Consumer Healthcare Products Australia

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09 October 2023

Committee Secretary
Senate Standing Committees on Community Affairs
PO Box 6100
Parliament House
Canberra ACT 2600

Submitted online and by email to: community.affairs.sen@aph.gov.au

Dear Sir or Madam,

Public Health (Tobacco and Other Products) Bill 2023, and the Public Health (Tobacco and Other Products) (Consequential Amendments and Transitional Provisions) Bill 2023

CHP Australia is the leading voice and industry body for manufacturers and distributors of consumer healthcare products, which includes non-prescription medicines. We strive to advance consumer health through responsible Self Care. Our key priorities for the industry include improving health literacy, growing the consumer healthcare products industry and increasing access to medicines where appropriate.

CHP Australia is concerned that the measures proposed in the Public Health (Tobacco and Other Products) Bill 2023, and the Public Health (Tobacco and Other Products) (Consequential Amendments and Transitional Provisions) Bill 2023 in relation to e-cigarettes, or nicotine vaping products (NVPs), overlap with existing regulations for therapeutic goods. By doing so, the enforcement of either regulation or legislation is likely to be weakened.

As such, taking the government's commitment to supporting "stronger controls on e-cigarette importation, contents and packaging and is working with states and territories to address the black market for e-cigarette products through the therapeutic goods framework and stronger border measures," CHP Australia proposes that the Government allow existing frameworks and regulations to be applied to NVPs through *either* the Therapeutic Goods Act or the Public Health (Tobacco and Other Products) Bill 2023, and the Public Health (Tobacco and Other Products) (Consequential Amendments and Transitional Provisions) Bill 2023, *but not both*.

On 20 September, CHP Australia made a submission to the Therapeutic Goods Administration (TGA) regarding a series of proposals for reforms to regulate vapes in Australia. These proposed reforms were all based on the premise that NVPs are a therapeutic smoking cessation device.

Less than a week after the TGA's proposal to reform vape regulation, the Australian Government proposed the public health (tobacco and other products) Bill 2023, and

the Public Health (Tobacco and Other Products) (Consequential Amendments and Transitional Provisions) Bill 2023. In contrast to the TGA's proposals, the Australian Government's proposals treat NVPs as tobacco products which are harmful to public health.

CHP Australia does not have the expertise to advise or comment on how NVPs should be categorised however the dual categorisation of this product could lead to:

- Unnecessary bespoke regulatory and legislative arrangements
- A regulatory approach which is inconsistent with the *Therapeutic Goods Act*
- Duplication of legislation, particularly in relation to advertising
- A regulatory approach which is inconsistent with the TGA's stated risk-based approach to regulation of therapeutic goods
- Confusion amongst the regulated industries, and potential exploitation of this uncertainty by manufacturers, importers, and retailers
- Manufactures and suppliers of therapeutic vapes being disincentivised from undertaking appropriate research to develop the evidence base and product dossiers that regulators, healthcare professionals and consumers rightly expect from therapeutic goods
- Medical legitimacy attributed to unapproved NVPs (through their scheduling as Prescription Only medicines
- Australian consumers being denied the protections that they are entitled to expect will be applied to therapeutic goods.

As mentioned, CHP Australia does not hold any view on which category NVPs should fall into, but strongly advise that any changes to NVP categorisation should not have any unintended consequences for existing NRT products.

The TGA's recent targeted consultation paper[1] makes it clear that, the use of NVPs is a serious health issue, that NVPs are being increasingly misused (despite regulatory interventions) and that products continue to be illegally supplied in Australia, noting that:

> "Vaping is a gateway to smoking" [page 8]
> "Vapes are associated with a range of short-term health risks and their long-term health effects are not yet known." [page 9]
> "There are no therapeutic vapes that have been evaluated by the TGA as being safe and effective for smoking cessation. Further, there is a wide range of smoking cessation products already on the Australian market that have been rigorously assessed by the TGA with an established safety and efficacy profile."[page 10]
> "There are currently no NVPs registered in the ARTG." [page 11]
> "Reforms are needed to address the disconcerting rate at which vape use is increasing in Australia outside lawful prescription pathways, and to make regulatory controls simpler to understand and easier to enforce." [page 13]

[1] Circulated by the Vaping Reform Team, Regulatory Legal Services Branch, Health Products Regulation Group to a targeted group of stakeholders on 7 September 2023

> "There is a widespread practice of concealing nicotine content to avoid regulatory controls" [page13]

The TGA's consultation paper also makes it clear that smoking cessation is a therapeutic claim and that products making therapeutic claims must be regulated as therapeutic goods by the TGA.

What the consultation paper failed to make clear was why NVPs required any special regulatory treatment at all. In the view of CHP Australia and our members, should NVPs be considered as therapeutic goods, then they should be treated just like all other therapeutic goods, they should meet the expected standards of quality, safety and efficacy required by legislation and by the TGA. If they are low-risk therapeutic goods, they may be listed on the ARTG. If they are higher-risk goods (as NVPs no doubt are) then they should be registered goods and assessed for quality safety and efficacy by the TGA prior to registration.

In our view, there is no justification for a "light" regulatory touch and there is no justification for special regulatory considerations for NVPs.

Similarly, the proposed new measures in the Government's Public Health (Tobacco and Other Products) Bill 2023, and the Public Health (Tobacco and Other Products) (Consequential Amendments and Transitional Provisions) Bill 2023 fail to address why existing TGA regulations require additional legislation, or why NVPs should be treated as novel and harmful tobacco products instead of therapeutic goods, as they currently are.

With regard to the Government's proposed changes in advertising permissions, CHP Australia is of the view that should NVPs be considered as therapeutic goods then they should be treated exactly like any other higher-risk therapeutic good: they should be registered goods, they should be assessed for quality safety and efficacy by the TGA prior to registration and they should be covered by all the existing post-market controls and obligations applicable to registered therapeutic goods. The advertising of NVPs can adequately be controlled under the existing arrangements already in place for all therapeutic goods.

As prescription only medicines, NVPs are already prohibited from being advertised to consumers. Despite this, there is a substantial amount of advertising to consumers that does take place (e.g. on social media platforms and on websites). It is difficult to see how further prohibitions will be useful. What is needed is more effective enforcement, not further prohibitions.

With regard to the Government's proposed measures to reduce palatability by restricting additives, pre-market assessment by the TGA would provide an opportunity to assess the appropriateness of any proposed flavour and the safety of any flavour ingredient(s) prior to supply. Noting that existing NRT products are available in a range of flavours, CHP Australia proposes that unapproved vapes should not be available in Australia.

With regard to the Government's proposed measures to reduce tobacco product attractiveness by regulating product design features that create novelty value, pre-market assessment by the TGA would ensure that the requirements of the existing Labelling Orders were met. Should NVPs be categorised as therapeutic goods, they would be registered goods and subject to assessment for quality safety and efficacy by the TGA prior to registration and covered by all the existing post-market controls and obligations applicable to registered therapeutic goods.

CHP Australia's full submission to the TGA's recent consultation is attached for further information.

CHP Australia is of the strong view that introducing new NVP specific regulations and legislation simultaneously catching NVPs in both a therapeutic goods category and a tobacco products category serves only to weaken enforcement and penalties for non-compliance with existing regulations. Such a dual approach to regulation will also create areas of uncertainty for unscrupulous players to exploit. The Government needs to decide whether NVPs are to be treated as therapeutic goods or as tobacco products. If the former, then the existing regulatory controls should be applied without modification. If the latter, then effective controls need to be introduced and enforced.

Please contact me should you require any further clarification relating to this submission.

Yours sincerely,
Luna Zivadinovic
Public Affairs Manager
CHP Australia

21 September 2023

Vaping Reform Team
Regulatory Legal Services Branch
Health Products regulation Group
Australian Government, Department of Health and Aged Care

Submitted online and by email to:

Dear Sir or Madam,

Therapeutic Goods Administration (TGA) targeted consultation on further details of proposed reforms to the regulation of vapes in Australia

We refer to your correspondence of 7 September re the above. Please find attached the CHP Australia responses to the consultation paper and survey.

CHP Australia is the leading voice and industry body for manufacturers and distributors of consumer healthcare products, which includes non-prescription medicines. We strive to advance consumer health through responsible Self Care. Our key priorities for the industry include improving health literacy, growing the consumer healthcare products industry and increasing access to medicines where appropriate.

CHP Australia members who sponsor and/or supply nicotine replacement therapy (NRT) products are being unfairly disadvantaged by the special regulatory treatment being given to vapes. All NRT products available in Australia will have undergone pre-market evaluation by the TGA to ensure quality, safety and efficacy. All NRT products available in Australia are subject to post-marketing controls (e.g. advertising restrictions, pharmacovigilance obligations, etc). Reducing the regulatory burden (and the associated costs) for vapes (without any corresponding reduction for NRT products) creates an unfair and inequitable marketplace.

CHP Australia is of the view that vapes should be treated exactly like any other higher-risk therapeutic good: they should be registered goods, they should be assessed for quality safety and efficacy by the TGA prior to registration and they should be covered by all the existing post-market controls and obligations applicable to registered therapeutic goods.

Please contact me should you require any further clarification relating to this submission.

Yours sincerely,

Steve Scarff
Regulatory and Legal Director

Proposal 1 – Restrictions on importation, manufacture and supply of all vapes

Q1. Do you support the proposed approach to ban disposable single use vapes absolutely and all other vapes, except those for legitimate therapeutic use in compliance with the TG Act?

Yes, disposable vapes should be banned completely.

CHP Australia is aware of concerns that disposable vapes pose significant risks from an environmental, sustainability and safety viewpoint (whether or not they contain nicotine). Reservoir liquids (some of which include nicotine), various plastics, metals, wiring and batteries are glued together, they cannot be separated into components for recycling and they end up in landfill. The batteries and the reservoir liquids also pose safety risks. While manufacturers of therapeutic goods are increasingly addressing concerns around sustainability, this does not appear to be the case with disposable vapes.

Yes, the only legitimate vapes should be those registered for therapeutic use in compliance with the *Therapeutic Goods Act*.

The consultation paper makes it clear that, vaping is a serious health issue, that vapes are being increasingly misused (despite regulatory interventions) and that products continue to be illegally supplied in Australia, noting that:

> "vaping is a gateway to smoking" [page 8]
> "Vapes are associated with a range of short-term health risks and their long-term health effects are not yet known." [page 9]
> "There are no therapeutic vapes that have been evaluated by the TGA as being safe and effective for smoking cessation. Further, there is a wide range of smoking cessation products already on the Australian market that have been rigorously assessed by the TGA with an established safety and efficacy profile."[page 10]
> "There are currently no NVPs registered in the ARTG." [page 11]
> "Reforms are needed to address the disconcerting rate at which vape use is increasing in Australia outside lawful prescription pathways, and to make regulatory controls simpler to understand and easier to enforce." [page 13]
> "There is a widespread practice of concealing nicotine content to avoid regulatory controls" [page13]

The consultation paper also makes it clear that smoking cessation is a therapeutic claim and that products making therapeutic claims must be regulated by the TGA.

What the consultation paper fails to make clear is why vapes require any special treatment at all. In the view of CHP Australia and our members, vapes should be treated like all other therapeutic goods, they should meet the expected standards of quality, safety and efficacy required of all other therapeutic goods in Australia. If they are low-risk therapeutic goods, they may be listed on the ARTG. If they are higher-risk

goods (as vapes no doubt are) then they should be registered goods and assessed for quality safety and efficacy by the TGA prior to registration.

There is no justification for a "light" regulatory touch for vapes.

There is no justification for special considerations for vapes.

Treating vapes like any other higher-risk therapeutic good, would:

- Do away with the need for bespoke regulatory arrangements
- Be consistent with the *Therapeutic Goods Act*
- Be consistent with the TGA's stated risk-based approach to regulation
- Be consistent with the controls on existing smoking cessation products
- Be more easily understood by the regulated industry
- Incentivise manufacturers and suppliers of vapes to undertake the appropriate research, to develop the evidence base and to produce the product dossiers that healthcare professionals and consumers rightly expect
- Remove the medical legitimacy (mistakenly) given to the unapproved prescription vapes that are currently being supplied
- Address all the issues raised in the consultation paper, and
- Provide Australian consumers with the protections they are entitled to expect.

The CHP view is that vapes should be treated exactly like any other higher-risk therapeutic good: they should be registered goods, they should be assessed for quality safety and efficacy by the TGA prior to registration and they should be covered by all the existing post-market controls and obligations applicable to registered therapeutic goods.

Q2. How would you anticipate industry and consumers to respond to a ban on the importation, manufacture and supply of non-therapeutic vapes?

CHP Australia and our members would support a ban on the importation, manufacture and supply of non-therapeutic vapes.

Q3. Do you support the proposal to remove the personal importation scheme exception for vapes? If not, what would be the impact on you?

NA. CHP Australia makes no comment regarding the personal import scheme.

Q4. Do you agree with the proposal to retain a traveller's exemption, including the proposed limits?

NA. CHP Australia makes no comment regarding the traveller's exemption.

Q5. Do you support the proposed approach to prohibiting the advertisement of all vapes (subject to limited exceptions)?

No. Consistent with the CHP proposal (see Q1) the advertising of vapes should be controlled under the existing arrangements already in place for all therapeutic goods.

As prescription only medicines, NVPs are already prohibited from being advertised to consumers. Despite this, there is a substantial amount of advertising to consumers that does take place (e.g. on social media platforms and on websites). It is difficult to see how further prohibitions will be useful. What is needed is more effective enforcement, not further prohibitions.

Q6. [If applicable] Suppliers, what part of the supply chain do you occupy? For example, are you an importer, manufacturer, warehouser, wholesaler, retailer or a combination of these (please specify)?

a. What proportion of your sales volumes is attributable to vape sales [i.e. quantity of vapes sold]?
NA
b. What proportion of your sales revenue is attributable to vape sales [i.e. revenue earned from sales]?
NA
c. What impact would the proposed measures have on your sales volumes?
NA
d. What impact would the proposed measures have on your sales revenues?
NA
e. What proportion of your vapes sales is attributable to disposable single use vapes versus refillable products?
NA
f. How would restricting the importation, manufacture and supply of disposable single use, and non-therapeutic, vapes in Australia impact you?
NA
g. How much stock do you have in Australia currently and how long would it take to sell that stock?
NA
h. What would be the cost to you if you were required to dispose or otherwise move on existing stock?
NA

Proposal 2 – Changes to market accessibility requirements, including better regulation of device components

2.1 Pre-market notification of TGO 110 compliance

Q7. Do you support the approach to require a pre-market notification of compliance with TGO 110?

No.

Consistent with the CHP proposal (see Q1), vapes should be treated exactly like any other higher-risk therapeutic good: they should be registered goods, they should be assessed for quality safety and efficacy by the TGA prior to registration and they should be covered by all the existing post-market controls and obligations applicable to registered therapeutic goods.

We do not support a separate TGO for vapes.

We do not support allowing importers, manufacturers and suppliers to self-declare compliance. Such self-declaration is permitted for low-risk listed medicines (which use permitted ingredients and permitted indications). This sort of self-declaration of compliance has no place in the regulation of higher-risk therapeutic goods, such as vapes.

Q8. [If applicable] For suppliers of therapeutic vapes, what impact would the proposed notification system have on your supply model and what transition period would you require to comply with the new notification requirement?

NA

2.2 Streamlined access under SAS and AP schemes

Q9. Do you support the proposed access to vapes under the SAS C notification system? What impact would this pathway have on facilitating patient access to therapeutic vapes?

No.

Consistent with the CHP proposal (see Q1), vapes should be treated exactly like any other higher-risk therapeutic good: they should be registered goods, they should be assessed for quality safety and efficacy by the TGA prior to registration and they should be covered by all the existing post-market controls and obligations applicable to registered therapeutic goods.

Access to vapes would then be the same as access to any other therapeutic good.

Q10. [If applicable] For prescribers, would the proposed new pathway likely change your approach to prescribing therapeutic vapes? How?

NA

Q11. [If applicable] For prescribers, which access pathway (SAS B, SAS C or AP) would you envisage using to prescribe therapeutic vapes? Why?

NA

Q12. [If applicable] For prescribers, would integration of SAS or AP applications or notifications into existing clinical software systems ease the administrative burden and/or encourage you to use the new pathway?

NA

2.3 Regulation of device components

13. Do you agree with the proposal to regulate both e-liquid and device components of unapproved vapes under the same part of the TG Act for simplicity?

No.

Unapproved vapes should not be available in Australia.

Consistent with the CHP proposal (see Q1), vapes should be treated exactly like any other higher-risk therapeutic good: they should be registered goods, they should be assessed for quality safety and efficacy by the TGA prior to registration and they should be covered by all the existing post-market controls and obligations applicable to registered therapeutic goods.

The performance of a vape will depend on both the formulation of the liquid and the design of the device. So will its safety. A proper assessment of the benefits and risks of any specific vape requires an assessment of the liquid ingredients, the soldering, the glues, the plastics, the heaters, the batteries, the specific shapes of the components, the variability within a batch and the variability from batch-to-batch.

The TGA's pre-market assessment of quality, safety and efficacy would allow a proper assessment of the liquid and device components consistent with existing TGA practices.

14. Will these changes have direct or indirect impact of you? Please provide details.

CHP members who sponsor and/or supply nicotine replacement therapy (NRT) products are being unfairly disadvantaged by the special regulatory treatment being given to vapes. All NRT products available in Australia will have undergone pre-market evaluation by the TGA to ensure quality, safety and efficacy. All NRT products available in Australia are subject to post-marketing controls (e.g. advertising restrictions, pharmacovigilance obligations, etc). Reducing the regulatory burden (and the associated costs) for vapes (without any corresponding reduction for NRT products) creates an unfair and inequitable marketplace.

15. Do you require time to adjust to these requirements? If yes, how long?

NA

Proposal 3 – Improving quality standards for unapproved (unregistered) vapes

3.1 Enhanced requirements for e-liquid components

Q16. Are the definitions of the nicotine and mint flavours appropriate? If not, please provide reasons.

Consistent with the CHP proposal (see Q1), vapes should be treated exactly like any other higher-risk therapeutic good: they should be registered goods, they should be assessed for quality safety and efficacy by the TGA prior to registration and they should be covered by all the existing post-market controls and obligations applicable to registered therapeutic goods.

Pre-market assessment by the TGA would provide an opportunity to assess the appropriateness of any proposed flavour and the safety of any flavour ingredient(s) prior to supply.

Existing NRT products are available in a range of flavours.

Q17. Do you agree with the proposed upper limit on the concentration of menthol in vapes? If not, please provide reasons.

Consistent with the CHP proposal (see Q1), vapes should be treated exactly like any other higher-risk therapeutic good: they should be registered goods, they should be assessed for quality safety and efficacy by the TGA prior to registration and they should be covered by all the existing post-market controls and obligations applicable to registered therapeutic goods.

Pre-market assessment by the TGA would provide an opportunity to assess the concentration of menthol (or any other ingredient) prior to supply.

Q18. [If applicable] Importers, manufacturers and suppliers, would the restrictions on flavour proposed above impact you?

CHP members who sponsor and/or supply nicotine replacement therapy (NRT) products are being unfairly disadvantaged by the special regulatory treatment being given to vapes. All NRT products available in Australia will have undergone pre-market evaluation by the TGA to ensure quality, safety and efficacy. All NRT products available in Australia are subject to post-marketing controls (e.g. advertising restrictions, pharmacovigilance obligations, etc). Reducing the regulatory burden (and the associated costs) for vapes (without any corresponding reduction for NRT products) creates an unfair and inequitable marketplace.

Existing NRT products are available in a range of flavours.

Q19. Do you agree with the proposal to require pharmaceutical-like packaging and presentation for vapes, e.g. vapes manufactured in black, white or grey coloured

materials, predominantly white background on packaging, clear warning statements and other restrictions on labels in addition to other selective TGO 91 requirements for vapes?

Consistent with the CHP proposal (see Q1), vapes should be treated exactly like any other higher-risk therapeutic good: they should be registered goods, they should be assessed for quality safety and efficacy by the TGA prior to registration and they should be covered by all the existing post-market controls and obligations applicable to registered therapeutic goods.

Pre-market assessment by the TGA would ensure that the requirements of the existing Labelling Orders were met.

Q20. [If applicable] What impact will the labelling and packaging changes have and how long would you need to transition your product to comply with the proposed requirements?

CHP members who sponsor and/or supply nicotine replacement therapy (NRT) products are being unfairly disadvantaged by the special regulatory treatment being given to vapes. All NRT products available in Australia will have undergone pre-market evaluation by the TGA to ensure quality, safety and efficacy. All NRT products available in Australia are subject to post-marketing controls (e.g. advertising restrictions, pharmacovigilance obligations, etc). Reducing the regulatory burden (and the associated costs) for vapes (without any corresponding reduction for NRT products) creates an unfair and inequitable marketplace.

Ensuring that vapes complied with the Labelling Orders would create a fairer and more equitable marketplace.

Q21. Do you agree with our approach to allow only permitted ingredients in vapes, instead of trying to prohibit individual chemical entities from use in e-liquids?

Consistent with the CHP proposal (see Q1), vapes should be treated exactly like any other higher-risk therapeutic good: they should be registered goods, they should be assessed for quality safety and efficacy by the TGA prior to registration and they should be covered by all the existing post-market controls and obligations applicable to registered therapeutic goods.

Pre-market assessment by the TGA would provide an opportunity to assess the appropriateness of all the ingredients in a proposed vape.

Q22. [If applicable] Importers, manufacturers and suppliers, will your therapeutic vapes need any re-formulation or other changes to comply with the permitted ingredients and ingredient quality requirements? How long will you need to make these changes? And what financial or business impacts would be associated with them?

NA

Q23. Do you support applying the same regulatory controls to zero-nicotine therapeutic vapes, as for NVPs?

Consistent with the CHP proposal (see Q1), vapes should be treated exactly like any other higher-risk therapeutic good: they should be registered goods, they should be assessed for quality safety and efficacy by the TGA prior to registration and they should be covered by all the existing post-market controls and obligations applicable to registered therapeutic goods.

Zero-nicotine vapes should be banned. Without nicotine, it is difficult to see how a therapeutic claim could be made and so the role of such products remains unclear. It is likely, however, that such products would only serve as a gateway to NVPs. The environmental impacts would be similar to NVPs. The safety risks (from the liquids and from the device components themselves) would also be similar to NVPs. If zero-nicotine products were permitted, then their presence in the marketplace would hamper compliance efforts as it would be necessary to consistently identify and separately deal with: compliant zero-nicotine products, non-compliant zero-nicotine products, compliant NVPs and non-compliant NVPs (all of which might have similar appearances, packaging and labelling).

Q24. What is the overall business cost on you to comply with a strengthened TGO 110?

NA

3.2 Requirements for device components

Q25. Do you agree with the proposed requirements under TGO 110 that will apply to unapproved device components of vapes?

No.

Unapproved device components should not be permitted.

Consistent with the CHP proposal (see Q1), vapes should be treated exactly like any other higher-risk therapeutic good: they should be registered goods, they should be assessed for quality safety and efficacy by the TGA prior to registration and they should be covered by all the existing post-market controls and obligations applicable to registered therapeutic goods.

The TGA's pre-market assessment of quality, safety and efficacy would allow an assessment of the device components consistent with existing TGA practices.

Q26. [If applicable] Suppliers, do you intend to include any vaping device on the register as an approved medical device? If not, why?

NA

Q27. [If applicable] Importers, manufacturers and suppliers, are you familiar with, and do your vapes currently comply with, relevant US FDA or MRHA guidance, and/or EU standards covering vaping devices? If not, what requirements do you meet, and how long would it take to achieve compliance?

NA

Q28. [If applicable] Importers, manufacturers and suppliers, are your vapes manufactured at facilities that hold relevant international standards for Quality Management Systems, such as ISO9001 or ISO 13485?

NA

Proposal 4 – Strengthening domestic compliance and enforcement mechanisms

Q29. Do you have any other comments in relation to this proposal?

Consistent with the CHP proposal (see Q1), vapes should be treated exactly like any other higher-risk therapeutic good: they should be registered goods, they should be assessed for quality safety and efficacy by the TGA prior to registration and they should be covered by all the existing post-market controls and obligations applicable to registered therapeutic goods.

The TGA's existing compliance and enforcement powers would then apply to vapes, as they do to all other therapeutic goods, without the need for any bespoke regulatory arrangements.

Supplementary questions:

Q30. [If applicable] Suppliers, please confirm if you intend to continue to supply therapeutic vapes under the proposed reforms described? If so, please outline the product range and the length of time it would take to meet the new requirements.

NA

Q31. [If applicable] Suppliers, please confirm if you intend to register your therapeutic vapes in the next 2 years? If so, what guidance and/or clarity of supporting data requirements do you need from TGA?

NA

Additional issues raised in the email of 19 September
(Feedback to be included in the free text fields)

Good manufacturing process (GMP) and short-fill vapes

Manufacturers will need to comply with good manufacturing practice (Part 3-3 of the Therapeutic Goods Act 1989) to manufacture therapeutic vapes in Australia including the requirement to obtain a manufacturing licence. Comparable GMP requirements are intended to be imposed on therapeutic vapes imported into the country. However, a reasonable transition period would be considered for manufacturers and importers (eg approximately 12-18 months) to enable such compliance. GMP compliance is appropriate in the circumstances consistent with the manufacture of other therapeutic goods.

Consistent with the CHP proposal (see Q1), vapes should be treated exactly like any other higher-risk therapeutic good: they should be registered goods, they should be assessed for quality safety and efficacy by the TGA prior to registration and they should be covered by all the existing post-market controls and obligations applicable to registered therapeutic goods.

Appropriate GMP requirements would thereby apply to vapes regardless of whether they were manufactured in Australia or overseas.

In relation to open system vapes, it is proposed that the addition of liquid nicotine in a refillable therapeutic vape will need to be undertaken by licenced manufacturers or pharmacists in appropriate conditions to address the highly toxic nature of the nicotine (if exposed directly). It is proposed that requirements would be imposed to ensure that patients are not adding liquid nicotine to e-liquids to therapeutic vapes.

Consistent with the CHP proposal (see Q1), vapes should be treated exactly like any other higher-risk therapeutic good: they should be registered goods, they should be assessed for quality safety and efficacy by the TGA prior to registration and they should be covered by all the existing post-market controls and obligations applicable to registered therapeutic goods.

Appropriate licensing requirements, and suitable controls over the handling of liquid nicotine, would thereby apply.