatographic–Densitometric Method. *Acta Chromatographica* 29(2017)3, 385–397

[2] Croaker A et al. *Sanguinaria canadensis*: Traditional Medicine, Phytochemical Composition, Biological Activities and Current Uses. *Int. J. Mol. Sci*. 2016, 17, 1414;

medicine production. For example, a raw material which contained sanguinarine above the schedule 10 cut-off could not be imported, could not be sold to a finished product manufacturer, could not be used in the (legitimate) manufacture of therapeutic goods.

Consideration of the alkaloid and sanguinarine content of dried *Chelidonium majus* suggests that neither the fresh nor dried material would be impacted by the proposed Schedule 10 entry in this case. This proposal does however demonstrate the way that scheduling decisions can have unintended, and unjustified, consequences when targeting specific herbal components that may occur in a range of species.

Conclusion

ASMI urges caution in proceeding with any scheduling decisions that could introduce unintended impacts on other herbal species.

ASMI requests that should a scheduling decision be made, that the decision be drafted so as to avoid any unintended consequences for registered and listed medicines and the raw materials used to prepare them.