

## Technical Alert

### **TGA Advisory Committees on Chemicals and Medicines Scheduling**

#### **Scheduling delegates' interim decisions and invitation for further comment: ACCS/ACMS, November 2016**

Dear member,

The Therapeutic Goods Administration (TGA) has released the delegates' interim decisions for amending the Poisons Standard (the *Standard for the Uniform Scheduling of Medicines and Poisons - SUSMP*). This relates to scheduling proposals initially referred to the November 2016 meetings of the Advisory Committee on Chemicals Scheduling (ACCS) and Advisory Committee on Medicines Scheduling (ACMS).

The interim decisions can be accessed via the TGA website at: <https://www.tga.gov.au/scheduling-decision-interim/scheduling-delegates-interim-decisions-and-invitation-further-comment-accsacms-november-2016>

#### **Implications for industry:**

The interim decisions include implications for:

- Fennel oil (see summary of interim decision below)
- Melatonin rescheduling application (see summary of interim decision below)
- Vitamin D
- Cannabis (hemp seed oil).

#### **Invitation for further submissions:**

The notice invites further submissions from applicants and other parties who made valid submissions in response to the original invitations for submissions in August and September 2016. TGA advises that further submissions must be:

- Relevant to the proposed amendment;
- Must address a matter mentioned in section 52E of the Therapeutic Goods Act 1989; and
- Be received by the closing date, **16 February 2017**.

TGA also advises that further submissions from parties other than those who made a valid submission in response to the original invitation or the applicant, or those received after the closing date, need not be considered by the delegate.

## Fennel oil:

The delegates' interim decision is that a new Schedule 5 entry be created for fennel oil, on the basis that basil oil is included in the SUSMP and also contains ethyl chavicol (estragole).

The proposed new Schedule, Appendix E and Part 2.4 entries for fennel oil are as follows:

### Schedule 5 - New Entry

FENNEL OIL except:

- a) in medicines for human therapeutic use, when packed in containers having a nominal capacity of 25 mL or less fitted with a restricted flow insert and compliant with the requirements of the Medicines Advisory Statements Specification;
- b) in preparations other than medicines for human therapeutic use, when packed in containers having a nominal capacity of 25 mL or less fitted with a restricted flow insert, and labelled with the warning:

KEEP OUT OF REACH OF CHILDREN; or

- c) in preparations containing 5 per cent or less of methyl chavicol.

### Appendix E, Part 2

FENNEL OIL

Standard Statements: A (For advice, contact a Poisons Information Centre (e.g. phone Australia 13 11 26; New Zealand 0800 764 766) or a doctor (at once).), G3 (If swallowed, do NOT induce vomiting).

### Part 2, Control on Medicines and Poisons, 2.4 Child-resistant closures

Column 1 Name of the poison	Column 2 Nominal capacity
Fennel oil when included in Schedule 5.	200 millilitres or less

Proposed implementation date: **1 June 2017.**

### **Melatonin:**

An application was submitted to exempt melatonin for human use in preparations containing 1 mg or less of melatonin, as follows:

#### **Schedule 4 - Amend Entry**

- MELATONIN for human use except when in preparations containing 1 mg or less of melatonin. (suggested amendment underlined)

The delegate's interim decision is that the current scheduling for melatonin remains appropriate.

### **Cannabis:**

The medicines scheduling delegate, in view of the upcoming rescheduling of cannabis and tetrahydrocannabinols (THCs), proposes to consider:

The final decision for cannabis provides for hemp seed oil to be exempt from Schedules 8 and 9 when the levels of total cannabinoids are 50 mg/kg or less.

Due to further information provided after the publication of the final decision, the scheduling delegate is undertaking further consideration. This proposal seeks to determine whether this cut-off for total cannabinoids is appropriate for hemp seed oil, and the delegate is requesting additional information on the levels of cannabinoids (including tetrahydrocannabinols) in hemp seed oil. The delegate is also proposing to add to the cannabis entries regarding the hemp seed oil exception the following:

"when labelled with either of the following warning statements:

- i. Not for internal use; or
- ii. Not to be taken."

Please go to the [TGA website](https://www.tga.gov.au) for more details regarding the delegate's deliberation on the scheduling of hemp seed oil.

**ENDS**