Complementary Medicines Australia *submission to the Therapeutic Goods Administration consultations:*

Item 2.2: Arbutin – Interim decisions on proposed amendments referred to the Advisory Committee on Chemicals Scheduling (ACCS #7, March 2020)

Item 1.3 – Melatonin Interim decisions on proposed amendments referred to the Advisory Committee on Medicines Scheduling (ACMS #29 March 2020)

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Item 2.2 Interim Decision - Arbutin

We support the principle proposed entry:

Schedule 4 - New entry

ARBUTIN (BETA) in oral preparations **except** herbal preparations containing 500 mg or less beta-arbutin per recommended daily dose.

We note that this purpose *has not been excluded from Schedule 6*:

Schedule 6 - New entries

….

ARBUTIN (BETA) **except**:

a. when included in Schedule 4; or
b. in preparations for application to the face containing 7 per cent or less beta-arbutin with hydroquinone levels of 10mg/kg or less.

This entry should include the additional exclusion for oral herbal preparations;

Schedule 6

ARBUTIN (BETA) **except**:

a..(as above)

b.. (as above)

c. in oral herbal preparations containing 500 mg or less beta-arbutin per recommended daily dose.

Item 1.3 Proposed Scheduling of Melatonin

CMA notes the interim decision for melatonin as a Schedule 3 substance, and supports the removal of the Appendix H requirement that has occurred through consultation.

The interim decision includes new requirements related to melatonin in Schedule 3, that it is restricted to those over 55 years for the treatment of primary insomnia. The interim decision notes:

> *the purposes for which a substance is to be used and the extent of use of a substance*
>
> - The TGA-approved indication is for 'Monotherapy for the short term treatment of primary insomnia characterized by poor quality of sleep in patients who are aged 55 or over.'

CMA submit that this restriction is based primarily upon the efficacy data, and it does not appear necessary to restrict the product for either the use or in persons who are adults in relation to the Poisons Standard, as these issues do not appear to have a direct bearing on the safety of the substance. Melatonin is freely available in Canada and the United States in doses of up to 10mg per dosage unit. A recent Australian systematic review[i] of clinical evidence concluded that the safety profile of melatonin is good, with minimal, self-limiting adverse events reported in clinical trials.

The appropriate adult age and use can be dealt with primarily by the approved indication through the registration process.

We submit that this could be amended such that it specifies:

MELATONIN in modified release tablets containing up to 2 mg of melatonin for adults only.

If melatonin is restricted to adults only this permits the exploration of therapeutic use for adults age 18-55 without the need to amend Scheduling again for each therapeutic use or age group that is trialled.

i Foley H and Steel A, 2019. *Adverse events associated with oral administration of melatonin: A critical systematic review of clinical evidence*. Complement Ther Med, 42: 65- 81. doi: 10.1016/j.ctim.2018.11.003. Epub 2018 Nov 3