Consumer Healthcare Products Australia

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28 August 2020

The Secretary
Scheduling Secretariat
GPO Box 9848
Canberra ACT 2601

Email: Medicines.Scheduling@tga.gov.au

Dear Sir/Madam,

Re: Call for further submissions on an interim decision to amend the current Poisons Standard in relation to melatonin

We refer to the notice inviting further comment under subsection 42ZCZP of the *Therapeutic Goods Regulations 1990* and would like to provide comment on the Delegate's Interim Decision arising from the March 2020 meeting of the ACMS to amend the current Poisons Standard in relation to melatonin.

CHP Australia is the leading voice and industry body for manufacturers and distributors of consumer healthcare products, which includes non-prescription medicines. We strive to advance consumer health through responsible Self Care and were previously known as the Australian Self Medication Industry (ASMI). Our key priorities for the industry include improving health literacy, growing the consumer healthcare products industry and increasing access to medicines where appropriate.

Summary

CHP Australia has considered the Delegate's Interim Decision and Reasons and would like to comment in relation to melatonin as follows:

- For the reasons outlined in our submission of 10 February 2020, we support the interim decision to include melatonin in Schedule 3 and to include melatonin in Appendix H.
- As a general principle, CHP Australia supports the setting of implementation dates as soon after the final scheduling decision as possible.

- However, for the reasons outlined below an implementation date of 1 October 2020 is not suitable for the melatonin re-scheduling.
- There has been conflicting advice as to the relevant regulatory pathway for seeking TGA approval of the new S3 product (see below). The appropriate implementation date will depend on the TGA approval date: TGA approval in November would support an implementation date of 1 February 2021 and TGA approval around late-February would support an implementation date of 1 June 2021 (adopting the usual, foreshadowed, implementation dates).

Reasons why 1 October 2020 is not suitable

Product impact

We understand that the effect of the re-scheduling decision will be to re-schedule every melatonin product marketed in Australia. This is not a situation where a subset of indications, patient groups or pack sizes is being re-scheduled. This decision affects every single melatonin product and no product will remain in Schedule 4.

Regulatory Pathways

In accordance with established TGA processes, affected sponsors cannot submit an application to register the S3 melatonin product until the final scheduling decision is published (originally anticipated to be 24 August).

There has been conflicting advice as to the relevant regulatory pathway for seeking TGA approval of the new S3 product:

- One member has been advised that such an OTC application would be classified as "C3" and that C3 applications have a target timeframe of 120 working days (i.e. 5-6 months) to completion.
- Another member has been advised that the pathway involves a Cat 3 application to the Prescription Branch with a request for the labelling to be reviewed by the OTC Branch. This path has a target timeframe of 45 working days (i.e. about 2-3 months).

Assuming the sponsor was ready to submit on the day that the final scheduling decision was published (and assuming this was 24 August) then the TGA approval of the S3 product registration (and revised labelling) would be anticipated around

24 February for the C3 OTC pathway, or in November for the Cat 3 Prescription pathway.

This means that there will be no S3 product in the marketplace at the 1 October implementation date and none likely to be in the marketplace until early 2021 (since the TGA approval date must be followed by a period in which the labels are finalised, printed, used in the product manufacture and then the finished product is distributed to the marketplace).

Transition

Sponsors of melatonin products will currently have stock of the S4 product on hand. Depending on their specific supply chain complexities, on the specific geographical elements of the supply chain and on each sponsor's own appetite for risk, there could be several months stock on hand of the S4 product at the present time.

Affected sponsors will therefore have to plan the run-out of the S4 labelled stock and the run-in of the S3 labelled stock with potential options being considered for re-working the old S4 stock into S3 packaging and/or destroying the old S4 stock.

Labelling

There is a considerable difference in the amount of label information between S4 and S3 products. With some scheduling changes, labelling exemptions may be obtained from the States and Territories to permit the old labelling to remain in the marketplace after the implementation date (provided the new supply requirements are complied with). A recent example of this is the up-scheduling of modified-release paracetamol where exemptions from the States and Territories were granted to permit the S2 labelled stock to remain in the marketplace - only so long as they were stored and supplied as S3 products. However, in the case of melatonin, labelling exemptions from the States and Territories to permit the S4 labelled stock to be treated as an S3 product for a period of time after the implementation date are very unlikely to be granted given the absence of important consumer information from the S4 labels. This means that any S4 stock on hand after the implementation date will need to be re-worked or destroyed. On this point it is worth noting that re-working existing S4 stock into S3 labelling will be complex and expensive.

As described above, sponsors will not know what their approved S3 labels will contain until after the TGA registration application has been completed and the new labelling approved by the TGA.

Sponsors cannot finalise the label artwork, start to procure packaging or begin manufacture until after they have had the label content approved by the TGA.

Sponsors are therefore faced with a series of complex decisions to determine what to do with the existing S4 labelled stock and how soon the new S3 labelled stock could be approved, manufactured, shipped and placed into the market.

Healthcare professional impacts

With the entire melatonin product range moving from S4 to S3 there will need to be careful co-ordination of the training and information provided to both doctors and pharmacists.

S3 materials and protocols will need to be developed and put in place so that pharmacists can supply the newly re-scheduled product appropriately.

As we understand it, pharmacists will not be able to supply S4 labelled melatonin without a prescription after the implementation date. Pharmacists wishing to supply the S4 labelled stock after the implementation date without a prescription will need to comply with a complex legal and professional process (which will involve their over-labelling of the S4 stock).

Advertising

On the basis of the Appendix H entry, the S3 melatonin products will be able to be advertised to consumers (the S4 products cannot).

Prior to the implementation date the products cannot be advertised.

After the implementation date the products can be advertised.

Aligning the implementation date with the likely date at which S3 labelled stock could be in the marketplace is therefore essential to effective communication about the product being developed. Where alignment is not possible, it may be preferable for the implementation date to precede (slightly) the arrival of the S3 stock in the marketplace. Establishing the implementation date in advance of the arrival of the S3 stock will mean that as soon as the S3 stock is available it can be supplied, and it can be advertised. If the S3 stock is on hand before the implementation date, the stock will not be able to be supplied or advertised.

Appropriate implementation date

Ideally, we would like to see an implementation date that coincided with the likely date at which S3 labelled stock could be in the marketplace.

Based on the information above, and on our discussions with affected members and other stakeholders, early in 2021 would be an appropriate time for implementation. We note that the two usual, foreshadowed, implementation dates in this period are 1 February 2021 and 1 June 2021.

Aligning the implementation date with the likely date at which S3 labelled stock could be in the marketplace is essential to effective communication about the product being developed and essential to the straightforward supply of the product by pharmacists. Where alignment is not possible, it would be preferable for the implementation date to precede (slightly) the arrival of the S3 stock in the marketplace so as to allow supply of the product and advertising of the product to occur as soon as the S3 stock is available.

As noted above, there has been conflicting advice as to the relevant regulatory pathway for seeking TGA approval of the new S3 product:

- For the C3 OTC pathway (i.e. 120 working days), approval could be anticipated around late-February 2021 and S3 product could be available closer to the middle of 2021. This would suggest that an implementation date of 1 June would be appropriate.
- For the Cat 3 Prescription pathway (i.e. 45 working days), approval could be anticipated in November 2020 and S3 product could be available in February 2021. This would suggest that an implementation date of 1 February would be appropriate.

Please do not hesitate to contact me should you require anything further.

Kind Regards

Steve Scarff
Regulatory and Legal Director
[redacted]