



Submission

**Notice of interim decisions to amend (or not amend) the
current Poisons Standard – 5 October 2023**

Version 1.0

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Prepared by: Tristan Carter on behalf of the Naturopaths and Herbalists Association
of Australia (NHAA)

**National Herbalists Association of Australia t/a Naturopaths and Herbalists
Association of Australia**

ABN 25 000 009 932

Founded 1920

PO Box 696, Ashfield NSW 1800

Phone: +61 2 9797 2244

Fax: +61 2 8765 0091

Email: nhaa@nhaa.org.au

Web: www.nhaa.org.au

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. 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.

NHAA response to the TGA Notice of the interim decisions to amend (or not amend) the current Poisons Standard - 5 October 2023.

The NHAA is grateful for the opportunity to respond to the interim decision in relation to amygdalin and hydrocyanic acid.

Interim decision in relation to amygdalin and hydrocyanic acid

Interim decision – “A Delegate of the Secretary has made an interim decision not to amend the current Poisons Standard in relation to amygdalin and hydrocyanic acid”.

As an association in support for the exemption of the Schedule 10 and Schedule 4 entries for amygdalin and hydrocyanic acid, when in ARTG listed preparations containing *Prunus serotina* (Wild Cherry Bark), the NHAA respectfully retort to the interim decision of the Delegate.

Firstly, it must be noted that Wild Cherry Bark has been extemporaneously compounded by a qualified naturopath and herbalist and not subject to self-selection by the general public. A general warning exists for prolonged use ¹. The interim decision provides speculative not substantive evidence to support that Wild Cherry Bark is harmful. The onus guiding the decision to ensure that amygdalin in relation to Wild Cherry Bark is not amended on the Poisons Standard remains feeble and unsupported, especially considering the following:

- Wild Cherry Bark is a traditional medicine providing centuries of therapeutic benefit ². ³. The sale, supply and use of Wild Cherry Bark has sustained a negligible public health risk during this period.
- The information provided in the interim document pertaining to therapeutic use and toxic dose states; “A wide range of expert committees have concluded that an oral intake of 5-20 mg/day amygdalin in a 60 kg adult is likely to be low risk”.
- The history of amygdalin misuse is based on only 5 case reports of adults with daily doses.
- There have been no adverse events reported to the TGA in the last five decades in relation to Wild Cherry Bark, or products containing amygdalin or HCN as an ingredient.
- Wild Cherry Bark contains trace amounts of amygdalin, a precursor to hydrocyanic acid (HCN), with toxicological reports demonstrating amygdalin toxicity via oral administration can be avoided ⁴
- Hydrolysis of amygdalin in the digestive tract ensures a slow release of low levels of HCN, which are easily detoxified by the body ¹
- Constituents within herbal medicines are often standardized, a process which can be used to specify levels of amygdalin.

Proposed Labelling Requirements

The NHAHA gratefully request consideration to the proposed labelling requirements for amygdalin and hydrocyanic acid as there remains insufficient evidence supporting toxicity or adverse events at a maximum daily dose < 5mg amygdalin or equivalent dose of hydrocyanic acid (HCN) < 0.3mg⁴. Potential risks for vulnerable groups, for example children or pregnant women, and long-term use/intentional misuse can also be mitigated by additional labelling requirements.

The NHAHA appeals for the Delegate to re-consider previous submissions and the benefits and use of Cherry Bark as an extemporaneously compounded therapy by Naturopaths and Herbalists nationwide.

Once again, the NHAHA appreciates the opportunity to respond to the interim decision to amend (or not amend) the current Poisons Standard - 5 October 2023. We acknowledge that concerns have been raised with the current scheduling of amygdalin, and thus an inability to utilize herbs including Wild Cherry Bark. We remain undeterred and assured that the current amygdalin scheduling presents a misguided and unconvincing action supported by insufficient evidence which does not duly defend that the health risks far outweigh the documented risks.

1. Mills SY, Bone K. The essential guide to herbal safety: Elsevier Health Sciences 2004.
2. Remington JP, & Wood, H.C., . Wild Cherry. Prun. Virg. [Wild Black Cherry Bark] Available: <https://www.henriettes-herb.com/eclectic/usdisp/prunus-sero.html>.
3. Lucius E Sayre. Wild Cherry Bark Available: <https://www.henriettes-herb.com/eclectic/sayre/prunus-sero.html>.
4. He XY, Wu LJ, Wang WX, et al. Amygdalin - A pharmacological and toxicological review. J Ethnopharmacol. 2020;254:112717.