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

Item 1.3. Interim decision in relation to **calcifediol** referred to the Advisory Committee on Medicines Scheduling (ACMS #28, November 2019)

Item 3.1. Interim decision in relation to **caffeine** referred to the Advisory Committee on Medicines and Chemicals Scheduling in joint session (Joint ACCS/ACMS #23, November 2019)

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Complementary Medicines Australia

CMA is committed to a vital and sustainable complementary medicines sector, and represents stakeholders across the value chain – including manufacturers, raw material suppliers, distributors, consultants, retailers and allied health professionals. The consumer demand for complementary medicines has resulted in the industry becoming a significant contributor to preventative and complementary healthcare.

We welcome the opportunity to respond to the scheduling decisions that are of relevance to our sector, including calcifediol and caffeine, as part of the scheduling consultation published 6 February 2020:

Consultation overview (6 February 2020)

PDF document - Notice of interim decisions made under Regulation 42ZCZN (6 February 2020).

Item 1.3 Interim decision relating to calcifediol

Interim decision

Pursuant to regulation 42ZCZN of the Regulations, a Delegate of the Secretary has, in relation to the proposed amendment, made an interim decision to amend the current Poisons Standard in relation to calcifediol as follows:

Schedule 4 – New Entry
CALCIFEDIOL for human internal therapeutic use **except** in preparations containing 10 micrograms or less of calcifediol per recommended daily dose.

Index – New Entry
CALCIFEDIOL
Schedule 4

The decision relies to some extent on the findings of the assessment of the substance for listed medicines, for which it was decided that 10 micrograms was the appropriate limit. These products can be sold in any retail context.

Calcifediol findings generally suggest that it has a higher rate of intestinal absorption than colecalciferol and is particularly useful when there are conditions associated with decreased intestinal absorption, as well as obesity (given its lower trapping in the adipose tissue), and interferences of drugs with the hepatic cytochrome P-450 enzyme system[1].

Considering its use is consistent with the purpose of calciferol, but more useful in specific circumstances, it would be appropriate to enable sponsors to make applications for the S3 Pharmacist Only category that is equivalent in dose to the Vitamin D entry in Schedule 3:

[1] Cesareo, Roberto et al. "Hypovitaminosis D: Is It Time to Consider the Use of Calcifediol?." *Nutrients* vol. 11,5 1016. 6 May. 2019, doi:10.3390/nu11051016

VITAMIN D for human internal therapeutic use in preparations containing 175 micrograms or less of vitamin D per recommended single weekly dose **except** in preparations containing 25 micrograms or less of vitamin D per recommended daily dose.

For calcifediol, this could mean an equivalent dose of around 60-70 micrograms on a weekly basis could be considered for Schedule 3, pending appropriate evaluation through the registration process, to ensure that health professionals have the tools available to allow patients to access appropriate medicines without the need for managing prescriptions on an ongoing basis unless a higher dose was indicated.

In summary, we propose that it would be appropriate to allow the gradation of access to calcifediol in an equivalent manner to colecalciferol.

Item 3.1 Interim decision relating to caffeine

Interim decision

Pursuant to regulation 42ZCZN of the Regulations, a Delegate of the Secretary has, in relation to the proposed amendment, made an interim decision to amend the current Poisons Standard in relation to caffeine as follows:

Schedule 6 – New Entry

CAFFEINE **except**:

a) when included in Schedule 4; or

in divided preparations for internal human therapeutic use when labelled with a maximum recommended daily dose of no greater than 600 milligrams of total caffeine; or

in undivided preparations for internal human therapeutic use with a concentration of less than 5 per cent of total caffeine and when labelled with a maximum recommended daily dose of no greater than 600 milligrams of total caffeine; or

in preparations for external use; or

in other preparations with a concentration of less than 5 per cent of caffeine.

Schedule 4 – New Entry

CAFFEINE for internal human therapeutic use **except**:

a) in divided preparations when labelled with a maximum recommended daily dose of no greater than 600 milligrams of total caffeine; or

in undivided preparations with a concentration of less than 5 per cent of caffeine and when labelled with a maximum recommended daily dose of no greater than 600 milligrams of total caffeine.

Index – New Entry

CAFFEINE
cross reference: PARACETAMOL, ASPIRIN, SALICYLAMIDE
Schedule 6
Schedule 4

Poisons Standard (Scheduling):

1) We support the S4 new entry Scheduling limit of >600mg MRDD.

2) We support the s4 new entry Scheduling limit of 5% in undivided preparations.

3) We propose that the Schedule 6 entry for preparations for external use must only apply above a certain percentage, so that caffeine as an excipient in topical Listed medicines (including in proprietary ingredients) is accounted for. Caffeine is used as an excipient in many preparations for external use in listed medicines, including proprietary ingredients such as flavours/fragrances/colours. It could cause major market disruption to schedule caffeine in all preparations for external use.

Permissible Ingredients Determination:

For the purposes of consistency and clarity for stakeholders and level application between Listed medicines and foods:

1) Align the listing requirements in the Permissible Ingredient Determination by increasing the limit from 1% to 5% in undivided preparations, once the final Scheduling decision is made effective.

   A very thorough and extensive safety review on the concentration of caffeine in undivided preparations has been conducted by:

   - FSANZ in 2019[2]
   - Scheduling Committee ACCS/ACMS in 2019/2020

   Comparatively, the safety analysis for the 1% caffeine in undivided preparations set for listed medicines was a rapid, less in-depth review, and was not subject to consultation. Now that the full reviews and consultations have occurred via both FSANZ and ACCS/ACMS, the evidence from these is in agreement that a 5% limit in undivided preparations is appropriate. This would create a level playing field between foods and therapeutic goods, and encourage more sponsors to use the therapeutic goods pathway with higher quality TGA GMP requirements.

[2] Food Standards Australia New Zealand (2019). Final consideration report – Urgent Proposal P1054 - **Pure and highly concentrated caffeine products** https://www.foodstandards.gov.au/code/proposals/Documents/P1054%20-%20Final%20consideration%20report.pdf