***Complementary Medicines Australia SUBMISSION** to FSANZ:*

P1054 – Pure and highly concentrated caffeine products (28 July 2020)

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Complementary Medicines Australia

Complementary Medicines Australia (CMA) welcomes the opportunity to provide comment on the FSANZ Proposal P1054 regarding pure and highly concentrated caffeine products.

CMA is committed to a vital and sustainable complementary medicines sector, and represents stakeholders across the value chain for products regulated as both foods and medicines, including manufacturers, raw material suppliers, distributors, consultants, retailers and allied health professionals.

We support the safe use of substances, foods and medicines, with access through appropriate and balanced risk-based regulation whilst still meeting consumer demand and a thriving, competitive business environment supporting Australia's economy and skilled and manufacturing jobs environment.

Relevant Background

On **1 November 2019**, Food Standards Australia New Zealand called for submissions by **14 November 2019** on an urgent proposal on pure and highly concentrated caffeine products.

In this consultation, CMA supported the proposed limitation of 5% caffeine restriction on Australian retail food products, to address some of the immediate risk posed to consumers by concentrated caffeine containing foods and ensure appropriate regulation to ensure that accidental severe overdoses or deaths do not occur from concentrated products purchased in Australia.

CMA's approach to safe caffeine consumption has been consistent. In May 2018 we advocated to the TGA that adequate advisory statements on therapeutic goods should raise awareness of caffeine levels so that consumers were aware of the level of their caffeine consumption on packaged products, coupled with appropriate quantity restrictions (up to 600mg per day), well before the coroner's report in June 2019 of an accidental overdose from a concentrated product of unknown origin.

Specifically, CMA supported via correspondence to the Therapeutic Goods Administration in May 2018 that listed medicines should contain the following:

> The existing requirement is that the quantity of caffeine is declared where there is >10mg caffeine. We would support the following (additional) precautions for higher-dose caffeine preparations.
>
> - A single dose of up to **100mg or 200mg** (aligned with EFSA 2015 safety evaluation, the Health Canada monograph and other contemporary resources), with at least 3 hours between doses, to a maximum dose of 600mg.
>
> When the route of administration is oral or sublingual..:
> a) ...(existing warning statement)
> b) ...(existing warning statement)
> c) more than **100mg** of caffeine the medicine requires the following warning statements on the medicine label:
> - **"80-100mg caffeine is approximately equivalent to 1 cup of coffee" (or words to that effect).** The statement is similar to ARGOM, and the number is consistent with FSANZ and EFSA and the Australian Beverages Council across different types of coffee.

- **"Pregnant women should limit caffeine to under 200mg caffeine per day" (or words to that effect)**. 200-300mg is consistent with the 2015 EFSA safety evaluation (200mg) and other contemporary sources. Health Canada recommend professional healthcare advice over 301mg.
- **(CHILD2) "Not suitable for children"**

Our submission to P1054 (Nov 2019) also noted that the proposal does not sufficiently mitigate accessibility through import pathways for personal use, and that there are potential risks of Australian overregulation through excessive restriction of in-demand products from consumers may cause some to revert to personal importations of either legal but significantly more concentrated or illegal substances. Therefore, regulatory restrictions must be balanced with consumer demand in order to have the most positive net impact.

Ongoing Necessity for a Whole-of-Government approach to Consumer Goods

In our November 2019 response to P1054 (FSANZ) and in communications to the TGA, we have noted that for caffeine in particular there should be a unified approach. Specifically that there are remaining issues of clarity for stakeholders at the food-medicine interface, recommended that FSANZ collaborate with the TGA and peak industry bodies to arrive at a consistent approach immediately and into the future, as this enables a much clearer, more sensible, and easy to navigate regulatory landscape for both consumers and businesses. Caffeine as a substance does not discriminate between regulatory boundaries.

However, collaboration appears to have not occurred, evident by a "silo-ed" approach continuing between the organisations, a disjointed approach to community consultation between organisations, and the wide gap between formulation and labelling policy approach for relatively similar goods.

The consultation paper discusses that there is currently a "two-pronged" approach to caffeine in foods and listed medicines and notes that there are some similarities, without acknowledging that the two-pronged approach results in different and illogical approaches and confusing information for industry and consumers on a number of products which from a consumer's view may be virtually indistinguishable. This will undoubtedly lead to consumer confusion, possible compliance issues, and other unexpected and discordant outcomes. It is not enough to say that a "two-pronged approach is appropriate", it is clearly inconsistent in a number of respects where it should be consistent, and it is therefore not appropriate. This is further addressed through our submission.

FSANZ are currently consulting extensively on foods, whilst the TGA has not responded to requests to re-open consultation on caffeine in listed medicines as part of the September 2020 consultation on Permissible Ingredients in listed medicines, despite the fact that the approach to caffeine in listed medicines has not been publicly consulted at all, and the approach to caffeine in listed medicines has failed to be the subject of any public consultation at all – despite multiple safety reviews that provide

alternative safety information to that which was arrived at by the TGA without public consultation or formal safety review. While the FSANZ proposal paper puts forth the view that the TGA and FSANZ are aligned in respect of a 5% limit for undivided preparations, this is fact not the case, as by far the main category of therapeutic goods which contain caffeine are listed medicines, which are currently not permitted to include 5% caffeine, they must include 4%, or from March 2021, only 1% - despite this not being subject to formal assessment or consultation. Therefore, foods and therapeutic goods are not primarily aligned at a 5% permissive limit.

Industry members manufacture packaged goods with added caffeine that may fall under either the food category or the therapeutic goods (vastly, listed medicines) category, depending on overall presentation and purpose. Despite this regulatory separation, consumers rarely discriminate between categories when seeking supplemental caffeine. To have a range of fast moving consumer goods which are not distinguished from one another but which have different limits and different warning statements does not result in good Government policy. There may be some partial exceptions to this rule, including specific standards for very specific subsets of products such as Formulated Caffeinated Beverages or the approach for tablets/capsules, but when considering foods and therapeutic goods as classes of goods that both supply caffeine, particularly in powders, liquids, and solids, there needs to be consistency of consultation, assessment and outcome as much as is practicable.

The Australian Public Service Commission's introduction to the concept of the Whole-of-Government raises issues relevant to this consultation:

> *A vital issue for the APS in delivering quality advice, programs and services is ensuring work is effective across organisational boundaries. Making whole of government approaches work better for ministers and government is now a key priority for the APS. There is a need to achieve more effective policy coordination and more timely and effective implementation of government policy decisions, in line with the statutory requirement for the APS to be responsive to the elected government. Ministers and government expect the APS to work across organisational boundaries to develop well informed, comprehensive policy advice and implement government policies in an integrated way.*
>
> *In addition, the Australian public increasingly expects services to individuals, business and communities to be tailored to their particular needs. They expect government to take full advantage of technology to do business better. There is now more expert and informed scrutiny of government, making the public more quickly aware of any approaches that appear to conflict.*

Of all policy issues that stand out as being clearly appropriate for a Whole-of-Government approach, there is none so less than caffeine, a substance in high demand and ubiquitously available in naturally occurring foods as well as formulated, packaged preparations for supplementary use in both foods and therapeutic goods. Caffeine does not discriminate and consumers rarely if ever distinguish between these regulatory siloes, why does the Government's regulatory schemes continue to regulate differently,

consult separately, and reach different conclusions for caffeinated products that are in the main, conceptually and functionally indistinguishable for consumers?

In many circumstances, where there is no other reason to support a separation of approach, industry also seek simplicity and reduced red tape, not an increased complexity and difference in rules.

Future Regulation of Caffeine

For the above reason, we see that the final regulatory outcomes between the approach to foods and listed medicines should not be significantly different unless there are specific supportable, well-examined, consulted-upon reasons to justify a difference for each class of sub-category of goods.

For example, for listed medicines (therapeutic goods), the TGA have a non-consulted limit of 1% that will be applicable to all undivided preparations from March 2021, despite the fact that listed medicines are produced in manufacturing facilities which are required by law to conform with pharmaceutical-level GMP requirements under the international Pharmaceutical Inspection Co-operation Scheme (PIC/S), with regular Product Quality Reviews, in comparison with foods which have less strict manufacturing controls, but are permitted to have up to 5% caffeine. This is illogical Government policy.

Requirements for listed medicines are specified in the Therapeutic Goods (Permissible Ingredients) Determination made under section 26BB of the *Therapeutic Goods Act 1989.*

For foods and listed medicines that are not the subject of a Schedule in the Poisons Standard, and that are not the subject of different specific requirements for the purposes of a specific Food Standard, we support that at a minimum, packaged foods and listed medicines are treated in the same manner on the following items:

CMA preliminary position on caffeine (pending further FSANZ and TGA consultation on more specific details)
Quantity restrictions on liquids (*Liquid caffeine concentrate products* – foods and listed medicines) **1% w/v (**equivalent to 100mg/10mL) **Supported, provided it is harmonisation between foods and listed medicines.**
Quantity restrictions on powders/solids: **5% w/w** **Supported, provided it is harmonisation between foods and listed medicines.** The FSANZ proposal provides that: Ingestion of a single serving of a heaped tablespoon of a caffeine powder containing 5% caffeine would be likely to deliver approximately 825 mg caffeine.1 Acute doses

in this range would be unlikely to cause severe health effects in healthy adults, although they could be expected to be associated with unpleasant effects such as anxiety.

Note: Listed medicines containing >80mg per recommended daily dose are required to include:

- (CAFFLMT) 'Limit the use of caffeine-containing products (including tea and coffee) when taking this product.'

Individually packaged portion-controlled caffeine products

In the context of sports supplements for adults, a higher quantity of caffeine is permitted in foods (for example, 160mg per dose instead of 100mg per dose). This higher quantity per individual dose should be harmonised for sports supplements that could be either foods or listed medicines.

This is particularly relevant to consider in respect of the ongoing Sports Supplements consultation clarifying that some products which are currently regulated as foods will be declared to be therapeutic goods.

Caffeine analogues

This must be considered in respect of the Sports Supplements consultation to ensure there is clarity for industry without causing costly errors or major competitive misalignment for Australian businesses trying to compete for Australian consumers' attention within an international e-commerce landscape.

Sensitive subpopulations – Children

The final consultation outcomes between foods and listed medicines must be consulted together and harmonised unless there is a specific and justifiable reason to take a different approach for a specific sub-category.

Currently, listed medicines require an 'Adults only' statement (or words to that effect) if there is >10mg caffeine per recommended daily dose.

Sensitive subpopulations – Pregnant women

The final consultation outcomes between foods and listed medicines must be consulted together and harmonised unless there is a specific and justifiable reason to take a different approach for a specific sub-category.

Currently, listed medicines with more than 10mg of caffeine per recommended daily dose require:

- (CAFFPREG) 'Caffeine intake more than 200 mg per day is not recommended during pregnancy or breastfeeding.'

For sensitive populations, we note that public health information is more likely to be a successful approach than additional warning statements on formulated products, considering that the majority source of caffeine from pregnant women and children is dietary tea, coffee, and chocolate. Therefore label warnings on a limited number of consumer goods that contain caffeine should not be considered a substitute for a wider and more effective Government approach, and that any crucially necessary warning statements on products should be kept short and effective which has a greater effects on consumers and more achievable for industry.

CYP1A2

Caffeine does not discriminate between sources. The Government must be consistent about their purpose and intent when messaging in regards to caffeine.

The following warning was added to listed medicines containing more than 80mg caffeine, without consultation and without specific justification being provided to the public on its relevance, need, context and usefulness. Medical practitioners do not regularly test for CYP1A2 or apply its meaning in context of caffeine. There are no Government webpages advising consumers on how to approach caffeine in respect of CYP1A2. There do not appear to be any Department of Health medical or consumer guidelines or information, or guidance for medical practitioners by the RACGP in respect of CYP1A2. There are many, many substances including tobacco and foods like cabbage and curcumin that interact with CYP1A2. There are not serious reports of caffeine interaction with CYP1A2 or other drugs. This warning statement is unjustified and out of context for meaningful understanding and application to the community for caffeine and as such we firmly oppose its requirement on both foods and listed medicines:

- (CAFFCYP) 'Caffeine interacts with enzyme CYP1A2 in the liver. Consult your health professional before taking with other medicines' (or words to that effect).

Caffeine present in non-proprietary and proprietary flavouring substances

Any regulations devised must take into consideration that small amounts of caffeine may be present in proprietary flavouring ingredients. The exact information and quantities present in flavouring ingredients may not be available to manufacturers of listed medicines and foods. Any regulations should take this into consideration and not apply requirements to small amounts of caffeine content (such as up to 10mg) as part of flavouring compounds.

Imported products

We note the additional detail provided on goods that imported and packaged for retail sale. In regards to products imported for personal use, we note that there are e-commerce websites that present as if they are or may be Australian websites and promise rapid delivery, and as such, there appears to be a lack of awareness of consumers that they may be purchasing international products or that they have

reduced safety protections. In a world where consumer good purchases increasingly occur in an online e-commerce environment, the Government must consider appropriate measures for consumers and to ensure a balanced approach and relatively fair playing field for local Australian manufacturing, as suggested by the Section 18(2) considerations.

'Prohibit unless Permit' suggestion

The proposal suggests that a 'prohibit unless permit' approach is being considered. We do not consider that this approach is an efficient method of risk reduction. Clear and easy to find messaging on the FSANZ and Government websites for the community including manufacturers, businesses and retailers in Australia is likely to be as effective without the red tape of permits and approvals. Very few businesses in Australia would seek to produce a product with more than 5% caffeine under unrestricted circumstances, and the possibility of it occurring in circumstances where the formulation requirement is easily findable and clearly communicated is almost non-existent. Any very minor residual risk can be defined in the post-market space, which is a more appropriate sphere considering that 'prohibit unless permit' can only be successful if there are no manufacturing issues, consequently it only deals with a portion of the overall risk whilst introducing large amounts of red tape for very minor outcomes. Post-market monitoring would be more cost-efficient and accurate in measuring risk than a pre-market approach.

Overall, we support further consultation, provided there is better harmonisation and consultation between FSANZ and TGA on caffeine specifically.

Thank you for the opportunity to respond to this consultation and please do not hesitate to contact us directly for any clarifications or questions in respect to the complementary health sector.