RACGP
Royal Australian College *of* General Practitioners

Healthy Profession.
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31 March 2021

Vaporiser Nicotine Standard Team
Therapeutic Goods Administration
Department of Health
PO Box 100
Woden ACT 2606

Email: nicotine.standard@health.gov.au

Dear Vaporiser Nicotine Standard Team,

Re: Therapeutic Goods Order (TGO) 110 - Standard for Vaporiser Nicotine Consultation

The Royal Australian College of General Practitioners (RACGP) welcomes the introduction of this standard and is pleased to provide the following comments. Comment is provided under each of the section headings as provided in the consultation paper.

1. Proposed scope of Therapeutic Goods Order (TGO)-110

The RACGP recommends that vaping devices should be within the scope of this standard or addressed in another standard. Without any regulation of vaping devices, it is difficult for prescribers to know if what the patient is using reaches an acceptable standard of quality and safety.

The RACGP agrees with the proposition that export only products should comply with TGO-110. This is an important requirement, as Australia should not export products for human use that do not meet standards for use in our own country. Similarly, clinical trial products should be required to comply with TGO-110 because this is a minimum standard.

Products that are the subject of an US Food and Drug Administration (FDA) premarket tobacco product application (PMTA) marketing order, or that are supplied in the UK, EU, Canada, NZ and / or another country in accordance with the relevant requirements of that country should be expected to demonstrate a measure of compliance with TGO-110. It is a minimum standard for doctors to have a measure of confidence in the safety of the vaporised nicotine products that they are prescribing for their patient.

2. Potential requirements for unapproved vaporiser nicotine products

2.1 Labelling – ingredient lists

The Standard proposes that all active and excipient ingredients should be listed on labels or information sheets, except ingredients of flavours. The RACGP supports this option, because prescribers of these products need to know about all active ingredients. Knowing that all active ingredients must be listed, provides a level of certainty to prescribers.

2.2 Labelling – nicotine concentration

The proposed Standard option is to state the nicotine concentration or content (subsection 8(3) of draft TGO-110). The RACGP supports this option. Products where nicotine concentration is not provided on the label should be excluded as complying even if they are the subject of an FDA PMTA marketing order. Prescribers will have greater confidence and consumers are better informed if all vaporiser nicotine products are labelled with the nicotine concentration.

2.3 Labelling – warning statements

There is a potential requirement for warning statements to be included on the label of the product, either on the label of the product or in an information sheet provided with the product. Warning statements may relate to safety directions, pregnancy warnings, and nicotine addictiveness warnings. The TGA Proposal is to rely on State / Territory requirements for warning statements and safety directions in the Poisons Standard (i.e. no requirements in TGO-110). The RACGP agrees this option is adequate.

3. Ingredients

3.1 Ingredients – prohibiting certain ingredients

The RACGP supports the TGA's first option to prohibit active ingredients other than nicotine (which may include caffeine and any vitamins) and the ingredients which carry known health risks: Ethylene glycol, Diethylene glycol, Diacetyl, 2,3-pentanedione and Vitamin E acetate.

3.2 Ingredients - flavours

The TGA proposes no limits on flavours. However, the RACGP recommends a more stringent approach to flavours, allowing certain flavours only (e.g. tobacco, mint, menthol).

An unlimited number of flavours will add to the uncertainty for prescribers. They will not know if there are other ingredients that may cause harm. Prescribers may also be concerned some flavours may particularly appeal to children and adolescents, which may result in a risk of diversion. If only a small number of flavours are allowed, prescribers cannot be pressured by patients to prescribe products they would prefer not to.

4. Packaging – child resistant packaging

Prescribers need to be assured that packaging is child resistant given the known dangers of ingestion by children. The RACGP supports the TGA's proposed option.

5. Nicotine concentration

The TGA proposes no limit on nicotine concentration or active ingredient content. This is the preferred option, supported by the RACGP because the prescriber needs to be able to titrate the nicotine dose up to an effective level for the individual patient. The suggested level for dosing can be addressed in clinical practice guidance advice to prescribers. However, if larger quantities of high concentration products were being dispensed on any one occasion, this would be of concern due to the increased risk of diversion.

Too low nicotine concentrations would make it difficult or impossible to titrate up to the most effective dose of nicotine.

6. Volume

Setting a maximum volume may assist to minimise the risks arising from accidental exposure to and /or ingestion of vaporiser nicotine products. The TGA does not propose setting a maximum container volume, but rather address the risks of accidental exposure through the child resistant packaging requirements.

The RACGP cautions against having no limit on the amount of nicotine that can be prescribed at any one time. A limit such as three months supply would be consistent with good practice and ensure the prescriber has the opportunity to monitor use.

If there is no limit on supply, prescribers are likely to be pressured to prescribe large quantities.

7. Other comments

Australia is the only country currently intending to make Vaporiser Nicotine available with a doctor's prescription. This is consistent with Australia's role as a leader in tobacco control and the aim should be to set a standard that could be adopted worldwide for therapeutically available nicotine.

The aim should be to support evidence-based use of these products and seek to ensure the products available in Australia meet standards for quality and safety. In this regard the statement on page 10 that the TGA will not require nicotine vaporiser products imported into Australia to meet Good Manufacturing Practice standards and provide a Certificate of Analysis is unacceptable.

The RACGP agrees to publication of this submission. If you have any queries please contact Mr Stephan Groombridge, Manager, eHealth and Quality Care on (03) 8669-0544 or at stephan.groombridge@racgp.org.au

Yours sincerely

Dr Karen Price
President