

3 April 2018

Queensland Government  
Department of Health  
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Cc. Hon Dr Steven Miles, Minister for Health: [health@ministerial.qld.gov.au](mailto:health@ministerial.qld.gov.au)  
Uma Rajappa, Director Environmental Hazards Unit

Dear Sophie,

**Your File Ref: C-ECTF-18/189 / GR013216**

I refer to my letter dated 3 January 2018 and your reply dated 29 January 2018 (copy attached). I am seeking clarification of questions 3 and 4 in my original letter.

The questions relate to the importation of nicotine under the TGA Personal Importation Scheme and the compounding of nicotine under the extemporaneous compounding exemption (in Item 6 of Schedule 5) of the *Therapeutic Goods Regulations (1990)* (Cth), specifically in Queensland.

**Q3. Why the provisions of the TGA Personal Importation Scheme do not apply in Queensland?**

You referred to the information on the TGA website:

'If the liquid nicotine is for a therapeutic use (such as smoking cessation), it is a prescription medicine. To import a prescription medicine you need to possess a valid prescription written by a registered Australian medical practitioner. Under most state and territory laws only a medical practitioner can write a prescription for a medicine, or prescribe a substance that is for therapeutic use. The Therapeutic Goods Administration has not assessed any of these products for therapeutic use.'

This information from the TGA confirms the legality of importing nicotine for a therapeutic purpose with a prescription written by a registered Australian medical practitioner under the Personal Importation Scheme.

Furthermore, I refer to the attached document by the TGA, *Sub0297.1 Supplementary - Department of Health, 'Answers to Questions on Notice'* to the Parliamentary inquiry on Use and Marketing of electronic cigarettes and personal vaporisers in Australia (8 September 2018). In answering question 2, the TGA confirms the approval of importing nicotine with a prescription (Schedule 4) as an unapproved therapeutic good under the 'personal importation exemption'. [\[link submission #297\]](#)

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'As nicotine when used in e-cigarettes is in Schedule 4 (Prescription Medicine Only) of the Poisons Standard, any supply in Australia would need a doctor's prescription. As there is no nicotine product to be used in e-cigarettes approved by the TGA and included in the Australian Register of Therapeutic Goods any use would need to be as an unapproved therapeutic good. To legally access an unapproved therapeutic good the prescribing doctor would need to either:  
... use an exemption such as the extemporaneous compounding exemption or the personal importation exemption.'

You stated in response to question 2 in your letter that 'the Queensland legislation has not overridden the Commonwealth legislation'. As that is the case, can you please explain why this clear approval from the TGA (which is discussed in a way that makes it clear that it applies Australia-wide) does not apply in Queensland?

**Q4. If compounded nicotine for a therapeutic purpose, prepared interstate, can be legally used in Queensland? If not, what specific legislation prevents it?**

Your answer does not appear to address my question about compounded nicotine. I have read Section 271 of the HDPR and it does not seem to apply.

As stated in the 'Answers to Questions on Notice above', compounded nicotine on prescription for a therapeutic purpose is re-classified as schedule 4 (not a regulated poison) and is exempt under the 'extemporaneous compounding exemption' of the *Therapeutic Goods Regulations* (Cth).

In summary, it appears that the TGA approves the importation and compounding of nicotine for a therapeutic purpose as described above. You state that the Queensland legislation does not override the Commonwealth legislation. Therefore, please clearly state what is the legal justification for overriding the clear guidelines from the TGA. In particular, please provide the specific titles of all Queensland legislation and the relevant sections in each piece of legislation.

Thank you for your assistance.

Colin Mendelsohn.

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