**Technical Alert**

# Interim scheduling decision: *Sanguinaria canadensis* (blood root)

## Summary

An interim scheduling decision has been made about *Sanguinaria canadensis* (blood root) based on consideration by the Advisory Committee on Medicines Scheduling (ACMS). The scheduling decision is to make the preparation of blood root, when containing more than 0.01% sanguinarine, a Schedule 10 substance due to its use in Black Salve (also known as red salve or cansema). Black Salve is generally a combination of blood root with zinc chloride and sometimes other ingredients, which has been promulgated or used by some as a natural remedy, but without compliance with the therapeutics goods Act, for use as a skin cancer treatment. Serious side effects have occurred.

Schedule 10 substances are regarded as such a danger to health as to warrant prohibition of sale, supply and use. It was previously known as Appendix C and contains some other herbs.

## Committee Considerations

A delegate of the TGA proposed the application to the Committee. The Committee considered application, as well as submissions received during the consultation phase. The main points raised in opposition to the original amendment, which included scheduling of all sanguinarine, related to the presence of sanguinarine in other herbal ingredients such as *Chelidonium majus* (Greater Celandine) and *Eschscholzia californica* (Californian Poppy). Secondly that scheduling may not have a strong impact on the sale of products called Black Salve.

## Interim proposed entry

The Committee recommended that a new Schedule 10 entry for sanguinarine be created which removes the indexed entry to the component 'sanguinarine', but keeps the content restriction the same for *Sanguinaria canadensis*. It does not refer to route of administration.

**Schedule 10 - New Entry**

SANGUINARIA CANADENSIS (bloodroot) in preparations for human use **except** in preparations containing 0.01 per cent or less of SANGUINARINE.

**INDEX - New Entry**

**SANGUINARIA CANADENSIS (bloodroot)**

Schedule 10

If this scheduling decision is made final, any preparation (whether oral or topical) containing *Sanguinaria canadensis* at a concentration above 0.01% will be regarded as a prohibited good and ineligible to be sold or supplied, which is also subject to individual state and territory legislation and enforcement. Preparations includes any preparation of blood root, including extemporaneously compounded preparations that are not on the ARTG, which exceed 0.01% of sanguinarine in the total preparation. Homoeopathics are not expected to be affected, or any existing ARTG listings.

## Next stage

The interim decision and proposed amendment are open for another round of consultation until **10 October 2019**. Instructions on how to make a submission can be found here.

**Members are encouraged to forward any identified issues to technical@cmaustralia.org.au for attention by the Committee Secretariat.**

**ENDS**