Public submissions on proposed amendments to the *Poisons Standard*

Subdivision 3D.2 of the *Therapeutic Goods Regulations 1990* (the Regulations) sets out the procedure to be followed where the Secretary receives an application under section 52EAA of the *Therapeutic Goods Act 1989* (the Act) to amend the current *Poisons Standard* and decides to refer the proposed amendment to an expert advisory committee. These include, under regulation 42ZCZK, that the Secretary publish (in a manner the Secretary considers appropriate) the proposed amendment to be referred to an expert advisory committee, the committee to which the proposed amendment will be referred, and the date of the committee meeting. The Secretary must also invite public submissions to be made to the expert advisory committee by a date mentioned in the notice as the closing date, allowing at least 20 business days after publication of the notice. Such a notice relating to the scheduling proposals initially referred to the November 2016 meeting of the Joint Advisory Committee on Medicines and Chemicals Scheduling (Joint ACMS-ACCS #14) was made available on the TGA website on 4 August 2016 and 22 September, closing on 1 September 2016 and 20 October 2016 respectively. Public submissions received on or before these closing dates were published on 2 February 2017 on the TGA website in accordance with regulation 42ZCZL.

Public submissions relating to the rescheduling of nicotine are published again here in accordance with regulation 42ZCZL of the Regulations. Also in accordance with regulation 42ZCZL , the Secretary has removed information that the Secretary considers confidential.

Under regulation 42ZCZN of the Regulations, the Secretary, after considering the advice or recommendation of the expert advisory committee, must (subject to regulation 42ZCZO) make an interim decision in relation to the proposed amendment. If the interim decision is to amend the current *Poisons Standard*, the Secretary must, in doing so, take into account the matters mentioned in subsection 52E(1) of the Act (including, for example, the risks and benefits of the use of a substance, and the potential for abuse of a substance) and the scheduling guidelines as set out in the *Scheduling Policy Framework for Chemicals and Medicines* (SPF, 2015), available on the TGA website.

Under regulation 42ZCZP of the Regulations, the Secretary must, among other things, publish (in a manner the Secretary considers appropriate) the scheduling interim decision, the reasons for that decision and the proposed date of effect (for decisions to amend the current *Poisons Standard*, this will be the date when it is expected that the current *Poisons Standard* will be amended to give effect to the decision).

Also in accordance with regulation 42ZCZP of the Regulations, the Secretary must also invite the applicants and persons who made a submission in response to the original invitation under paragraph 42ZCZK(1)(d), to make further submissions to the Secretary in relation to the interim decisions by a date mentioned in the notice as the closing date, allowing at least 10 business days after publication of the notice. Such a notice relating to the interim decisions of substances initially referred to the November 2016 meeting of the Joint Advisory Committee on Medicines and Chemicals Scheduling (Joint ACMS-ACCS #14) was made available on the TGA website on 2 February 2017 and closed on 16 February 2017.

Public submissions received on or before 16 February 2017 are published here in accordance with regulation 42ZCZQ of the Regulations. Also in accordance with regulation 42ZCZQ , the Secretary has removed information that the Secretary considers confidential.

Privacy statement

The Therapeutic Goods Administration (TGA) will not publish information it considers confidential, including yours/other individuals' personal information (unless you/they have consented to publication) or commercially sensitive information. Also, the TGA will not publish information that could be considered advertising or marketing (e.g. logos or slogans associated with products), information about any alleged unlawful activity or that may be defamatory or offensive.

For general privacy information, go to https://www.tga.gov.au/privacy. The TGA is part of the Department of Health and the link includes a link to the Department's privacy policy and contact information if you have a query or concerns about a privacy matter.

The TGA may receive submissions from the public on a proposed amendment to the Poisons Standard where there has been an invitation to the public for submissions on the proposal in accordance with the Therapeutic Goods Regulations 1990. These submissions may contain personal information of the individual making the submissions and others.

The TGA collects this information as part of its regulatory functions and may use the information to contact the individual who made the submissions if the TGA has any queries.

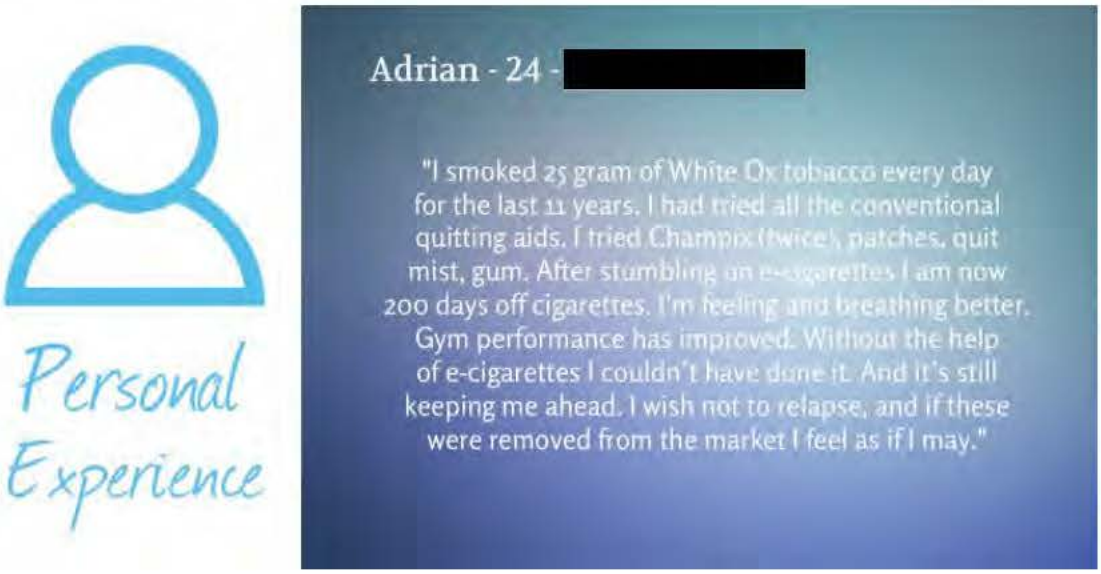
As set out above, the TGA is required to publish these submissions unless they contain confidential information.

If you request for your submission to be published in full, including your name and any other information about you, then the TGA will publish your personal information on its website. However, if at any point in time, you change your mind and wish for your personal information to be redacted then please contact the Scheduling Secretariat at medicines.scheduling@health.gov.au so that the pubic submissions can be updated accordingly.

Please note that the TGA cannot guarantee that updating the submissions on the TGA website will result in the removal of your personal information from the internet.

Please note that the TGA will not publish personal information about you/others without your/their consent unless authorised or required by law.

25. MyChoice Australia wishes furthermore to draw the committee's attention to comments we received that it was requested we pass on as lived expirience:



Toxicity

26. It is submitted that capping the scheduling exemption of nicotine at solutions of 3.6% would equate to 36mg/mL, an amount which would meet the needs of the vast majority of people who use ENDS for NRT purposes. For reference, a UK study found that only 9% of vapers are using concentrations of 19mg/mL or more.

27. The Committee's attention is drawn to the United Kingdoms' Royal College of Physicians recent comments on the changing consensus regarding the lethal dose of nicotine:

"Although nicotine is a toxic compound, overdosing on nicotine products used as directed is almost impossible, given the individual ability to titrate dose and the short half-life of nicotine ... However, ingestion of high doses (purposeful or accidental) can be fatal. Historically, the lethal dose of nicotine for a human adult has consistently been stated to be about 60 mg, corresponding to an oral median lethal dose (LD50) of approximately 0.8 mg/kg. However, this figure has recently been disputed in the light of reports of non-fatal suicide attempts or accidents involving nicotine ingestion, leading to an estimate that the lower dose limit for fatal outcomes is likely to be 500–1,000 mg ingested nicotine, equivalent to an oral LD50 of 6.5–13 mg/kg." [15]

[15] Tobacco Advisory Group to the Royal College of Physicians (UK) 2016, 'Nicotine without smoke: Tobacco harm reduction', page 57

28. As such, at a concentration of 3.6%, it would be impossible for a person to receive a lethal dose of nicotine through ENDS 'liquid'.

29. It is also noted that Royal Society for Public Health (UK) advised in August 2015 that nicotine is "no more harmful to health than caffeine".[16]

Potential for abuse

30. Evidence suggests that people who use ENDS for NRT purposes are highly unlikely to become dependent: "*The relatively slow delivery of nicotine to the brain achieved by NRT is much less reinforcing, and hence much less likely to generate dependence, than cigarette smoking. However, forms of NRT that deliver nicotine relatively quickly, such as the nasal spray, are thought to be more likely to generate dependence than others. Overall, however, the addictive potential of cigarettes is much higher than that of NRT or other non-inhaled nicotine products. Clinically, very few users of NRT become dependent on it."*[17]

31. The ATA and MCA further submit that the potential for abuse of nicotinated liquid for vapour consumption that is distributed at concentrations of 3.6 percent and lower is inconsequential in relation to both a) The potential harm that is minimized by substituting or incorporating e-cigarette use over continuing current tobacco use, and b) The potential abuse of nicotine using other existing NRT products.

32. It is further submitted that concerns about children using nicotinated e-liquid are without basis in evidence, as almost all minors who have used an e-cigarette with nicotinated e-liquid had also tried at least one cigarette [18]. It is also worth noting that a recent study in Tobacco Control Magazine found that "'the majority of US youth who use vaporisers and e-cigarettes do not vape nicotine."[19]

Additional comments

33. It is noted that, for the purposes of the present application, the committee is considering solely the use of nicotine-containing liquids for use in ENDS. The ATA and MC submits that alternative ENDS methods, for instance using "heat not burn" tobacco be included in such an exemption, and that the language remains flexible enough to anticipate further technological developments.

[16] Royal Society for Public Health, 13 August 2015, 'Nicotine "no more harmful to health than caffeine"' Press release [online]
[17] Tobacco Advisory Group to the Royal College of Physicians (UK) 2016 op cit p53
[18] Christopher Ingraham (25 August 2016) 'Teen vaping is not what you think it is, researchers say' Washington Post [online]
[19] Richard Miech, Megan E Patrick, Patrick M O'Malley, Lloyd D Johnston. What are kids vaping? Results from a national survey of US adolescents. August 25, 2016. Downloaded from http://tobaccocontrol.bmj.com/

Conclusion

34. It is submitted that the scientific evidence, and the growing consensus in the worldwide public health community, demonstrate that there is no reason to prevent adults from accessing nicotinated e-liquid at a concentration of 3.6 percent or less. It is not potent enough at this concentration to pose a health risk to individual ENDS users or to public health, an would be a great benefit to health system budgets and a benefit to the length and quality of life of many smokers. While recognizing that, if the exemption is granted, individual States may choose not to replicate and implement the decision, the Australian Taxpayers' Alliance and MyChoice Australia recommend to ACMS that nicotine should be exempted from Schedule 7 under the specific circumstances proposed.

Recommendations

35. The ATA and MC strongly recommend that the Therapeutic Goods Administration:
    a. Melatonin be exempt from scheduling in preparations of 3mg or less
    b. Paracetamol compounded with caffeine be exempt from Schedule 2 when supplied in primary packs of not more than, 10 tablets/capsules or, 5 sachets of powders or granules.
    c. Nicotine be exempt from Schedule 7 at concentrations of 3.6 per cent or less of nicotine for self-administration with an electronic nicotine delivery system ('personal vaporiser' or 'electronic cigarette') for the purpose of tobacco harm reduction.

36. Neither the ATA nor MC hold any view on any other application currently before the committee, and a lack of comment is not to be interpreted in any way as opposition.

37. The ATA and MC thank the committee once again for the opportunity to present this submission, and note our willingness to present further testimony if required.

Timothy Andrews
Executive Director
Australian Taxpayers' Alliance

Lara Jeffery
Executive Director
MyChoice Australia

Interim decision consultation: Proposed amendments to the Poisons Standard, ACMS Meeting, November 2016

To: medicines.scheduling@tga.gov.au
Subject: Proposed Amendments to the Poisons Standard (Medicines)

Introduction

I wish to add my voice to the call for the legal sale, purchase & possession of low concentration nicotine for use in electronic cigarettes within Australia.

Proposed Changes to Poisons Standard

I propose that the 3% nicotine allowance for animal use as seen below, currently in Schedule 6 (Poison) be moved to Schedule 5 (Caution).

> NICOTINE in preparations containing 3 per cent or less of nicotine when labelled and packed for the treatment of animals.

I further propose that 3.6% nicotine for use in e-cigs be added to Schedule 5.

> NICOTINE in preparations containing 3.6 per cent or less of nicotine when labelled and packed for use in e-cigarettes (AKA Electronic Nicotine Delivery Systems or ENDS).

Evidence in Support of Proposed Change

How much nicotine kills a human? Tracing back the generally accepted lethal dose to dubious self-experiments in the nineteenth century. Bernd Mayer.
http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3880486/

Nicotine at the proposed level of 3.6% should be used with *caution*, but it is not a dangerous *poison* at the proposed level of dilution.

About Me

After having smoked for 29 years, all that I got from smoking was a huge hole in one lung. Even knowing that my health was ruined by smoking, I could not or perhaps more accurately would not, give up smoking as I found it too pleasurable in an otherwise miserable world. I thought I'd die both a smoker, and because of it.

But around 28 months ago, I heard of an amazing new development that might give me what I wanted, without killing me. E-cigarettes. After doing extensive research on them through the internet

and on local & international forums. I waited until I was able to get the Centrelink $500 loan and invested in some basic vape (e-cigarette) gear [redacted]. The reason I needed the $500 is that the postage from America was prohibitively expensive, [redacted]

The hardware (ordered from a vendor in WA - where sale of devices is now banned) arrived [redacted]

By the time I exhaled that first breath of vape, I was an ex-smoker. ***Amazing!***

Time has passed & I've since:

- [redacted].
- Joined a nicotine advocacy group.
- Recommend vaping to any and all smokers that will listen.

Unfortunately there are some aspects of the current situation that put many smokers off:

1. That possession of nicotine is illegal. While I am prepared to break the law in order to give up smoking, there are others who aren't. Some even fear their employment will be terminated if they should be charged with nicotine possession.
2. Ordering over the internet. This is something I'm comfortable with, but many (especially those on a low income) are computer illiterate and don't trust an on-line site enough to put their money down.
3. The cost of postage from the United States, China or more recently, New Zealand.
4. Either the expense & uncertainty of buying pre-mixed nicotine (a), or the complexity of mixing it at home (b)).
    a. This problem stems from uncertainty as to what nicotine strength will be needed, which flavours and the ratio of PG/VG diluent will work best. Which can be solved by buying more concentrated, unflavoured nicotine and mixing it yourself, unfortunately..
    b. Mixing your own involves doing calculations as to the amounts of flavour (many new users prefer 'cigarette flavour' - but quickly move on to more delicious flavours), nicotine (I was a heavy smoker & made the initial e-liquid at 33 mg/mL - but soon dropped the concentration and am now using 12 mg/mL), PG & VG are needed (PG provides a good 'throat hit', while VG makes that vapor more cloudy) for a particular effect. To ease this problem, Being a programmer by trade, I wrote a small application to do the calculations for the amounts of each component, though there are also on-line calculators. This requires counting drops, or weighing the developing mix on a scale. As you might appreciate, this is not a method for obtaining e-liquid that is open to many people & is largely restricted to enthusiasts.

Counterpoints to the opponents

There will undoubtedly be opponents to this proposal - from public health advocates, representatives of pharmaceutical companies or tobacco companies (who typically argue for closed systems of limited flavour choice and strength, that lock consumers to their hardware & refill cartridges).

[redacted]

These arguments might take any of the following forms, plus more that don't immediately spring to mind:

- Think of the children! E-cigs might be a gateway to smoking.
- E-cigs allow Big Tobacco to circumvent advertising bans.
- Use of e-cigs renormalises smoking.
- Use of e-cigs encourages dual use of cigarettes and e-cigs, thereby delaying smokers making a successful attempt to quit smoking.
- The long term safety of e-cigarettes has not been proven.
- …

I feel that many of these people are failing to see the forest for the trees, or even more concerning, that they are actually opposed to any use of nicotine for pleasure and that they are, therefore, closet prohibitionists that recognise their view would not get support, so couch their objections in different terms as seen above.

For that reason, I would like the committee to put the following hypothetical question to them with the view to putting their reply on record.

> The Prime Minister & Health Minister call you to a meeting on e-cigarettes:
>
> **PM:** Great news! We can get bipartisan support for legislation to allow access to e-cigarettes to smokers as a consumer product as long as we can get your official 'tick of approval'. The legislation puts a variety of conditions on success, and if it fails to meet any one of them, it will be *automatically* cancelled. Further, it will expire after 12 months unless it is explicitly renewed. The conditions are as follows:
>
> - It leads to a net increase in smokers successfully quitting smoking completely. I.E. unless it *accelerates* the rate at which the smoking rate is falling, it will have failed.
> - For every person who has never smoked & takes up e-cigarettes then goes on to smoke conventional cigarettes, there will be at least 100 smokers who convert completely to vaping using e-cigarettes.
> - That advertising is not targeted at children and non smokers.
> - That big tobacco companies cannot use e-cigarettes to get around falling profits, and further, that they will be de facto excluded from the e-cigarette market in a way that is easily defensible in a court of law.
> - That no long term, significant dangers (that e.g. make e-cigs more than 5% as harmful as smoking) become apparent.
> - That no quantifiable harms come to those in the vicinity of vaping.
>
> **Do we have your approval for this legislation to allow nicotine containing e-cigarettes to be sold to consumers through licenced retail outlets?**

If a public health professional truly wants to lower smoking rates and thereby increase the level of public health, it should get their enthusiastic approval. But I'd bet my bottom dollar that **most of the dissenters would still resist approving e-cigarettes**.

As an aside, I do have ideas on federal legislation to achieve exactly those aims. The legislation may not be popular with some current e-cig advocates ***or*** vendors, but it **would work** &I have little doubt it would be renewed until the government became convinced it provides the best approach and made

the legislation permanent. My aim is not to please current vapers or vendors, but to **provide a viable alternative for current smokers**.

I did not include those ideas because as I understand it, the legislation is beyond the remit of the Therapeutic Goods Administration & the Poisons Standard. But if you are curious (or I misunderstand) please get in contact and I'll be glad to share them either in writing or in person before the committee.

On the WHO FCTC & Harm Reduction

Australia is a signatory to the Framework Convention on Tobacco Control. Article 1(d) of the FCTC states:

> "tobacco control" means a range of supply, demand and **harm reduction strategies** that aim to **improve the health of a population** by eliminating or reducing their consumption of tobacco products and **exposure to tobacco smoke**;

Australia has implemented the strategy to 'reduce the motivation' to consume tobacco using the stick. I would like to say 'using the carrot & the stick' but as a smoker for 29 years, it always seemed like just the stick to me. There was:

- Banning smoking indoors, and more recently, outdoors (for which there is absolutely no health justification).
- Demonisation of tobacco smoke, and more importantly, of smokers themselves.
- Scare messages on cigarette packs.
- Increasing the price of tobacco products.

None of that worked for me. I got used to outdoor smoking, I turned the demonisation around and reveled in being a rebel. I thought the scary messages on cigarette packs were funny, and so wildly exaggerated or manipulated (e.g. showing the results of chemotherapy and implying that was the effects of either smoking or the cancer that the person had developed) as to be meaningless. [redacted] Always the rebel!

But it seems to me that Australia is not fulfilling its FCTC obligations in providing access to the harm reduction strategies outlined in article 1(d). If it had not been for my own research on the internet, I'd have never heard of e-cigarettes, and not been able to get the advice I needed in order to justify outlaying the money needed to try one (with nicotine).

Australia should change its tune on this, because my experience listening to smokers convinces me that many are still smoking for the reasons that kept me smoking. The supply of smokers who can be shamed, bludgeoned or cajoled into giving up is quickly becoming depleted. Each smoker will concede that they feel the harm smoking is doing them, yet they still smoke.

It is for the sake of the health of **those** people that I implore Australian Tobacco Control to forge a new path. Embrace e-cigarettes and offer the current smokers a carrot. A (much) reduced harm alternative to smoking, that is also ***enjoyable***, could go a long way to dropping smoking rates below the magic 5% figure quoted as being the smoking 'end-game'. It is long overdue.

I'll close with a quote from the Royal College of Physicians report Nicotine Without Smoke: Tobacco Harm Reduction:

[redacted]

A risk-averse, precautionary approach to e-cigarette regulation can be proposed as a means of minimizing the risk of avoidable harm, e.g. exposure to toxins in e-cigarette vapour, renormalisation, gateway progression to smoking, or other real or potential risks. However, if this approach also makes e-cigarettes less easily accessible, less palatable or acceptable, more expensive, less consumer friendly or pharmacologically less effective, or inhibits innovation and development of new and improved products, then it **causes harm by perpetuating smoking**. (Section 12.10 page 187)

[redacted]

27 March 2017

Heart Foundation
ABN 98 008 419 761

[redacted]

Advisory Committee on Chemicals and Medicines Scheduling
Department of Health
GPO Box 9848
CANBERRA ACT 2601

Via email: chemicals.scheduling@health.gov.au
CC: medicines.scheduling@health.gov.au

Dear Committee Members

Interim decision not to amend the current scheduling of nicotine

The Heart Foundation supports the scheduling delegates' interim decision not to amend the current scheduling of nicotine.

Our submission noted the key arguments raised by the Cancer Council Australia and we also share the concerns raised by the Joint Advisory Committee on Chemicals and Medicines Scheduling in its advice to the delegates.

We also note that in addition to the evidence on which the interim decision was based, there have been significant new reports and publications confirming that this is the appropriate approach and raising further causes for possible concern.

Adverse cardiovascular outcomes have been associated with e-cigarette in research published in *JAMA Cardiology*. A study at the School of Medicine at the University of California found **users of e-cigarettes were more prone to increased cardiac sympathetic activity and increased oxidative stress - both signs of tobacco-related cardiovascular risk.**

Other recent research also indicates that non-smoking teens are four times more likely to take up tobacco cigarettes if they have used e-cigarettes, raising concerns they are a 'one-way' bridge to smoking.

The interim decision is the right one which we believe is in the best interests of the Australian community.

Yours sincerely

[redacted]

A TALE OF TWO DOCTORS: A COMPARISON OF THE DEKKER AND NITSCHKE CASES[1]

HON NICK GOIRAN MLC[2], MISS ELIZABETH STORER[3]

The value of standardization depends upon the possibility of comparison.
Ernst Christopher Meyer, PhD

Abstract

This paper compares high profile case studies of two medical practitioners in the Australian jurisdiction. The authors set out key moments in a twelve year timeframe from 2002 to 2014 and seek to contrast the treatment by The Medical Board of Australia of the two practitioners in order to re-pose the question of what constitutes improper and/or infamous conduct for medical practitioners. Indeed the authors note the move towards new terms such as professional misconduct and unprofessional conduct and ask whether such moves have been caused, in part, by the apparent difficulties with the former terms.

1 - DR LEILA DEKKER

The tale of Dr Leila Dekker began on 27 April 2002. At around 6pm that evening the then 55 year-old radiologist was driving, with a passenger, near Roebourne in regional north Western Australia.[4]

After another driver, in a Land Rover, narrowly missed her car and rolled into a ditch Dekker did not stop to assist despite hearing the subsequent crash.[5] It was dark, and as Dekker did not have a mobile phone, first aid equipment or a torch with her, she instead drove to the nearest police station and reported the incident.[6]

A passenger in the Land Rover was thrown out of the vehicle, suffered severe injuries and died at the scene.[7]

For Dekker what would then follow would be a litany of court cases for the next twelve years.

---

[1] This version of the paper was presented by Hon Nick Goiran MLC at the Britain Pacific Medical & Legal Conference at The University of London on 5 January 2015.

[2] LLB, B Com. Member of the Parliament of Western Australia representing the South Metropolitan Region. Chairman of the Joint Standing Committee on the Corruption and Crime Commission since 18 June 2009.

[3] BA, MHumRights.

[4] Medical Board of Australia and Dekker [2013] WASAT 182 at 7

[5] Ibid

[6] Medical Board of Australia and Dekker [2013] WASAT 182 at 8

[7] Dekker v The State of Western Australia [2009] WASCA 72 at 3

1.1 State of Western Australia v Leila Marie Dekker, District Court of WA, December 2005

More than three and a half years after the accident, Dekker appeared as the defendant in a District Court of Western Australia trial held at Karratha[8].

The prosecution's opening statement and closing argument was based on the testimony of the other driver who alleged that Dekker pulled out in front of him and the evasive action he took resulted in him running off the road and rolling over.

Dekker testified that she was stopped at the intersection and pulled out to avoid a collision when the oncoming vehicle was on the wrong side of the road and was headed to broadside her car. Dekker's passenger also testified accordingly.

Notwithstanding the corroborating evidence of Dekker's passenger, Dekker was convicted by a jury of dangerous driving causing death, fined $10,000 and disqualified from driving for two years.

1.2 Complaint by Medical Board of Western Australia, July 2006

In July 2006 the Medical Board of Western Australia filed a complaint against Dekker in the Western Australian State Administrative Tribunal under section 13(2) of the Medical Act 1894[9] (WA) based on her being a medical practitioner convicted of a criminal offence.

S 13(2) of the Medical Act read:

Where it appears to the Board that a medical practitioner or a person who is a member of a body corporate that is registered as a medical practitioner under this Act has been convicted of an offence in this State or elsewhere that in the opinion of the Board renders that person, or would, if that person were a medical practitioner, render that person, unfit to practise as a medical practitioner the Board may allege to the State Administrative Tribunal that disciplinary action should be taken against the medical practitioner for that reason.

1.3 WAPOL v Leila Marie Dekker, Magistrates Court of WA, February 2008

Almost six years after the accident, Dekker was tried in the Magistrates Court at Roebourne on a separate charge of dangerous driving causing bodily harm arising from the injuries sustained by the other driver.

[8] Karratha is large city in regional north Western Australia approximately 39 kms from Roebourne.
[9] This Act was subsequently repealed by the Medical Practitioners Act 2008 s. 160(1) (No. 22 of 2008) as at 1 Dec 2008 (see s. 2 and Gazette 25 Nov 2008 p. 4989).

This time, however, Dekker's defense was bolstered by Mr Robert Davey, widely regarded as Western Australia's foremost expert in traffic crash examination and reconstruction. Davey testified that photos taken of tyre marks on the road showed that the oncoming vehicle had reached 'critical speed' and was 'out of control' some distance before the tyre marks depicted on a drawing introduced as evidence during Dekker's District Court trial. Troy Pillage, a police major crash investigator testified in agreement with Davey's conclusion.

On this occasion Dekker was acquitted.

1.4 Dekker v The State of Western Australia, Court of Appeal (WA), April 2009

Although Dekker instructed her lawyer to file an appeal immediately after her District Court conviction, it was not done.[10] Subsequently, Dekker changed lawyers several times and discussed filing an appeal with them also.

Dekker's new lawyer filed a notice of appeal for her 2005 conviction in June 2008 accompanied by an application for extension of time within which she could appeal. Dekker's appeal claimed her conviction was a miscarriage of justice based on new evidence discovered after her trial and favorable evidence that was not disclosed by the prosecution. Her alleged "new evidence"[11] consisted of affidavits by Robert Davey, her trial counsel, and the trial prosecutor.

In a majority decision, the Court of Appeal granted Dekker leave to appeal and quashed Dekker's conviction with Miller JA stating that:

"In the present case, the evidence was insufficient to justify a conviction. That is because the evidence revealed a set of circumstances different from those which were advanced by the prosecutor at trial."[12]

The Court also determined against a retrial and ordered remittance of what Dekker had paid on her $10,000 fine within 28 days.

If Dekker was understandably relieved by this substantial victory in the Court of Appeal, such relief would prove temporary.

1.5 Medical Board of Australia and Dekker, November 2013

Following the Court of Appeal's quashing of Dekker's conviction, the Medical Board amended their complaint to the Tribunal alleging Dekker committed 'infamous or

[10] H Sherrer, *Leila M. Dekker Found Guilty Of Improper Medical Conduct After Her Acquittal In Two Criminal Prosecutions* (Feb 2014) Justice Denied <http://justicedenied.org/wordpress/archives/2693>
[11] Readers interested in why this evidence was deemed neither fresh nor new, should refer to the detailed reasons of Miller JA in Dekker v The State of Western Australia [2009] WASCA 72 at 136-158.
[12] Ibid at 179

improper conduct in a professional respect' in violation of the then Medical Act section 13(1)(a).

Section 13(1) read:

Where it appears to the Board that a medical practitioner, not being a body corporate, may be —
(a) guilty of infamous or improper conduct in a professional respect;
(b) affected by a dependence on alcohol or addiction to any deleterious drug;
(c) guilty of gross carelessness or incompetency;
(d) guilty of not complying with or contravening a condition or restriction imposed by the Board with respect to the practice of medicine by that medical practitioner; or
(e) suffering from physical or mental illness to such an extent that his or her ability to practise as a medical practitioner is or is likely to be affected, the Board may allege to the State Administrative Tribunal that disciplinary action should be taken against the medical practitioner for that reason.

More than eleven years after the accident which gave rise to the complaint the State Administrative Tribunal of Western Australia found Dekker guilty of improper conduct. Judge D R Parry concluded:

Although the practitioner's conduct did not occur in medical practice, there is a sufficiently close link or nexus between her conduct and the profession of medicine for the conduct to be 'in a professional respect'. The practitioner is therefore guilty of 'improper conduct in a professional respect' within the meaning of s 13(1)(a) of the Medical Act.[13]

The Tribunal determined that Dekker's failure to stop, make an assessment and render assistance when she was physically able and had the knowledge and skills to do so, would "reasonably be regarded as improper by medical practitioners of good repute and competency". The Tribunal observed that had Dr Dekker not promptly reported the event to the police, her conduct would have constituted infamous conduct.

In the Tribunal's view, "saving human life and healing sick and injured people is a core purpose and ethic of the medical profession".[14]

The Tribunal determined to hold a further hearing to consider the appropriate penalty and any orders as to costs.

[13] Medical Board of Australia and Dekker [2013] WASAT 182 at 46
[14] Ibid at 39

1.6 Dekker v Medical Board of Australia, November 2014

This time there would be no delay by Dekker in lodging an appeal. Her main contention was to appeal the Tribunal's improper conduct finding on grounds including that there was no evidence of a specific professional duty.

The Court of Appeal unanimously found there was no clear evidence Dekker's decision would have been considered improper, according to the professional standards required of reputable and competent doctors.

In their joint judgment delivered on 21 November 2014, Martin CJ and Newnes and Murphy JJA concluded that:

It appears, on the proper construction of the reasons, that the Tribunal has formulated and relied upon a specific professional duty without regard to whether it was generally accepted by members of the medical profession of good repute and competency in 2002. This, in itself, is an error of law.[15]

The Court found the Tribunal had erred in finding that Dekker should have stopped to help, when there were no clear guidelines at the time that dictated the responsibilities of a doctor towards someone who was not their patient at the scene of such an accident, and no experts had been called to prove she had not acted in a manner expected from her profession.

The Court set aside the Tribunal's decision and further dismissed the Medical Board's application for want of evidence.

Most importantly for Dekker, the Court determined that due, in part, to the length of time since the accident the matter ought not be remitted back to the tribunal.

2 - DR PHILIP NITSCHKE

In 1996 Dr Philip Nitschke shot to fame as the first doctor in the world to administer a legal, lethal "voluntary" injection.[16] This was done under the short-lived *Rights of the Terminally Ill Act 1995* (NT)[17] during which four of Nitschke's terminally ill patients used this law to end their lives.

[15] Dekker v Medical Board of Australia [2014] WASCA 216 at 82

[16] C Moreton, *'People say I'm a killer. I just have to live with it'* (May 2009) The Guardian <http://www.theguardian.com/society/2009/may/08/assisted-suicide-euthanasia-philip-nitschke>

[17] Passed by the Northern Territory Legislative Assembly on 25 May 1995 under the stewardship of Marshall Perron, and entering into law on 1 July 1996, the Act allowed terminally ill patients to commit medically assisted suicide.

Following the overturning of the *Rights of the Terminally Ill Act 1995* in March 1997[18], Nitschke founded the Voluntary Euthanasia Research Foundation (now Exit International) which is dedicated to championing euthanasia.

I do not believe that telling people that they have a right to life while denying them the means, manner, or information necessary for them to give this life away has any ethical consistency... And someone needs to provide this knowledge, training, or recourse necessary to anyone who wants it, including the depressed, the elderly bereaved, the troubled teen…. if suicide is legal, then advising, counselling, or assisting people to carry out this legal act should also be legal.[19]

Aiding and abetting suicide or counselling someone to commit suicide is a crime in Australia.[20]

For the purposes of comparing the Dekker and Nitschke case studies, we now consider reported events during the same twelve year period between 2002 and 2014.

2.1 May 2002

Using Nembutal, the drug Nitschke says he "promotes", 70-year-old Gold Coast widow Nancy Crick killed herself in May 2002. Nitschke had been her doctor, publicised her case, told her how to kill herself and helped arrange for her to die surrounded by 21 euthanasia activists.[21]

An autopsy later revealed Crick had no trace left of cancer - a fact of which her son said she was not aware.[22]

Nitschke said whether or not she had cancer was "irrelevant".[23]

2.2 July 2002

In July 2002, Nitschke announced the production of plastic bags with drawstrings which people could put over their heads to euthanize themselves.[24]

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[18] On 25 March 1997, the Federal Parliament passed the *Euthanasia Laws Act 1997,* which, although not technically repealing the *Rights of the Terminally Ill Act*, rendered it of no legal effect.

[19] Philip Nitschke, Fiona Stewart, *Killing Me Softly: Voluntary Euthanasia and the Road to the Peaceful Pill* (Penguin Books, 2005)

[20] Section 288 (3) of the Criminal Code (Western Australia) provides that "*Any person who aids another in killing himself is guilty of a crime and is liable to imprisonment for life*."

[21] A Bolt, *Philip Nitschke leaves trail of lonely dead* (March 2009) Herald Sun <http://www.heraldsun.com.au/news/nitschke-leaves-trail-of-lonely-dead/story-e6frf7jo-1225692810834>

[22] Ibid

[23] P Goodenough, *Right-To-Die Woman Had No Cancer At Time Of Death* (July 2008) CNS News <http://cnsnews.com/news/article/right-die-woman-had-no-cancer-time-death>

[24] AAP, *Nitschke launches suicide machine* (December 2002) The Sunday Morning Herald <http://www.smh.com.au/articles/2002/12/03/1038712920730.html>

2.3 November 2002

In November 2002, after attending three workshops with Nitschke, Syd and Marjorie Croft, a healthy couple in their late 80s, took a fatal drug overdose at a retirement village at Bundaberg in south-east Queensland.[25]

2.4 Later in November 2002

Two weeks after the death of the Crofts, Lisette Nigot took a fatal overdose in her Perth home. Nigot was not ill or in pain – she was 79 and just did not want to live to 80.[26] Ms Nigot, who is believed to have appeared in one of Nitschke's how-to-suicide videos, left a suicide note describing Nitschke as her inspiration, thanking him for his support, and describing him as a crusader working for a worthwhile humane cause.

Nitschke released the note himself.[27]

2.5 December 2002

Nitschke launched, in December 2002, a $100 DIY suicide machine (COGEN) enabling people to take their own lives by breathing in pure carbon monoxide. A supposedly simple device which could be built at home, COGEN mixed acids together to form lethal carbon monoxide.

"The only side effect is sudden death," said Nitschke. "Once you start this, there's no turning back."[28] He was further reported at the time as saying that it would be difficult for governments to stop the distribution of the machine as it would be sold for other uses.[29]

2.6 December 2002

Ruth[30], a Sydney woman in her 80s who described Nitschke as a friend, ended her life. Ruth was not terminally ill or depressed.[31]

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[25] G Roberts, *Spectre of loneliness led to pact* (November 2002) The Age <http://www.theage.com.au/articles/2002/11/26/1038274306223.html>

[26] AAP, *Healthy woman thanks Dr Nitschke, then kills herself* (December 2002) The Sunday Morning Herald <http://www.smh.com.au/articles/2002/11/25/1038173695743.html>

[27] Ibid

[28] AAP, *Nitschke launches suicide machine* (December 2002) The Sunday Morning Herald <http://www.smh.com.au/articles/2002/12/03/1038712920730.html>

[29] Ibid

[30] Full name cannot be revealed for legal reasons.

[31] G Roberts, *Too tired to go on, Ruth, 80, takes lethal dose* (December 2002) The Sunday Morning Herald < http://www.theage.com.au/articles/2002/11/26/1038274306223.html>

2.7 January 2003

Nitschke had his prototype death machine, COGEN, confiscated at Sydney Airport along with a set of drawstring plastic "exit bags" as he boarded a flight to the US, in December 2003, to conduct a seminar hosted by the Hemlock Society, a US-based pro-euthanasia group that gave Nitschke $20,000 towards the machine.[32]

2.8 June 2004

A documentary, *Mademoiselle and the Doctor*, premiered at the Sydney Film Festival in June 2004. The film was based on the 2002 deaths of Lisette Nigot and Nancy Crick following advice from Nitschke.[33] Featuring archive footage of Crick, the film also featured Nitschke himself.

Nitschke attended the premiere, taking questions afterward.[34]

My philosophical position is... mature, rational people over a certain age - which remains undefined - should have access to the ways and means of a peaceful death. And that's all people, not just sick people.[35]

2.9 June 2004

In June 2004, Nitschke and a team of advisers formulated a recipe for a home-made pill which can provide a so-called peaceful, reliable and legal death.

Nitschke stated that the pill has "a big future and not only for the seriously ill but for all rational, elderly members of our community"[36]:

No government will be able to bring itself to ban these substances, so I think the process is safe. And if people can do it all themselves, with no help, there is no breach of the law…. The emphasis has gone into making a process which is straightforward enough that any competent person with reasonable ability and an average kitchen could easily manufacture it themselves. That is not a crime [but] if I go and make it and give it to someone, I will be assisting their suicide and I will be in prison for the rest of my life.[37]

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[32] M Bradley, *Nitschke to bring machine from US* (January 2003) The Age <http://www.theage.com.au/articles/2003/01/13/1041990231378.html>

[33] A Bolt, *Philip Nitschke leaves trail of lonely dead* (March 2009) Herald Sun <http://www.heraldsun.com.au/news/nitschke-leaves-trail-of-lonely-dead/story-e6frf7jo-1225692810834>

[34] S Creagh, Right to die resurrected by Mademoiselle's debut (June 2004) The Sydney Morning Herald <http://www.smh.com.au/articles/2004/06/13/1087065031231.html>

[35] Ibid

[36] Philip Nitschke, Fiona Stewart, *Killing Me Softly: Voluntary Euthanasia and the Road to the Peaceful Pill* (Penguin Books, 2005)

[37] L Murdoch, *Nitschke develops "legal" death pill* (June 2004) The Age <http://www.theage.com.au/articles/2004/06/10/1086749839084.html>

2.10 November 2005

In November 2005, Nitschke demonstrated quick and easy ways to commit suicide at a conference in Brisbane, showing a series of step-by-step techniques to 250 attendees at Exit International's Peaceful Pill seminar.[38]

Nitschke's suicide demonstrations to a mostly-elderly audience employed "readily available equipment which could be used with the minimal amount of engineering".[39]

The session highlighted the latest device being promoted by Nitschke's group, Exit International: the Aussie Exit Bag. Nitschke said delegate bags given to all conference goers had been especially designed to use with "helium gas cylinders lying around the place" for a quick death.

2.11 2006

In 2006, Exit International published the *Peaceful Pill Handbook*, co-authored by Nitschke.[40]

The *Peaceful Pill Handbook* enables readers to compare for themselves the benefits of various options such as Nembutal, Helium and the Exit Bag, prescription drugs, carbon monoxide, cyanide and the DIY peaceful pill.

The Handbook's contents included:

1. End of Life Considerations
2. Suicide and the Law
3. The Peaceful Pill
4. The Exit RP Test
5. Hypoxic Death & Exit Bag
6. Carbon Monoxide
7. Cyanide
8. Introduction to Drugs
9. Drug Options: Morphine
10. Drug Options: Propoxyphene
11. Drug Options: Nembutal
12. The Peanut Project
13. Overseas Options
14. After it's All Over
15. Concluding Comments

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[38] AAP, *Dr Death demonstrates suicide techniques* (November 2005) The Age <http://www.theage.com.au/news/National/Euthanasia-a-dangerous-weapon/2005/11/05/1130823434494.html>

[39] Ibid

[40] Book and Magazine Censorship: Peaceful Pill Handbook in *Refused-Classification.com – Censorship in Australia* <http://www.refused-classification.com/censorship/books-magazines/peaceful-pill-handbook.html>

The *Peaceful Pill Handbook* was banned by the Australian Federal Government in February 2007.[41]

Exit International conducts workshops on how to bypass the Australian Government's internet filter to order and download the *Peaceful Pill Handbook* and continue to revise and sell new editions at its website, on Amazon and for Kindle.[42]

2.12 March 2006

In March 2006, Graeme Wylie, a 71 year-old former pilot with advanced Alzheimer's disease, died from Nembutal at his northern Sydney home.

During the six-week trial in May 2008 regarding Wylie's death, Nitschke told the Sydney jury he met Caren Jenning, Wylie's long-term family friend, through Exit International.[43] She had been involved in a documentary film about the group's work and was appointed Exit's Sydney coordinator in 2004. He said he had also met Wylie's partner, Shirley Justins, twice.

The women said Wylie wanted to end his own life, but the jury found he lacked the capacity to decide due to his Alzheimer's disease.

Jenning, 75, was convicted as an accessory to Wylie's manslaughter for illegally importing the Nembutal from Mexico.

Justins was convicted of manslaughter for administering the drug.

Justice Roderick Howie granted Nitschke a certificate preventing any of his answers being used to press charges against him in NSW.

Nitschke damned the verdict against Jenning and Justins as "disgusting", and his backers raised $100,000 for the defence.[44]

Petrified of going to jail, Jenning took her life with the same drug she illegally obtained for Wylie.[45]

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[41] Ibid

[42] S Steele, D Worswick, *Destination death: A review of Australian legal regulation around international travel to end life* (Thomson Reuters, 2013) 21 JLM 415

[43] AAP, *Euthanasia advocate given legal protection at murder trial* (May 2008) The Australian <http://www.theaustralian.com.au/archive/news/nitschke-given-protection-at-trial/story-e6frg6o6-1111116359578>

[44] A Bolt, *Philip Nitschke leaves trail of lonely dead* (March 2009) Herald Sun <http://www.heraldsun.com.au/news/nitschke-leaves-trail-of-lonely-dead/story-e6frf7jo-1225692810834>

[45] K Arlington, *Caren Jenning was "bullied" into euthanasia* (September 2008) The Daily Telegraph <http://www.dailytelegraph.com.au/caren-bullied-into-euthanasia/story-e6freuy9-1111117557658>

2.13 February 2008

In February 2008, Nitschke was arrested at Auckland Airport and released after three hours in custody.[46] Police confiscated his books and props he was going to use in a series of workshops on euthanasia in New Zealand.

Nitschke said he intended to show the book to New Zealand's chief censor, Bill Hastings, to try to convince him to approve its circulation in the country. Nitschke said the workshops he was due to hold would go ahead "but they will be a bit sterile as some of my props have been taken away."[47]

2.14 April 2008

In April 2008, Western Australian mother of four Erin Berg flew to Mexico to buy Nembutal after reading Nitschke's book *Killing Me Softly*. She died in hospital after 10 days in a coma.[48]

2.15 May 2009

In May 2009, after being allowed to enter Britain after being held for nine hours by immigration officials at Heathrow Airport, Nitschke brought the first of his suicide workshops to the UK, demonstrating his DIY suicide kit including an 'exit bag' and 'peaceful pills' at a meeting in Bournemouth, largely populated by elderly people.

He discussed drugs, inert gases and euthanasia clinics, as well as legal loopholes that allow doctors or vets to legally assist suicide. A video called 'Do It Yourself with Betty' was played, which showed a pensioner constructing a plastic bag to be used for suicide. The video stated: 'We have chosen a large-sized oven bag because it fits all heads.'[49]

2.16 June 2009

In June 2009, Nitschke unveiled a new euthanasia aid in the form of a kit for testing the potency of the prohibited euthanasia drug Nembutal. Developed by Exit Australia, the kit had already been launched in the United Kingdom.

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[46] L Murdoch, *NZ Police detain Dr Philip Nitschke* (January 2008) *The Age* <http://www.theage.com.au/news/national/nz-police-detain-dr-philip-nitschke/2008/01/31/1201714134995.html>

[47] L Murdoch, *Nitschke arrested in NZ* (January 2008) The Sydney Morning Herald <http://www.smh.com.au/news/world/nitschke-held-over-euthanasia-books/2008/01/31/1201714137586.html >

[48] N Boddy, *Health System Failed Erin, Says Family* (January 2013) The West Australian <https://au.news.yahoo.com/thewest/a/15825017/health-system-failed-erim-says-family/>

[49] DMR, "*Dr Death" holds his first British DIY suicide workshop*' (May 2009) Daily Mail Australia <http://www.dailymail.co.uk/news/article-1177468/Dr-Death-holds-British-DIY-suicide-workshop.html>

According to Nitschke, people go to great lengths to obtain the drug and the kit will give them peace of mind "so that if they take it in the way that it's suggested they will, not might, have a peaceful and reliable death."[50]

2.17 2010

In 2010, a report from the Victorian Institute of Forensic Medicine researched 51 people who died from Nembutal in Australia. The report found that young people and depressed people were more likely to die by Nembutal than terminally ill people in Australia.[51] Of the 38 known deaths that were investigated by a coroner, only 11 had a significant physical illness or chronic pain. The remaining 27 cases showed no signs of physical problems.

In February 2010 Nitschke stated in response to the Victorian Institute of Forensic Medicine report that:

There will be some casualties … but this has to be balanced with the growing pool of older people who feel immense well-being from having access to this information.[52]

2.18 2011

In 2011, an inquiry into Dr Nitschke's application to import the euthanasia drug Nembutal through the Department of Health and Ageing's Therapeutic Goods Administration Special Access Scheme[53] was launched by the Australian Medical Board.[54]

2.19 April 2011

In April 2011, members of Exit International, Don and Iris Flounders took a dose of Nembutal and were found dead in their home. Both in their 80s, Don had mesothelioma while Iris was healthy but wanted to die with her husband. The

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[50] *Nitschke unveils new euthanasia aid* (June 2009) ABC News <http://www.abc.net.au/news/2009-06-18/nitschke-unveils-new-euthanasia-aid/1324714>

[51] A Schadenberg, *"Nitschke continues to sell suicide over the internet"* (September 2013) NRL News Today <http://www.nationalrighttolifenews.org/news/2013/09/nitschke-continues-to-sell-suicide-over-the-internet/#.VJ1jkMDAeA>

[52] D Penberthy, *"There will be casualties": Euthanasia/Assisted Suicide advocate Philip Nitschke says* (June 2013) Sunday Herald Sun <http://www.nationalrighttolifenews.org/news/2013/06/there-will-be-casualties-euthanasiaassisted-suicide-advocate-phillip-nitschke-says/#.VIAgi9CQ-70>

[53] This scheme permits medical practitioners to apply to import drugs for use on terminally ill patients under strict conditions.

[54] P Stewart, *Euthanasia campaigner faces another challenge* (September 2012) ABC NEWS <http://www.abc.net.au/news/2012-09-07/nitschke-euthanasia-australian-medical-board-inquiry/4248274>

Victorian couple made a video on 19 April to make their story public and to outline their decision to end their lives together.[55]

Following Mr Flounders's diagnosis in 2007, the couple had travelled to Mexico in 2008 to buy Nembutal from a vet clinic there. "Don decided to go overseas to gain the drug and I gave him advice on what he should do" said Nitschke.[56]

Five days after they returned, their home was raided by the Australian Federal Police, who searched unsuccessfully for the lethal stash.[57]

In May 2011, Nitschke challenged police to charge him over his involvement in the elderly couple's suicide pact saying:

Unless the police are going to run some line that telling someone how they can go to Mexico constitutes assisting, that would be a difficult and interesting case that I'd like them to try on.[58]

2.20 September 2012

In September 2012, Nitschke faced a second investigation by the Australian Medical Board into his suitability to practise medicine and his role in promoting and importing nitrogen cylinders that can be used for euthanasia.[59]

2.21 November 2013

In November 2013, Nitschke opened a clinic in suburban Adelaide which offered consultations and testing of euthanasia drugs, provided euthanasia advice and information, and distributed nitrogen kits.[60] He said the clinic's reach extended well

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[55] B O'Connell, *Nitschke: try me over suicide pact* (May 2011) Sunday Herald Sun <http://www.couriermail.com.au/ipad/dr-philip-nitschke-try-me-over-suicide-pact/story-fn6ck4a4-1226052044076?nk=6e9be2e33fc5eab3c95cad053cff215b>

[56] *Euthanasia planner slams AFP's 'heavy-handed' approach* (March 2008) ABC NEWS <http://www.abc.net.au/news/2008-03-05/euthanasia-planner-slams-afps-heavy-handed-approach/1063488>

[57] AFP, AAP, *Tourists flock to Mexico for euthanasia drug* (May 2008) The Sydney Morning Herald <http://www.smh.com.au/news/world/tourists-flock-to-mexico-for-euthanasia-drug/2008/05/20/1211182781788.html>

[58] Ibid

[59] P Stewart, *Euthanasia campaigner faces another challenge* (September 2012) ABC NEWS <http://www.abc.net.au/news/2012-09-07/nitschke-euthanasia-australian-medical-board-inquiry/4248274>

[60] *Aust first euthanasia clinic in Adelaide* (November 2013) news.com.au <http://www.news.com.au/national/breaking-news/voluntary-euthanasia-clinic-for-adelaide/story-e6frfku9-1226757941411>

beyond South Australia, with online consultations occurring regularly with clients in other states.[61]

Police in New South Wales and Queensland contacted Nitschke after the nitrogen cylinders of his company, Max Dog Brewing, were found next to bodies in both states.[62]

Nitschke said he had had many enquiries from police over the years:

Police will ring up and say they've found a copy of the [Peaceful Pill Handbook] book and wanting to know whether we were involved in that person's death.[63]

2.22 May 2014

Facing charges over his wife's death, 45 year-old Perth man Nigel Brayley ended his life by taking Nembutal in May 2014. Brayley had spoken with Nitschke at one of his workshops, bought The Peaceful Pill eHandbook and swapped emails with him.[64]

2.23 July 2014

In July 2014, the Medical Board of Australia voted to use emergency powers to immediately suspend Nitschke after he admitted to supporting Brayley's suicide despite knowing he was not terminally ill.[65]

The Board said it took action to "keep the public safe".[66]

Nitschke said it was "clearly stupid" to claim he is a risk to public safety:

That's about the most ludicrous thing they've said, that... telling me I'm no longer a practising doctor is going to somehow or other change things.... We've still got heavily booked workshops all over Australia. People will be coming in their hundreds - I would estimate thousands now - wanting to know how they can end their lives... Whether they remove my medical licence or not is not likely to change that one bit,

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[61] A Mann, *Philip Nitschke's Adelaide euthanasia clinic comes under police scrutiny* (December 2013) ABC NEWS <http://www.abc.net.au/news/2013-12-05/philip-nitschkes-new-euthanasia-clinic-in-adelaide/5138602>

[62] Ibid

[63] Ibid

[64] L Croy, *Nitschke backs man's choice to die* (July 2014) The West Australian. July 2014 <https://au.news.yahoo.com/thewest/a/24384606/nitschke-backs-mans-choice-to-die/>

[65] *Euthanasia advocate Philip Nitschke suspended by the Medical Board of Australia* (July 2014) ABC NEWS <http://www.abc.net.au/news/2014-07-24/euthanasia-advocate-philip-nitschke-suspended-by-medical-board/5615268>

[66] H Davidson, *Philip Nitschke: politicians out of step with public's attitude to euthanasia* (November 2014) The Guardian <http://www.theguardian.com/australia-news/2014/nov/09/philip-nitschke-politicians-out-of-step-with-publics-attitude-to-euthanasia >

and the idea there'll be more people somehow or other being influenced to end their lives I think is quite stupid.[67]

2.24 September 2014

In September 2014, it was reported that Nitschke was being investigated by police in every Australian state over his possible role in nearly 20 deaths in the previous three years, all of them apparently suicides.[68]

One investigation by Victoria Police concerned the death of a 55-year-old Geelong man who allegedly killed himself using a DIY kit bought through a company affiliated with Exit International.

All of the deaths being investigated involved the use of the two suicide methods promoted by Nitschke – Nembutal or a nitrogen inhalant device.

2.25 November 2014

In November 2014, Nitschke appealed in the Northern Territory Civil and Administrative Tribunal against the decision by the Medical Board of Australia to suspend his registration.

3 – CONCLUSION

In the same twelve year period in which Dekker suffered a trail of both criminal and medical prosecutions for not rendering assistance following a rural night car accident, Nitschke was not prosecuted once despite consistently flouting the law and leaving a trail of dead in his wake.

While the authors note that there is a fundamental difference between the relationship between Dekker and the occupants of the Land Rover and the relationship between Nitschke and those who had communicated with him, the comparison of these two cases raises the question of what constitutes improper and/or infamous conduct for medical practitioners in Australia.

Notably during the twelve year Dekker case the Medical Act 1894 was repealed by the Parliament of Western Australia passing the Medical Practitioners Act 2008 which, amongst other things, sought to distinguish disciplinary matters from competency matters and impairment matters.

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[67] *Euthanasia advocate Philip Nitschke suspended by the Medical Board of Australia*, Op Cit

[68] J Davies, *Euthanasia campaigner Nitschke investigated over more deaths* (September 2014) The Age <http://www.smh.com.au/national/euthanasia-campaigner-nitschke-investigated-over-more-deaths-20140927-10msng.html>

Relevantly, section 76 of the Medical Practitioners Act 2008 still referred to practitioners acting “improperly”, being “convicted” and engaging in conduct “that falls short of the standard [expected]”.

Section 76 (1) read as follows:

The following are disciplinary matters —
(a) that a person has contravened a condition applying to that person’s registration or the practice of medicine by that person;
(b) that a person in the course of his or her practise as a medical practitioner —
(i) acted carelessly;
(ii) acted incompetently;
(iii) acted improperly;
(iv) breached this Act;
(v) failed to comply with an undertaking given to the Board under this Act;
(vi) provided services that were excessive, unnecessary or not reasonably necessary for the recipient’s wellbeing;
(c) that a person has been convicted of an offence the nature of which renders the person unfit to practise as a medical practitioner;
(d) that a person has engaged in conduct in a professional respect that falls short of the standard —
(i) that a member of the public is entitled to expect of a medical practitioner; or
(ii) that a member of the medical profession would reasonably expect of a medical practitioner;
(e) that a person has engaged in sexual misconduct.

This Act in turn was repealed shortly thereafter by the Health Practitioner Regulation National Law (WA) Act 2010 which prefers the terms "professional misconduct" and "unprofessional conduct". These terms are defined in section 5 as follows:

professional misconduct, of a registered health practitioner, includes —
(a) unprofessional conduct by the practitioner that amounts to conduct that is substantially below the standard reasonably expected of a registered health practitioner of an equivalent level of training or experience; and
(b) more than one instance of unprofessional conduct that, when considered together, amounts to conduct that is substantially below the standard reasonably expected of a registered health practitioner of an equivalent level of training or experience; and
(c) conduct of the practitioner, whether occurring in connection with the practice of the health practitioner’s profession or not, that is inconsistent with the practitioner being a fit and proper person to hold registration in the profession;

unprofessional conduct, of a registered health practitioner, means professional conduct that is of a lesser standard than that which might reasonably be expected of the health practitioner by the public or the practitioner’s professional peers, and includes —

(a) a contravention by the practitioner of this Law, whether or not the practitioner has been prosecuted for, or convicted of, an offence in relation to the contravention; and
(b) a contravention by the practitioner of —
(i) a condition to which the practitioner's registration was subject; or
(ii) an undertaking given by the practitioner to the National Board that registers the practitioner; and
(c) the conviction of the practitioner for an offence under another Act, the nature of which may affect the practitioner's suitability to continue to practise the profession; and
(d) providing a person with health services of a kind that are excessive, unnecessary or otherwise not reasonably required for the person's well-being; and
(e) influencing, or attempting to influence, the conduct of another registered health practitioner in a way that may compromise patient care; and
(f) accepting a benefit as inducement, consideration or reward for referring another person to a health service provider or recommending another person use or consult with a health service provider; and
(g) offering or giving a person a benefit, consideration or reward in return for the person referring another person to the practitioner or recommending to another person that the person use a health service provided by the practitioner; and
(h) referring a person to, or recommending that a person use or consult, another health service provider, health service or health product if the practitioner has a pecuniary interest in giving that referral or recommendation, unless the practitioner discloses the nature of that interest to the person before or at the time of giving the referral or recommendation;

Whether these defined terms improve upon the historical terms remains to be seen.

Meanwhile, Nitschke may yet be freed of his one penalisation. In a possible twist to the tale of these two case studies, the Western Australian Court of Appeals decision to overturn the State Administrative Tribunal's ruling in Dekker is now being cited as precedent by Nitschke in his appeal.[69]

[69] A Corderoy, *Precedent cited in Philip Nitschke case overturned* (November 2014) The Sydney Morning Herald <http://www.smh.com.au/national/health/precedent-cited-in-philip-nitschke-case-overturned-20141123-11s6z3.html>

[redacted]

16 February 2017

[redacted]

Email:
medicines.scheduling@health.gov.au

Dear delegates

Interim decision regarding proposed amendments to the Poisons Standard for cannabis and tetrahydrocannabinols

1. We provide this submission in response to the scheduling delegates' interim decision dated 2 February 2017 (***Interim Decision***) regarding proposed amendments to the entries for cannabis, tetrahydrocannabinols and cannabidiol in the Standard for the Uniform Scheduling of Medicines and Poisons (***SUSMP***).[1]

Background

2. The Interim Decision was made in the following context.

3. On 31 August 2016, the scheduling delegate made a final decision to include certain cannabis and tetrahydrocannabinols products for human therapeutic use in Schedule 8 of the SUSMP from 1 November 2016 (***Initial Decision***).

4. However, in recognition of the need to address inconsistencies in the hemp seed oil exceptions provided in the Initial Decision, the scheduling delegate decided to review those entries and referred the matter back to the Advisory Committee on Chemicals and Medicines Scheduling (***Committee***) for further consideration at its November 2016 meeting.

5. The Committee subsequently provided advice (***Committee Proposal***) to the scheduling delegates recommending a number of amendments to the SUSMP entries for cannabis, tetrahydrocannabinols and cannabidiol, including:

   (a) the insertion of labelling requirements in the hemp seed oil exceptions in the Schedule 8 and 9 entries for cannabis to mirror those in the hemp seed oil exceptions present in the tetrahydrocannabinols entries prior to and following the Initial Decision;

   (b) the introduction of an exception for "*products for purposes other than internal human use*" (the "product exception") into the Schedule 8 and 9 entries for cannabis to mirror those present in the tetrahydrocannabinols entries prior to and following the Initial Decision; and

[1] [redacted]

(c) a uniform cannabinoid content limit for the purposes of the hemp seed oil and product exceptions, namely 20 mg/kg or less of tetrahydrocannabinols and 50 mg/kg or less of total cannabinoids.

6. The Committee Proposal was published concurrently with the Interim Decision and, as far as we are aware, no public comment was sought by the scheduling delegates in relation to the Committee's recommendations prior to making the Interim Decision.

7. Nevertheless, the Interim Decision proposes to adopt certain aspects of the Committee Proposal, including the revised cannabinoid content limits for, and insertion of labelling requirements in, the hemp seed oil exceptions in the Schedule 8 and 9 entries for cannabis.

8. However, it departs from the Committee Proposal in a number of important respects. In particular, the Interim Decision:

   (a) deletes the word "*internal*" (in relation to human use) in each instance of the hemp seed oil exception; and

   (b) entirely removes the product exception from each of the entries.

9. For convenience, we have attached a table in **Annexure 1** setting out the Schedule 8 and 9 entries for cannabis and tetrahydrocannabinols:

   (a) as per the SUSMP at October 2016 (prior to the implementation of the Initial Decision);

   (b) as per the SUSMP at 1 November 2016 (following implementation of the Initial Decision);

   (c) as proposed in the Committee Proposal; and

   (d) as proposed in the Interim Decision.

Submissions in response to the Committee Proposal

10. In our view, the Committee Proposal goes some way towards addressing the ambiguity which arose from the Initial Decision regarding the scheduling status of low-tetrahydrocannabinol products derived from cannabis seeds, extracts or resins (other than fibre) that are not intended for human therapeutic or internal non-therapeutic use (***Products***), for which there is already an established market in Australia. Such Products include, for example, topical human cosmetic products containing low tetrahydrocannabinol hemp oil derived from the flowering heads or leaves of cannabis plants and pet foods.

11. In accordance with the view expressed in our letter to the Committee dated 19 October 2016 (***Initial Submission***), which responded to the invitation for public comment on the Initial Decision, we consider the imposition of Schedule 9 supply restrictions on these Products to be unjustified, due to the low risk of diversion for illicit purposes (as expressly acknowledged in the scheduling delegates' reasoning for the Interim Decision).

12. We therefore welcome the Committee's recommendations to create uniform product and hemp seed oil exceptions in the Schedule 9 entries for cannabis and tetrahydrocannabinols which essentially mirror the exceptions which were present in

the Schedule 9 entry for tetrahydrocannabinols prior to the implementation of the Initial Decision.

13. However, we disagree with the Committee Proposal in two respects.

14. Firstly, whilst the Committee Proposal makes consistent the exceptions in the relevant Schedule 9 entries, the Committee's proposed Schedule 8 entries are inconsistent insofar as:

    (a) the hemp seed oil exception is differently expressed in the entries for cannabis and tetrahydrocannabinols; and

    (b) the product exception is present in the tetrahydrocannabinols entry, but not the cannabis entry.

15. In any event, we consider the inclusion of these exceptions in the Schedule 8 entries for cannabis and tetrahydrocannabinols to be misconceived, given that the Schedule 8 entries are limited to therapeutic use. We therefore agree with the scheduling delegates' Interim Decision not to include the hemp seed oil and product exceptions in the Schedule 8 entries for cannabis and tetrahydrocannabinols.

16. Secondly, consistent with the position expressed in our Initial Submission, we regard the Committee's recommendation to impose a stricter cannabinoid content limit in either or both of the hemp seed oil and product exceptions as entirely unjustified, given that the Australian market for low-tetrahydrocannabinol Products such as topical cosmetics and pet foods referred to above was established on the basis of the product exception currently included in the Schedule 9 entry for tetrahydrocannabinols, which existed prior to the Initial Decision and imposes a limit of 50 mg/kg of tetrahydrocannabinols.

17. The only justification offered by the Committee for this recommendation, which would have the effect of up-scheduling many products containing less than 50 mg/kg of tetrahydrocannabinols, is that other (unspecified) jurisdictions have tetrahydrocannabinol limits lower than 50 mg/kg.

18. We note that where European jurisdictions have imposed lower tetrahydrocannabinols content limits, they appear to be directed at products intended for human consumption, rather than external use. Further, these limits are often guidance values, which do not have the effect of automatically rendering products unlawful. Indeed, some European jurisdictions place no limit whatsoever on tetrahydrocannabinols content, even in the context of food products.[2] The Committee has not explained why the approach taken in some jurisdictions is preferable to that of others.

19. Even putting the above to one side, in our submission, the existence of lower limits in some overseas jurisdictions **cannot** itself be used to justify the imposition of a stricter standard in Australia.

20. Subsection 52E(1) of the *Therapeutic Goods Act 1989* (Cth) sets out the matters which **must** be taken into account in amending the SUSMP, being:

[2] L Sarmento *et al*., "Scientifically Sound Guidelines for THC in Food in Europe," *nova-Institute,* July 2015. <http://eiha.org/media/2015/08/15-07-24-Report-Scientifically-Safe-Guidelines-THC-Food-nova-EIHA.pdf>.

[redacted]

(a) the 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;

(d) the dosage, formulation, labelling, packaging and presentation of a substance;

(e) the potential for abuse of a substance;

(f) any other matters that the Secretary considers necessary to protect public health.

21. Relevantly, paragraphs (a) through (e) are all concerned with the nature of the substance under consideration. Paragraph (f) makes clear that any other matters considered ought to concern the protection of public health.

22. Having regard to the above, in our submission, the overseas regulatory treatment of a substance is, in and of itself, completely irrelevant to any of the matters prescribed by subsection 52E(1). Even if it could be regarded as a permissible consideration, it can and should not outweigh the mandatory considerations in subsection 52E(1), and particularly should not be used as the basis for imposing restrictions on substances that were previously exempt.

23. We further note, relevantly, that the Committee has failed to identify, with respect to currently exempted Products (*viz* products containing 50 mg/kg or less of tetrahydrocannabinols):

(a) any risks associated with their use (paragraph 52E(1)(a));

(b) any concerns arising with the purposes for which they are used (paragraph 52E(1)(b));

(c) any toxicity concerns (paragraph 52E(1)(c));

(d) any issues with their labelling, packaging and presentation (paragraph 52E(1)(d));

(e) any potential for abuse (paragraph 52E(1)(e)); or

(f) any other matters relevant to public health (paragraph 52E(1)(f)).

24. Accordingly, in our view, if a final decision is made on the same basis as the Interim Decision, it would constitute an improper exercise of the power under paragraph 52D(2)(a).

Impact on industry

25. Australian hemp industry stakeholders have, up until now, relied on the Products exception in the development of their business, such that the proposed changes could have a significant, deleterious effect on their businesses and livelihood. For example, the reduction to 20 mg/kg tetrahydrocannabinols could mean that at least some cultivators and producers of hemp will not be able to use strains they have spent many years breeding for hemp-based products.

26. Noting the above, we are concerned that the scheduling delegates have reduced the permissible quantities of tetrahydrocannabinols without first disseminating the Committee's recommendations and/or undertaking any form of wider industry consultation on the matter particularly given that, like the Committee, the scheduling delegates expressly acknowledged that there is no evidence of diversion or abuse of

[redacted]

low-tetrahydrocannabinol cannabis products. In our view, the inherent risk of such diversion or abuse is extremely low.

27. In addition, we are greatly concerned that the positive aspects of the Committee Proposal (referred to at paragraph 12 above) have not been adopted by the scheduling delegates and that the Interim Decision actually imposes *tighter* restrictions on the supply of Products that were not contemplated in the Initial Decision, the initial request for submissions, or the Committee Proposal.

28. These restrictions arise from the practical effects of the scheduling delegates' proposals in the Interim Decision:

    (a) to remove the word "*internal*" from the hemp seed oil exceptions in the Schedule 9 entries for cannabis and tetrahydrocannabinols, which would capture hemp seed oil for *any* non-therapeutic human use (whether external or internal) in Schedule 9. This would result, for example, in the effective prohibition of cosmetics containing low-cannabinoid hemp seed oil, which have previously been entirely exempt from scheduling; and

    (b) not to include the product exception in the Schedule 9 entry for cannabis and remove it from the Schedule 9 entry for tetrahydrocannabinols, which would capture in Schedule 9 any product containing cannabis or tetrahydrocannabinols that is not either: (i) intended for human therapeutic use in accordance with the Schedule 4 entry for cannabidiol or Schedule 8 entries for cannabis and/or tetrahydrocannabinols; or (ii) a hemp seed oil product intended for non-human use; regardless of the level of cannabinoid/tetrahydrocannabinol in the product. That is, this change would effectively capture a pet food or cosmetic Product containing a very low concentration of cannabis/tetrahydrocannabinols derived from a non-hemp seed oil component of cannabis in Schedule 9.

29. We note that the above changes were not proposed or foreshadowed in the original request for submissions on this matter. Accordingly, stakeholders who did not provide initial submissions have been deprived of an opportunity to comment on them.

30. It is our view that the scheduling delegates' reasoning in respect of the Interim Decision is flawed in a number of key respects and also internally inconsistent to the extent that it acknowledges the low-risk nature of the Products and yet puts forward the proposals in the Interim Decision discussed at paragraphs 28(a) and 28(b) above. We have set out a table at **Annexure 2** identifying the apparent flaws we have identified in the scheduling delegates' reasoning for the Interim Decision**.**

Conclusion

31. The proposed amendments in the Interim Decision differ in significant respects from those in the Committee Proposal, as well as from the current and previous SUSMP entries for cannabis and tetrahydrocannabinols. Importantly, the Interim Decision will have the entirely unjustified effect of capturing certain previously lawful Products in Schedule 9 of the SUSMP.

32. It appears that the Committee and the scheduling delegates are unnecessarily rushing to implement changes to the SUSMP in light of recent and ongoing policy

[redacted]

developments with respect to cannabis and are doing so without the requisite level of careful consideration and public consultation.

33. In our view, there are obvious flaws in many of the substantive changes to the existing exceptions and cannabinoid content limits proposed in the Interim Decision which should be the subject of wider industry consultation before any final decision is made. This is especially so where the changes made in the Interim Decision go far beyond the basis on which this consultation was initially conducted.

34. In light of the above, and given our concerns with the scheduling delegates' reasoning outlined above and in **Annexure 2**, we strongly recommend that the Interim Decision be reconsidered and, in particular, submit that the scheduling delegates should instead adopt the Committee Proposal, with the following amendments:

    (a) The removal of the product and hemp seed oil exceptions from each of the Schedule 8 entries; and

    (b) The reinstatement of the previously applicable limits for hemp seed oil and other products of 50 mg/kg or less of tetrahydrocannabinols and no limits for other cannabinoids, at the very least until this issue can be the subject of proper industry consultation and dialogue.

35. We thank the scheduling delegates for their consideration of our submission.

36. Please do not hesitate to contact the undersigned if you have any questions or require any further clarification regarding our submission.

Yours sincerely

[redacted]

[redacted]

ANNEXURE 1

	SUSMP ENTRIES PRE-INITIAL DECISION (October 2016)	SUSMP ENTRIES POST-INITIAL DECISION (from 1 November 2016)	COMMITTEE PROPOSAL	INTERIM DECISION
Cannabis (S9)	CANNABIS except: a) when separately specified in these Schedules; or b) processed hemp fibre containing 0.1 per cent or less of tetrahydrocannabinol and products manufactured from such fibre.	CANNABIS (including seeds, extracts, resins, and the plant and any part of the plant when packed or prepared), except: a) when separately specified in these Schedules; or b) processed hemp fibre containing 0.1 per cent or less of tetrahydrocannabinols and hemp fibre products manufactured from such fibre; or c) in hemp seed oil for purposes other than internal human use containing 50 mg/kg or less of cannabinols.	CANNABIS (including seeds, extracts, resins, and the plant and any part of the plant when packed or prepared), except: a) when separately specified in these Schedules; or b) processed hemp fibre containing 0.1 per cent or less of tetrahydrocannabinols, and hemp fibre products manufactured from such fibre; or c) in hemp seed oil for purposes other than internal human use containing 20 mg/kg or less of tetrahydrocannabinols and 50 mg/kg or less of total cannabinoids when labelled with either of the following warning statements: i) Not for internal use; or ii) Not to be taken. d) in products for the purposes other than internal human use containing 20 mg/kg or less of tetrahydrocannabinols and 50 mg/kg or less of total cannabinoids.	CANNABIS (including seeds, extracts, resins, and the plant and any part of the plant when packed or prepared), except: a) when separately specified in these Schedules; or b) processed hemp fibre containing 0.1 per cent or less of tetrahydrocannabinols, and hemp fibre products manufactured from such fibre; or c) in hemp seed oil for purposes other than human use containing 50 mg/kg or less of total cannabinoids, including 20 mg/kg or less of tetrahydrocannabinols, when labelled with either of the following warning statements: i) Not for internal use; or ii) Not to be taken.

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	SUSMP ENTRIES PRE-INITIAL DECISION (October 2016)	SUSMP ENTRIES POST-INITIAL DECISION (from 1 November 2016)	COMMITTEE PROPOSAL	INTERIM DECISION
THC (S9)	TETRAHYDROCANNABINOLS and their alkyl homologues except: a) when separately specified in this Schedule; b) when included in Schedule 4 or Schedule 8; c) in hemp seed oil, containing 50 mg/kg or less of tetrahydrocannabinols when labelled with a warning statement: i) Not for internal use; or ii) Not to be taken; or d) in products for purposes other than internal human use containing 50 mg/kg or less of tetrahydrocannabinols.	TETRAHYDROCANNABINOLS and their alkyl homologues, except: a) when included in Schedule 4 or Schedule 8; or b) processed hemp fibre containing 0.1 per cent or less of tetrahydrocannabinols, and hemp fibre products manufactured from such fibre; or c) in hemp seed oil, containing 50 mg/kg or less of tetrahydrocannabinols when labelled with either of the following warning statements: i) Not for internal use; or ii) Not to be taken; or d) in products for purposes other than internal human use containing 50 mg/kg or less of tetrahydrocannabinols.	TETRAHYDROCANNABINOLS and their alkyl homologues, except: a) when included in Schedule 4 or Schedule 8; or b) processed hemp fibre containing 0.1 per cent or less of tetrahydrocannabinols, and hemp fibre products manufactured from such fibre; or c) in hemp seed oil, containing 20 mg/kg or less of tetrahydrocannabinols and 50 mg/kg or less of total cannabinoids when labelled with either of the following warning statements: i) Not for internal use; or ii) Not to be taken; or d) in products for purposes other than internal human use containing 20 mg/kg or less of tetrahydrocannabinols and 50 mg/kg or less of total cannabinoids.	TETRAHYDROCANNABINOLS and their alkyl homologues, except: a) when included in Schedule 4 or Schedule 8; or b) processed hemp fibre containing 0.1 per cent or less of tetrahydrocannabinols, and hemp fibre products manufactured from such fibre; or c) in hemp seed oil for purposes other than human use containing 50 mg/kg or less of total cannabinoids, including 20 mg/kg or less of tetrahydrocannabinols when labelled with either of the following warning statements: i) Not for internal use; or ii) Not to be taken.

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	SUSMP ENTRIES PRE-INITIAL DECISION (October 2016)	SUSMP ENTRIES POST-INITIAL DECISION (from 1 November 2016)	COMMITTEE PROPOSAL	INTERIM DECISION
Cannabis (S8)	-	CANNABIS (including seeds, extracts, resins and the plant, and any part of the plant) when prepared or packed for human therapeutic use, when: a) cultivated or produced, or in products manufactured, in accordance with the Narcotic Drugs Act 1967; and/or b) for use in products manufactured in accordance with the Narcotic Drugs Act 1967; and/or c) imported as therapeutic goods, or for use in therapeutic goods, for supply, in accordance with the Therapeutic Goods Act 1989; and/or d) in therapeutic goods supplied in accordance with the Therapeutic Goods Act 1989, except when: i) it is a product to which item 4, 8, 10, 11 or 12 of Schedule 5A to the Therapeutic Goods Regulations 1990 applies; or ii) separately specified in Schedule 4; or iii) separately specified in the NABIXIMOLS entry in this Schedule; or iv) in hemp seed oil for purposes other than internal human therapeutic use containing 50 mg/kg or less of cannabinoids.	CANNABIS (including seeds, extracts, resins and the plant, and any part of the plant) when prepared or packed for human therapeutic use, when: a) cultivated or produced, or in products manufactured, in accordance with the Narcotic Drugs Act 1967; and/or b) for use in products manufactured in accordance with the Narcotic Drugs Act 1967; and/or c) imported as therapeutic goods, or for use in therapeutic goods, for supply, in accordance with the Therapeutic Goods Act 1989; and/or d) in therapeutic goods supplied in accordance with the Therapeutic Goods Act 1989, except when: i) it is a product to which item 4, 8, 10, 11 or 12 of Schedule 5A to the Therapeutic Goods Regulations 1990 applies; or ii) separately specified in Schedule 4; or iii) separately specified in the NABIXIMOLS entry in this Schedule; or iv) in hemp seed oil for purposes other than internal human therapeutic use containing 20 mg/kg or less of tetrahydrocannabinols and 50 mg/kg or less of total cannabinoids when labelled with either of the following warning statements: (A) Not for internal use; or (B) Not to be taken.	CANNABIS (including seeds, extracts, resins and the plant, and any part of the plant) when prepared or packed for human therapeutic use, when: a) cultivated or produced, or in products manufactured, in accordance with the Narcotic Drugs Act 1967 and/or b) for use in products manufactured in accordance with the Narcotic Drugs Act 1967 and/or c) imported as therapeutic goods, or for use in therapeutic goods, for supply, in accordance with the Therapeutic Goods Act 1989; and/or d) in therapeutic goods supplied in accordance with the Therapeutic Goods Act 1989, except when: i) it is a product to which item 4, 8, 10, 11 or 12 of Schedule 5A to the Therapeutic Goods Regulations 1990 applies; or ii) separately specified in Schedule 4; or iii) separately specified in the NABIXIMOLS entry in this Schedule.

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	SUSMP ENTRIES PRE-INITIAL DECISION (October 2016)	SUSMP ENTRIES POST-INITIAL DECISION (from 1 November 2016)	COMMITTEE PROPOSAL	INTERIM DECISION
THC (S8)	-	TETRAHYDROCANNABINOLS when extracted from cannabis for human therapeutic use, when: a) included in products manufactured in accordance with the Narcotic Drugs Act 1967; and/or b) imported as therapeutic goods, or for use in therapeutic goods, for supply, in accordance with the Therapeutic Goods Act 1989; and/or c) in therapeutic goods supplied in accordance with the Therapeutic Goods Act 1989, except when: i) it is in a product to which item 4, 8, 10, 11 or 12 of Schedule 5A to the Therapeutic Goods Regulations 1990 applies; or ii) in hemp seed oil, containing 50 mg/kg or less of tetrahydrocannabinols when labelled with either of the following warning statements: (A) Not for internal use; or (B) Not to be taken; or iii) in products for purposes other than for internal human use containing 50 mg/kg or less of tetrahydrocannabinols; or iv) separately specified in the NABIXIMOLS entry in this Schedule.	TETRAHYDROCANNABINOLS when extracted from cannabis for human therapeutic use, when: a) included in products manufactured in accordance with the Narcotic Drugs Act 1967; and/or b) imported as therapeutic goods, or for use in therapeutic goods, for supply, in accordance with the Therapeutic Goods Act 1989; and/or c) in therapeutic goods supplied in accordance with the Therapeutic Goods Act 1989, except when: i) it is in a product to which item 4, 8, 10, 11 or 12 of Schedule 5A to the Therapeutic Goods Regulations 1990 applies; or ii) in hemp seed oil, containing 20 mg/kg or less of tetrahydrocannabinols and 50 mg/kg or less of total cannabinoids when labelled with either of the following warning statements: (A) Not for internal use; or (B) Not to be taken; or iii) in products for purposes other than for internal human use containing 50 mg/kg or less of tetrahydrocannabinols; or iv) separately specified in the NABIXIMOLS entry in this Schedule.	TETRAHYDROCANNABINOLS when extracted from cannabis for human therapeutic use, when: a) included in products manufactured in accordance with the Narcotic Drugs Act 1967; and/or b) imported as therapeutic goods, or for use in therapeutic goods, for supply, in accordance with the Therapeutic Goods Act 1989; and/or c) in therapeutic goods supplied in accordance with the Therapeutic Goods Act 1989, except when: i) it is in a product to which item 4, 8, 10, 11 or 12 of Schedule 5A to the Therapeutic Goods Regulations 1990 applies; or ii) separately specified in the NABIXIMOLS entry in this Schedule.

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ANNEXURE 2

	DELEGATES' REASONING	COMMENTS
1.	*The delegates acknowledge the committee's advice.*	No comment.
2.	*There is low risk associated with the concentration of cannabinoids permitted under the exceptions. The toxicity will be low if the THC content is low. International jurisdictions have cut off limits lower than 50 mg/kg; some jurisdictions have as low as 10 mg/kg.*	This aspect of the delegates' reasoning appears to be inconsistent with the proposals in the Interim Decision to: 1. remove the word 'internal' from the hemp seed oil exceptions; and 2. not adopt the Committee Proposal to include an amended "products" exception; in the Schedule 9 entries for cannabis and tetrahydrocannabinols, given that the practical effect of: 3. the proposal in dot-point 1 would be to capture hemp seed oil for *any* human use (whether external or internal), other than a therapeutic use falling within one of the Schedule 4 or 8 entries, in Schedule 9; and 4. the proposal in dot-point 2 would be to capture any non-therapeutic, non-hemp seed oil product containing <u>any</u> level of cannabis, cannabinoids or tetrahydrocannabinols in Schedule 9 (*e.g.* a pet food product containing a very low

[redacted]

	DELEGATES' REASONING	COMMENTS
		cannabinoid concentration from a non-hemp seed oil ingredient). With respect to the reference to international jurisdictions, we refer to our comments at paragraphs 19 to 24 in the submission body.
3.	*Low THC hemp seed oil has been used in cosmetic and pet food products. Limiting human use to 'external only' mitigates against risk of internal consumption of cannabinoids, particularly tetrahydrocannabinols and cannabidiol. Hemp seed oil contains fatty acids considered useful as skin conditioners and topical use is a low risk, particularly if the level of psychoactive cannabinoid is minimal.*	We refer to our comments at Item 2 above. Seemingly inconsistent with the delegates' reasoning on this point, the proposals in the Interim Decision would have the effect that all cosmetic products containing hemp seed oil, or any level of cannabis, cannabinoids or tetrahydrocannabinols, would fall within Schedule 9.
4.	*Label warning statements 'not for internal use' or 'not to be taken' would apply and make it clear the products are not for human internal use. Including specific instructions about "Not for internal use" and/or "Not to be taken" makes it clear that oral formulations are not exempted from scheduling.*	We refer to our comments at Item 2 above. The delegates' reasoning here implies that external human use of hemp seed oil would be exempt from scheduling pursuant to the amendments proposed in the Interim Decision, when this is not the case. Further, it is unclear why hemp seed oil falling within the Schedule 9 exceptions proposed in the Interim Decision would need to be marked 'not for internal use' and 'not to be taken' given that it could not be for human use at all (whether external or internal).

[redacted]

	DELEGATES' REASONING	COMMENTS
5.	*There does not appear to be any evidence of misuse or abuse of the products that currently contain low concentrations of tetrahydrocannabinols/cannabinoids. Limiting the tetrahydrocannabinols content for exemption from scheduling reduces the risk of abuse and diversion.*	We refer to our comments at Item 2 above. The delegates' reasoning on this point is seemingly inconsistent with the practical effect of the Interim Decision, and is not a basis for restricting the content of cannabinoids other than tetrahydrocannabinols.
6.	*The amendments to the schedule entries would provide clarity and avoid any ambiguity about the products intended to be captured. There is merit in having consistent exemptions across all cannabis and tetrahydrocannabinols entries in Schedules 8 and 9 and the Schedule 4 entry for cannabidiol, in particular the limits for total cannabinoids and tetrahydrocannabinols.*	We agree that it is desirable for there to be consistency in the exceptions provided in the cannabis and tetrahydrocannabinols entries in Schedules 8 and 9 and the Schedule 4 entry for cannabidiol. However, for the reasons set out in these submissions, we are of the view that the exceptions proposed in the Interim Decision are unsatisfactory and contrary to the delegates' reasoning.
7.	*The product exemption applying to products for purposes other than internal human use containing 50 mg/kg or less of tetrahydrocannabinols is being omitted as this is inconsistent with the operation of the Narcotic Drugs Act 1967 (the ND Act) and may be breaching Australia's obligations under the Single Convention on Narcotic Drugs 1961(the Single Convention). Any manufacture of drugs would be regulated under ND Act, and would require the manufacturer to be holding a manufacture licence and a permit. In view of the recent amendments to the ND Act, the*	We refer to our comments at paragraphs 20 and 21 of the submission body regarding the considerations relevant to scheduling decisions. None of the delegates' stated reasons – being consistency with the ND Act, the existence of offences in the Criminal Code, and Australia's obligations under the Single Convention – are proper considerations under section 52E of the *Therapeutic Goods Act 1989* (Cth). Notwithstanding the above, the scheduling delegates' focus on the

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	DELEGATES' REASONING	COMMENTS
	Secretary must refuse to grant a manufacture licence involving cannabis, unless satisfied on reasonable grounds that at least one of the circumstances set out in subsection 11K(2) of the ND Act is met. Thus the end use of the manufactured cannabis under the ND Act is limited for a person to be granted a manufacture licence, irrespective of the concentration of cannabis in the end product to be supplied. Similarly, the cultivation and production of cannabis or cannabis resins are regulated under the ND Act. *i. Any person who manufactures, cultivates cannabis plants or produces cannabis or cannabis resins without a licence may be committing an offence under the Criminal Code Act. Any importation of drugs would be regulated under the Customs (Prohibited Imports) Regulations 1956.* ii. *The Single Convention does not apply to the cultivation of cannabis plants exclusively for industrial purposes (fibre and seed) or horticultural purposes. However, it applies to the cultivation of cannabis plants for the production of cannabis or cannabis resins, and requires amongst others that the manufacture of drugs be under licence, subject to exemptions, and that trade in and distribution of drugs be under licence, subject to exemptions.*	ND Act is in any event misconceived. The ND Act establishes a licensing scheme for the cultivation, production and manufacture <u>in Australia</u> of cannabis plants and products exclusively for <u>medicinal or research purposes.</u> Products for other than medicinal or research use containing 50 mg/kg or less of tetrahydrocannabinols do not fall under that particular licensing scheme. Products containing low levels of tetrahydrocannabinol could, at least historically, be imported from overseas by a licensed importer,[3] or produced by an industrial hemp manufacturer licensed under State or Territory legislation (such as the NSW *Hemp Industry Act 2008*). Such activities do not violate, and are in no way "inconsistent with the operation of", the ND Act. Finally, the reference to the Criminal Code is equally misconceived – under sections 10.5 and 313.1, the relevant drug offences do not apply to conduct which is "justified or excused" by a State, Territory or Commonwealth law. As noted above, the ND Act is not the only potential avenue for such justification or excuse.

[3] In particular, we are instructed that licences and permits have previously been granted in respect of hemp oil, seed, flower, and leaves,

[redacted]

	DELEGATES' REASONING	COMMENTS
8.	*The cannabidiol Schedule 4 entry covers only therapeutic use. Therefore non-therapeutic use falls under other Schedule entries for cannabis.*	No comment.
9.	*The cannabidiol entry amendment is to clarify that the cannabidiol must contain at least 98 per cent cannabidiol relative to the total amount of other cannabinoids in the cannabidiol.*	No comment.
10.	*Amending the Schedule 9 entries for cannabis and tetrahydrocannabinols to introduce specific limits for total cannabinoids including tetrahydrocannabinols.*	The Committee Proposal would also achieve this purpose, but see our comments in these submissions regarding the limits proposed.
11.	*NICNAS have advised that there are no cannabinoids approved as ingredients in cosmetics (i.e. external human use). Therefore there is no requirement for an exemption, as no approved products exist. This would lead to removal of the exemptions for hemp seed oil from the tetrahydrocannabinols and cannabis Schedule 8 entries and removal of the exemptions for products from the tetrahydrocannabinols and cannabis Schedule 9 and Schedule 8 entries.*	Although there are no cannabinoids currently listed in the public section of the Australian Inventory of Chemical Substances (***AICS***), *Cannabis sativa* / hemp extract (CAS No. 89958-21-4) is listed in the public section of AICS and may therefore currently be used as an ingredient in cosmetic products without notification to NICNAS.[4] Accordingly, it is incorrect to conclude that the absence of a specific cannabinoids listing in AICS means that there are no cosmetic products currently available which lawfully contain cannabinoids pursuant to the hemp seed oil and products

[4] NICNAS, AICS entry for 'Cannabis sativa, extract', available at <https://www.nicnas.gov.au/search/chemical?id=32253> (last accessed 8 February 2017).

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	DELEGATES' REASONING	COMMENTS
		exceptions currently found in the Schedule 9 entries for tetrahydrocannabinols and cannabis. It simply means that the ingredient used in those products is *Cannabis sativa*/hemp extract.
12.	*Food is not considered as part of this decision.*	No comment.
13.	*Earliest possible implementation date.*	As noted in our submissions, it appears that the Committee and scheduling delegates are in a rush to introduce these amendments to the SUSMP in light of the present policy focus on cannabis. However, consultative and careful decision-making should not be sacrificed for purported efficiency, especially given the significant issues we have identified with the delegates' interim Decision. As noted by the scheduling delegates, there is currently no evidence of abuse of products containing low concentrations of tetrahydrocannabinols or other cannabinoids and hence no particular reason for urgency.

[redacted]

24 February 2017

The Hon Greg Hunt MP
Minister for Health; Minister for Sport
Parliament House
Canberra ACT 2600
greg.hunt.mp@aph.gov.au

SUSMP amendments to cannabidiol and tetrahydrocannabinols listings pose risk to cosmetic and medicinal cannabis industries

Dear Minister,

I write seeking an urgent meeting to discuss with you the recent interim decision regarding proposed amendments to the Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP) for cannabidiol (CBD) and tetrahydrocannabinols (THC).

It is MGC Pharmaceuticals' (MGC) view that the 2 February Scheduling Delegates' interim decision regarding the entries for CBD, cannabis and THC in the SUSMP is unwarranted and poses a serious risk to the future of Australia's cosmetic cannabis industry.

Further, many companies have invested in the burgeoning Australian medicinal cannabis industry knowing their investment was significantly de-risked by the option of developing lines of topical human cosmetic products derived from cannabis, were they unsuccessful in obtaining approval for their medicinal products.

MGC (ASX:MXC) is an Israeli-Australian medical and cosmetic cannabis company which has been engaging your colleagues, government departments, the Therapeutic Goods Administration (TGA), and others on the issue of medicinal cannabis in Australia.

As specialists in the cultivation and manufacture of medicinal cannabis, MGC Pharmaceuticals believes it is imperative to work with you and your Department to determine best practice in what is a new market for Australia.

Both the medicinal cannabis and cosmetic cannabis industry provide an opportunity for farmers and other regional producers to be involved in an expanding market within Australia and abroad, as well as for manufacturing and supply chain groups to be integral to the evolution of the industry.

However, the 2 February interim decision proposes the removal of exceptions applying to hemp seed oil, and other low-THC cannabis products, for external human use, rendering such products (including cosmetics) unlawful. The decision also imposes, in respect of products for non-human use, a stricter limit on the allowable concentration of THC and a new limit on the concentration of other, previously unrestricted, cannabinoids (cannabinoids other than THC are non-psychoactive, that is, they do not produce the 'high' associated with smoking or ingesting cannabis). As such, this decision will result in the effective prohibition of cosmetics containing low-THC hemp seed and hemp oil, which have previously been entirely exempt from scheduling.

[redacted]

Australian hemp industry stakeholders have, up until now, relied on the various scheduling exceptions in the development of their business, such that the proposed changes could have a significant, deleterious effect on their businesses and livelihood.

For example, the reduction in the THC content limit and imposition of a limit in the total cannabinoid content could mean that at least some cultivators and producers of hemp will not be able to use strains they have spent many years breeding for hemp-based products, and the removal of exceptions applying to products for external human use would effectively render the entire hemp-based cosmetics industry unlawful.

The scheduling delegates made this decision without first disseminating the recommendations of the Advisory Committee on Chemicals and Medicines Scheduling (ACCMS) and/or undertaking any form of wider industry consultation.

What is particularly concerning is that, like the ACMMS, the scheduling delegates have expressly acknowledged that there is no evidence of diversion or abuse of low-THC cannabis products.

I would very much like to discuss with you the reinstatement of the previously applicable scheduling exceptions for low-THC cannabis products, at the very least until this issue can be the subject of proper industry consultation and dialogue. I am also concerned that if this interim decision is implemented, it could have unintended but disastrous effects on many small and large businesses in Australia operating in this emerging industry.

I have attached an in-depth background paper explaining MGC's concerns, which are shared by many others in the medicinal and cosmetic cannabis industries.

Yours faithfully,

[redacted]

[redacted]

Australia's entire hemp-based cosmetics industry rendered unlawful by unjustified SUSMP amendments to cannabidiol and tetrahydrocannabinols listings

Issue

The Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP) is a national classification system that controls how medicines and poisons are made available to the public.

Medicines and poisons are classified into Schedules according to the level of regulatory control over the availability of the medicine or poison, required to protect public health and safety.

Some substances can be exempted from a schedule if they are used in a certain way (e.g. not for internal use). These are known as 'exceptions'.

On 2 February the scheduling delegates released an **interim decision** outlining proposed amendments to the entries for cannabis, tetrahydrocannabinols (THC) and cannabidiol (CBD) in the SUSMP.

It is MGC Pharmaceuticals' (MGC) view that the 2 February decision is **unwarranted and poses a serious risk to the future of Australia's cosmetic cannabis industry.**

Further, **many companies have invested in the burgeoning Australian medicinal cannabis industry** knowing their investment was significantly de-risked by the option of developing lines of topical human cosmetic products derived from cannabis, were they unsuccessful in obtaining approval for their medicinal products.

Both the medicinal cannabis and cosmetic cannabis industry provide an opportunity for farmers and other regional producers to be involved in an expanding market within Australia and abroad, as well as for manufacturing and supply chain groups to be integral to the evolution of the industry.

The proposed amendments differ in significant respects from the current and previous SUSMP entries for CBD and THC.

Importantly, the Interim Decision will have the entirely unjustified effect of capturing certain previously lawful products such as some topical human cosmetic products in Schedule 9 of the SUSMP (prohibited products).

The removal of exceptions applying to products for external human use would effectively render the entire hemp-based cosmetics industry unlawful.

Background

On 31 August 2016 the scheduling delegate made a final decision to include certain cannabis and THC products for human therapeutic use in Schedule 8 (controlled drug) of the SUSMP from 1 November 2016 **(Initial Decision).**

However, in recognition of the need to address inconsistencies in the hemp seed oil exceptions provided in the Initial Decision, the scheduling delegate decided to review those entries and referred the matter back to the Advisory Committee on Chemicals and Medicines Scheduling (ACCMS) for further consideration at its November 2016 meeting.