FINAL DECISION & REASONS FOR DECISION BY DELEGATE OF THE SECRETARY TO THE DEPARTMENT OF HEALTH AND AGEING

AUGUST 2012

The following is the delegate's final decision and reasons on the scheduling of 1,3-dimethylamylamine (DMAA) referred to the June 2012 meeting of the Advisory Committee on Medicines Scheduling (ACMS) [**ACMS#6**].

Notice under subsections 42ZXZS and 42ZCZX of the Therapeutic Goods Regulations 1990 (the Regulations)

A delegate of the Secretary to the Department of Health and Ageing hereby gives notice of delegate's final decisions for amending the Poisons Standard (commonly referred to as the *Standard for the Uniform Scheduling of Medicines and Poisons* – SUSMP) under subsections 42ZCZS and 42ZCZX of the Regulations. This notice also provides the reasons for each decision and the date of effect of the decision.

Matter referred to ACMS#6

The delegate's interim decision on advice and recommendations on 1,3-dimethylamylamine (DMAA) from the ACMS#6 was published on 10 July 2012, accessible at http://www.tga.gov.au/industry/scheduling-decisions-1207-interim.htm. This public notice invited further comment from the applicant and from those parties who made a submission in response to the original invitation for submissions.

Further submissions from parties other than those who made an initial submission in response to the original invitation, or from the applicant, or those submissions received after the closing date, may not be considered by the delegate.

Redacted versions of further public submissions on the interim decision are also available at http://www.tga.gov.au/industry/scheduling-submissions.htm.

In accordance with subsection 42ZCZR of the Regulations, if a delegate makes an interim decision on an application, that delegate may make a final decision confirming, varying or setting aside the interim decision only after considering any further valid submissions.

Implementation

The SUSMP and its amendments are available electronically at the ComLaw website, a link to which can be found at www.tga.gov.au/industry/scheduling-poisons-standard.htm.

TABLE OF CONTENTS

FINAL DECISION ON MATTERS REFERRED TO AN ADVISORY COMMITTEE

1. MATTERS INITIALLY REFERRED TO ACMS#6 – JUNE 2012

1.1 1,3-dimethylamylamine (DMAA)

SCHEDULING PROPOSAL

The medicines scheduling delegate initiated a proposal to include of 1,3-dimethylamylamine (DMAA) in Schedule 9 of the Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP). This was in response to New Zealand's temporary Class Drug Notice of 8 March 2012 advising that DMAA would be classified as a temporary class drug (equivalent to Schedule 9). New Zealand's temporary prohibition of DMAA came into effect on 9 April 2012.

SCHEDULING STATUS

DMAA is not specifically scheduled in Australia.

PRE-MEETING SUBMISSIONS

Six pre-meeting submissions were received. One submission supported the proposed prohibition, noting that DMAA is addictive. The other five submissions did not support the prohibition, indicating that DMAA is safe, effective and has no negative health effects. One submission also suggested that DMAA be regulated rather prohibited.

The redacted public submissions are available at http://www.tga.gov.au/industry/scheduling-submissions.htm

ADVISORY COMMITTEE ON MEDICINES SCHEDULING (ACMS) DISCUSSION

The Committee considered the referral from the medicines scheduling delegate to include 1,3-dimethylamine or 4-methylhexane-2-amine (DMAA) in Schedule 9 of the Standard for the Uniform Scheduling of Medicines and Poisons.

Members deliberated over the proposed scheduling of DMAA and whether it should be included in Schedule 4, Schedule 9 or Appendix C. Members noted that:

- There is inadequate evidence to suggest DMAA's toxicological and pharmacological properties warrant a Schedule 9 listing.
- DMAA is not listed in either Schedule IV to the *United Nations Convention on Narcotic Drugs, 1961* or in Schedule 1 to the *United Nations Convention on Psychotropic Substances, 1971*.

- There is a lack of supporting evidence to reach the conclusion that DMAA needs the same level of control as amphetamine.
- DMAA's toxicological properties meet the Appendix C scheduling criteria.

Members agreed that DMAA should be included in Appendix C for the following reasons:

- DMAA has no current accepted therapeutic use.
- DMAA has a stimulant effect which can induce a psychoactive effect.
- DMAA is being actively promoted and used as a party drug as well as a sports supplement.
- There is no real evidence of dependence on DMAA.
- There are a number of significant adverse events including cardiac, nervous and psychiatric disorders that have been reported with use of DMAA including cerebral haemorrhage and heart attacks.
- The potential for misuse and abuse is high.

DELEGATE'S CONSIDERATION

The delegate considered the following in regards to this proposal:

- New Zealand's temporary Class Notice;
- International scheduling decisions, including the United States FDA, Canada and United Kingdom;
- public submissions received;
- ACMS advice;
- section 52E of the *Therapeutic Goods Act 1989*;
- scheduling factors[1];
- other relevant information.

DELEGATE'S INTERIM DECISION

The medicines scheduling delegate made an interim decision on 10 July 2012 to include 1,3-dimethylamylamine in Schedule 9 of the SUSMP. The delegate also agreed to the inclusion of a cross reference to the index from DMAA to 1,3-dimethylamylamine and 4-methylhexane-2-amine.

The proposed implementation date for this decision was 1 August 2012.

The delegate decided that the relevant matters under section 52E(1) of the *Therapeutic Goods Act 1989* include (a) risks and benefits of the use of a substance, (b) the purposes for which a substance is to be used and the extent of use of a substance, (c) the toxicity of a substance, and (e) the potential for abuse of a substance.

In response to safety concerns surrounding the abuse of DMAA and following advice from the ACMS and public consultation, the delegate has made an interim decision to include

[1] Scheduling Policy Framework for Medicines and Chemicals http://www.tga.gov.au/industry/scheduling-spf.htm

DMAA in Schedule 9 of the SUSMP. The decision to introduce broader controls on DMAA included the following reasons:

- there are no current approved therapeutic uses for DMAA;
- there are no benefits but there are significant risks;
- there are risks due to DMAA's toxicity;
- DMAA presents a high risk of abuse, misuse and illicit use;
- reports of adverse events including high blood pressure, psychiatric disorders, cerebral haemorrhage and stroke;
- an absence of studies demonstrating the long-term safety of DMAA; and
- the wide variability in the potency of the different doses of DMAA.

SUBMISSIONS ON INTERIM DECISION

Three public submissions[2] were received. These submissions were not in support of the interim decision.

The redacted public submissions are available at http://www.tga.gov.au/industry/scheduling-submissions.htm

DELEGATE'S FINAL DECISION

The delegate has made a final decision to include, 3-dimethylamine or 4-methylhexane-2-amine (DMAA) in Appendix C of the SUSMP.

The delegate also agreed to the inclusion of a cross reference to the index from DMAA to 1,3-dimethylamylamine and 4-methylhexane-2-amine.

The implementation date for this decision is 8 August 2012.

The delegate decided that the relevant matters under section 52E(1) of the *Therapeutic Goods Act 1989* include (a) risks and benefits of the use of a substance, (b) the purposes for which a substance is to be used and the extent of use of a substance, (c) the toxicity of a substance, and (e) the potential for abuse of a substance.

The decision to introduce broader controls on DMAA included the following reasons:

- there are no current approved therapeutic uses for DMAA;
- there are no benefits but there are significant documented risks;
- DMAA is widely used in supplements and is being used as a party drug;
- there are risks due to DMAA's toxicity;
- DMAA presents a high risk of abuse, misuse and illicit use;
- reports of adverse events including high blood pressure, psychiatric disorders, cerebral haemorrhage and stroke;

[2] As per sub-section 42ZCZP (C) of the Therapeutic Goods Regulations 1990, the delegate invites those who made a submission in response to the original invitation to again provide further comment on the interim decision. Any submissions that are provided outside the parameters of the scheduling framework, are forwarded to the delegate for consideration but are not made publically available.

- an absence of studies demonstrating the long-term safety of DMAA; and
- the wide variability in the potency of the different doses of DMAA.

NEW SCHEDULE ENTRY

Appendix C – New entry

1,3-DIMETHYLAMYLAMINE (DMAA).

SUSMP Index – New cross-reference entries

DMAA
See 1,3- DIMETHYLAMYLAMINE

4-METHYLHEXANE-2-AMINE

See 1,3- DIMETHYLAMYLAMINE