
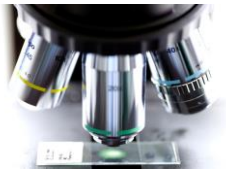


Member Alert

TGA Proposed Decision to permit Arbutin in Herbal Medicines

Dear Member,

Complementary Medicines Australia is extremely pleased to communicate that our Scheduling application made in March to return access of arbutin-containing herbs to the complementary medicine industry, practitioners and public, has resulted in an "interim decision" by the TGA delegate to accept the proposal on the basis of safe and acceptable use. Currently the limitation on preparations of 0.0025% is very low and is difficult to reliably measure, which has resulted in the reduction or removal of supply of many or most affected herbal preparations. This newly proposed interim decision makes a much wider limit of 500mg arbutin in oral herbal preparations for general access, including via listed medicines through the Permissible Ingredients Determination. If this decision becomes the "final decision", for which your public support in the TGA's public consultation is invited, it will widely return the herbs Bearberry (*Arcostaphylos uva-ursi*), Damiana (*Turnera diffusa*), and another nine arbutin-containing herbs to availability in medicinal preparations after the recommended implementation date of **1 June 2020**.

The application was developed and submitted by CMA in association with the National Herbalists Association of Australia. A group of members from both associations worked on this submission, for which we would especially like to acknowledge the invaluable technical input and assistance voluntarily provided by NHAA, Integria Healthcare, Metagenics (Australia), with significant contributions by Hans Wohlmuth (Integria) and Jason Rainforest (NHAA).

YOUR LETTER OF SUPPORT SOUGHT – TGA PUBLIC CONSULTATION

CMA highly recommends that CMA members, practitioners, herbalists, and interested parties make a submission to the TGA's public consultation on the interim decision. The delegate will consider all applications received.

Last day to submit supporting letter for i

CLOSING: 10 October 2019 **CALENDAR REMINDER**:

FORMAT: Word or PDF letter sent to medicines.scheduling@health.gov.au with a TGA coversheet
SUBMISSIONS: Can be as simple as saying that you "support the delegate's interim decision to permit 500mg or less of arbutin in oral herbal preparations to be available for access". If you wish you may provide additional information in support.

INTERIM DECISION THAT WOULD PERMIT THE WIDER RETURN OF ARBUTIN CONTAINING HERBS

The proposed decision is to REMOVE the cross-reference between arbutin and hydroquinone (which resulted in the removal of arbutin herbs), and replace it with the following (proposed by CMA as applicant):

Schedule 4 - New Entry

ARBUTIN **except** in oral herbal preparations containing 500 mg or less of arbutin per recommended daily dose.

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This will mean that oral herbal preparations at 500mg or below will be available for practitioners and for general supply (anything above would be "prescription only"). The rationale of the 500mg was based upon expert input that the commonly prescribed dose by herbalists in Australia is equivalent to approximately 420mg of arbutin per day from preparations of Bearberry (*Arctostaphylos uva-ursi)*, which appears repeatedly as a standard dose in herbal research. 500mg per daily dose allows for a margin of error of ~20%, including herbal variability. With Bearberry as the highest arbutin content herb, it is expected that all other arbutin-containing herbal preparations would also contain less than that amount.

Delegate's reasons

In summary, the TGA delegate provided the following reasons for making the interim decision to allow 500mg of arbutin in oral herbal preparations:

- *I am of the view that arbutin and hydroquinone are separate substances of differing toxicity and molecular make up and as a result, should each have separate entries in the Poisons Standard. I agree with the data presented in the application that arbutin has a significant history of traditional use and is present in many food sources, as well as being a component of eleven herbal ingredients included in the TGA Permitted Ingredients Determination.*
- *I have taken into consideration the toxicological data presented and I find that the proposed cut-off of 500 mg or less of arbutin per recommended daily dose as proposed by the Applicant to be acceptable. The amount of free hydroquinone following absorption of a 500 mg dose of arbutin would result in acceptable amounts of free hydroquinone in accordance with the cut-offs for hydroquinone in the Poisons Standard. I acknowledge that this cut off is well within the safe levels outlined by the European Scientific Cooperative on Phytotherapy (ESCOP), the European Medicines Agency (EMA) monograph and the British Pharmacopoeia (PB) monograph.*
- *I find the Schedule 4 entry for arbutin appropriate, noting that any dosage of arbutin above the cut-off requires medical management by a general practitioner.*

Other respondents to the proposal had additionally requested a change to the topical use of arbutin. The delegate decided that the topical use of arbutin should be considered in a separate consultation to allow for specific consideration of toxicity data on the dermal effects of arbutin.

Background

In 2018, a number of herbal medicines for therapeutic use containing the naturally occurring component 'arbutin' were affected in their ability to be supplied when it became clear that a cross-reference in the Poisons Standard to 'hydroquinone' resulted in herbal preparations at levels exceeding 0.0025% becoming scheduled, whether in practitioner compounded medicines or listed (over the counter) products. Due to the uncertainty around the low cutoff, some herbal supply was ceased altogether. Potentially affected herbs included *Achillea millefolium* (yarrow); *Arctostaphylos uva-ursi* (bearberry or uva ursi); *Chimaphila umbellate* (pipsissewa); *Kalmia latifolia* (mountain laurel); *Ledum palustre* (marsh tea); *Origanum majorana* (oregano); *Pyrus communis* (pear); *Pyrus pyrifolia* (Asian pear); *Rhododendron ferrugineum* (alpenrose); *Turnera diffusa* (damiana); *Vaccinium vitis-idaea* (lingonberry).

Resources

- TGA Sep 2019 FULL DETAILS on the TGA's Interim Decision on Arbutin; and How to make a submission
- CMA Member Alerts 2018: Explainer- Poisons Standard Scheduling of Herbs that contain Arbutin and Update
- CMA Member Alert Apr 2019: Un-scheduling Arbutin in Herbal Medicines – Call for Public Submissions
- CMA Technical Alert: TGA Testing of Herbal Medicines that may contain Arbutin exceeding 25ppm - Jul 2019

ENDS

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