



Department of Health

Enquiries to: Uma Rajappa
Director
Environmental Hazards Unit
Telephone: 07 3328 9338
Ref: C-ECTF-18/2749
GR013283

Associate Professor Colin Mendelsohn
Chairman, Australian Tobacco Harm Reduction Association
School of Public Health and Community Medicine
11 Carlotta Rd
DOUBLE BAY NSW 2028

Email: c.mendelsohn@unsw.edu.au

Dear Associate Professor Mendelsohn

I refer to your letter dated 3 April 2018 seeking clarification for controls for liquid nicotine regulations under the Queensland's Health (Drugs and Poisons) Regulation 1996 (HDPR).

In Queensland, the Schedules and the sections in Part 2 of the *Poisons Standard March 2018* (Cth) ('Poisons Standard') in relation to packaging and labelling are given legal effect by the HDPR.

Liquid nicotine is considered:

- a 'dangerous poison' under Schedule 7 (S7) of the Poisons Standard, and therefore an 'S7 poison' and 'regulated poison' under the HDPR, where it is not contained in preparations for human therapeutic use; and
- a 'prescription only medicine' under Schedule 4 (S4) of the Poisons Standard, and therefore a 'restricted drug' under the HDPR, where it is contained in preparations for human therapeutic use.

I am advised that there are no e-cigarette products containing liquid nicotine included in the Australian Register of Therapeutic Goods (ARTG). However, upon further consideration of the issue Queensland Health has taken the view that liquid nicotine which is contained in preparations for human therapeutic use is a 'prescription only medicine' under S4 of the Poisons Standard, and therefore a 'restricted drug' under the HDPR, even where the product in question is not included in the ARTG.

Persons seeking to access unapproved products containing liquid nicotine for human therapeutic use may do so under the Special Access Scheme or the Personal Importation Scheme of the Therapeutic Goods Administration (TGA). Under these schemes, the prescribing doctor would need to follow requirements prescribed by the TGA. The requirements applicable to a 'restricted drug' under the HDPR would also apply.

Office
Department of Health
Level 3
15 Butterfield Street
HERSTON QLD 4006

Postal
PO Box 2368
FORTITUDE VALLEY BC
QLD 4006

Phone
(07) 3328 9268

Email
edhpu@health.qld.gov.au

In relation to your question about whether compounded nicotine for a therapeutic purpose prepared interstate can be legally used in Queensland, the exception for extemporaneous compounding is contained in item 6 of Schedule 5 of the *Therapeutic Goods Regulations 1990* (Cth).

This item exempts from the operation of pt 3-2 of the *Therapeutic Goods Act 1989* (Cth) ('TG Act') 'medicines that are dispensed, or extemporaneously compounded, for a particular person for therapeutic application to that person'.

Queensland Health's view is that nicotine which is compounded outside Queensland and then supplied to a patient in Queensland at a later time is not extemporaneously compounded for that patient. The liquid nicotine would therefore not meet the criterion of being 'extemporaneously compounded, for a particular person for therapeutic application to that person'. The compounded product would therefore not be exempt under item 6 and its supply would be subject to the offence and civil penalty provisions in pt 3-2 of the TG Act.

Thank you for bringing your concerns about this matter to our attention again. Should you have further questions, please do not hesitate to contact Uma Rajappa, Director of the Environmental Hazards Unit on telephone 07 3328 9338.

Yours sincerely



Sophie Dwyer PSM
Executive Director
Health Protection Branch

b 16/18