Technical Alert 11.02.20

Caffeine Scheduling

Caffeine restrictions for Listed Medicines amended in 2019

In 2019, the TGA began a "first round" restriction of caffeine by making restrictions within the Permissible Ingredients Determination, which affect Listed medicines only.

Following a safety review by the TGA on caffeine and caffeine-containing ingredients within listed medicines in 2018, the Therapeutic Goods Amendment (Permissible Ingredients) Determination (No. 1) 2019 commenced on 2 September 2019, outlining new requirements for the use of caffeine.

Among other changes, the TGA imposed in the 26BB list a limit of 33% of caffeine in divided preparations such as tablets and capsules however, undivided preparations have been restricted to 4%, with an upcoming further restriction to 1% in 2021.

Current Scheduling 'interim decision' relating to Caffeine

Currently, there is a "second round" review of restrictions for caffeine that is occurring via the Scheduling mechanisms which results in (inclusion of caffeine in the Poisons Standard. Changes here affect the use of caffeine more widely, and can also influence both Listed and Registered OTC medicine policy.

On 6 February 2020, an interim decision and invitation for further comment on substances referred to the November 2019 ACMS/ACCS meetings was announced by the TGA.

The interim Scheduling decision is open for consultation and due to close on **5 March 2020**.

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, which can be found on **pages 116-134** of the *Notice of interim decisions made under Regulation 42ZCZN of the Therapeutic Goods Regulations 1990* document.

The proposed new Scheduling entry is also included below, with CMA comments.

Schedule 6 – New Entry CAFFEINE **except**: a) when included in Schedule 4; or a) 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 b) 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 c) in preparations for external use; or d) in other preparations with a concentration of less than 5 per cent of caffeine.	*CMA comments* This Schedule 6entry means that caffeine preparations that do not meet the conditions on the left for exclusion from either S4 or S6 would be classified as: **'Poison**: Substances with a moderate potential for causing harm, the extent of which can be reduced through the use of distinctive packaging with strong warnings and safety directions on the label.'
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 b) 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.	Caffeine preparations that do not meet the conditions on the left for Schedule 4 would become Prescription Only. a) The comparative quantity restriction in **Listed medicines** (via the Permissible Ingredients Determination) for **divided preparations** (such as tablets, capsules) is **400mg** from all sources, with only **100mg** from pure (non-herbal) caffeine, no greater than 100 mg of total caffeine within a 3 hour period and a concentration not greater than **33%**. b) The comparative quantity restriction in **Listed medicines** (via the Permissible Ingredients Determination) for **undivided preparations** (such as powders, liquids) is **400mg** from all sources, with only **100mg** from pure (non-herbal) caffeine, no greater than 100 mg of total caffeine within a 3 hour period and concentration not greater than **4%**, with this amount decreasing to **1%** for all Listed medicines from 2 March 2021.
Index – New Entry **CAFFEINE** cross reference: PARACETAMOL, ASPIRIN, SALICYLAMIDE Schedule 6 Schedule 4	

CMA Draft Position

Below are the key points of CMA's draft position, pending further member & Committee feedback:

Poisons Standard (Scheduling):

1) Support the S4 Scheduling limit of >600mg MRDD (based on prior Committee deliberations)
2) Support the Scheduling limit of 5% in undivided preparations (consistent with CMA's previous submission to FSANZ)
3) 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.

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. This is based on the safety analysis for 5% caffeine in undivided preparations by both the Scheduling Committee ACCS/ACMS and FSANZ.
2) That the Permissible Ingredients Determination requirements for caffeine are reviewed for simplification and reduction of red-tape. Currently, the application of either caffeine versus herbs containing caffeine is highly confusing and creates issues with proprietary ingredients.

Submissions to the TGA for this consultation are due on or before **5 March 2020.**
The proposed date of the Poisons Standard amendment is **1 June 2020**.

Member comments, feedback and questions in relation to CMA's position are welcome, please send to Lucy.Lang@cmaustralia.org.au

Resources:

- CMA submission to FSANZ on the pure and highly concentrated caffeine products
- CMA Technical alert - TGA changes to caffeine, 2019.
- TGA High-moderate risk changes to permissible ingredients – Caffeine, 2019

END