16 April 2012

Partner
Mark Love

Contact
John Larkings
Nathan Moy

Our Reference
20120981

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

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

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 your instructions to provide advice in respect of the final decision of the delegate of the Secretary of the Department of Health and Ageing (the **Department**) to schedule certain substances, including an entry for all synthetic cannabinomimetics. You have instructed us to advise specifically in relation to the following issues:

1. As of 1 May will it be illegal to import the new scheduled substances into Australia? Will it also be illegal to possess these substances or would that only come into effect when the states amend their respective legislation?

2. How fast can the individual states add the schedule changes to their own laws?

3. If a compound were able to mimic the effects of a cannabinoid yet work on another receptor such as a 5-HT receptor would this still fall under the new group entry?

4. If a substance is sold for non-human consumption, is it still subject to the schedule?

   (This will not involve advice in relation to whether any such importation might constitute a scheme to evade the restrictions contained in relevant regulation and legislation)

5. Has the committee's recommendation for a proposed blanket listing to include all synthetic ingredients, compounds, materials and preparations without naming individual or class listing as a cannabinoid substance by systemic name exceeded the powers of the TGA because it fails to observe the preliminary requirements contained in parts a, b, c, d and e of subsection 1 of s 52E of the *Therapeutic Goods Act 1989* (Cth)?

6. How would a case in the Federal Court to contest the validity of such a law fare? Would you expect that all the states would seek leave to present their argument in such a case?

Level 8, 28 University Avenue Canberra City ACT 2600 | GPO Box 3243 Canberra ACT 2601 | T +61 2 6263 9900 F +61 2 6263 9999 | DX 5626 CANBERRA www.wln.com.au
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1. Background

1.1 In February 2012, the delegate of the Secretary of the Department made a final decision (the **Decision**) pursuant to s 52D(2) of the *Therapeutic Goods Act 1989* (Cth) (the **Therapeutic Goods Act**) to create new entries for a number of synthetic cannabinoids in Schedule 9 of the *Standard for the Uniform Scheduling of Medicines and Poisons* (the **Poisons Standard**) as follows:

> **Schedule 9 – New entries**
>
> BENZOYLINDOLES **except** when separately specified in these Schedules.
>
> CYCLOHEXYLPHENOLS **except** when separately specified in these Schedules.
>
> DIBENZOPYRANS **except** when separately specified in these Schedules.
>
> NAPHTHOYLINDOLES **except** when separately specified in these Schedules.
>
> NAPHTHYLMETHYLINDOLES **except** when separately specified in these Schedules.
>
> NAPHTHOYLPYRROLES **except** when separately specified in these Schedules.
>
> NAPHTHYLMETHYLINDENES **except** when separately specified in these Schedules.
>
> PHENYLACETYLINDOLES **except** when separately specified in these Schedules.
>
> SYNTHETIC CANNABINOMIMETICS **except** when separately specified in these Schedules.

1.2 The Poisons Standard is enabled by the Therapeutic Goods Act and provides a framework for the States and Territories to adopt a uniform approach to control the availability and accessibility, and to ensure the safe handling, of poisons in Australia.[1] The relevant language of the Poisons Standard is that it provides recommendations of what substances *should* be prohibited. The scheduling of poisons is implemented through relevant State and Territory legislation.[2]

1.3 The Poisons Standard contains nine schedules although only Schedules 2-9 are used. Generally speaking, medicines are included in Schedules 2, 3, 4 and 8; poisons are included in Schedules 5, 6 and 7; and prohibited substances (such as cannabis and heroin) are included in Schedule 9. The Poisons Standard also contains a number of appendices which supplement the schedules by setting out additional controls, qualifications and exceptions for some substances.[3]

1.4 The manufacture, possession, sale or use of Schedule 9 substances is prohibited by State and Territory laws except when required for medical or scientific research, or for analytical, teaching or training purposes with approval of Commonwealth and/or State or Territory health authorities.

1.5 It is apparent from the Decision that:

(a) The scheduling of synthetic cannabinoids followed a request in May 2011 by the Western Australian State Drugs and Poisons Unit for the scheduling of:

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[1] *Therapeutic Goods Act 1989* (Cth), s 4(1); Explanatory Statement – Poisons Standard 2011 (F2011L01612)

[2] Introduction to the Poisons Standard, Page v

[3] *Roche Products v NDPSC* (2007) 163 FCR 451 per Branson J at 458 (paragraph 23)

(i.) individual synthetic cannabinoids with demonstrated harmful effects or potential for significant harmful effects; and

(ii.) broader synthetic cannabinoid groups in Schedule 9.[4]

(b) The delegate referred the matter to the Advisory Committee on Chemicals Scheduling (the **Committee**), which recommended that:

(i.) eight (8) individual groups of synthetic cannabinoids be scheduled in Schedule 9[5];

(ii.) a 'group entry' be created for synthetic cannabinomimetics to capture all synthetic cannabinoids except those separately scheduled[6];

(iii.) there be no unscheduled 'cut-off' for synthetic cannabinoids with lower concentrations[7]; and

(iv.) that an implementation dated of 1 May 2012 was appropriate[8].

(c) The delegate's interim decision adopted the recommendations of the Committee.[9]

(d) Having reviewed submissions on the interim decision, on reconsideration the delegate confirmed the interim decision.[10]

2. *As of 1 May 2012, will it be illegal to import the new scheduled substances into Australia?*

2.1 The scheduling of synthetic cannabinoids in Schedule 9 will not of itself make their importation illegal. The importation of goods is controlled by the *Customs (Prohibited Imports) Regulations 1956* (Cth) (the **Customs Regulations**). For the importation of synthetic cannabinoids to be illegal, they will need to be included in Schedule 4 of the Customs Regulations, which prohibits the import of certain substances to Australia without a licence and permission.

2.2 As we understand it, the current Customs Regulations do not include a prohibition on the import of *synthetic* cannabinoids. However, Schedule 4 currently includes:

34 Cannabinoids

35 Cannabis

36 Cannabis resin

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[4] Final Decisions & Reasons for Decisions by Delegates of the Secretary to the Department of Health and Ageing, February 2012 page 129

[5] ibid. page 142

[6] ibid. page 142

[7] ibid. page 142

[8] ibid. page 143

[9] ibid. page 143-4

[10] ibid. page 147

2.3 In our view, the generic term "cannabinoids" may arguably already include *synthetic* cannabinoids. In that case, the effect of inclusion of cannabinoids in Item 34 would be that the importation of *synthetic* cannabinoids may *already* be illegal.

2.4 There is no current indication of whether the Customs Regulation will be amended prior to 1 May 2012. At present there are no tabled amendments before the Commonwealth Parliament to give effect to the scheduling of synthetic cannabinoids from 1 May 2012.[11] Consequently, it is impossible to estimate how long it might take the Commonwealth to amend the Customs Regulations to specifically prohibit the import of the newly scheduled substances. Unlike legislation, regulations can, however, be amended relatively quickly.

2.5 As a matter of caution, it should be assumed that the prohibition on the importation of any of the newly prohibited substances will be illegal from that date, especially into States or Territories that automatically adopt the Poisons Standards to illegalise such substances.

3. *Will it also be illegal to possess these substances or would that only come into effect when the states amend their respective legislation?*

3.1 Generally speaking once the amendments to the Poisons Standard are adopted and implemented by the States and Territories (including any necessary amendments to their legislation on the control of prohibited drugs in those jurisdictions that do not automatically adopt the Poisons Standard), it will be illegal to:

- manufacture;
- supply (including issuing a purchase order);
- obtain;
- possess; or
- administer

the synthetic cannabinoids captured in the amended Schedule 9.[12]

3.2 The adoption of the Poisons Standard is mandated the Australian Capital Territory, Northern Territory, Queensland and South Australia.[13] In New South Wales, Victoria

[11] We have reviewed the publication details on the Comlaw website, the Commonwealth Parliament website and the Attorney-General's website.

[12] NSW: *Drug Misuse and Trafficking Act 1985* (NSW); WA: *Poisons Act 1964* (WA) and *Misuse of Drugs Act 1981* (WA); ACT: *Medicines, Poisons and Therapeutic Goods Act 2008* (ACT); QLD: *Drugs Misuse Act 1986* (QLD), *Drugs Misuse Regulation 1987* (QLD), *Health (Drugs and Poisons) Regulation 1996* (QLD); VIC: *Drugs, Poisons and Controlled Substances Act 1981* (Vic); TAS: *Poisons Act 1971* (Tas); NT: *Misuse of Drugs Act* (NT); SA: *Controlled Substances (Controlled Drugs, Precursors and Plants) Regulations 2000* (SA), *Controlled Substances Act 1984* (SA).

The only exemption is if a licence and/or the necessary authority has been obtained. Approval will only be granted where the synthetic cannabinoids are required for medical or scientific research, or for analytical, teaching or training purposes. This is because they are substances which are considered to have the potential to be abused or misused, and so they are prohibited generally.

[13] Although it has been adopted with some modifications.

and Western Australia the use of the Poisons Standard is permissive (that is, the legislation does not dictate it must be adopted).

3.3 The changes to the Poisons Standard scheduling synthetic cannabinoids will automatically be incorporated on 1 May 2012 in those jurisdictions mandating the use of the Poisons Standard. This is because the legislation in these jurisdictions provides that amendments to the Poisons Standard come into effect on the day declared by the TGA or otherwise that the Poisons Standard applies as in force and amended from time to time.[14]

3.4 In those jurisdictions that do not automatically incorporate amendments to the Poisons Standard, the following must be done to give the amendments effect:

(a) in New South Wales a proclamation will need to be made by the Governor and published on the NSW legislation website;[15]

(b) in Victoria a notice must be published in the Government Gazette for amendments to be incorporated into the Victorian Poisons Code;[16]

(c) in Western Australia the relevant Minister must make an order published in the Government Gazette for amendments to be incorporated to the Schedules used in Western Australia (which largely replicate the Poisons Standard);[17]

(d) in Tasmania the relevant Minister must make an order published in the Government Gazette for amendments to be incorporated to the Poisons List used in Tasmania.[18]

4. *How fast can the individual states add the scheduled changes to their own laws?*

4.1 As stated above, the changes to the Poisons Standard scheduling synthetic cannabinoids will automatically be incorporated on 1 May 2012 in those jurisdictions mandating the use of the Poisons Standard, namely Australian Capital Territory, Northern Territory, Queensland and South Australia.

4.2 On the basis of our investigations, these other jurisdictions are yet to gazette the incorporation of the changes to the Poisons Standard. At present there are no tabled changes in those jurisdictions that do not automatically incorporate the Poisons Standard to give effect to the scheduling of synthetic cannabinoids from 1 May 2012.

4.3 The time taken by the States and Territories to implement changes varies, for example:

(a) New South Wales has implemented changes relatively quickly in the past. For example, the NSW Government announced on 28 June 2011 that it was going to

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[14] ACT: *Medicines, Poisons and Therapeutic Goods Act 2008* (ACT), s 15; NT: *Poisons and Dangerous Drugs Act 1983* (NT), s 6A and the *Poisons and Dangerous Drugs Regulations 2005* (NT), regs 7-9, 12-13; QLD: *Health (Drugs and Poisons) Regulation 1996* (QLD); SA: *Controlled Substances Act 1984* (SA), s 11A, *Controlled Substances (Controlled Drugs, Precursors and Plants) Regulations 2000* (SA).

[15] *Poisons and Therapeutic Goods Act 1966* (NSW), s 8(6).

[16] *Drugs, Poisons and Controlled Substances Act 1981* (Vic), s 12K.

[17] *Poisons Act 1964* (WA), ss 20A-21.

[18] *Poisons Act 1971* (Tas), s15.

ban the sale and possession of certain synthetic cannabinoids (those contained in herbal preparations such as 'Kronic'). The ban was implemented through amendments to the *Drug Misuse and Trafficking Amendment (Prohibited Drugs) Regulation 2011* (NSW) which were published on 8 July 2011; and

(b) amendments in Queensland to ban the same synthetic cannabinoids by contrast took four (4) months between when the proposed ban was announced on 16 June 2011 and when the amendments to the *Drugs Misuse Regulation 1987* (Qld) came into force on 14 October 2011 (having been signed by the Governor on 8 September 2011).[19]

4.4 It is therefore likely that the necessary amendments will be made at the time of or shortly following the implementation of the revised Poisons Standard on 1 May 2012.

5. ***If a compound were able to mimic the effects of a cannabinoid yet work on another receptor, such as a 5-HT receptor, would it still fall under the new group entity?***

5.1 As we understand it, the Committee agreed that outcome-based entries should be used for the proposed scheduling of synthetic cannabinoids and agreed that the term 'synthetic cannabinomimetics' should be used to achieve this outcome.[20] It is clear from the Committee's discussion that the effect of this entry "would make it explicitly clear that all synthetic cannabinoids (except where specifically scheduled) were to be considered Schedule 9 substances..."[21]

5.2 We emphasise the stated public policy intention is that all synthetic cannabinoids will be captured by the amendments to Schedule 9, thus limiting the promotion of 'legal mixes' that are not caught by specific individual entries in the Poisons Standard.

5.3 In our opinion, the better view is that a compound mimicking the effects of a cannabinoid would be captured either by the 'synthetic cannabinomimetics' entry or the derivatives clause in paragraph 1(2) of Part 1 of the Poisons Standard, regardless of its chemical composition.

6. ***If a substance is sold for non-human consumption, is it still subject to the schedule?***

6.1 The Poisons Standard does not make any distinction between substances intended for human consumption and those that are not. As noted, the intended effect of the changes to the Poisons Standard is to ban all synthetic cannabinoids, regardless of their chemical composition.

6.2 In any event, State and Territory legislation banning the supply or possession of prohibited substances does not distinguish between products intended for human consumption and those which are not. The focus of the prohibition is the substance itself, not its intended use.

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[19] Whilst Queensland mandates the use of the Poisons Standard it has an additional step requiring that the schedules be implemented in the specific legislation controlling the sale and possession of prohibited drugs.

[20] Final Decisions & Reasons for Decisions by Delegates of the Secretary to the Department of Health and Ageing, February 2012 page 143

[21] ibid. page 143

7. *Has the committee's recommendation for a blanket listing exceeded the powers of the TGA?*

7.1 In considering amendments to the Poisons Standard, the Secretary of the Department must:

(a) where relevant, take into account the matters listed in s 52E(1) of the Therapeutic Goods Act; and

(b) comply with the applicable guidelines. The current guidelines are the *Scheduling Policy Framework for Medicines and Chemicals* (effective 1 July 2010) (the **Guidelines**).[22]

7.2 The only case relevant in respect of the challenge to the scheduling of substances in the Poisons Standard is the Federal Court decision of *Roche Products Pty Ltd v National Drugs and Poisons Schedule Committee* (2007) 163 FCR 451 (the **Roche case**).

7.3 The Roche case generally related to the powers to amend the Poisons Standard under the Therapeutic Goods Act. Roche was the sponsor (importer or manufacturer) of a medicine called Xenical (a brand name for Orlistat), which was used as a treatment for excessive body weight. It was originally scheduled as a non-prescription pharmacy medicine but, after several complaints in respect of its advertisement in prime time television programs, the forerunner to the current scheme (the **Committee**) decided to reconsider the scheduling and subsequently removed it from the appendix to the relevant schedule. The effect was that Xenical could not be directly advertised to consumers.

7.4 Roche challenged the decision on the bases that:

(a) there was an error of law in the way the Committee applied ss52C, 52D and 52E[23];

(b) the decision was so unreasonable that no reasonable person could have exercised the power in the way the delegate did[24];

(c) there was an improper exercise of power[25];

(d) there was no proper decision by the Committee (for example, because the decision was made at the behest of another person)[26]; and

(e) there was a denial of natural justice.[27]

7.5 Roche was unsuccessful in each of its challenges to the Committee's decision.

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[22] Therapeutic Goods Act 1989, s 52E(1)-(2)

[23] Refer to page 467

[24] Refer to page 476

[25] Refer to page 478

[26] Refer to page 478

[27] see the discussion in the Roche case at 467-480.

7.6 Roche contended that the Committee misapplied ss 52C, 52D and 52E because it took into account the complaints made about the advertising of Xenical and the experiences of pharmacists, and made its decision in the absence of new data about the risks of using Xenical.[28] The basis for the challenge was that the Committee should not have taken these matters into account.

7.7 Branson J of the Federal Court adopted a wide interpretation of s 52E of the Therapeutic Goods Act saying (at 467):

> ...it would be inappropriate to take a narrow view of the matters identified in s 52E(1)(a) to (i). In particular, the reference in (i) to "any other matters that the [Secretary] considers necessary to protect public health" discloses a legislative intention that the [Secretary] should be free to give consideration to a wide range of matters concerning public health.

7.8 Later on, Her Honour held that (at 471):

> I reject the argument [put forward by Roche] that the language of s 52E(1)(d) discloses a legislative intention that the [Secretary] may not give consideration to the likely effect of an exercise of [his/her] powers under s 52D(2) on the extent and patterns of use of a substance. The references to potentialities in the description of other matters that the [Secretary] is to take into account do not, in my view, carry the significance that Roche attributes to them. The potential hazards associated with use of a substance and the potential for abuse of the substance are factors inherent in the substance — albeit that they may be identified in part by speculation as to the uses that may be made of the substance. Just as the [Secretary] is entitled to take into account the likely effect of its decision on the extent and patterns of use of a substance, [he/she] is also entitled to take into account the likely effect of its decision on the potential hazards associated with the use of the substance and on the potential for abuse of the substance.

7.9 The relevance of the above extracts is that it reinforces the view that the Secretary can take into account a broad range of matters that he or she considers necessary to protect public health.[29]

7.10 The power under s 52D(2)(b) of the Therapeutic Goods Act allows the Secretary to schedule classes of substances. On our analysis, there is no requirement in the Therapeutic Goods Act that the Secretary schedule individual substances.

7.11 In respect of the blanket listing of "synthetic cannabinomimetics", the reasons for the delegate's decision indicate that he or she had regard to relevant matters set out in s 52E(1) of the Therapeutic Goods Act, namely:

(a) the risks and benefits of the use of synthetic cannabinoids (s 52E(1)(a)), particularly:

(i.) the possible effects of their use (pp130, 137, 139);

(ii.) that smoking synthetic cannabinoids may be adverse to peoples' health (p130);

(iii.) that evidence considered by the UN indicated that they might have a higher addictive potential compared to cannabis (p132);

[28] Refer to page 467

[29] s 52E(1)(f); Refer to page 467

(iv.) the lack of evidence on the long-term effects of synthetic cannabinoid use (p 142); and

(b) the purpose and extent of use, as well as the potential for abuse (s 52E(1)(b)-(e)), particularly:

(i.) that there did not appear to be (at present) a legitimate therapeutic use for synthetic cannabinoids (pp 131, 136);

(ii.) that Schedule 9 would still allow access to synthetic cannabinoids for approved purposes (medical or scientific research and analytical, teaching and training purposes (p 142);

(iii.) the concern that novice drug users were using synthetic cannabinoids to 'get high' without breaking the law (p 128, 131);

(iv.) the concern that some users were taking synthetic cannabinoids because they could not be detected in drug screening tests used by employers (p 131);

(v.) the potential for dependence (p 131);

(c) broader public health concerns (s 52E(1)(f)) including:

(i.) the unknown long-term effects of synthetic cannabinoid use (p 142); and

(ii.) the potential effect of scheduling on future use of synthetic cannabinoids (e.g. the experience in Western Australia following scheduling: see p 136).

7.12 The lack of scientific evidence supporting the delegate's concerns about the risks and use of synthetic cannabinoids does not of itself invalidate the decision because:

(a) the Secretary has a broad power to give considerations to broad issues of public health and there is no statutory requirement that particular weight be given to any of the considerations set out in subparagraphs (a) – (f) of s 52E of the Therapeutic Goods Act;

(b) in light of the decision in the Roche case, it was open to the delegate to consider the possible effect of scheduling synthetic cannabinoids on their future use in the community, within the matrix of broader public health concerns; and

(c) a Court is likely to accept that it was open to the delegate to consider that the broader interests of public health justified a precautionary approach to the scheduling of synthetic cannabinoids because it has detailed its consideration that:

(i.) there is no reliable evidence on the long-term effects of their use;

(ii.) there is currently no legitimate therapeutic use for human use of synthetic cannabinoids;

(iii.) there was the potential for misuse of synthetic cannabinoids by users who wished to get high without breaking the law or for the purpose of avoiding detection in drug testing; and

(iv.) many synthetic cannabinoids were synthesised with the aim of using them as a laboratory tool to identify marijuana receptors and to determine the mechanism of action of cannabis.

7.13 The delegate's considerations (as set out above) took into account those matters that the Secretary must have regard to in the guidelines, including:

(a) that synthetic cannabinoids have no current therapeutic value (and therefore no legitimate therapeutic use); and

(b) the potential risks to the community and individuals:

(i.) given the lack of research into the long-term effects of synthetic cannabinoid use; and

(ii.) in respect of possible dependency and misuse.

7.14 The legislative procedure for amending the Poisons Standard has been followed by the delegate and the Committee, namely:

(a) subdivision 3D.2 of the Regulations, which sets out the procedure to be followed if a proposed amendment of the Poisons Standard is referred to the Committee; and

(b) s 52E(3) of the Therapeutic Goods Act, which provides that the delegate must have regard to any recommendation of the Committee in amending the Poisons Standard.

7.15 On the above analysis, the Secretary (via the delegate's decision) has not exceeded her powers in scheduling synthetic cannabinoids in Schedule 9 of the Poisons Standard.

8. ***How would a case in the Federal Court to contest the validity of such a law fare? Would all states seek leave to present their argument in such a case?***

8.1 Some decisions made by the Secretary or his or her delegate under the Therapeutic Goods Act are reviewable under s 60 of the Therapeutic Goods Act, firstly by the relevant Minister and secondly by the Administrative Appeals Tribunal. It is necessary for such decisions to qualify for review, that is, they must be within the definition of an "initial decision". That definition does not include scheduling decisions under s 52D of the Therapeutic Goods Act.

8.2 The Federal Court generally has the power to review decisions made by the Executive under the *Administrative Decisions (Judicial Review) Act 1977* (Cth) (the **ADJR Act**) and the *Judiciary Act 1903* (Cth) (the **Judiciary Act**). Accordingly, there are two possible avenues of review by the Federal Court:

(a) an application for judicial review under s 5 the ADJR Act by reason that the Decision is of an administrative character made under an enactment or by a Commonwealth authority; and/or

(b) an application under s 39B of the Judiciary Act by reason that a writ of mandamus or prohibition or an injunction is sought against an officer or officers Commonwealth.

In either case, even if the decision is open to challenge (as to which see below), it would be subject to review for legal error only: the merits of the decision would not be open to review.

Judicial Review

8.3 Reviewable decisions are those which are of an "administrative character": s 3(1) of the ADJR Act. In the Roche case, the Federal Court considered whether a decision under s 52D of the Therapeutic Goods Act was of an "administrative character". Her Honour Justice Branson concluded that decisions under s 52D were not of an administrative character but instead were of a legislative character within the meaning of the ADJR Act (at 459-460):

> In this case I have found the following considerations, each of which tends to suggest that an exercise of power under s 52D(2) is legislative in character, to be significant.
>
> First, the inclusion of a substance in a particular schedule of the Poisons Standard, or an appendix thereto, determines the future lawfulness of conduct in relation to that substance...That is, a decision under s 52D determines the content of rules of general application.
>
> Secondly, although a sponsor of therapeutic goods may initiate the process which leads to a decision under s 52D(2), any decision made under the subsection will apply to the substance in general, not merely to the substance when manufactured or supplied by that sponsor.
>
> Thirdly, public consultation is an important element of the process that leads to a decision under s 52D(2)...
>
> Fourthly, the Poisons Standard is an important element of a national system of controls relating to the quality, safety, efficacy and timely availability of therapeutic goods. It is also intended to, and does, form part of a framework for the States and Territories to adopt a uniform approach to the control and regulation of poisons in Australia...
>
> Fifthly, there is no provision for merits review of the decision of the [Secretary] – other than by the [Secretary] [himself/herself] as provided for by reg 42ZCZ...
>
> I conclude that an exercise of power under s 52D(2) of the Act is legislative...

8.4 Consequently, because the decision to amend the Poisons Standard was held to be of a legislative character and not an administrative character, it was not open to an aggrieved party to apply for review of the decision under the ADJR Act. We expect that the Federal Court would reach the same conclusion if the Association were to challenge the decision to schedule synthetic cannabinoids under the ADJR Act.

Application under the Judiciary Act

8.5 Section 39B of the Judiciary Act provides that the Federal Court has original jurisdiction with respect to "any matter in which a writ of mandamus or prohibition or an injunction is sought against an offer or officers of the Commonwealth".[30]

8.6 A writ of prohibition will only issue where there is jurisdictional error; that is, if the delegate acted outside the limits of his or her power or made a decision that he or she was not authorised to make.[31]

8.7 A writ of mandamus works to compel the performance of a public duty that remains unperformed.[32] It can also be issued to compel the performance of a public duty which a decision maker has purported to perform, but which at law is ineffective because the decision maker has misconceived their duty or failed to comply with some essential element to make the decision valid.[33]

8.8 The circumstances where a writ of prohibition or a writ of mandamus might be warranted in the context of a challenge to the amendment of the Poisons Standard include:

(a) where there is an error of law in the way the delegate applies ss52C, 52D and 52E;

(b) where the decision is so unreasonable that no reasonable person could have exercised the power in the way the delegate did;

(c) where there is an improper exercise of power;

(d) where there is no proper decision by the delegate (for example, because the decision was made at the behest of another person); and

(e) where there is a denial of natural justice.[34]

8.9 In the Roche case, the applicant challenged the decision by the (then) Committee to remove Xenical from Annexure H to the Poisons Standard on all of these grounds. None of the grounds were successful, primarily because:

(a) the Court held that the Committee had a broad power to take into account matters concerning public health, including the likely effect of its decision on:

(i.) the extent and patterns of use of a particular substance;

(ii.) the potential hazards associated with the use of the substance; and

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[30] A writ of mandamus is a writ issued to a government official compelling them to perform their duties according to law. A writ of prohibition, as its name suggests, prohibits a government official from performing an act which would exceed the government's power.

[31] *Re Refugee Review Tribunal; Ex parte Aala* (2000) 204 CLR 82 (at 141 per Hayne J)

[32] *Randall v Northcote Corporation* (1910) 11 CLR 100 (at 105 per Griffith CJ).

[33] *R v War Pensions Entitlement Appeal Tribunal; Ex parte Bott* (1933) 50 CLR 228 (at 242 per Rich, Dixon & McTiernan JJ).

[34] see the discussion in the Roche case at 467-480.

(iii.) the potential for abuse of the substance.

accordingly, there was no error of law by the Committee in taking these matters into account;[35]

(b) for the same reasons, the decision of the Committee was not so unreasonable that a reasonable person could not have exercised the power under s 52D of the Therapeutic Goods Act in the same way, nor was it a decision that lacked evidence such that it could be properly characterised as 'irrational'[36]; and

(c) the Therapeutic Goods Act did not disclose an intention that a decision of the Committee should be void because members of the Committee acted at the behest of the governments they represented. Accordingly, it was not an improper exercise of power for members of the Committee to vote in line with the wishes of their respective governments.[37]

8.10 With respect to the issue of natural justice, in *Pro Health Products Pty Limited v McEwen* [2004] FCA 1790 Justice Emmett of the Federal Court found that, in respect of the procedure set out in the Regulations for scheduling decisions (at [43]):

> I do not consider that those provisions operate to exclude the general rules requiring procedural fairness. However, while I do not consider that the scheme of the Therapeutic Goods Act and the Regulations cut down any entitlement to procedural fairness as such, the scheme dictates the content of procedural fairness in relation to decisions made under the Therapeutic Goods Act and the Regulations. The scheme indicates what is to be regarded as procedural fairness in circumstances such as this.

8.11 Accordingly, the Court held that, provided the procedural requirements of the Regulations have been followed, the requirements of natural justice will be taken to have been met.

8.12 In the absence of any evidence that the delegate's decision has been made unlawfully (set out above) and given the approach taken by the Federal Court in the Roche case to the review of scheduling decisions, we are of the view that a challenge to the decision under s 39B of the Judiciary Act is unlikely to succeed. This conclusion is based primarily on the Court's approach in the Roche case, which raised many of the same issues potentially relevant here. If you would like to obtain the advice of Senior Counsel on whether the Court might be persuaded to take a different approach, we would be happy to arrange this.

Summary conclusions

On the basis of the above analysis, we provide the following summary of answers:

1. *As of 1 May will it be illegal to import the new scheduled substances into Australia? Will it also be illegal to possess these substances or would that only come into effect when the states amend their respective legislation?*

[35] ibid. at 476-478

[36] ibid. at 478

[37] ibid. at 479

Short answer: It will be illegal to import the newly scheduled substances once the *Customs (Prohibited Imports) Regulations 1956* are amended. It appear that the necessary amendments have not been tabled in Parliament yet although you should expect this will be done in the near future. It is arguable that the current prohibition on the importation of "cannabinoids" may already include *synthetic* cannabinoids. In that case, it is possible that the importation of *synthetic* cannabinoids may *already* be illegal.

It will be illegal to possess the newly scheduled substances from 1 May 2012 in jurisdictions that automatically adopt the Poisons Standard (i.e. the Australian Capital Territory, Northern Territory, Queensland and South Australia); in other jurisdictions it will be illegal once the necessary legislative and regulatory amendments are made.

2. *How fast can the individual states add the schedule changes to their own laws?*

Short answer: In the ACT, NT, QLD and SA, the amendments will automatically be adopted on 1 May 2012. In NSW, VIC and WA, a proclamation, notice or order must be published. It is difficult to ascertain with certainty how quickly the States will add the schedule changes to their own laws, although it may only be a matter of weeks (perhaps shorter).

3. *If a compound were able to mimic the effects of a cannabinoid yet work on another receptor such as a 5-HT receptor would this still fall under the new group entry?*

Short answer: Yes, for the reasons discussed above.

4. *If a substance is sold for non-human consumption, is it still subject to the schedule?*

Short answer: Yes, for the reasons discussed above.

5. *Has the committee's recommendation for a proposed blanket listing to include all synthetic ingredients, compounds, materials and preparations without naming individual or class listing as a cannabinoid substance by systemic name exceeded the powers of the TGA because it fails to observe the preliminary requirements contained in parts a, b, c, d and e of subsection 1 of Sect 52E of the Act?*

Short answer: In our view, the Secretary of the Department has not exceeded her powers. The reasons for decision indicate that the delegate took into account all the matters required by law and has exercised those powers within the boundaries of the legislation and the relevant case law.

6. *How would a case in the Federal Court to contest the validity of such a law fare? Would you expect that ALL the states would seek leave to present their argument in such a case?*

Short answer: An application to the Federal Court either for judicial review or under s 39B of the *Judiciary Act 1903* (Cth) is unlikely to succeed (noting our conclusions on question 5).

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