Australian Tobacco Harm Reduction Association

9 July 2018

Queensland Government
Department of Health
Uma Rajappa
Director Environmental Hazards Unit
Email: Uma.rajappa@health.qld.gov.au

cc Sophie Dwyer
Executive Director
Health Protection Branch, Prevention Division
Email: EDHPU@health.qld.gov.au

Your Ref: C-ECTF-18/2749
GR013283

Dear Uma,

I would like further clarification of my query about the legality of compounded nicotine for a therapeutic purpose prepared interstate for a specific person in Queensland.

In your letter dated 6 June 2018 you stated

> '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.

The following sources appear to contradict this statement:

1. TGA website [link], the criteria for extemporaneous compounding are:

'A pharmacist may be exempt from the requirement to include a medicine in the ARTG where it is extemporaneously compounded for a particular person for therapeutic application to that person. A pharmacist should therefore ensure that there is an identified person for whom the medicine is being compounded before undertaking any steps in manufacture. Pharmacists are not permitted to store excess quantities of compounded medicines in case additional prescriptions are subsequently presented by patients.'

2. Therapeutic Goods Regulations 1990 (Cth), Schedule 5, section 6 [link]

'medicines (other than medicines used for gene therapy) that are dispensed, or extemporaneously compounded, for a particular person for therapeutic application to that person' are exempt 'from the operation of Parts 3-2 and 3-2A of the Act.

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3. Pharmacy Board of Australia's Guidelines of Compounding of Medicines, March 2015 [link].

Assuming an interstate pharmacist compounds a nicotine solution in full compliance with these criteria, on what legal basis does Queensland Health not accept this as compliant with the 'extemporaneous compounding exemption' of the Therapeutic Goods Regulations 1990 (Cth)?

Just to clarify, the scenario is:

- a patient has a valid prescription from a registered Australian medical practitioner for a compounded nicotine e-liquid which is not commercially available
- a compounding-trained Australian pharmacist receives the prescription
- then freshly mixes the individual ingredients together in appropriate facilities to make up the preparation according to the information on the prescription for the named patient
- then immediately supplies it via mail or courier to the patient.

Please provide the specific titles of all Queensland legislation and the relevant sections in each piece of legislation that you feel are relevant.

Thank you for your assistance.

Sincerely,

Associate Professor Colin Mendelsohn
Chairman, Australian Tobacco Harm Reduction Association
School of Public Health and Community Medicine, University of New South Wales, Sydney