

26 April 2012

Partner
Mark Love

BY POST & EMAIL: fiona@eros.org.au

Contact
John Larkings
Nathan Moy

The Eros Association Inc.
PO BOX 69
Deakin West ACT 2600

Our Reference
20120981

Attention: Ms Fiona Patten, Executive Officer

PRIVATE & CONFIDENTIAL

Dear Fiona,

**ADVICE ON THERAPEUTIC GOODS ADMINISTRATION DELEGATE DECISION
TO CREATE A NEW GROUP OF CANNABINOMIMETICS**

We refer to your email of 17 April 2012 in which you forwarded some comments from a member raising some issues with our advice of 16 April 2012. We respond to those comments as follows:

Comment 1

2.3 The issue is not about cannabinoids, but about 'cannabinoid agonists'. Hence your advice that the substances may already be illegal is invalid. Synthetic cannabinoids have always been illegal - synthetic cannabinoid agonists [that are non-cannabinoid in structure] are not. In fact, the new legislation has nothing to do with synthetic cannabinoids even if that name is frequently used on all sides.

1. Our paragraph 2.3 related to the importation of prohibited substances and the general prohibition on cannabinoids. In that specific paragraph, our advice referred to synthetic cannabinoids in a general manner and it does not refer to the newly scheduled substances. That issue is addressed in paragraph 2.4.

Comment 2

2.4 This advice is misleading. Regulation changes do not need to go through parliament and can be altered in a matter of days via ministerial decree.

2. Our paragraph 2.3 relates to the *Customs (Prohibited Imports) Regulations 1956*, which is a Commonwealth regulation. Commonwealth regulations must be tabled before Federal parliament. This is to provide Parliament with an opportunity to disallow the regulations because they are drafted without consultation from the legislature. Our advice never said that the Commonwealth regulatory changes "need to go through parliament".

Comment 3

3.2 and 3.4 In WA the poisons standard is automatically incorporated into their poisons list. Here is the relevant Section: Schedule 9 All substances listed in Schedule 9 to the SUSMP, subject to the following modification —The following substances are added to Schedule 9 to the SUSMP —

In NSW the poisons standard is automatically included in the Poisons Act: The "Poisons and Therapeutic Goods Act" of NSW part 4A, division 1, section 31 states: Part 4A Application in New South Wales of Commonwealth therapeutic goods laws Division 1 31 Application of Commonwealth therapeutic goods laws to New South Wales (1) The Commonwealth therapeutic goods laws, as in force for the time being and as modified by or under this Part, apply as a law of New South Wales.

3. There is an important difference between the Poisons Standard (Cth) being *incorporated* into a state or territory poisons lists and the *illegalisation of possession* of prohibited substances under the *Drug Misuse and Trafficking Act 1985* (NSW) and the *Misuse of Drugs Act 1981* (WA).
4. The mere incorporation of a prohibited substance in the Western Australian Poisons List and the New South Wales Poisons List does not have the effect of incorporating the prohibited substance into relevant schedules to the *Drug Misuse and Trafficking Act 1985* (NSW) and the *Misuse of Drugs Act 1981* (WA), although it does in other jurisdictions such as the Australian Capital Territory where the Poisons Standard (Cth) is automatically adopted in respect of the regulation of possession of prohibited substances.
5. Schedule 9 of Appendix A to the *Poisons Act 1964* (WA) (the **WA Poisons Act**) does automatically adopt the substances listed in all schedules of the Poisons Standard (Cth). The adoption is subject to the Minister's powers in ss 20A and 21 of the WA Poisons Act to publish orders varying the WA schedule or the way substances are described in the schedule. As per our advice, the use of the Poisons Standard is *permissive* in Western Australia and the WA Government has the power to vary the way in which the Poisons Standard is incorporated into WA law, or how prohibited substances are banned generally, noting that WA was the first jurisdiction to ban a number of synthetic cannabinoids.
6. With respect to NSW, we note that whilst the *Therapeutic Goods Act 1989* (Cth) (the **Commonwealth Therapeutic Goods Act**) is incorporated into NSW law by s 31 of the *Poisons and Therapeutic Goods Act 1966* (NSW) (the **NSW Therapeutic Goods Act**), this does not mean that Schedule 9 of the Poisons Standard is automatically incorporated into NSW law. This is because:
 - a. the meaning of 'Commonwealth therapeutic laws' in s 4 of the NSW Therapeutic Goods Act is as follows:

Commonwealth therapeutic goods laws means:

 - (a) the *Therapeutic Goods Act 1989* of the Commonwealth, and
 - (b) all regulations, orders and manufacturing principles in force under that Act.
 - b. The Commonwealth therapeutic goods laws do not regulate the sale, *possession*, supply, manufacture or administration of prohibited substances listed in Schedule 9. These laws are concerned with the sale, possession, supply, manufacture or

administration of *therapeutic goods* (that is, goods which have a defined therapeutic use).

7. As set out in s 4 of the Commonwealth Therapeutic Goods Act, the purpose of the Poisons Standard is to provide the states and territories with a framework for the regulation of poisons in Australia (including prohibited substances in Schedule 9). The implementation laws concerning the sale, *possession*, supply, manufacture or administration of Schedule 9 substances is a matter for the States and Territories. This is confirmed in the Scheduling Policy Framework For Medicines And Chemicals (1 July 2010) (the **Guidelines**). The Guidelines relevantly state:

State and territory governments are responsible for imposing legislative controls on the supply of poisons. Generally, these controls flow from the schedule in which the poison has been included.¹

8. NSW gives effect to the national framework in the Poisons Standard (as it relates to Schedule 9) through the *Drug Misuse and Trafficking Act 1985* (NSW) (the Drug Misuse and Trafficking Act) which creates a series of offences relating to the sale, possession, supply, manufacture or administration of prohibited substances (set out in Schedules 1 and 2 to this Act).
9. Sections 44 and 44A of the Drug Misuse and Trafficking Act provides that the prohibited substances list in NSW can be amended by regulation. For example in 2011, the NSW government adopted the inclusion of a number of synthetic cannabinoids in the Poisons Standard into NSW law by the *Drug Misuse and Trafficking Amendment (Prohibited Drugs) Regulation 2011* (NSW). We expect that a similar regulation will be required to adopt the current proposed changes into NSW law.

Comment 4

5.2 & 5.3 With respect, I don't think the author has understood the question.

10. We reiterate our advice that the stated public policy intention is that (1) all synthetic cannabinoids will be captured by the amendments to Schedule 9 with the intent of limiting the promotion of 'legal mixes' that are not caught by the present individual listings and (2) accordingly the 'synthetic cannabinomimetics' entry (and the derivatives clause in the Poisons Standard) will capture *all chemical compounds mimicking the effects of a cannabinoid* regardless of their chemical composition.

Comment 4

7.10 The whole of question 10 is about whether blanket class schedules are within the delegate's power, yet much of this opinion is unrelated. There is a guideline somewhere that requires the delegate to schedule specific substances rather than groups [I don't know where this guideline is, but even the delegate refers to it in one of the record of reasons related to Viagra. The power to schedule groups was already questioned with the Viagra class scheduling. This was actually the only question that wasn't obvious and it would have been nice to see a good legal opinion on this. It seems to me that the author is not aware of the scheduling guidelines.

11. The Guidelines currently allow group entries where there is a chemical group with similar toxicological or pharmacological activity² provided that the Secretary

¹ Scheduling Policy Framework For Medicines And Chemicals (1 July 2010), page 1

determines what description is to be used and the scope of the entry. Whilst the Poisons Standard recognises a move towards scheduling individual substances (refer to page vii of the Poisons Standard), it also states that 'exceptions are necessary in some cases' and group entries will be retained where considered appropriate.

12. We reiterate our advice at paragraphs 7.7 to 7.15 of our letter of 16 April 2012.

If you wish to discuss further, please contact our Mr Nathan Moy or Mr John Larkings on (02) 6263 9900.

Yours faithfully,

WILLIAMS LOVE & NICOL

A handwritten signature in blue ink, consisting of a circular loop followed by a long, wavy horizontal line that ends in a small upward tick.

² Poisons Standard (Cth), Federal Register of Legislative Instruments F2011L01612, page viii.