Submission

Consultation: Proposed amendments to the Poisons Standard - ACCS, ACMS and Joint ACCS/ACMS meetings, June 2019

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[redacted]

BACKGROUND

About the NHAA

The NHAA is the peak professional association for the naturopathy and Western herbal medicine profession in Australia. Established in 1920, it is also the oldest professional association of complementary therapists in the country. The NHAA represents around 2,000 practitioners and is a member of the World Naturopathic Federation (WNF) which represents practitioners globally.

Our members provide primary care services to people suffering both acute and chronic disease. We use a combination of therapies, including diet, exercise, stress management, supplementation and herbal medicine formulations to deliver holistic treatments. We work alongside other health professionals to support conventional treatment. We play an important role in public health, including the quality use of medicines by Australian consumers.

The primary aims of the NHAA are to:

- Promote, protect and encourage the learning, knowledge and service delivery of naturopathic and Western herbal medicine
- Disseminate such knowledge through available media and networks
- Encourage the highest ideals of professional and ethical standards
- Promote naturopathic and Western herbal medicine as safe and effective public healthcare
- Engage with legislative tools and their representatives as they relate to the practice of naturopathic and Western herbal medicine in Australia

The vision of the NHAA is:

- Practitioners and the practice of naturopathic medicine and Western Herbal medicine are fully integrated into the primary healthcare system in Australia
- The NHAA is recognised as the peak body for naturopathic and Western Herbal medicine
- Naturopathic and Western Herbal medicine is accessible to all
- The integrity of the profession of naturopathic and Western Herbal medicine is maintained
- The standards and quality of education of the professions continue to be promoted
- Career opportunities and research pathways for naturopathic and Western Herbal medicine professionals are developed and maintained
- The integration of traditional knowledge and evolving science is continued

The NHAA publishes the quarterly *Australian Journal of Herbal & Naturopathic Medicine (AJHNM)*. The AJHNM publishes material on all aspects of medical herbalism and naturopathic practice including philosophy, phytochemistry, pharmacology and clinical application of medicinal plants. The NHAA also holds annual seminars throughout Australia, with the Herbal and Naturopathic International Conference held biennially (recently in March 2019 the *11th Herbal & Naturopathic International Conference* kicked off the NHAA's 100th year Celebrations). Since its inception, the NHAA and its members have been at the forefront of naturopathic and Western Herbal medicine and have been influential in areas ranging from education and practice to ethical, regulatory and industry standards.

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1. Proposed amendments referred for scheduling advice to ACMS #27

1.4 Sanguinarine

The NHAA does not support the proposed amendment adding sanguinarine to Schedule 10.

The NHAA recognises the risk associated with the topical use *Sanguinaria canadensis* as a component of “black salve” and its inappropriate promotion as an alternative treatment for skin cancers. However, the proposal to classify the benzylisoquinoline alkaloid sanguinarine as a Schedule 10 substance may unintentionally and needlessly restrict other herbal medicines currently available in Australia.

Chelidonium majus is an approved herbal ingredient in Australia for use in Listed and Registered medicines. This herbal ingredient isknown to contain a range of benzylisoquinoline alkaloids including chelidonine, chelerythrine, coptisine, berberine, stylopine, sanguinarine, and others, at a total quantity of between 0.1-1% in the dried aerial parts[1]. *Chelidonium majus* is an ingredient of a Registered medicine on the Australian Register of Therapeutic Goods (ARTG), specifically [redacted]. This product has been the subject of a number of clinical trials, and non-interventional and retrospective studies evaluating both efficacy and safety, with the incidence and severity of adverse reactions being exceptionally low, further confirmed through international pharmacovigilance data[2].

Furthermore, *Eschscholzia californica* (also an approved herbal ingredient in Australia) contains between 0.5-1.2% total alkaloids including eschscholtzine, eschscholtzidine, californidine, norargemonine, bisnorargemonine, laurotetamine, protopine, chelidonine, chelerythrine, and sanguinarine (amongst others)[3]. The European Medicines Agency (EMA) states that “no major safety concerns can be derived in relation to the use of *E. californica* in the recommended posology and conditions of use”[3].

Adding sanguinarine to Schedule 10 may have the impact of automatically restricting these herbal medicines, depending upon the exact concentration of sanguinarine in finished preparations. This appears to be an unintentional and inappropriate consequence of the proposed amendment.

The reasons for the amendment as proposed do not mention the regulatory impact on the other herbal medicines described above. The only mention is of the use of *Sanguinaria canadensis* and sanguinarine in the context of topical use for skin cancers. Additionally, the rationale mentions that sanguinarine is in two listed medicines on the ARTG, but given the above information that is clearly incorrect. *Sanguinaria canadensis* (but not the isolated sanguinarine) is included as an ingredient in two products (ARTG [redacted]) however both products are homeopathic oral preparations, and are not recommended for topical use in the treatment of skin cancers. A search of the ARTG database shows that *Eschscholzia californica* is found in an additional 13 products, and *Chelidonium majus* in another 7 products. This is not including herbal liquid extracts and dry herbal material for extemporaneous dispensing by herbalists and naturopaths.

Therefore, the NHAA does not support the currently proposed Scheduling amendment for sanguinarine. The NHAA believes the current proposal and its regulatory impact seem to have been poorly conceived, and may not consider unintentional consequences on the use of certain herbal medicines. However, we would be in support of further discussion and

consultation with the aim of imposing limitations on the unfortunate and misleading use of *Sanguinaria canadensis* and its derivatives for the alternative topical treatment of skin cancers. Such consultation should consider how to effectively limit this inappropriate usage but simultaneously avoid unnecessary restriction of other safe and valuable herbal medicines containing sanguinarine.

2. Proposed amendments referred for scheduling advice to the Joint ACMS-ACCS #22

2.1 Arbutin

The NHAA supports the proposed new entry under Schedule 4, specifically exemption (d) "in oral herbal preparations containing 500mg or less of arbutin per recommended daily dose".

The proposed upper limit of 500mg of arbutin or less per daily recommended dosage is well within the European Medicines Agency (EMA) safe level of 840mg per day as stated in their assessment report on *Arctostaphylos uva-ursi*[4].

Additionally, the NHAA supports the proposed removal of the cross reference of arbutin to hydroquinone.

Whilst arbutin can be hydrolysed to hydroquinone, pharmacokinetic data indicate that it is stable in gastric acid[5], and only deglycosylated once in the liver, whereby the liberated hydroquinone is immediately conjugated to hydroquinone glucuronide and hydroquinone sulfate[6]. Subsequent hydrolysis to hydroquinone only occurs at the point of excretion in the urine, providing the known urinary antimicrobial effect of herbal medicines such as *Arctostaphylos uva-ursi*[7].

Furthermore the molar mass of arbutin is 272.243g/mol compared to 110.112g/mol for hydroquinone. Thus, from a toxicological perspective, arbutin and hydroquinone cannot be regarded as equivalent when consumed orally in the context of a herbal preparation.

The NHAA believes the proposed amendments concerning arbutin will ensure public safety whilst at the same time ensure availability of valuable herbal medicines such as *Arctostaphylos uva-ursi* and *Turnera diffusa*.

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