

PUBLIC SUBMISSIONS ON THE PROPOSED AMENDMENTS TO THE POISONS STANDARD

Regulation 42ZCZL, Therapeutic Goods Regulations 1990 (the Regulations)

A delegate of the Secretary of the Department of Health and Ageing publishes herein 5* valid public submissions made in response to the invitation for public submission on the proposed amendments to the Poisons Standard on 1,3-dimethylamylamine (DMAA). These submissions were considered by the Advisory Committee on Medicines Scheduling (ACMS#6) on 27 June 2012.

In accordance with the requirements of subsection 42ZCZL of the Regulations these submissions have had the confidential information removed.

Material claimed to be commercial-in-confidence was considered against the guidelines for the use and release of confidential information set out in Chapter 6 of the Scheduling Policy Framework (SPF), issued by the National Coordinating Committee on Therapeutic Goods. The SPF is accessible at www.tga.gov.au/industry/scheduling-spf.htm.

*six valid public submissions were received. One public submission has not been published due to the commercial-in-confidential nature of the submission.



To "smp@health.gov.au" <smp@health.gov.au>
cc
bcc
Subject Submission regarding the Scheduling of DMAA [SEC=No Protective Markin

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Submission Regarding the Scheduling of DMAA

The TGA advisory committee is considering scheduling DMAA in schedule 9 of the Therapeutic Goods Act. Schedule 9 is reserved for drugs or poisons with no therapeutic potential. The fear regarding this substance is that its vaso-constrictive effects can increase blood pressure and could therefore create heart attacks in susceptible individuals when taken at high dosages. I propose that S9 is inappropriate for this substance for the following reasons:

- While it is important for the TGA to monitor the potential side effects and dangers of supplements that are on the market, it is also crucial that we remember that any substance used incorrectly, at excessive dosages or by a susceptible individual have the potential for harm (especially those that have marked effects on the human body, such as all medicinal substances).
- Automatic scheduling of these kinds of substances into S9 without a rigorous scientific enquiry into the real harms, risks and benefits has the potential to deny the public substances that can assist them in their health aims.
- Automatic scheduling also limits the scope for scientific research to be conducted, and thereby limits future medical breakthroughs.

Under s52E, certain matters must be taken into account when scheduling a substance, especially the risks and benefits of the use of a substance.

- DMAA is known to be an effective weight-loss and fitness aid, which, although this may not be considered a health outcome in and of itself, has wide-reaching positive health effects due to the numerous chronic health problems associated with obesity in Australia today.
- What is more, DMAA has a similar risk and safety profile to synephrine, which is derived from *Citrus aurantium* immature fruit, and is commonly used in Traditional Chinese Medicine to increase metabolism and boost a sluggish digestion. Despite both synephrine and DMAA displaying similar risks and potentials for harm when used incorrectly, the TGA advisory committee decided to impose a maximum dosage limit, which has effectively mitigated adverse effects from this substance. Above the 100mg cut off limit, synephrine is S4 (pharmacist prescription only), which allows those who can benefit from this

substance, and are not at risk of developing negative side effects, access via the carefully-controlled prescription process.

Section 52E of the Therapeutic Goods Act also requires the purposes for which a substance is to be used, the extent of use of a substance and the potential for abuse of a substance be taken into account. DMAA is widely used across the developed world in body-building and weight loss supplements.

- Users report significant increases in energy and endurance, along with a feeling of wellbeing, without the energy crash associated with high caffeine intake.

Considering the wide-spread use and availability of this substance, it seems highly likely that any potential for abuse would have already been exploited, and be obvious by now. Therefore, one can conclude that **DMAA's potential for abuse is low.**

It is my sincere suggestion that DMAA be treated the same way as synephrine: imposed a maximum dosage of 100mg, and above this level being scheduled in S4.



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Subject Hi [SEC=No Protective Marking]

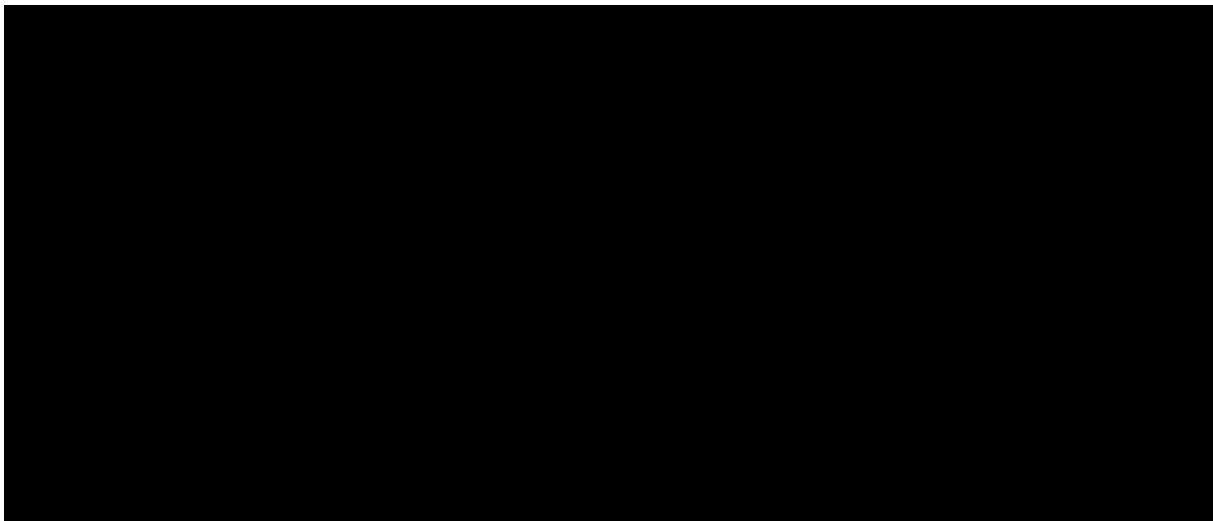
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Hi,

I believe the DMAA when used in correct dosage is 100% safe and effective. This is evident by the fact it has been around for 6 years and there have been no negative effects conclusively linked to the ingredient, whereas in the same period alcohol, tobacco and obesity has killed a countless amount of people.

So, I oppose this ban, I believe being stricter on quality and quantity would be more suitable for this ingredient.

Otherwise, why not ban caffeine and vitamin b next?





To "SMP@health.gov.au" <SMP@health.gov.au>
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Subject Proposal to include DMAA in Schedule 9. [SEC=No Protective Marking]

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Pre-workout powders that contain Geranium are no stronger than a couple cups of coffee. The main ingredients of the products that might be banned are Beta-Alanine and Creatine. The dmaa is only an extra energy spike. The tingling sensation some people feel when taking these products comes from beta-alanine, an amino acid proven to improve strength and endurance during muscle contractions.

Someone in New Zealand died after taking the equivalent of 22 scoops of a certain pre-workout product and drank a huge amount of alcohol. There will always be a very small minority that will abuse these types of products. Pre-workout powders are used because of the ability to keep the steroid free weightlifter in positive nitrogen balance so they do not become catabolic during exercise. Dmaa and caffeine provide some energy to get motivated for your workout.

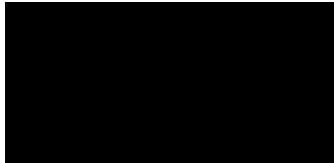
If you follow the direction on the products label there are no side effects at all and the energy provided is quite low really.

Not all pre-workout products contain Dmaa and are just as good for energy. I find caffeine to be much stronger than geranium and will probably just drink a few cups of coffee before my workout if Geranium is banned.

I feel that it should be up to the individual to decide what products they choose on their path to fitness. I've been using most brands of pre-workout powders on the Australian market, even when I was in the Army, and never had a problem. And I've never heard of anyone having problems with these products. It would be a disgrace to ban a product because of a little bit of naturally occurring Geranium.

Looks like Big Brother is getting worse every year.

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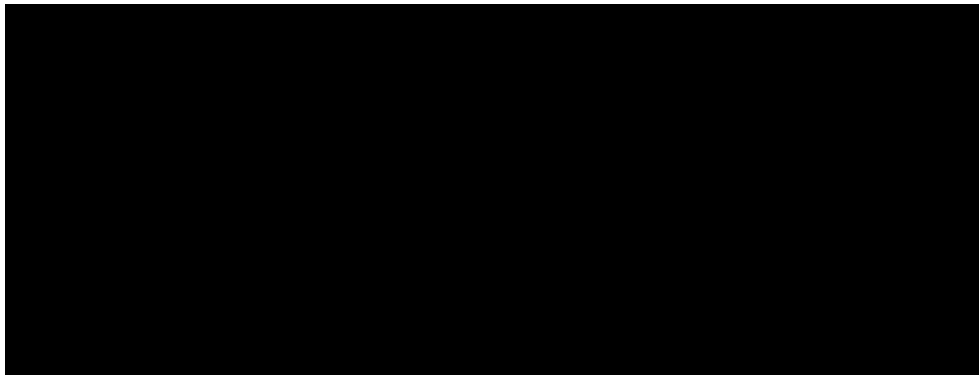
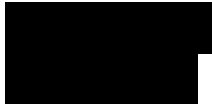
Subject Ban of DMAA [SEC=No Protective Marking]

DOCUMENT NOT YET CLASSIFIED

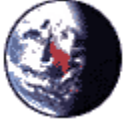
To the Scheduling Secretary,

DMAA (1,3-dimethylamylamine) has been around and in use for over 6 years and there have been no negative effects conclusively linked to it. How many deaths have been caused by legal substances such as alcohol and tobacco, not to mention correctly and incorrectly prescribed pharmaceutical medicines.

Regulating the dosages of this ingredient would be a far more effective approach.



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Subject DMAA in Australia and within Supplements sold in Australia [SEC=No Protection]

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It is nothing more than a pure shame that this ingredient has been allowed to be sold within Australia for as long as it has. From its origin of being used within party pills in New Zealand to its use by supplement companies and stores to sell products for no other reason than it's addictive properties.

As an Australian [REDACTED] I am really appalled that both New Zealand and the US have banned this ingredient before Australia. Especially when there were so many people like myself that spoke up years ago about this.

If up to me you couldn't ban DMAA quick enough. Tomorrow is too late.

