



# Classification of 1,3-dimethylamylamine (DMAA)

Submission to the Medicines Classification Committee

**Medsafe**  
**July 2015**



New Zealand Government

## Background

1,3-dimethylamylamine (DMAA) is a straight chain aliphatic amine with sympathomimetic physiological effects.

DMAA was first synthesized and patented in 1944 by pharmaceutical company Eli Lilly. It was originally patented as a nasal decongestant.

DMAA is currently commonly sold in dietary supplements (usually for weight loss by appetite suppression), pre-workout supplements (due to its stimulant properties) and in a range of over-the-counter party pills.

DMAA is not found in any food stuff that is considered a normal part of the human diet. Therefore, it was Medsafe's view prior to 2008 that DMAA did not meet the definition of a dietary supplement and should not be regulated under the Dietary Supplement Regulations 1985.

In August 2008, the Ministry of Health made a submission<sup>1</sup> regarding DMAA to the Expert Advisory Committee on Drugs (EACD). Following restrictions on the use of benzylpiperazine, DMAA was also identified as the active ingredient in party pills. At their meeting on 5 November 2009<sup>2</sup>, the EACD noted that the Minister of Health had accepted their advice that DMAA should be scheduled as a restricted substance. However, at that time there was insufficient evidence of harm to make a decision to classify DMAA under the Misuse of Drugs Act 1975.

Based on its stimulant properties, DMAA is currently regulated under the Psychoactive Substances Act 2013. However, the Psychoactive Substances Regulatory Authority has indicated that it is unlikely that a psychoactive product containing DMAA would be approved. This is because the substance itself poses more than a low risk of harm which is contrary to the principles of the Psychoactive Substances Act 2013.

DMAA was placed under a Temporary Class Drug Notice pursuant to section 4(c) of the Misuse of Drugs Act 1975. The Temporary Class Drug Notice was in place from 9 April 2012 until 18 July 2013, when the Psychoactive Substances Act 2013 came into effect.

In October 2014, the Ministry of Health made another submission<sup>3</sup> to the EACD. This submission was made due to the concern that there was the potential for DMAA containing products to be supplied as dietary supplements or food. This is because the Dietary Supplement Regulations 1985 and the Food Act 1981 take precedence over the Psychoactive Substances Act 2013.

At their meeting on 23 October 2014<sup>4</sup>, the EACD acknowledged the potential of DMAA to cause harm and agreed that the substance required regulation. The EACD considered that DMAA does not meet enough of the criteria or reach the appropriate harm threshold in order to be classified as a controlled drug. It was therefore recommended that DMAA be referred to the Categorisation Committee for consideration on the basis that the substance was originally developed as a medicine and is structurally and functionally similar to a substance which is scheduled as a pharmacy-only medicine. If the Categorisation Committee agreed that DMAA is a medicine, the Categorisation Committee would refer DMAA to the Medicines Classification Committee for classification.

In March 2015, a categorisation decision<sup>5</sup> was made by the Categorisation Committee that confirmed DMAA as a medicine. The current classification of DMAA is general sale medicine because this is the default in New Zealand.

This submission for classification requests that DMAA is classified as a prescription medicine; except when present as an unmodified, naturally occurring substance.

Although the structural and functional analogue of DMAA, 2-aminoheptane, is classified as a pharmacy-only medicine in New Zealand, there has not been enough market experience for this new medicine to also be classified as pharmacy-only. Based on the lack of evidence of safety and need for consumer access, Medsafe considers the prescription medicine classification to be more appropriate.

Evidence suggests it is likely that DMAA does occur naturally in geranium plants, although in negligible amounts levels can vary from undetectable to between 500 ppb and 13 ppm<sup>6</sup>. Therefore the statement 'except when present as an unmodified, naturally occurring substance' will exclude any naturally occurring substance when not used for a therapeutic purpose.

## Part A

**1. International Non-proprietary Name (or British Approved Name or US Adopted Name) of the medicine**

1,3-dimethylamylamine (DMAA).

**2. Proprietary name(s)**

DMAA has never been marketed as a medicine in New Zealand.

**3. Name of the company / organisation / individual requesting a reclassification**

Medsafe – following advice from the Categorisation Committee.

**4. Dose form(s) and strength(s) for which a change is sought**

Not applicable.

**5. Pack size and other qualifications**

Not applicable.

**6. Indications for which a change is sought**

Not applicable.

**7. Present classification of the medicine**

General sale medicine.

**8. Classification sought**

Prescription medicine; except when present as an unmodified, naturally occurring substance.

**9. Classification status in other countries (especially Australia, UK, USA, Canada)**

DMAA is banned by the United States Food and Drug Administration<sup>7</sup>, Therapeutic Goods Administration (Australia)<sup>8</sup>, and by Irish, Swedish, Danish and Finnish Authorities<sup>3</sup>. It is also listed in Appendix C of the Australian Poisons Standard (July 2015) meaning that the sale, supply and use would be prohibited because DMAA is considered to be a substance of such danger to warrant this<sup>9</sup>.

DMAA is not authorised for use in food supplements in the European Union and is a prohibited stimulant according to the World Anti-Doping Agency<sup>9</sup>.

Health Canada classified DMAA as a drug, subject to its Food and Drug Regulations. Health Canada has further clarified that DMAA is not an acceptable non-medicinal ingredient in drugs or natural health products or as a food additive due to its pharmacological activity<sup>10</sup>.

In the United Kingdom, the Medicines and Healthcare Products Regulatory Agency ruled that a sports supplement containing DMAA is an unlicensed medicinal product and that it, and all other DMAA containing products, need to be removed from the market amid concerns of potential risks to public safety<sup>11</sup>.

**10. Extent of usage in New Zealand and elsewhere (eg, sales volumes) and dates of original consent to distribute**

Unknown.

**11. Labelling or draft labelling for the proposed new presentation(s)**

Not applicable.

**12. Proposed warning statements if applicable**

Not applicable.

**13. Other products containing the same active ingredient(s) and which would be affected by the proposed change**

DMAA is commonly sold in dietary supplements, pre-workout supplements and in a range of over-the-counter party pills.

The exact number of products is unknown.

**Part B**

**Reason for requesting classification change**

**1. A statement of the benefits to both the consumer and to the public expected from the proposed change**

The primary aim of this classification is to reduce the risks, to the consumer and to the public, associated with DMAA use.

**2. Potential risk of harm to the consumer as a result of the proposed change, and factors to mitigate this risk**

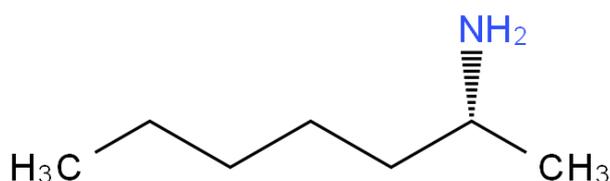
There is no risk of harm to the consumer as a result of classifying DMAA.

**3. Ease of self-diagnosis or diagnosis by a pharmacist for the condition indicated**

Not applicable.

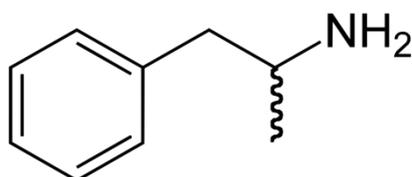
**4. Relevant comparative data for like compounds**

DMAA is structurally and functionally similar to 2-aminoheptane and is a physiological stimulant banned by the World Anti-Doping Agency (WADA). There are currently no approved medicines containing 2-aminoheptane (shown below) in New Zealand, but one previous product was marketed as a nasal decongestant<sup>3</sup>.



(CAS # 123-82-0)

DMAA is also structurally similar to the amphetamines, shown below (although it lacks the characteristic ring structure). One study showed that DMAA was the cause of 92.3% of the false positive results in amphetamine screening kits used by the United States Department of Defence drug screening laboratories<sup>12</sup>.



(CAS # 300-62-9)

**5. Local data or special considerations relating to New Zealand**

Users of DMAA are likely to have already converted to the use of other substances since it has effectively been banned in New Zealand for the last two years<sup>3</sup>. Because the addictive potential is low, users of DMAA are likely to convert to different products.

**6. Interactions with other medicines**

Unknown.

**7. Contraindications and precautions**

Unknown.

## **8. Possible resistance**

Not applicable.

## **9. Adverse events – nature, frequency, etc**

Medsafe is aware of the following case reports of adverse effects in users of DMAA in New Zealand:

- a. 30 year old female experienced headache, vomiting, agitation and hypertension after DMAA ingestion<sup>1</sup>.
- b. 30 year old male experienced severe headache, vomiting, agitation and hypertension after DMAA ingestion and potentially injecting it. A CT scan ruled out the potential for cerebral haemorrhage<sup>1</sup>.
- c. 17 year old male experienced severe headache, nausea and vomiting, and marked hypertension after ingesting two party pills assumed to contain DMAA<sup>1</sup>.
- d. 45 year old male experienced a haemorrhagic stroke after consuming DMAA<sup>1</sup>.
- e. 33 year old male experienced abdominal pain, hypertension and coldness and ingesting a party pill containing DMAA (report from the Centre of Adverse Reactions Monitoring database).

The main effects of DMAA therefore appear to be severe headache, nausea and vomiting, and hypertension. The hypertension was significant enough to require treatment and has the potential to cause stroke.

Long term effects remain unknown.

## References

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6. Thomas DG. 2013. Evidence for the Presence of 1,3-dimethylamylamine (1,3-DMAA) in Geranium Plant Materials. *Analytical Chemistry Insights*. (8): 29-40.
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