

## **About the Naturopaths and Herbalists Association of Australia (NHAHA)**

The NHAHA 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 NHAHA represents around 2,000 practitioners and is currently chair of the World Naturopathic Federation (WNF) which represents naturopathic practitioners globally.

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

The NHAHA 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 NHAHA also holds educational events regularly, including an annual international symposium.

Since its inception, the NHAHA and its members have been at the forefront of naturopathic and Western herbal medicine and have been strongly influential in areas ranging from policy, education and practice, to ethical, regulatory and industry standards.

## **Consultation: Proposed amendments to the Poisons Standard**

### **NHAHA response to 2.3 Amygdalin and hydrocyanic acid**

#### **Background**

The NHAHA lodges this submission in support of the proposal to amend the Poisons Standard and exclude from scheduling low levels of the naturally occurring constituents amygdalin (Schedule 10) and hydrocyanic acid (Schedule 4) found in preparations of *Prunus serotina* (Wild Cherry Bark), subject to additional labelling requirements.

Wild Cherry Bark is a valued therapeutic herb for conditions such as the symptomatic treatment of cough and is typically limited to short term use. The herb is used by herbalists and naturopaths as part of their 'tools of trade'.

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 (1). In addition, hydrolysis of

amygdalin in the digestive tract ensures a slow release of low levels of HCN, which are easily detoxified by the body (2).

The reinstatement of Wild Cherry Bark within allowable low levels of amygdalin and related HCN supports consumer right choices to access cost effective support for self-limiting conditions.

### **Proposed labelling requirements**

The NHAHA supports the labelling requirements proposed in consideration of insufficient evidence supporting toxicity or adverse events at a maximum daily dose < 5mg amygdalin or equivalent dose of hydrocyanic acid < 0.3mg (1).

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 would like it noted that Wild Cherry Bark which is extemporaneously compounded by a qualified naturopath and herbalist and not subject to self-selection by the general public, also be considered for inclusion, subject to the requirements above.

### **Scheduling Factors**

The evidence guiding the decision by the Therapeutic Goods Administration (TGA) to schedule amygdalin in relation to Wild Cherry Bark remains unconvincing as it does not take into consideration nor substantiate health risks outweighing the health benefits at lower allowable limits, thus effectively banning the use of the herb.

In addition, 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.

### **Schedule 4 – HCN Hydrocyanic acid**

Wild Cherry Bark has been used for ailments and symptoms which are often self-managed and do not require medical intervention. Scheduling of HCN has inappropriately placed Wild Cherry Bark in the domain of an adjunct therapy, requiring co-administration, specialist training, or personal protective equipment to administer. Further, evidence does not support that the proposed dosage level could produce dependency or support the potential of abuse/misuse (1).

The evidence base does not support the requirement for a stricter control or contribute to communal harm, nor does it validate the reason for HCN to be deemed an illicit therapeutic product based on the absence of severe adverse effects, interactions, or contraindications.

### **Schedule 10 – Amygdalin**

Amygdalin is a naturally occurring ubiquitous glycoside found in numerous plants of the Rosaceae family, including foods commonly consumed, as well as herbs

such as Wild Cherry bark, with the latter having over a century of documented therapeutic use (3, 4) in Asia and Europe (1).

The sale, supply and use of Wild Cherry Bark has sustained a negligible public health risk during this period. Rather than an isolate, amygdalin can be considered as a minor but necessary part of the complex phytochemical synergy i.e., the combined effect of all other bioactive constituents working in unison (5).

Previously, the TGA evaluated that a maximum daily dose of 5mg of amygdalin may be appropriate. This evaluation remains relevant and applicable, given it is below commonly consumed foods, and significantly below what is considered lethal or harmful to humans.

### The amygdalin scheduling incongruence

We acknowledge that concerns have been raised with the current scheduling of amygdalin, and thus an inability to utilize herbs including Wild Cherry Bark. However, the current amygdalin scheduling of 0% presents a misguided and unconvincing action supported by insufficient evidence which does not duly defend that the health risks of < 5mg of amygdalin far outweigh the health benefits. To illustrate this point, a risk-benefit analysis for amygdalin use is detailed below.

Figure 1 – Risk benefit assessment

Activity	Potential Benefit	Possible hazard	Who is at risk?	Precautions
<b>Access to use Wild Cherry Bark</b> [>5mg amygdalin]	Therapeutic freedom and choice	Treatment bureaucracy. Unwarranted therapeutic control	Australian herbal medicine consumers and practitioners	Labelling requirements
<b>Oral administration</b> *Amygdalin*	Antitussive (Cough)	Potential for HCN toxicity	Australian herbal medicine consumers	Dose + labelling requirements
	Astringent (Common cold)	Potential for HCN toxicity	Australian herbal medicine consumers	Dose + labelling requirements
<b>Product presentation</b> Labelling requirements	Consumer protection	Long-term use and high dosage	Australian herbal medicine consumers	Quality assurance
<b>Intentional misuse</b> Wild Cherry Bark labelling requirements	Consumer protection	Unproven 'alternative' cancer therapy unlikely due to low dose of amygdalin	Australian herbal medicine consumers	Quality assurance

1. He XY, Wu LJ, Wang WX, Xie PJ, Chen YH, Wang F. Amygdalin - A pharmacological and toxicological review. *J Ethnopharmacol.* 2020;254:112717.
2. Mills SY, Bone K. *The essential guide to herbal safety: Elsevier Health Sciences*; 2004.
3. King's American Dispensatory. *Prunus Virginiana (U.S.P) - Wild Cherry* Henriette's Herbal Homepage 1898 [Available from: <https://www.henriettes-herb.com/eclectic/kings/prunus-sero.html>].
4. Lucius E Sayre. *Wild Cherry Bark* Henriettes Herbal Homepage 1917 [Available from: <https://www.henriettes-herb.com/eclectic/sayre/prunus-sero.html>].
5. Yarnell E. Synergy in herbal medicines. *J Restor Med.* 2015;4(1):60.