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26 September 2019
The Secretary
Scheduling Secretariat
GPO Box 9848
Canberra ACT 2601

Email to: medicines.scheduling@health.gov.au

Dear Sir or Madam,

Notice inviting public submissions under regulation 42ZCZK of the *Therapeutic Goods Regulations* 1990. Proposed Amendments to the Poisons Standard to be considered at the ACMS Meeting, November 2019

We refer to the notice inviting public comment under Regulation 42ZCZK of the *Therapeutic Goods Regulations* and would like to provide the comments on the liquid paracetamol scheduling proposal that will be referred to the November 2019 meeting of the ACMS.

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.

CHP Australia appreciates the opportunity to provide public comment in relation to the ACMS agenda. Please find enclosed, under cover of this letter, CHP Australia's comments in relation to the paracetamol scheduling proposal.

As an industry representative, CHP Australia is a key stakeholder in scheduling matters and we are keen to provide further input as required. We look forward to the Delegate's interim decisions and greater detail on the final scheduling proposals.

Please contact me should you require any further clarification relating to this submission.

Yours sincerely,

Steve Scarff
Regulatory and Legal Director

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Paracetamol

Overview

The scheduling proposal is to include a Schedule 4 entry for liquid preparations and to amend the Schedule 2 entry to include the following:

> *"Liquid preparations for oral use containing no greater than 50 mg per mL of paracetamol in 100 mL with a maximum of 50 g paracetamol per container."*

For the reasons outlined below, CHP Australia suggests that the Schedule 2 entry should instead be amended to include the following:

> *"Liquid preparations for oral use containing ~~no greater than 50 mg per mL of paracetamol in 100 mL with~~ a maximum of 50 g paracetamol per container."*

Procedural Issues

It is clear that an error has occurred in the drafting of the proposed change to the Schedule 2 entry for paracetamol. Firstly, because the proposal does not make sense logically or *mathematically*. Secondly, because the proposal *will* have a significant impact on existing S2 products (despite the contrary wording of the invitation to comment and despite written assurances subsequently provided to us).

CHP Australia contacted the TGA on two separate occasions seeking to have the error corrected. The TGA refused to admit to the error and refused to publish a correction, instead we were advised to "*provide a full submission for consideration*" so that "*any unintended consequences of the proposal*" could be incorporated in the advice from the ACMS to the Delegate.

We were further advised that *"there is no intention for the proposed amendments to lower the total volume of liquid paracetamol in products currently available on the market."*

We therefore formally raise the following concerns with the procedure:

- Such an ambiguous/erroneous/incomprehensible proposal creates unnecessary effort/concern as stakeholders need to prepare lengthy responses to all the potential interpretations/misinterpretations instead of simply responding to a clearly articulated proposal (with the follow-on increase in workload for the scheduling secretariat, the Committee, the Delegate etc)

- A proposal of this nature may be inconsistent with the process outlined in the TGA's own Scheduling Handbook[1]
- A proposal of this nature may be inconsistent with the process described in the Act and the Regulations (in particular Regulation 42ZCZK[2] which requires the Secretary to publish a notice of "the proposed amendment" setting out the "details of the proposed amendment")

Before any interim decision is made in relation to the current proposal, the TGA should therefore seek advice as to whether the legislated process has been followed or not. A failure to follow the proper process would leave any subsequent final scheduling decision subject to challenge.

Introduction

Paracetamol has a long history of safe use in Australia. It was first used commercially in Australia in 1956 and paediatric paracetamol products have been available in Australia for over 40 years.

The current Schedule 2 entry for paracetamol includes an upper limit in relation to divided doses (e.g. 100 tablets) (e.g. 50 individually wrapped powders or sachets of granules) but no corresponding upper limit in relation to liquid preparations.

The apparent intention behind this scheduling proposal is to correct an administrative oversight by introducing an upper limit on Schedule 2 products for all paracetamol dosage forms.

We note that the invitation to comment states that the aim is:

> *"… to minimise the risk of accidental poisoning by limiting the total dose in a pack. However, there is no limit on the amount of paracetamol that can be supplied in the liquid form in Schedule 2."*

We have also received subsequent advice from the Scheduling Secretariat that:

> *"As outlined in the published reasons, the intent of the proposal is to place a restriction on the total amount of paracetamol that is available per bottle of formulated liquid preparations for human use. There is no intention for the proposed amendments to lower the total volume of liquid paracetamol in products currently available on the market."* [emphasis added]

[1] https://www.tga.gov.au/publication/scheduling-handbook-guidance-amending-poisons-standard

[2] http://www.austlii.edu au/cgi-bin/viewdoc/au/legis/cth/consol_reg/tgr1990300/s42zczk.html

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To the extent that the proposal would correct an administrative oversight, CHP Australia supports the proposal to include an upper limit on the schedule 2 entry for liquid paracetamol products.

However, CHP Australia does not support the proposal as it is written for the following reasons:

- The "proposal" does not make sense logically or mathematically
- The "proposal" will re-schedule many existing S2 products to S4
- There is no safety signal which would warrant such large-scale re-scheduling of existing products
- Given the erroneous and ambiguous nature of the wording, questions naturally arise as to whether (or not) the specified legislated process has been followed.

The proposal does not make logical or mathematical sense

The proposal is to amend the Schedule 2 entry to include the following:

> *"Liquid preparations for oral use containing no greater than 50 mg per mL of paracetamol in 100 mL with a maximum of 50 g paracetamol per container."* [emphasis added]

As explained below, no product can be imagined which meets all three of the numerical requirements in the proposal (so at least one requirement – and possibly two – are in error).

The proposed amendment to the Schedule 2 entry as a whole does not make sense because the three limits are incompatible:

- 100mL of a liquid containing 50mg/mL would in fact contain a maximum of *5g* of paracetamol (not 50g) (since 50mg x 100 = 5,000mg).
- You would in fact need *1000mL* of a liquid containing 50mg/mL to provide a total of 50g of paracetamol (not 100mL) (since 50mg x 1000 = 50,000mg).
- A concentration of *500mg/mL* would be required to deliver 50g of paracetamol in 100mL (not 50mg/mL) (since 50,000mg divided by 100 = 500mg).

Given that all three numerical requirements cannot be simultaneously complied with, it is therefore not possible to determine what the proposal actually is. Removing one or more of the numerical requirements would create a mathematically possible proposal, but which numerical requirement(s) ought to be removed so as to bring the Delegate's vision to life? Stakeholders cannot know and are left to guess.

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Re-scheduling to S4

The limits chosen will have a significant impact on current S2 products because: (a) existing S2 products do contain paracetamol at a concentration above 50mg/mL (e.g. infant drops at 100mg/mL in 20mL bottles with a dropper/syringe), and (b) existing S2 products are in containers larger than 100mL (e.g. 200mL). However, the stated intention of the proposal is to "minimise the risk of accidental poisoning by limiting the total dose in a pack" (in line with the recent amendments to the paracetamol entries for divided doses to include such an upper limit).

The TGA's invitation to comment lists the currently available products.

If only a 50 mg/mL cut-off was introduced, then the following (struck-through) products would become S4:

- 24 mg/mL paracetamol in 50, 100, 200 and 500 mL pack sizes;
- 48 mg/mL paracetamol in 50, 100, 200 and 500 mL pack sizes;
- 50 mg/mL paracetamol in 60, 100, 200 and 1000 mL pack sizes;
- ~~100 mg/mL paracetamol in 5 and 20 mL pack sizes;~~
- 32.5 mg/mL paracetamol + 1 mg/mL dextromethorphan in 120, 240 and 360 mL pack sizes

If only a 100 mL cut-off was introduced, then the following (struck-through) products would become S4:

- 24 mg/mL paracetamol in 50, 100, ~~200 and 500 mL~~ pack sizes;
- 48 mg/mL paracetamol in 50, 100, ~~200 and 500 mL~~ pack sizes;
- 50 mg/mL paracetamol in 60, 100, ~~200 and 1000 mL~~ pack sizes;
- 100 mg/mL paracetamol in 5 and 20 mL pack sizes;
- 32.5 mg/mL paracetamol + 1 mg/mL dextromethorphan in ~~120, 240 and 360 mL~~ pack sizes

If both the 50 mg/mL and the 100 mL cut-offs were introduced, then the following (struck-through) products would become S4:

- 24 mg/mL paracetamol in 50, 100, ~~200 and 500 mL~~ pack sizes;
- 48 mg/mL paracetamol in 50, 100, ~~200 and 500 mL~~ pack sizes;
- 50 mg/mL paracetamol in 60, 100, ~~200 and 1000 mL~~ pack sizes;
- 100 mg/mL paracetamol in ~~5 and 20 mL~~ pack sizes;
- 32.5 mg/mL paracetamol + 1 mg/mL dextromethorphan in 120, 240 and 360 mL pack sizes

Rather than having no impact on currently available products, these two cut-offs would effectively remove 11 of the 17 current products from the OTC market!

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Of the three numerical requirements in the proposal, only a 50 g total cut-off would permit the existing products to continue as S2s.

50g Upper Limit

CHP Australia would support a 50g upper limit being included in the Schedule 2 entry as this figure would be consistent with that currently in place for tablets (i.e. 100 tablets of 500mg each) and this figure would leave the scheduling of the current products unchanged.

Any other upper limit apart from 50g would need to be justified in terms of the need for the limit and the scientific basis for the limit chosen.

No safety signal

CHP Australia is not aware of any safety signal that would warrant the re-scheduling of any single liquid paracetamol product (much less the bulk rescheduling of 11 of the 17 current OTC products as apparently proposed).

If the Delegate's proposal is based on such information, then the data should be made available (and should have been included with the invitation to comment).

In the absence of any safety signal, re-scheduling is unwarranted.

Conclusion

For the reasons outlined above, CHP Australia suggests that the Schedule 2 entry should instead be amended to include the following:

> *"Liquid preparations for oral use containing ~~no greater than 50 mg per mL of paracetamol in 100 mL with~~ a maximum of 50 g paracetamol per container."*