



**Australian Government**

**Department of Health**

Therapeutic Goods Administration

# Notice of final decision to amend the current Poisons Standard in relation to melatonin

28 September 2020

**TGA** Health Safety  
Regulation

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# 1 Notice of final decision to amend the current Poisons Standard in relation to melatonin

This web publication constitutes a notice for the purposes of regulation 42ZCZS of the *Therapeutic Goods Regulations 1990* (the **Regulations**). In accordance with regulation 42ZCZS, this notice publishes:

- the decision made by a delegate of the Secretary pursuant to regulation 42ZCZR;
- the reason for the final decision; and
- the date of effect of that decision.

## 2 Final decision on proposed amendments to the current Poisons Standard under regulation 42ZCZR

### 2.1 Final decisions on proposed amendments referred to the Advisory Committee on Medicines Scheduling (ACMS #29, March 2020)

#### Final decision in relation to melatonin

##### *Final decision*

Pursuant to regulation 42ZCZR of the Regulations, a delegate of the Secretary has made a final decision to vary the interim decision and amend the current Poisons Standard in relation to melatonin as follows:

##### **Schedule 4 – Amend Entry**

MELATONIN for human use, **except when included in Schedule 3.**

##### **Schedule 3 – New Entry**

**MELATONIN in modified release tablets containing 2 mg or less of melatonin for monotherapy for the short term treatment of primary insomnia characterised by poor quality of sleep for adults aged 55 or over, in packs containing not more than 30 tablets.**

##### **APPENDIX H – New Entry**

**MELATONIN**

##### **Index – Amend Entry**

**MELATONIN**

Schedule 4

**Schedule 3**

**Appendix H**

### ***Materials considered***

In making this final decision, the delegate considered the following material:

- the [application](#) to amend the current Poisons Standard with respect to melatonin;
- the eight [public submissions](#) received in response to the [pre-meeting consultation](#) under regulation 42ZCZK of the Regulations;
- the advice received from the Advisory Committee on Medicines Scheduling (ACMS #29);
- the [six public submissions](#) received in response to the [interim decision consultation](#) under regulation 42ZCZP of the Regulations;
- the [eight public submissions](#) received, under regulation 42ZCZP of the Regulations, in response to an [invitation for further submissions](#) specifically on the implementation date of 1 October 2020 set out in the [interim decision](#);
- the additional advice obtained from the State and Territory Health Department representatives on the Advisory Committee on Medicines Scheduling (ACMS) under regulation 42ZCZQ(2) on the implementation date of 1 October 2020 recommended at the ACMS #29;
- [Australian Public Assessment Report \(AusPAR\) for melatonin \(PM-2008-2125-1\)](#);
- provisions of the *Therapeutic Goods Act 1989* (the **Act**) relating to the scheduling of substances (Part 6-3) particularly those matters identified in subsection 52E(1) of the Act;
- provisions in the Regulations relating to the procedure for amending the current Poisons Standard (Division 3D of Part 6);
- the Australian Health Ministers' Advisory Council's [Scheduling Policy Framework](#) (SPF 2018); and
- the [Scheduling handbook: Guidance for amending the Poisons Standard \(version 1.1 July 2019\)](#).

### ***Reasons for the final decision (including findings on material questions of fact)***

I have made a final decision to vary my [interim decision](#) to amend the current Poisons Standard with respect to melatonin. Specifically, I have decided to make a minor amendment to the indication for which melatonin is to be used under a Schedule 3 classification, and to change the implementation date to 1 June 2021. The detailed reasons for my decision are outlined in the interim decision with the following qualifications and additional observations.

Melatonin is currently approved for monotherapy for the short-term treatment of primary insomnia characterised by poor quality of sleep in patients who are aged 55 or over. I have decided to modify the Schedule 3 entry to more closely align with the TGA approved indication (in the interests of public safety) through the inclusion of 'monotherapy' and restriction to short-term use in the entry. I note the recommendation of the Australian Drug Evaluation Committee (ADEC) in a Australian Public Assessment Report (AusPar) to restrict the indication for a melatonin medicine to monotherapy on the basis that the available data are not adequate to support use in combination with other hypnotic agents. Additionally, it was recommended that treatment should be limited to a maximum duration of three weeks consistent with the evidence from the pivotal efficacy study, Neurim VII.

In making my final decision, I have taken into account the material set out in in the [interim decision](#) and the six public submissions received on or before the second closing date in response to the call for further submissions published on 10 June 2020 under regulation 42ZCZP of the Regulations. I note that of the submissions received on or before the second closing date, there

were no submissions in opposition, five submissions in support with caveats and one submission with a new proposal.

A number of public submissions requested an extension of the allowable age range from 55 years and over to individuals aged 18 years and over. For the same reasons set out in my [interim decision](#), I have not identified any compelling evidence which establishes that melatonin can be safely supplied to consumers, by a pharmacist, outside the current approved indications, which include a restriction to individuals aged 55 years and over.

At the time of making my interim decision, there was only one registered medicine containing 2mg modified release melatonin on the [Australian Register of Therapeutic Goods \(ARTG\)](#). At the time of making my final decision, I note there are now a total of ten registered medicines containing 2mg modified release melatonin on the ARTG. The approved indication of these new products are consistent with the Schedule 3 entry and accordingly, these products will be captured by the new Schedule 3 entry when my decision comes into effect.

I have made a final decision to make an editorial revision to the explanation of the dosage cut-off in the Schedule 3 entry to state to '2mg or less' to clarify the intended capture is inclusive of formulations containing 2mg of modified release melatonin.

I note the recent approval of a medicine containing 1mg modified release melatonin which is indicated for use in children up to 18. This medicine will continue to be captured in Schedule 4, and is therefore not affected by my final decision.

One public submission proposed an alternate scheduling of melatonin to include immediate release formulations, which in my view, is a matter for a separate scheduling application. Therefore, I have not relied on the material in that public submission in making my final decision.

I have decided on an implementation date of 1 June 2021. My reasons are set out below.

In accordance with regulations 42ZCZP of the *Therapeutic Goods Regulations 1990* (Cth) (Regulations) I made a [call for further submissions](#) specifically in relation to the 1 October 2020 implementation date set out in my [interim decision](#) (closed 28 August 2020). I have taken into account the submissions received in response to that call for further submissions.

A total of eight public submissions were received. The balance of the public submissions received in response to the invitation for further submissions did not address the implementation date directly, in accordance with the invitation, rather they covered the substantive content of the proposed scheduling decision. I have considered these submissions (particularly those opposing the interim decision) but I am not persuaded to alter my decision to down-schedule melatonin in modified release formulations to Schedule 3 for the same reasons given in the interim decision. I am satisfied that the risk profile of melatonin is well defined and the adverse effects, interactions and contraindications are known, identifiable and manageable by a pharmacist. Consumer consultation with a pharmacist is necessary to reinforce and/or expand on aspects of the safe use and appropriate supply in line with the approved indications. There may be potential for harm if melatonin is used inappropriately, however, I am satisfied that it is substantially safe with pharmacist intervention. Where risk of misuse, abuse or illicit use is identified, I am satisfied that the risk can be minimised through pharmacist-consumer consultation.

The submissions that addressed the implementation date, which I note were from industry stakeholders, expressed firm objection to a 1 October 2020 implementation date citing insufficient time for sponsor companies of modified release melatonin products to carry out all of the regulatory, manufacturing, transportation and distribution steps necessary to comply with the down-scheduling.

In recognition of the concerns raised in the public submissions on the practicality of the implementation date for businesses affected by the proposed changes I have decided a 1 June 2021 implementation date is appropriate to allow sufficient time for labelling changes to be made and for a Schedule 3 product to be registered and supplied. I note that this deferred implementation date will allow additional time for industry to carry out a communication plan for consumers and healthcare professionals, and that this would be in the interest of promoting public health. I note that a delayed implementation date of 1 June 2021 is consistent with a recent final decision made in relation to [adapalene](#), which was also considered at the ACMS #29, to down-schedule from Schedule 4 to Schedule 3 of the Poisons Standard.

In reconsidering the implementation date and in accordance with regulation 42ZCZQ(2), I obtained additional advice from State and Territory Health Department representatives on the Advisory Committee on Medicines Scheduling (ACMS). I am in agreement with the majority view that a delayed implementation date is appropriate to allow sufficient time for the development of educational material for pharmacists to promote evidence-based use and facilitate discussions for compliance with the age requirement of 55 years and over.

***Date of effect of the decision***

**1 June 2021**