From: s.22
To: Streamlined Submission; [redacted]
Subject: FW: Liber Pharmaceuticals - meeting request [SEC=OFFICIAL]
Date: Tuesday, 10 August 2021 11:38:19 AM
Attachments: Liber - TGA meeting agenda.pdf

FYI

From: [redacted]
Sent: Tuesday, 10 August 2021 11:36 AM
To: [redacted]
Cc: [redacted]
Subject: FW: Liber Pharmaceuticals - meeting request [SEC=OFFICIAL]

Dear Team,

Can you please review the agenda and let me know the availability for next 2 weeks?

I will organise a pre-meeting session to review the questions and for our response.

Kind regards

[redacted]

From: [redacted]@liber.com.au>
Sent: Tuesday, 10 August 2021 10:51 AM
To: [redacted]@health.gov.au>
Subject: Liber Pharmaceuticals - meeting request

REMINDER: Think before you click! This email originated from outside our organisation. Only click links or open attachments if you recognise the sender and know the content is safe.

Dear [redacted],

We hope that you are well. It has been some months since we last corresponded, however, we have been working hard in the background. With 1 October 2021 rapidly approaching, we would like to request a meeting with you and your team to provide you with an update on our progress to date, our domestic launch into the new framework and to discuss how best to move forward with our plans for submitting an ARTG application.

As you are aware, Liber has developed an NVP, the Nicovape Q, which Liber will be launching into the new framework, and for which we intend to file an application to register on the ARTG in mid-2022. We have completed the bulk of our non-clinical work and are progressing with preparations for a Phase 1 (pharmacokinetics) study.

We have prepared a draft agenda in support of our meeting request, including a list of questions for discussion with you. Please find this attached.

Our team will be available to meet at your earliest possible convenience. We understand that two weeks prior to any meeting we should share our presentation and any supporting documents with you. To that end, we propose sharing a presentation with you by close of business on Tuesday, providing an overview of:

- Liber's progress to date;
- Liber's non-clinical development program;
- The protocol for the Phase 1 study;
- Liber's proposed approach to clinical works; and
- Liber's proposed approach to ARTG registration.

We would be grateful if you could consider our request and propose a time and date for the meeting. We consider that one hour would be sufficient to run through our presentation and facilitate Q&A.

We look forward to hearing from you in due course.

Kind Regards,

s.22

Liber Pharmaceuticals Pty Ltd

www.liber.com.au

This message has been sent as part of a discussion between Liber Pharmaceuticals Pty Ltd and the addressee(s) specified above. If you have received this email by error, please notify us immediately and delete the original message. Do not use, store or copy the information in any medium or disclose its contents to any other person. Any unauthorised use is strictly prohibited.

Private and confidential
9 August, 2021

Therapeutic Goods Administration | Liber Pharmaceuticals

Proposed meeting to discuss Liber's plans for its nicotine vaping product, the Nicovape Q

Introduction

The objectives of this proposed meeting are to introduce TGA to Liber Pharmaceuticals, inform TGA on Liber's plans for providing access to Liber's nicotine vaporiser products (**NVPs**) under the new regulatory framework, and importantly, to discuss the process of seeking ARTG registration of Liber's products.

Liber has identified two key focal areas for this meeting:

1. Liber's nonclinical development program for its Nicovape Q product; and
2. Liber's approach to seeking ARTG registration, including whether a provisional determination is appropriate for NVPs.

There is no domestic Australian or global precedent of any licensed and marketed NVP distributed within a medical framework. Consequently, and with ongoing questions about the safety and efficacy of the broader technology, it is important to understand the appropriate data and information necessary for preparation of the required dossiers for ARTG registration of an NVP.

Liber requests this early meeting to ensure that further formal pre-submission meetings with the TGA regarding Liber's development plans for its Nicovape Q product are constructive and informative, and to ensure that Liber's development programs can be designed and conducted in a manner that provides the TGA with sufficient information to make a decision on the medicinal registration of Liber's NVP offering.

As the only jurisdiction globally with an established medicinal pathway for NVPs (albeit with no commercialised product), the UK's Medicines and Healthcare products Regulatory Agency approach has substantially informed Liber's product development and proposed clinical approach. For an overview of Liber's proposed approach, please refer to Table 1 - Quality (Module 3) and Nonclinical (Module 4) studies proposed for ARTG submission, and Table 2 - Clinical (Module 5) studies proposed for ARTG submission.

This meeting is proposed to comprise a presentation of approximately 30 minutes by Liber, followed by a Q&A session. This meeting is intended to be informal in nature, with the principal intention of updating the TGA on

our approach and to ensure that such an approach is consistent with the TGA's expectations. Liber will make formal presentations to the appropriate TGA teams on the meeting content discussed here at the convenience of the TGA.

Attendees

Attendee	Title
Liber:	
Richard Lee	Chief Executive Officer - Liber Pharmaceuticals
s.22	
Consultants:	
s.47	
Apologies:	
s.47	

Proposed Agenda

Set out below is a suggested agenda for the 30 minute presentation by Liber. The meeting is intended to be an open discussion and we would be delighted to address any other matters that are of particular interest with the TGA in this agenda.

Topic	Duration	Points for consideration
Liber progress update	10 mins	Overview of Liber and its market readiness for launch into the new regulatory framework, presented by RIchard Lee (CEO) • Product update - Launch product - Standards framework - Other considerations

		• Work with key stakeholders
		- Patient assessment
		  - Telehealth
		  - GPs
		- Distribution
		  - Wholesalers
		  - Banner Groups
		- Education
		  - Doctors
		  - Pharmacists
		  - Consumers

		• Path to ARTG
Introduction to Liber's development program	10 mins	Overview of the Nonclinical Development Program of Nicovape Q, presented by s.47) • Overview of approach (interim and ARTG) • Product characterization • Desk-based toxicology approach • Experimental toxicology (in vitro/in vivo) approach • Objectives for follow-up meeting with the TGA on Liber's non-clinical development program
Overview of Liber's ARTG strategy	10 mins	Liber's approach to seeking ARTG registration, presented by Richard Lee (CEO) | s.47 • Approach to seeking a provisional determination • New Medicine | Significant advancement approach • Satisfaction of the five criteria for predetermination • Efficacy literature review plan • Consideration of MHRA pathway for medicinal NVPs • Proposed observational study (current in-market use)
Q&A | Next steps		

Specific questions

While the meeting is intended to provide a status update to the TGA , there are a number of questions that Liber would seek guidance on from the TGA, including the following:

Guidance for applicants seeking ARTG registration for NVPs

Questions:

- *Has the TGA developed any guidance for NVP manufacturers seeking ARTG registration?*
- *Has the TGA considered the MHRA's approach for medicinal licensing of e-cigarettes, in general terms or specifically, as a template for effective regulation?*

Registration as a new medicine - Could Liber seek a provisional determination for its NVP?

Liber believes that NVPs potentially satisfy the basis for registration as a new medicine, because:

s.47

Questions:

- *Does TGA consider that this is a plausible route for a provisional determination?*
- *Does the TGA consider the MHRA's approach to efficacy (for NVPs) as appropriate for product registration in Australia?*
- *What additional studies would TGA envision taking place after the provisional determination?*

Non-clinical development program

Question:

s.47

s.47

Clinical trial approval pathway

s.47

Question:

- *Liber requires guidance from the TGA regarding the appropriate or anticipated approval pathway for our clinical trial, and in particular, whether it is required to follow the CTN or CTA pathway?*

Sterile /non-sterile requirements for NVPs as a medicine

- TGA guidance for inhaled medicines refers to EMEA'S Guideline on the Pharmaceutical Quality of Inhalation and Nasal Products[1] - single-dose → sterile | multi-dose → non-sterile (Table 4.5.1).
- Recent TGO 110 guidance[2] for microbiological testing refers to Section 11(1) of TGO 100[3], which provides acceptance criteria for microbiological quality attributes of a non-sterile medicine.

Question:

- *Is the TGA contemplating non-sterile requirements for NVPs registered on the ARTG?*

GMP licencing/certification requirements

s.47

Question:

- *Is this in line with the TGA's expectation for NVPs as an approved medicine for inhalation?*

[1] European Medicines Agency (2006) Guideline on the Pharmaceutical Quality of Inhalation and Nasal Products
[2] Guidance for the Therapeutic Goods (Standard for Nicotine Vaping Products) (TGO 110) Order 2021 and related matters Version 1.2, July 2021
[3] **Therapeutic Goods (Microbiological Standards for Medicines) (TGO 100) Order 2018 -** https://www.legislation.gov.au/Details/F2018L01685

Status update - progress to ARTG submission

Table 1 Quality (Module 3) and Nonclinical (Module 4) studies proposed for Nicovape Q ARTG submission

Module	Product Component – CTD Section	Module Information (CTD Section)	Studies completed for launch/ pre-clinical Phase 1 study	Additional work proposed for ARTG submission
Quality (Module 3)	**Drug Substance (Nicotine) – CTD Section 3.2.S*** **considered mandatory requirement for an effective application*	Drug substance – Nicotine general properties (3.2.S.1)	s.47	
		Drug substance – Nicotine manufacturing (3.2.S.2)		
		Drug substance – nicotine characterization (3.2.S.3)		
		Control of drug substance nicotine (3.2.S.4)		
		Drug substance – nicotine reference standards (3.2.S.5)		

	Drug Product (Excipients and Device) – CTD Section 3.2.P* ****considered mandatory requirement for an effective application***	Drug Product -Liquid Ingredients (excipients) description and composition (3.2.P.1)	s.47
		Pharmaceutical development (3.2.P.2)	
		Manufacturing (3.2.P.3)	
		Control of excipients (3.2.P.4)	

		Control of drug product (3.2.P.5)	s.47
		Reference standards (3.2.P.6)	
		Container closure system (3.2.P.7)	
		Stability (3.2.P.8)	
		Other device development	

			s.47
Nonclinical (Module 4)	**Liquid Formulation**	Drug substance – Nicotine pharmacology, pharmacokinetics (PK), and toxicology	
		Excipients – humectants and pH adjuster nonclinical evaluation	
		Flavour excipients nonclinical toxicology evaluation	
		Impurities toxicological risk assessment	
Nonclinical (Module 4)	**Device Materials**	Materials component ingredient and leachables toxicological risk assessment	
Nonclinical (Module 4)	**Aerosol constituents**	TRA of select excipients/targeted assessment of HPHCs in aerosol	

		Toxicology of unknown heat degradation products and reactive compounds (NTA)	s.47
		Stability evaluation to assess toxicological risks over proposed shelf-life	
Nonclinical (Module 4)	**Whole aerosol**	*In vitro* toxicology studies	
		In vivo toxicology studies	

Table 2 Clinical (Module 5) studies proposed for ARTG submission

Study (Phase)	Details	Status Timing	To be included in ARTG submission?
Sensory Evaluation of Nicotine Salts (Pre-clinical)	s.47		
Nicotine PK and subjective effects of Nicovape Q in comparison to combustible cigarettes and Nicotrol inhaler (Phase one)			
Observational Cohort Studies			
Literature Reviews			

From: RMP Coordinator
To: s.22
Cc: Streamlined Submission
Subject: RMP - Liber Pharmaceuticals - meeting request - Nicovape Q - No RMP attendance required - advice to delegate [redacted] - from RMP Coord - 12 August 2021 [SEC=OFFICIAL]
Date: Thursday, 12 August 2021 5:28:13 AM
Attachments: image003.jpg
image004.jpg

Hi s.22
The RMP evaluator has considered the need for RMP attendance for Liber Pharmaceuticals, Nicovape Q and has decided No RMP attendance is required at this stage, based on the sponsors email below.
I provide the following from the RMP evaluator:

Risk Management Section does not intend to send an RMP representative to the meeting as there are no RMP-related matters raised in the enquirer's attached agenda. As always, our Section is able to provide follow-up assistance in addressing any of enquirer's RMP-related submission questions.
Please further advise Nitin that the determination of application type by TGA will guide the requirement for an RMP to submitted:

- provisional application will always require an RMP to be submitted
- "Type F" may also lead to requirement for an RMP if the variation may introduce new or heightened safety risks

The sponsor should consult TGA's RMP guidance available online for further information on the Australian requirements https://www.tga.gov.au/publication/risk-management-plans-medicines-and-biologicals
Please reach out if you require further input from RMS.
Warm regards,
[redacted]

From: s.22 [redacted]@liber.com.au>
Sent: Tuesday, 10 August 2021 10:51 AM
To: [redacted]@health.gov.au>
Subject: Liber Pharmaceuticals - meeting request

Duplicate email
[redacted]

From: s.22
To: Streamlined Submission
Cc:
Subject: Re: Liber Pharmaceuticals - meeting request [SEC=OFFICIAL]
Date: Monday, 30 August 2021 10:05:41 PM
Attachments: Liber - request-for-pre-submission-meeting.pdf
ATT00001.htm

Dear s.22

My sincere apologies, following our team meeting this evening, our slide deck now needs to be revised by our regulatory consultants. We have a follow up meeting scheduled at 5pm tomorrow and will revert to you with all outstanding materials as soon as possible following that meeting.

In the meantime, I have attached a copy of the pre-submission meeting request form for you attention.

Regards

s.22

Logo

Liber Pharmaceuticals Pty Ltd

www.liber.com.au

This message has been sent as part of a discussion between Liber Pharmaceuticals Pty Ltd and the addressee(s) specified above. If you have received this email by error, please notify us immediately and delete the original message. Do not use, store or copy the information in any medium or disclose its contents to any other person. Any unauthorised use is strictly prohibited.

On 30 Aug 2021, at 4:23 pm, Streamlined Submission <streamlinedsubmission@health.gov.au> wrote:

Dear

Thank you for your prompt response and update.

We look forward to receiving the information soon.

Kind regards

s.22

Medicines Regulation Division | Health Products Regulation Group
Prescription Medicines Authorisation Branch
Australian Government Department of Health
T: 02 6232 8113 | E: streamlinedsubmission@health.gov.au
Location: Symonston Building
PO Box 100, Woden ACT 2606, Australia

The Department of Health acknowledges the traditional owners of country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to elders both past and present.

Australian Government
Department of Health
Therapeutic Goods Administration

TGA use only

This form, when completed, will be classified as '**For official use only**'.
For guidance on how your information will be treated by the TGA see: Treatment of information provided to the TGA at <https://www.tga.gov.au/treatment-information-provided-tga>.

Request for pre-submission meeting

Our guidance at the meeting is nonbinding and without prejudice. As knowledge evolves over time, the initial guidance we gave at the meeting may become out of date or be superseded.

Applicant

Company	Liber Pharmaceuticals Pty Ltd
Address	Suite 8, 35 Old Northern Road, Baulkham Hills, 2153, NSW

Contact person

Name	s.22
Position	
Mailing address	
Phone	
Email	

Proposed scheduling information

Proposed date	Friday, 3 Spetember 2021.
Proposed time	10:00am
Proposed meeting length	(1 to 1.5 hours maximum, unless agreed otherwise)

Once TGA receives your initial completed meeting request, we will consider your request and then advise if it is appropriate for a meeting to proceed or whether the issues can be appropriately addressed via email.

Proposed meeting type (tick preferred option):

☐ **Face to face meeting**

Face to face meeting at TGA (Symonston) or in the location of Delegate e.g. Melbourne.

If an alternate location to TGA (Symonston) is required, the applicant must organise a location convenient to TGA and provide a toll free dial in number to use on the day. Presentation slides need to have been made available with the full briefing package (at least 2 weeks prior to the meeting).

Additional facilities required:

☐ Computer ☐ Projector ☐ Other (please specify)

If required, TGA is able to provide a meeting specific dial in number and code for the purpose of conducting a meeting. However be aware that the security and IT connectivity of the number provided by the TGA cannot be guaranteed.

■ **Teleconference/videoconference only**

A Teleconference/videoconference must be arranged by the applicant at a time that is mutually convenient.

Subject matter for discussion

■ Prescription medicine registration

☐ Orphan drug designation

☐ Priority review prescription medicine designation

☐ Over-the-counter medicine

☐ Registered complementary medicine

☐ Assessed listed complementary medicine

☐ Ingredient for use in listed medicines

☐ Medical device (manufacturer)

☐ Medical device (sponsor)

☐ In vitro diagnostic medical device (manufacturer or sponsor)

☐ Biological (cell and tissue-based products)

☐ Disinfectant (manufacturer or sponsor)

☐ Other (please specify)

Medicine

Generic name	n/a
Trade name	Nicovape Q
Substance name	Nicotine
Dosage form(s)	INH
Indications	Smoking cessation
Patient population	Current adult smokers
Other relevant information	The medicine will be assessed in conjunction with the delivery device.

Medical device

Device name or Unique Product Identifier (UPI)	Nicovape Q
GMDN Code	novel product - GMDN application underway
Device Classification	Class IIa (low-moderate risk)
Device Description	Nicotine Vaping Product (NVP)
Intended Purpose	Smoking cessation
Other relevant information	The device will be assessed in conjunction with the medicine.

Biological

Product name	n/a
Trade name	
Biological ingredient name	
Dosage form(s)	
Other relevant information	

Name	s.22		
Signature		Date	30-August-2021

Please ensure that all information set out below is provided with the initial request.

Background information

1. Proposed agenda

2. Overview of the product and its development program (quality, nonclinical, and clinical)

Include a brief background to the disease that the product is supposed to treat, the place of this product in the treatment algorithm and any relevant regulatory history.

For medical devices include a brief background of the device description, mode of action, relevant regulatory history (including any approval overseas) and the intended purpose.

3. Purpose and objectives of the meeting

Include a:

a. brief statement of the purpose and objectives of the meeting

b. description of the issues underlying the agenda, and

c. summary of:

i. completed or planned studies

ii. clinical trials or data that the sponsor/applicant intends to discuss at the meeting

iii. the general nature of the critical questions to be asked, and

iv. where the meeting fits in overall development plans

Although the statement should not provide detailed documentation of trial designs or completed studies and clinical trials, it should provide enough information to facilitate understanding of the issues, such as a small table that summarises major results.

4. List of questions

Include a list of proposed questions, grouped by discipline (quality, non-clinical, clinical), with a brief explanation of the context and purpose of each question.

5. List of participants

Include a list of individuals, including titles and affiliations, from the sponsors /applicant's organisation or consultants who will attend the proposed meeting.

Include any requests for particular TGA staff or disciplines to participate in the proposed meeting. These people may not attend but are represented.

6. Full Briefing Package

To be provided electronically **2 weeks** prior to the scheduled meeting

Checklist

☐ Final agenda

☐ Overview of the product and its development program (quality, non-clinical and clinical)

Include a brief background to the disease that the product is supposed to treat, the place of this product in the treatment algorithm and any relevant regulatory history

For medical devices include a brief background of the device description, mode of action, relevant regulatory history (including any approval overseas) and the intended purpose

☐ Purpose and objectives of the meeting

Although the statement should not provide detailed documentation of trial designs or completed studies and clinical trials, it should provide enough information to facilitate understanding of the issues, such as a small table that summarises major results

☐ List of final questions

☐ List of confirmed participants

☐ Meeting presentation (or as agreed)

This is to be provided no later than 2 days before the scheduled meeting. However, if provided closer to the scheduled meeting **no new/additional** information is to be included to that which has been provided in the “full Briefing Package” otherwise this may result in the meeting being postponed

FOI 27-3600 - Document 4

Private and confidential

31 August, 2021

Therapeutic Goods Administration | Liber Pharmaceuticals

Meeting to discuss Liber's plans for its nicotine vaping product, the Nicovape Q

Executive Summary

Liber Pharmaceuticals Pty Ltd (**Liber Pharmaceuticals**) is delighted to seek the opportunity to present initial development plans for its Nicovape Q products, a closed nicotine vaping system, which has been developed to be launched into the new medical framework to be implemented by the Therapeutics Goods Administration (the **Administration**) on 1 October 2021. In addition to meeting the standards of TGO 110, Liber Pharmaceuticals has developed its nicotine vaping product (**NVP**) with a view to seeking admission to the Australian Register of Therapeutic Goods (the **ARTG**).

It is with this in mind that Liber Pharmaceuticals seeks this meeting, as an opportunity to present our proposed product, and to outline our nonclinical development program, with a view to commencing regular dialogue in anticipation of filing a formal application in 2022.

Proposed Agenda

Set out below is a suggested agenda for the 30-minute presentation by Liber. The meeting is intended to be an open discussion and we would be delighted to address any other matters that are of particular interest with the TGA in this agenda.

Topic	Duration	Points for consideration
Liber progress update	10 mins	Overview of Liber and its market readiness for launch into the new regulatory framework, presented by RIchard Lee (CEO) • Product update • Launch infrastructure • Launch product • Ensuring access
Liber's approach to ARTG registration	10 mins	Liber's approach to seeking ARTG registration, presented by Richard Lee (CEO) | s.47 PhD (Consultant,Toxicology) • Overview of Liber's approach s.47

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		s.47 [redacted]
Introduction to Liber's development program	10 mins	Overview of the Nonclinical Development Program of Nicovape Q, presented by s.47 [redacted] PhD (Consultant, Toxicology) • Overview of approach (interim and ARTG) • Product characterization • Desk-based toxicology approach • Experimental toxicology (in vitro/in vivo) approach • Objectives for a follow-up meeting with the TGA on Liber's non-clinical development program
Q&A | Next steps		

Overview of the product and its development program

According to World Health Organization (**WHO**) data, tobacco use including smoking causes the highest percentage of healthy years of life lost attributable to behavioural factors across the world – more so than alcohol use, high blood pressure, physical inactivity, and drug use (Figure 1)[1]. Ways to decrease and mitigate the health impacts of tobacco use have been of keen interest to Health Departments across the world in varying approaches, as the health impacts, both in terms of early death and healthy years of life lost, remain severe.

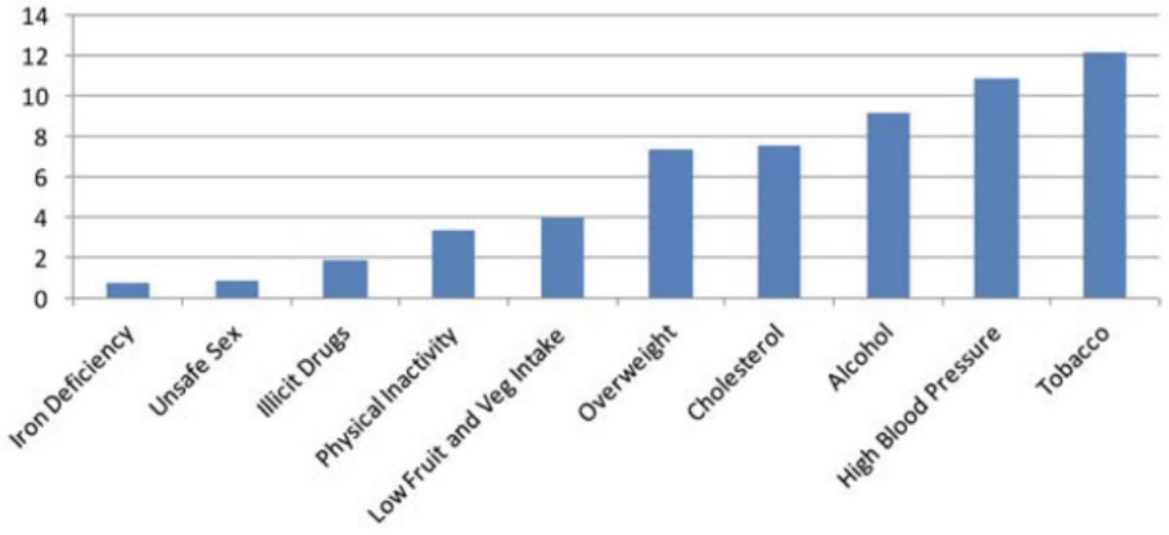


Figure 1. Percentage of healthy years of life lost attributable to behavioural factors (WHO data, 2002)

[1] World Health Organization (WHO). 2002. The World health report: Reducing risks, promoting healthy life. Accessed on August 25, 2021; Accessed from: https://apps.who.int/iris/bitstream/handle/10665/42510/WHR_2002.pdf

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Due to successful public health strategies over many decades, Australia reportedly has one of the lowest daily smoking proportions among Organisation for Economic Cooperation and Development (**OECD**) countries. However, tobacco smoking is still the leading cause of preventable disease and death in Australia[2]. The most recent data from the National Drug Strategy Household Survey (**NDSHS**) estimated that 11.6% of adults smoked daily in 2019, a reduction from an estimated 12.8% in 2016.[3] However, tobacco use in Australia still accounts for 15-19% of deaths over the age 30, similarly to other OECD countries like the US, Canada, the UK and Germany (Figure 2)[4].

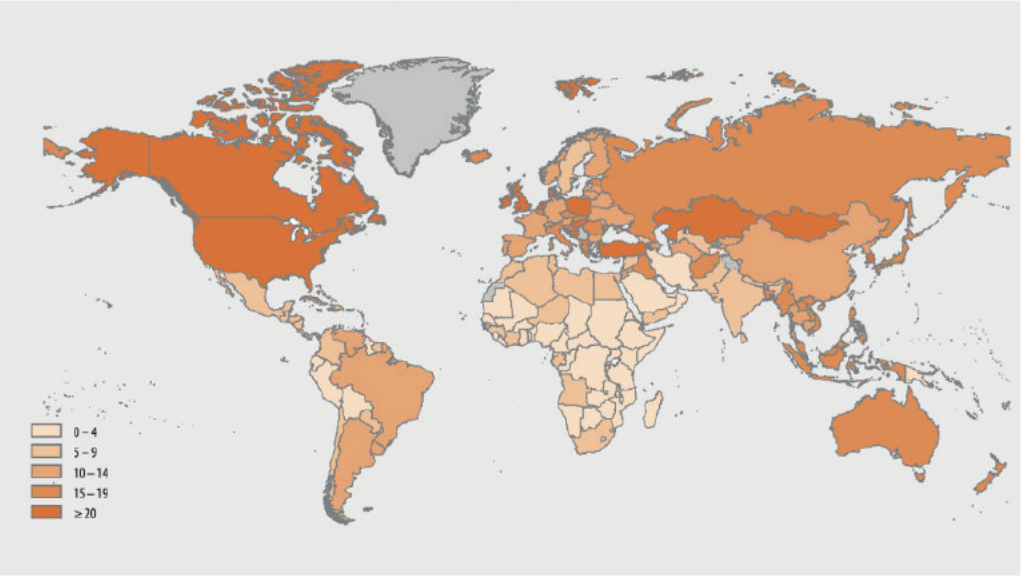


Figure 2. Percentage of deaths over age 30 years caused by tobacco, 2004.

Data available from 2015 indicate that smoking was responsible for 9.3% of the total burden of disease in Australia.[5] Nearly three-quarters (73%) of the burden due to smoking was due to premature death, with smoking responsible for more than 1 in every 8 (21,000) deaths. The burden of disease from smoking in Australia includes:

- Cancers (43%), of which lung cancer accounted for 28%;
- Chronic obstructive pulmonary disease (**COPD**) (30%); and
- Cardiovascular diseases (17%), primarily related to coronary heart disease (10%) and stroke (3.1%).[6]

Even with the projected rate of the overall current disease burden caused by smoking diminishing by a further 10% by 2025[7], the burden of disease caused by past smoking, which has risen in the same period to 2015 by

[2] Australian Institute of Health and Welfare (AIHW). 2021. Tobacco smoking. Accessed on August 25, 2021; Accessed from: https://www.aihw.gov.au/reports/australias-health/tobacco-smoking

[3] AIHW 2021: https://www.aihw.gov.au/reports/australias-health/tobacco-smoking

[4] World Health Organization (WHO). 2009. Global health risks: mortality and burden of disease attributable to selected major risks. Accessed on August 25, 2021; Accessed from: https://www.who.int/healthinfo/global_burden_disease/GlobalHealthRisks_report_full.pdf

[5] AIHW 2021: https://www.aihw.gov.au/reports/australias-health/tobacco-smoking

[6] Australian Institute of Health and Welfare (AIHW). 2019. Burden of tobacco use in Australia: Australian Burden of Disease Study 2015. Australian Burden of Disease series no. 21. Cat. no. BOD 20. Canberra: AIHW

[7] AIHW 2019

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15%, will account for significant health burdens and effects on life expectancy and healthy years of life for those affected.

With no additional actions or tools to mitigate or change smoking rates throughout the population, even with a continuing trend of fewer current smokers through quitting alone, rates of cancer and other smoking-related diseases are likely to grow in the coming decades rather than diminish as, for example, average lifespans generally increase, intensifying the total burden of disease to a degree not offset by the current percentage decline of smoking.

For smokers, the cessation of tobacco smoking is the best way to reduce the risk of harm from tobacco-related disease.[8] However, due to the addictiveness of nicotine, sustained quitting rates (> 6 months) are low.[9] Although nicotine is the active constituent in tobacco smoke, the harmful effects of cigarette smoking are not due to nicotine, but from inhalation exposure to thousands of chemicals formed during the combustion of tobacco including harmful and potentially harmful constituents (**HPHCs**), which are globally recognized as associated with tobacco-related diseases such as cancer, cardiovascular disease, respiratory toxicity, and reproductive and developmental toxicity.[10] [11] [12] [13] [14] [15] Thus, the aim of smoking cessation products has been to offer nicotine in forms without combustion products, including as nicotine replacement therapies (**NRTs**) in the forms of gum, lozenges, oral strips, spray, inhaler, patches (16- or 24-hour release), and sublingual tablets. These nicotine replacement therapies can also be prescribed alongside varenicline and bupropion pharmaceuticals.[16] While these products have typically been authorized for short-term use and immediate smoking cessation, the UK's MHRA (2010)[17] and National Institute for Health and Care Excellence (**NICE**)

[8] Choi et al. 2020

[9] Australian Government Department of Health and Aging (AUDHA). 2004. Smoking cessation Guidelines for Australian general practice. Practice Handbook: https://untobaccocontrol.org/impldb/wp-content/uploads/reports/Australia_annex8_smoking_cessation_guidelines.pdf

[10] U.S. Food and Drug Administration. 2012. Harmful and Potentially Harmful Constituents in Tobacco Products and Tobacco Smoke; Established List. Federal Register
Health Canada 2000, MHRA 2017)

[11] U.S. Food and Drug Administration. 2019a. Final Guidance for Industry: Premarket Tobacco Product Applications for Electronic Nicotine Delivery Systems.

[12] U.S. Food and Drug Administration. 2019b. Harmful and Potentially Harmful Constituents in Tobacco Products; Established List; Proposed Additions

[13] World Health Organization (WHO). 2019. TobReg Scientific Recommendation: Updated Priority List of Toxicants in Combusted Tobacco Products

[14] Health Canada, Tobacco Reporting Regulations, SOR/2000-273, Last Amended on March 4, 2019, Available at, 2019, https://laws-lois.justice.gc.ca/PDF/SOR-2000-273.pdf

[15] Medicines and Healthcare products Regulatory Agency (MHRA). 2017. Licensing procedure for electronic cigarettes as medicine. Accessed on January 10, 2021. Accessed from: https://www.gov.uk/government/organisations/medicines-and-healthcare-products-regulatory-agency

[16] McDonough M. 2015. Update on medicines for smoking cessation. Aust Prescr 2015; 38:106-11. https://doi.org/10.18773/austprescr.2015.038. Accessed on August 25, 2021; Accessed from: https://www.nps.org.au/australian-prescriber/articles/update-on-medicines-for-smoking-cessation

[17] MHRA (2010) Nicotine replacement therapy and harm reduction. Accessed from: https://www.gov.uk/drug-safety-update/nicotine-replacement-therapy-and-harm-reduction)

(2013[18], 2015[19]) authorised and set public health guidelines and standards for the use of the products for "harm reduction".

The UK's Harm Reduction approach to smoking cessation through a change in indications for NRT (MHRA, 2010)[20], public health guidelines (Nice, 2013)[21] and NICE Quality Standard (2015)[22]. All possible use-cases for NRT in smokers are considered, including that of smoking reduction in smokers unwilling to quit.

- **Stoppingsmoking**, but using one or more licensed nicotine-containing products as long as needed to prevent relapse
- **Cutting down prior to stopping smoking** (cutting down to quit)
  - with the help of one or more licensed nicotine-containing products (the products may be used as long as needed to prevent relapse)
  - without using licensed nicotine-containing products.
- **Smokingreduction**
  - with the help of one or more licensed nicotine-containing products (the products may be used as long as needed to prevent relapse)
  - without using licensed nicotine-containing products.
- Temporary abstinence**fromsmoking**
  - with the help of one or more licensed nicotine-containing products
  - without using licensed nicotine-containing products.

[23]

Figure 3: "Box 1" from NICE Public Health Guideline 45 (2013)

Overall, the UK approach was based on the following considerations:

1. There is no case in which it is better to smoke than to use NRT
2. Evidence shows that usage of NRT by smokers is associated with increased subsequent cessation.
3. The UK Harm Reduction approach would expand NRT access to smokers unwilling or unready to quit and, consequently, unlikely to access Stop Smoking Services

[18] http://guidance.nice.org.uk/PH45
[19] https://www.nice.org.uk/guidance/qs92
[20] MHRA (2010) Nicotine replacement therapy and harm reduction. Accessed from: https://www.gov.uk/drug-safety-update/nicotine-replacement-therapy-and-harm-reduction)
[21] NICE (2013) Public health guideline [PH45] Smoking: harm reduction Accessed from: http://guidance.nice.org.uk/PH45
[22] NICE (2015) Quality standard [QS92] Smoking: harm reduction Accessed from: https://www.nice.org.uk/guidance/qs92
[23] NICE (2013) Public health guideline [PH45] Smoking: harm reduction Accessed from: http://guidance.nice.org.uk/PH45

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However, NICE (2013) qualified the "smoking reduction" use-case with a research advisory, since there was a lack of clarity on the long-term benefits of smoking reduction on morbidity/mortality. The additional indications approved by MHRA in 2010 were consequent to an application by the manufacturer of Nicorette Inhaler; in addition to that specific approval, MHRA applied the changes to all licenced NRT. These additional indications built on the last previous revisions, which took place in 2005, and had approved the indication for "step-down-to-quit" (aka "stepping-stone") smoking reduction ahead of a planned quit attempt.

For smoking cessation, the advantage of delivering nicotine through inhalation exposure includes a faster nicotine delivery route to the brain than other forms of administration. When inhaled, nicotine diffuses through the alveoli to reach the brain within 10–20 seconds[24].[25] [26] Nicotine exerts its pharmacological effects by binding to the nicotinic acetylcholine receptors and triggering release of dopamine and other neurotransmitters. This, in turn, may produce similar subjective effects to those produced by cigarettes, facilitating levels of compliance to the intervention higher than NRT.

Another advantage of administering nicotine through inhalation for smoking cessation is the potential reinforcement of the behaviour from environmental cues during inhalation. Because of the similar exposure route for nicotine and the lack of tobacco combustion products, NVPs, also termed electronic nicotine delivery systems (**ENDS**) or e-cigarettes, have been recommended for smoking cessation by the UK National Health Service.[27]

NVPs are available on the UK consumer market, regulated under the Tobacco Products Directive (**TPD**). One concern in the UK before the regulations were enacted was that the enabling of general consumer availability of NVPs would create a pathway for non-smokers to take up NVP (and possibly cigarette) use, causing harm to people that were not currently smoking. Care was taken to monitor the population use of NVPs, and the evaluation 5 years after TPD implementation can be seen in figure 4, with a very small percentage of non-smokers taking up NVP usage.[28]

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[24] Benowitz, N.L. 2009a. Pharmacology of nicotine: addiction, smoking-induced disease, and therapeutics. Annu Rev Pharmacol Toxicol. 2009;49:57-71. doi: 10.1146/annurev.pharmtox.48.113006.094742. PMID: 18834313; PMCID: PMC2946180.

[25] Benowitz, N.L., Hukkanen, J. and Jacob, P. 2009b. Nicotine Chemistry, Metabolism, Kinetics and Biomarkers. Handb Exp Pharmacol. 2009; (192): 29 60. doi:10.1007/978-3-540-69248-5_2

[26] Mathur, A, and OJ Dempsey. 2018. Electronic cigarettes: a brief update. J R Coll Physicians Edinb 2018; 48: 346 51. Accessed from: https://www.rcpe.ac.uk/sites/default/files/jrcpe_48_4_mathur.pdf

[27] National Health Service (NHS). 2021. Smokefree. Accessed on August 25, 2021; Accessed from: https://www.nhs.uk/smokefree/help-and-advice/e-cigarettes

[28] Behavioural Insights Team (BIT). 2015. Accessed on August 25, 2021; Accessed from: https://www.bi.team/wp-content/uploads/2015/08/BIT_Update-Report-Final-2013-2015.pdf

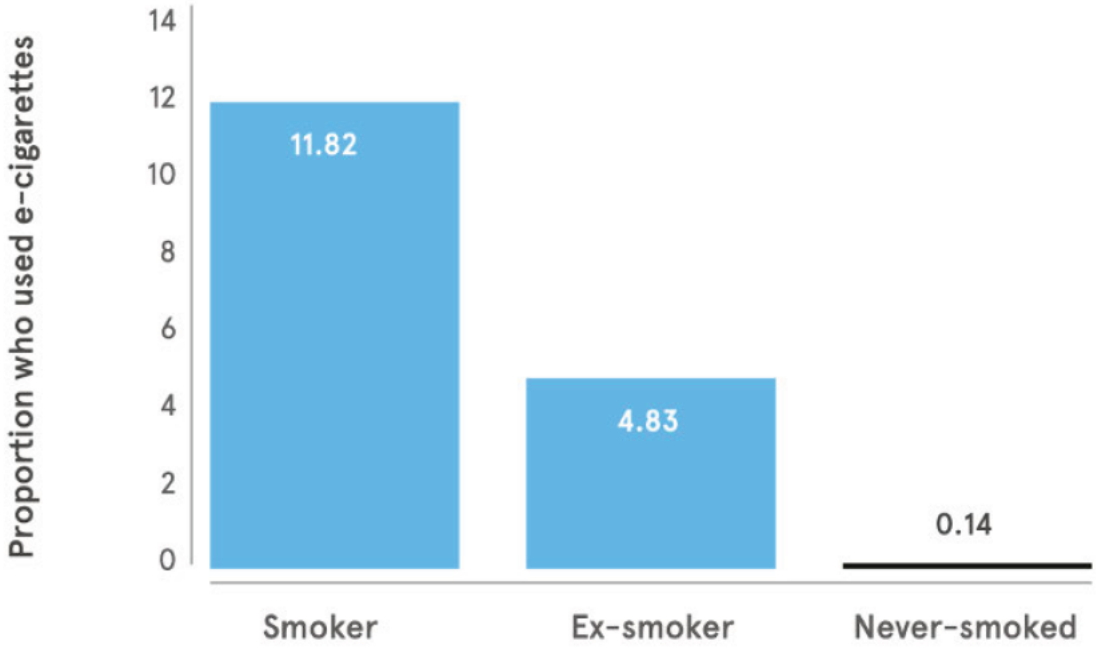


Figure 4. NVP (e-cigarette) usage, by smoking status in the UK

In Australia, the Royal Australian College of General Practitioners (**RACGP, 2019**) reviewed the evidence supporting the use of NVPs as cessation products. It concluded that NVPs may be a reasonable intervention to recommend for people that have tried and failed to quit smoking using approved pharmacotherapies, that are still motivated to quit smoking and that have asked their healthcare practitioner to consider aiding them in cessation using NVPs. However, RACGP concluded that the lack of approved NVPs mandated that a conditional recommendation for use was warranted due to a lack of information on long-term health effects.[29]

Although NVPs are available on the UK consumer market through the TPD, the UK Medicines and Healthcare products Regulatory Agency (**MHRA**) has also provided a route to license NVPs as medicinal products, with specific guidance for manufacturers to demonstrate the product quality, safety, and pharmacological profile through nonclinical and clinical studies, for submission in a Marketing Authorisation Application (MAA).[30] MHRA has to date issued market authorization for one NVP (2016, "E-Voke"), although that product was never commercialised. But, MHRA has developed expertise following its E-voke experience. Additionally, pressure has been exerted on MHRA to ensure that the medical pathway is developed urgently, with Public Health England (the Executive Agency of the UK Department of Health) publicly stating in February 2021, "the lack of a medicinally licensed product needs also to be urgently reviewed."[31]

[29] Royal Australian College of General Practitioners (RACGP). 2019. Supporting smoking cessation: a guide for health professionals, second edition. 2nd edn. East Melbourne, Vic: RACGP, 2019.

[30] https://www.gov.uk/guidance/licensing-procedure-for-electronic-cigarettes-as-medicines

[31] Public Health England. 2021. Vaping in England: 2021 evidence update summary. Accessed on August 26, 2021; Accessed from: https://www.gov.uk/government/publications/vaping-in-england-evidence-update-february-2021/vaping-in-england-2021-evidence-update-summary

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The opportunity for NVPs as smoking cessation medicines relies on products' ability to deliver satisfying levels of nicotine while meeting pharmaceutical quality standards, and on the characterization of their safety, including the potential long-term risks and benefits to patients. Notably, NVPs as smoking cessation products have the potential to deliver nicotine with significantly reduced levels of HPHCs compared to combustible cigarettes.[32] The number of chemicals in cigarette smoke, greater than 7000, exceeds that of NVP aerosol by approximately 2 orders of magnitude.[33] Furthermore, among potentially toxic substances common to both products, cigarette smoke generally contains substantially larger quantities than NVP aerosol[34]).

The Royal College of Physicians[35] have reported that:

1. E-cigarettes [NVPs] are not currently made to medicines standards and are probably more hazardous than nicotine replacement therapy (NRT).
2. Technological developments and improved production standards could reduce the long-term hazard of e-cigarettes [NVPs].
3. There is a need for regulation to reduce direct and indirect adverse effects of e-cigarette [NVP] use, but this regulation should not be allowed significantly to inhibit the development and use of harm-reduction products by smokers.

Thus, NVPs have the best potential as smoking cessation products if they improve manufacturing standards and quality, utilize technological advances to reduce potential hazards, and reduce the harmful components compared to combustible cigarettes. In Australia, there are currently no NVPs registered in the ARTG. However, consumers can legally access 'unapproved' NVPs that are not registered in the ARTG with a valid prescription via established access pathways beginning October 1, 2021[36] [37]. TGA has established access pathways to unapproved medicines in recognition that there are circumstances where patients need access to therapeutic goods that are not on the Australian Register of Therapeutic Goods (ARTG)[38]. Such is the case with NVPs for smoking cessation. In such a special access situation, most of the risk – benefit consideration is undertaken by a health professional working with an individual patient[39]. According to TGA, this decision balances the need to prevent adolescents and young adults from taking-up NVPs while allowing current smokers to access these products for smoking cessation with appropriate medical advice[40].

[32] Royal College of Physicians. 2016. Nicotine without smoke: Tobacco harm reduction. London: RCP, 2016.

[33] Balfour D.J. et al. Balancing Consideration of the Risks and Benefits of E-Cigarettes Am J Public Health. Published online ahead of print August 19, 2021:e1 e12. https://doi.org/10.2105/AJPH.2021.306416

[34] Balfour et al. 2021

[35] RCP 2016

[36] TGA 2019

[37] Australian Therapeutic Goods Administration (TGA). 2021a. Nicotine e-cigarette access. Accessed on August 26, 2021; Accessed from: https://www.tga.gov.au/nicotine-e-cigarette-access

[38] Australian Therapeutic Goods Administration (TGA). 2021b. Product regulation according to risk: Overview of the way the Therapeutic Goods Administration (TGA) considers risks and benefits during the evaluation and post-market monitoring of products. Accessed on August 26, 2021. Accessed from: https://www.tga.gov.au/product-regulation-according-risk

[39] TGA 2021b

[40] TGA 2021a

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Given Australia's precautionary approach to the marketing and use of NVPs for smoking cessation, it follows that NVPs authorized for medicinal use in Australia on the ARTG should be supported by a development program that ensures the quality of the product and appropriately characterizes the potential health risks and benefits of the product through nonclinical and clinical studies. Liber's objective with Nicovape Q is to utilize technological developments and quality manufacturing processes to create an NVP, the risk-benefit assessment of which is in-line with the TGA's expectations of all medicines..

The Nicovape Q system is a pharmaceutical drug-device combination product, consisting of pharmaceutical grade nicotine (drug) with an inhalation delivery device (device) that assists in smoking cessation by providing smokers a safe and effective nicotine delivery product that relieves or prevents cravings and withdrawal symptoms associated with smoking cigarettes. Liber Pharmaceuticals is proposing that the Nicovape Q system be indicated to aid smokers to quit smoking and prevent relapse to smoking.

Product Description - Overview

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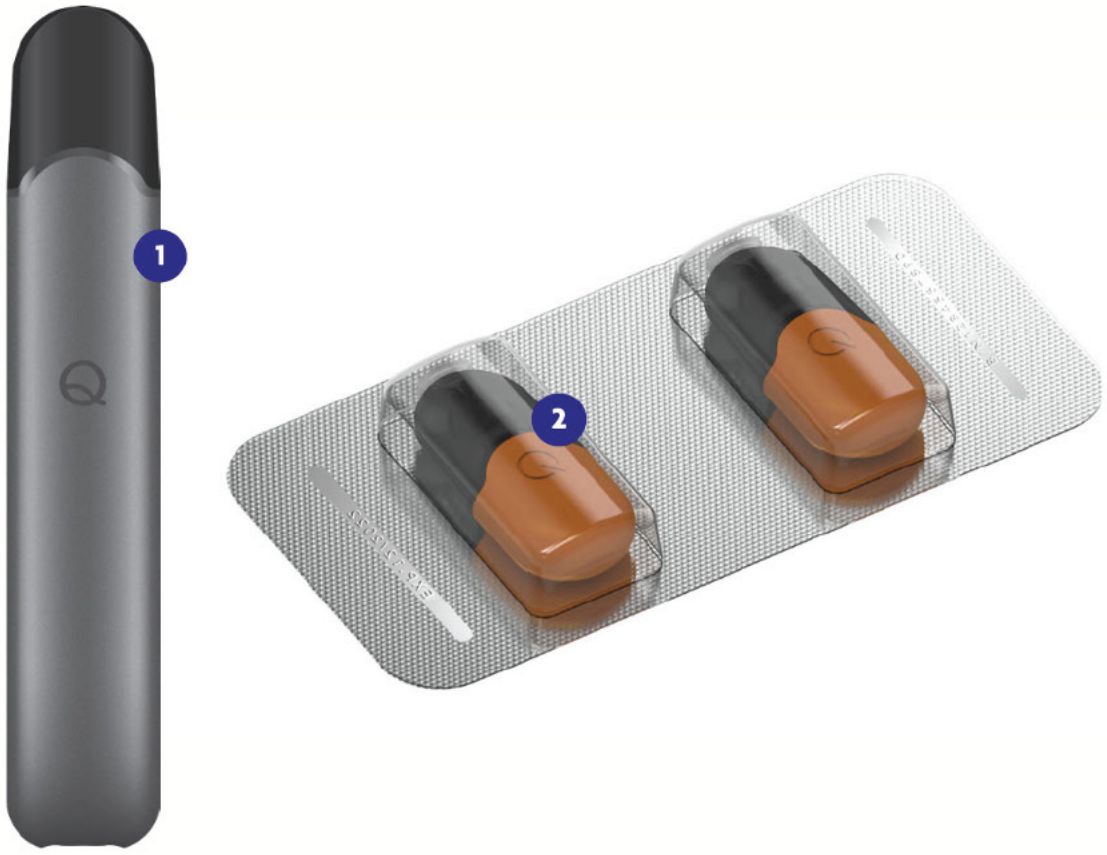


Figure 5. Nicovape Q (1) device, pictured with an attached cartridge and (2) consumable cartridges "Pods", pictured in their blister packaging.

Mode of Operation - Overview

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The Nicovape Q device

The Nicovape Q device contains:

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Nicovape Q pods

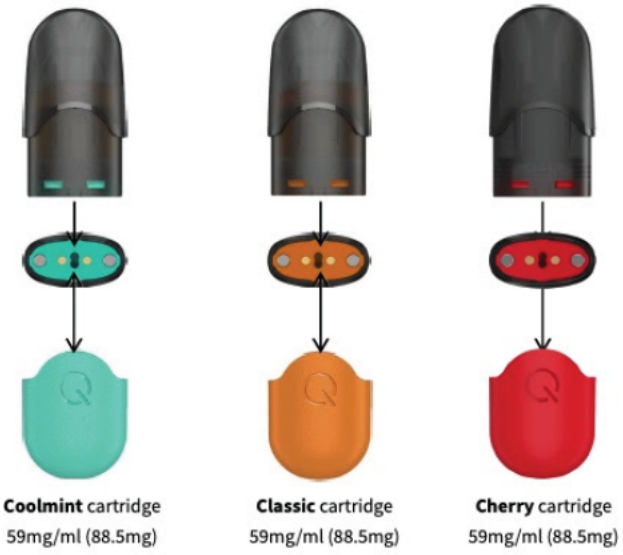




Figure 7. The Nicovape Q pods and caps, colour coded by flavour

The Nicovape Q pod forms the mouthpiece through which users inhale vaporised nicotine.

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For complete details of the standards applied to Nicovape Q please see **Annexure 2: Standards framework for the Nicovape Q system (device, pods and e-liquids) in relation to TGO 110**.

Nonclinical development - Overview

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Liber's non-clinical work is summarised in Tables 1 and 2 in "**Annexure 1: Status update - progress to ARTG submission**."

Licensing NVPs as a medical product - The MHRA approach

In determining how best to approach establishing safety and efficacy in the case of NVPs, as a leading Medical Regulatory Authority (**MRA**) with an established pathway for assessing NVPs as a medicine, we have looked to the guidance provided by the UK's Medicines and Healthcare products Regulatory Agency (**MHRA**).

The MHRA has decided that there is sufficient evidence to approve an NVP as a medicine if its manufacturers can demonstrate their product delivers nicotine effectively. That is to say that the MHRA considers that if a product delivers nicotine it will be efficacious, even if the precise power of that efficacy cannot be determined.

In their guidance on licensing NVPs, the MHRA notes that[51]:

[51] Medicines and Healthcare products Regulatory Agency (UK) - Licensing procedure for electronic cigarettes as medicines. https://www.gov.uk/guidance/licensing-procedure-for-electronic-cigarettes-as-medicines#clinical-efficacy-and-safety-requirements (accessed 26 July 2021)

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> *"MHRA advice is that an abridged application submitted under Article 10 of Directive 2001/83/EC, as amended, would be appropriate. This legal basis allows for submission of a dossier which is abbreviated in relation to safety and efficacy by using a comparative pharmacokinetic (PK) study comparing the new product to an appropriate reference medicinal product."*

In providing guidance as to why this approach is considered sufficient, the MHRA notes the following[52]:

> *"To what extent a nicotine-containing product (NCP) will have an effect in a smoker depends on the concentration of nicotine in the individual's blood (plasma) which that product will produce when inhaled.*
>
> *Therefore, as a general principle, an applicant will be required to demonstrate that the plasma nicotine concentration which their product will achieve when used correctly is both effective and safe. This can be achieved by comparing the plasma nicotine concentration achieved in a group of volunteers with the test product to that achieved with a currently authorised form of Nicotine Replacement Therapy (NRT). This is known as a comparative bioavailability study. The comparator product should be chosen on a like-for-like basis, e.g. an inhaled product should ideally be compared to another inhaled product."*

While the efficacy of specific NVPs has been shown in RCTs, that evidence is limited and does not offer sufficient insight into the specifics of what is a heterogeneous category of product types.

What would an appropriate PK study to establish safety and efficacy look like?

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[52] ibid.

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Complementing a PK study with a systematic literature review

s.47

Purpose and objectives of the meeting

The objectives of this proposed meeting are to introduce TGA to Liber Pharmaceuticals, inform TGA on Liber's plans for providing access to Liber's nicotine vaporiser products (**NVPs**) under the new regulatory framework, and importantly, to discuss the process of seeking ARTG registration of Liber's products.

Liber has identified two key focal areas for this meeting:

1. Liber's nonclinical development program for its Nicovape Q product; and
2. Liber's approach to seeking ARTG registration.

There is no domestic Australian or global precedent of any licensed and marketed NVP distributed within a medical framework. Consequently, and with ongoing questions about the safety and efficacy of the broader technology, it is important to understand the appropriate data and information necessary for preparation of the required dossiers for ARTG registration of an NVP.

Liber requests this early meeting to ensure that further formal pre-submission meetings with the TGA regarding Liber's development plans for its Nicovape Q product are constructive and informative, and to ensure that Liber's development programs can be designed and conducted in a manner that provides the TGA with sufficient information to make a decision on the medicinal registration of Liber's NVP offering.

As the only jurisdiction globally with an established medicinal pathway for NVPs (albeit with no commercialised product), the UK's Medicines and Healthcare products Regulatory Agency approach has substantially informed Liber's product development and proposed clinical approach. For an overview of Liber's proposed approach, please refer to Table 1 - Quality (Module 3) and Nonclinical (Module 4) studies proposed for ARTG submission, and Table 2 - Clinical (Module 5) studies proposed for ARTG submission.

This meeting is proposed to comprise a presentation of approximately 30 minutes by Liber, followed by a Q&A session. This meeting is intended to be informal in nature, with the principal intention of updating the TGA on

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our approach and to ensure that such an approach is consistent with the TGA's expectations. Liber will make formal presentations to the appropriate TGA teams on the meeting content discussed here at the convenience of the TGA.

List of questions

While the meeting is intended to provide a status update to the TGA , there are a number of questions that Liber would seek guidance on from the TGA, including the following:

Guidance for applicants seeking ARTG registration for NVPs

Questions:

- *Has the TGA considered the MHRA's approach for medicinal licensing of NVPs, in general terms or specifically, as a template for effective regulation?*
- *Does TGA consider MHRA's approach to efficacy (for NVPs) as appropriate for product registration in Australia?*
- *Has the TGA developed any guidance for NVP manufacturers seeking ARTG registration?*
- *Does the TGA consider the Libers approach to nonclinical, efficacy and safety studies (for NVPs) as appropriate for product registration in Australia?*

Would there be any path to consider provisional determination or a similar framework for NVPs?

Question:

- *Does TGA consider that there is a plausible route for a provisional determination?*

Non-clinical development program

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Sterile /non-sterile requirements for NVPs as a medicine

TGA guidance for inhaled medicines refers to EMEA'S Guideline on the Pharmaceutical Quality of Inhalation and Nasal Products[53] - single-dose → sterile | multi-dose → non-sterile (Table 4.5.1).

Recent TGO 110 guidance[54] for microbiological testing refers to Section 11(1) of TGO 100[55], which provides acceptance criteria for microbiological quality attributes of a non-sterile medicine.

Question:

- *Is the TGA contemplating non-sterile requirements for NVPs registered on the ARTG?*

GMP licencing/certification requirements

s.47

Question:

- *Is this in line with the TGA's expectation for NVPs as an approved medicine for inhalation?*
- *Will TGA require GMP Licensing of the API/Drug Substance site of manufacture?*

Adverse event reporting under the TGO 110 framework

Understanding that NVP devices are exempt from TGA regulatory requirements and are unapproved therapeutic goods:

- *Will TGA be developing post-market vigilance requirements that would otherwise apply to medical devices?*
- *In relation to unapproved nicotine e-liquids, will the TGA be developing pharmacovigilance requirements?*

[53] European Medicines Agency (2006) Guideline on the Pharmaceutical Quality of Inhalation and Nasal Products

[54] Guidance for the Therapeutic Goods (Standard for Nicotine Vaping Products) (TGO 110) Order 2021 and related matters Version 1.2, July 2021

[55] Therapeutic Goods (Microbiological Standards for Medicines) (TGO 100) Order 2018 https://www.legislation.gov.au/Details/F2018L01685

Private and confidential

31 August, 2021

List of participants

Attendee	Title
Liber:	
Richard Lee	Chief Executive Officer - Liber Pharmaceuticals
s.22	
Consultants:	
s.47	

Annexure 1: Proposed development program for ARTG submission

Table 1 Quality (Module 3) and Nonclinical (Module 4) studies for Nicovape Q ARTG submission

The following table is provided to set out Liber's proposed approach to developing the Modules for an ARTG submission. Liber anticipates that this will be reviewed in detail at a subsequent meeting with the TGA.

Module	Product Component – CTD Section	Module Information (CTD Section)	Studies completed for launch/ pre-clinical Phase 1 study	Additional work proposed for ARTG submission
Quality (Module 3)	**Drug Substance (Nicotine) – CTD Section 3.2.S*** **considered mandatory requirement for an effective application*	Drug substance – Nicotine general properties (3.2.S.1)	s.47	
		Drug substance – Nicotine manufacturing (3.2.S.2)		
		Drug substance – nicotine characterization (3.2.S.3)		
		Control of drug substance nicotine (3.2.S.4)		

		Drug substance – nicotine reference standards (3.2.S.5)	s.47
	Drug Product (Excipients and Device) – CTD Section 3.2.P* **considered mandatory requirement for an effective application*	Drug Product -Liquid Ingredients (excipients) description and composition (3.2.P.1)	
		Pharmaceutical development (3.2.P.2)	
		Manufacturing (3.2.P.3)	
		Control of excipients (3.2.P.4)	

		Control of drug product (3.2.P.5)	s.47
		Reference standards (3.2.P.6)	
		Container closure system (3.2.P.7)	
		Stability (3.2.P.8)	
		Other device development	

Nonclinical (Module 4)	**Liquid Formulation**	Drug substance – Nicotine pharmacology, pharmacokinetics (PK), and toxicology	s.47
		Excipients – humectants and pH adjuster nonclinical evaluation	
		Flavour excipients nonclinical toxicology evaluation	
		Impurities toxicological risk assessment	
Nonclinical (Module 4)	**Device Materials**	Materials component ingredient and leachables toxicological risk assessment	
Nonclinical (Module 4)	**Aerosol constituents**	TRA of select excipients/targeted assessment of HPHCs in aerosol	
		Toxicology of unknown heat degradation products and reactive compounds (NTA)	

		Stability evaluation to assess toxicological risks over proposed shelf-life	s.47
Nonclinical (Module 4)	**Whole aerosol**	*In vitro* toxicology studies	
		In vivo toxicology studies	

Table 2 Clinical (Module 5) studies proposed for ARTG submission

Study (Phase)	Details	Status Timing	To be included in ARTG submission?
Sensory Evaluation of Nicotine Salts (Pre-clinical)	s.47		
Nicotine PK and subjective effects of Nicovape Q in comparison to combustible cigarettes and Nicotrol inhaler (Phase one)			
Observational Cohort Studies			
Literature Reviews			

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Annexure 2: Standards framework for the Nicovape Q system (device, pods and e-liquids) in relation to TGO 110

Category	Compliance requirements	Nicovape Q compliance	Compliance status	Commentary
Battery safety	Product complies with international standards for Lithium-ion batteries	s.47	Voluntary Mandatory Voluntary	s.47
	Product complies with EU Restriction of Hazardous Substances Directive		Voluntary	
	Product complies with EU Registration, Evaluation, Authorisation and Restriction of Chemicals Directive		Voluntary	
Device safety	Product complies with Electromagnetic compatibility regulations		Mandatory	
	Product complies with EU Restriction of Hazardous Substances Directive		Voluntary	
	Product complies with EU Registration, Evaluation, Authorisation and Restriction of Chemicals Directive		Voluntary	
Device quality	Product complies with international Quality Manufacturing Standards		Current default for vaping products Upgrade in progress	
	Product sponsor provides certification for the quality of resin (plastic) used to manufacture pods/mouthpiece		Current default for vaping products	

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		s.47	Upgrade in progress	s.47
	Cotton used for wicking the nicotine e-liquid complies with international Quality Manufacturing Standards		Voluntary	
Liquid Quality	Production complies with Good Manufacturing Practices		Current default for vaping products Upgrade in progress	
	Product nonclinical evaluation and batch testing complies with Good Laboratory Practices		Voluntary	
Ingredient purity	Product sponsor provides certification pharmaceutical grade ingredients: Nicotine | Vegetable Glycerin | Propylene glycol		Voluntary	
Liquid safety	Product sponsor provides a declaration that liquids have been subjected to Hazard Screening and are within acceptable limits		Voluntary	
	Product sponsor provides a declaration that flavour compounds have been molecularly defined and subjected to a Toxicological Risk Assessment (TRA) and are below levels of toxicological concern		Voluntary	
Aerosol safety	Product sponsor provides a declaration that the emissions testing has been conducted and any Harmful or Potentially Harmful Constituents (HPHCs) are below levels of toxicological concern		Voluntary	

TGO 110 requirements	Product sponsor provides a declaration that: - The NVP contains nicotine as the only active ingredient - Nicotine concentration is between 90 /110% of the stated content - No substance specified in Schedule 1 to TGO 110 added as an ingredient - Records are maintained demonstrating conformance with TGO 110	s.47	Mandatory for Domestic Sponsors	s.47
Microbiological Testing	Product sponsor provides a declaration that the NVP liquids comply with Section 11(1) of *Therapeutic Goods (Microbiological Standards for Medicines) Order 2018* (TGO 100)		Mandatory	
Insurance	Product sponsor provides a Certificate of Currency for Product Liability Insurance coverage for the prescribed NVP		Voluntary	
AE reporting	Product sponsor has an established process to facilitate the adverse event reporting for the prescribed NVP		Mandatory for Domestic Sponsors	
Packaging	Product complies with TGO 91 (Standard for labels of prescription and related medicines)		Voluntary	
	Product complies with TGO 95 (Child-resistant packaging requirements for medicines)		Mandatory	
	Product applies GS1 barcoding and serial numbering protocols.		Voluntary	
CMI	Product sponsor provides a Consumer Medicines Information (CMI) leaflet with the product		Voluntary	

Mandatory - regulatory requirement to supply NVPs as an unregistered therapeutic good in Australia.

Voluntary - international quality and safety standards or TGA best practice/guidance applied by Liber.

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Transition to pharmaceutical GMP compliance

In addition to the standards framework that is detailed above, and to which the Nicovape Q system currently adheres, Liber is implementing a program of works to build a full pharmaceutical GMP supply-chain in anticipation of filing an application to register the Nicovape Q device and range of nicotine e-liquids on the ARTG in 2022.

While pharmaceutical GMP is not a requirement for unregistered NVPs being supplied pursuant to TGO 110, Liber has made the decision to fast-track the pharmaceutical GMP compliance of our supply-chain.

To facilitate this transition, Liber is undertaking the following processes:

- A Bureau Veritas audit of our device manufacturing facility for conformance with ISO 13485 (medical devices). The facility is certified to ISO 9001 and US 21 CFR part 110 (GMP for Human Food). A fit-gap audit has been conducted to ensure the facility meets the requirements of ISO 13485;
- An MHRA (UK) inspection of our liquid manufacturer for compliance with pharmaceutical GMP for liquid dose manufacturing. In this regard, Liber notes that the TGA has a Mutual Recognition Agreement with the MHRA for GMP inspections; and
- An upgrade of the food-grade resin used to manufacture the Nicovape Q pods to a medical-grade (ISO 10993) resin.

To mitigate any safety concerns regarding the use of food-grade materials during the transition period, Liber notes the following:

- The API and excipients used to manufacture the Nicovape liquids are produced under pharmaceutical GMP standards and comply with the respective monographs;
- The liquids have been subjected to Hazard Screening, and are within acceptable limits;
- The flavour compounds used in the liquids have been molecularly defined and subjected to a Toxicological Risk Assessment, and are below levels of toxicological concern; and
- The liquids and device (in combination) will be subjected to emissions testing for Harmful or Potentially Harmful Constituents (HPHCs), to ensure emissions fall below levels of toxicological concern.

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Annexure 3: Protocols Overview

s.47 has completed two draft protocols and one methodological synopsis for consideration.

Pharmacokinetic and Subjective Effects Study Protocol

Title	Nicotine Pharmacokinetic and subjective effects assessments of the Nicovape Q Electronic Nicotine Delivery System (ENDS) In Comparison to a combustible cigarette and the Nicotrol Inhaler.
Objectives	**Primary objectives:** • To determine kinetics of nicotine absorption into the blood of subjects when they use the Nicovape Q ENDS, smoke a conventional cigarette, or use the Nicotrol® Inhaler. • To compare nicotine delivery from the Nicovape Q ENDS with that from a conventional cigarette and the Nicotrol® Inhaler. **Secondary objectives:** • To determine additional nicotine pharmacokinetic parameters during/after use sessions. • To assess reductions in urge to smoke a cigarette when subjects use the study products. • To assess subjective effects using items on the Product Evaluation Questionnaire (PES), a generic subjective effects questionnaire, and product liking and intent to use again scales, for all study products. • To assess overall safety and tolerability of Nicovape Q ENDS.
Endpoints	**Primary endpoints:** • Baseline-adjusted plasma nicotine C_{max} and T_{max} during first use session • Baseline-adjusted plasma nicotine $C_{max,lastdose\ t}$ during fourth use session **Secondary endpoints:** • Baseline-adjusted plasma nicotine partial$AUC_{0\ tau}$ during first use session • Baseline-adjusted plasma nicotine partial$AUC_{lastdose\ t}$ during fourth use session • Baseline-adjusted plasma nicotine $AUC_{0\ t}$ for each use session • Baseline-adjusted plasma nicotine $AUC_{0\ \infty}$ for each use session • Baseline-adjusted C_{max} for use sessions 2-4 • Maximum urge to smoke change from baseline (E_{max}) • Mean score for each multi-item subscale of the mCEQ **Subjective effects scores** • Physiological measures (blood pressure and heart rate **Safety Endpoints:** • Heart rate and blood pressure during product use sessions • Adverse events (AE)/Serious adverse events (SAE)

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31 August, 2021

Literature Review Protocol

Title	s.47
Synopsis	
Next steps	

Proposed Efficacy Study - Synopsis

Title	s.47
Objectives	
Endpoints	

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Liber Pharmaceuticals Pty Ltd

Nicotine Vaping Products for Smoking Cessation
Progress update and strategy for ARTG registration

Discussion Materials

3 September 2021 - 10am

FOI 27-3600 - Document 5

Agenda

- Progress update - Nicovape Q
- Proposed approach to ARTG registration
- Non-clinical development program
- Q&A

Attendees

Liber

- **Richard Lee** (CEO)

s.22

Consultants:

s.47

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Progress Update

The Nicovape Q product - Appropriate and ready for 1 October

Devices and pods to be onshore and ready for 1 October

Liquids:

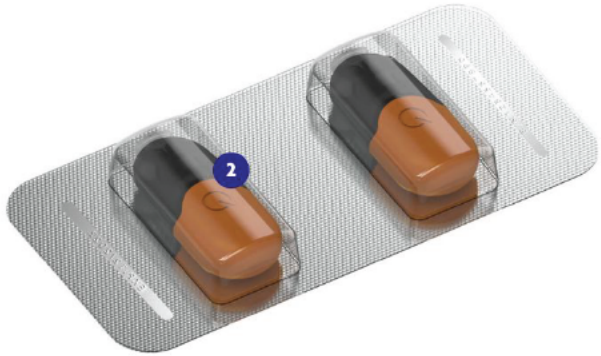
- **Active ingredient:** Nicotine
- **Concentration:** 59 mg/ml strength nicotine
- **Flavours**: Classic, Coolmint, Cherry

Product info will be uploaded to MIMS | Fred IT | MIMFOS

Education:

- **Doctors**: Telehealth cohorts
- **Pharmacies**: Wholesalers | banner groups





Nicovape Q (1) device, pictured with an attached cartridge and (2) consumable cartridges "Pods", pictured in their blister packaging.

Providing an appropriate product for 1 October

The Nicovape Q will be launched into the new framework as a product that:

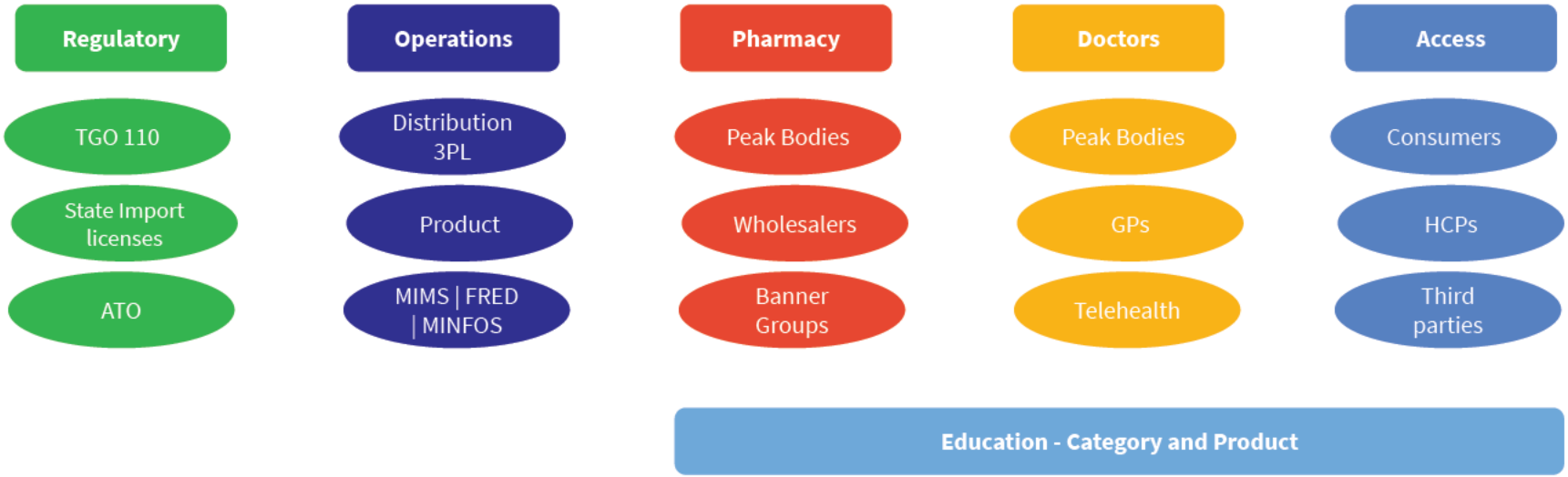
- **TGO 110**: Exceeds the requirements of TGO 110 (See briefing document)

s.47

- **Standards**: Ensures a transparent explanation of standards that the Nicovape Q satisfies
- **Education**: Has launched education to key stakeholders to ensure that they understand NVPs and the Nicovape Q
- **Therapeutic focus:** Expert design of device and nicotine-liquid characteristics to maximise efficacy for dependent smokers.

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Building a comprehensive launch infrastructure



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Ensuring access from 1 October

Telehealth

Primary focus: Immediate availability

- MBS Codes - bulk billed telehealth assessments
- Two bulk-billed cohorts on 1 October:
- Training of other cohorts on Nicovape Q

GPs

Secondary focus: Broader uptake over time

- Multiple outreach initiatives
- Outreach to more than 20,000 GPs and specialists
- Comprehensive GP packs on opt-in basis

Banner Groups

Primary focus: Immediate availability

- Ensuring proactive access to majority of market
- Encouraging link to telehealth cohorts
- Three largest banner groups in Australia

Wholesalers

Focus: Broader uptake over time

- Onboarded with Symbion and API
- Access by all 5,500 pharmacies across Australia
- Education rollout via wholesalers

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Online resources - Being more than just a product

smokefree

iNRT

Consumers

- Complete solution:
  - Education
  - Assessment
  - Prescription
- Focus on smoking cessation, not vaping
- Access to independent cohort of assessing doctors
- Focal point for partnerships

Healthcare Professionals

- Firewall access (AHPRA number)
- Comprehensive toolkit for doctors and pharmacists
  - Vaping history
  - Registration as an AP
  - How to assess products
  - About the Nicovape Q
- Referral of patients to Smokefree

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Regulating a medical NVP

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ARTG registration - Overview

The market needs an ARTG registered NVP

- Addresses concerns about safety and efficacy
- Removes low quality products from the market
- Creates pathway to down-scheduling

What happens if no NVPs are registered?

- No answer to questions on safety and efficacy
- Fails to meet needs of any stakeholders
- Fragmentation inevitable over time

Will manufacturers seek ARTG?

- No global history of medical pathway
- Significant cost | Limited benefit
- Commercial acceptance of consumer framework?

LIBER is serious about ARTG

- Product created specifically for medical route
- Have assembled global expertise for project
- Believes NVPs can provide significant benefit

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Liber's approach to ARTG

Overarching aim is to:

- Create a systematic, science-based approach that characterizes the NVPs
- Ensuring that the NVPs meet acceptable quality, safety and efficacy standards
- While allowing efficient nicotine delivery and an efficacious smoking cessation tool

In a manner that:

- Represents a pragmatic use of time and resources
- Underpinned by a robust risk-benefit analysis

How to achieve ARTG:

- Build a team capable of working with the TGA to create a global precedent
- Learn from existing regulatory approaches to NVPs
- Adapt those approaches to the unique characteristics of Australia
- Understand and meet the needs of stakeholders

Building a team with international and local expertise

International Expertise

- s.47 [redacted]

Local Expertise

s.47 [redacted]

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Why is the approach of MHRA important in developing Liber's ARTG strategy?

MHRA is appropriate as a starting point for an Australian registration, to be customised to account for the unique aspects of the new framework:

- Having issued its guidance in 2017, MHRA have an established process for the medical approval of NVPs.
- MHRA is recognised by the TGA as a comparable Regulatory Authority, and there is a strong history of cooperation and reliance between both Authorities.

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[redacted]

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Key learnings from MHRA Guidance and Scientific Advice Meetings



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Comparisons between MHRA and ARTG

UK MHRA [2017] - Licensing procedure for electronic cigarettes as medicines

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Nonclinical development program

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Objectives of Liber's non-clinical program

Objectives
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Overview of Liber's non-clinical program

A stepped approach to Liber's nonclinical program considers guidance on NVPs from several agencies:

- MHRA Licensing procedure for electronic cigarettes as medicines (2017)
- US FDA Nonclinical Testing of Orally Inhaled Nicotine-Containing Drug Products Guidance for Industry (2020)
- TGA Guidance for TGO 110 (2021); TGA Guidance 23: Nonclinical guidance (2014)

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Product Analysis

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Desk-Based Toxicology

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- Based on human health risk assessment approach as outlined by numerous regulatory and authoritative bodies:
  - National Research Council (NRC)
  - USEPA for inhaled compounds
  - Peer-reviewed literature
- Follows MHRA guidance to provide detailed safety review of all the components, “such as… excipients, in the formulation from the available literature” considering long term exposure, maximum daily dose, and target population
- Incorporates *in silico* techniques
- Identify available toxicological data and potential gaps for key health endpoints

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Drug Product Formulation

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Device Materials

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Aerosol





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Experimental Toxicology



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Goals for Future TGA Engagement

- Discuss the product characterization data to date
- Assess the proposed nonclinical plan in detail and the specific methodologies for the desk-based and *in vitro* toxicology

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- Gain input and agreement of the proposed nonclinical studies to support use of Nicovape Q in clinical studies and as a prescription product

Q&A

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Liber's questions for the TGA team

Guidance for applicants seeking ARTG registration for NVPs

- Has the TGA considered the MHRA's approach for medicinal licensing of e-cigarettes, in general terms or specifically, as a template for effective regulation?
- Does TGA consider MHRA's approach to efficacy (for NVPs) as appropriate for product registration in Australia?
- Does the TGA intend to develop any guidance for NVP manufacturers seeking ARTG registration?
- Does the TGA consider the Libers approach to nonclinical, efficacy and safety studies (for NVPs) as appropriate for product registration in Australia?

GMP licensing | certification requirements

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- Is this in line with the TGA's expectation for NVPs as an approved medicine for inhalation?
- Will TGA require GMP Licensing of the API/Drug Substance site of manufacture?

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Liber's questions for the TGA team

Non-clinical development program

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Liber's questions for the TGA team

Sterile /non-sterile requirements for NVPs as a medicine

- Is TGA contemplating non-sterile requirements for NVPs registered on the ARTG?

Would there be any path to consider provisional determination or a similar framework for NVPs?

- Does TGA consider that there is a plausible route for a provisional determination?

Adverse event reporting under the TGO 110 framework

Understanding that NVP devices are exempt from TGA regulatory requirements and are unapproved therapeutic goods:

- Will TGA be developing post-market vigilance requirements that would otherwise apply to medical devices?
- In relation to unapproved nicotine e-liquids, will the TGA be developing pharmacovigilance requirements?

Private and confidential
12 September 2021

Minutes - Liber | TGA pre-submission meeting

10:00am | 3 September 2021

Attendees

TGA

- Jenny Francis - Principal Legal Advisor, Health Products Regulation Group
- Dr Grant Pegg - Branch Head, Prescription Medicines Authorisation Branch

s.22 [redacted]

Liber

- Richard Lee - Chief Executive Officer

s.22 [redacted]

s.47 [redacted]

Private and confidential
12 September 2021

Minutes

TGA - s.22 **(Chair)**

Acknowledgement of Country

I would like to acknowledge the Traditional Owners and Custodians of the lands on which we meet today and pay my respects to Elders past, present and emerging. I would like to extend that acknowledgement and respect to any Aboriginal and Torres Strait Islander peoples here today. Acknowledgement also extended to the traditional owners of the lands where you are dialing in from today.

Chair advises meeting participants to be aware that:

- knowledge evolves over time,
- guidance from TGA may become out of date or be superseded
- any guidance given by the TGA during this pre-submission teleconference meeting is non-binding and is given without prejudice.
- TGA requests that Liber Pharmaceuticals provides draft minutes within 2 weeks of this presubmission meeting.

Introductions

- The TGA team introduced themselves individually - all proposed attendees were present.
- The Liber team was introduced by Liber CEO, Richard Lee - all proposed attendees were present.
- No apologies were registered.

Meeting Commenced

Sponsor – Richard Lee

- Provides an update on Liber's product development progress and status in relation to the implementation of TGO 110.
- Liber's products will be onshore and ready to be distributed on 1 October 2021:
    - Have received our State import license,
    - Products will be updated onto MIMS, Fred and Minfos for 1 October 2021.
    - Onboarded with both Symbion and API
    - Secured distribution with the 3 largest pharmacy banner groups.
    - Rolling out a comprehensive education framework to doctors and to pharmacies.

- Liber have received R&D Tax Incentive approval from AusIndustry (including an advance overseas finding) in relation to our R&D work.
- Liber has put together a team with global expertise in the vaping category to develop that in the Australian context.

Sponsor-s.47

- Provides an overview of work with MHRA, FDA.
- MHRA is the only regulatory body to have provided guidance across the CTT modules for quality, nonclinical and clinical for an NVP as a medicinal product.
- MHRA used as the starting point for developing our strategy for an ARTG registration.
- MHRA guidance:
    - As a drug with an established history of use, the clinical pharmacology and toxicology of nicotine is well understood - new nonclinical studies for nicotine are not expected.
    - Considers safety and efficacy can be demonstrated through desk-based techniques, such as *in silico* techniques as well as *in vitro* toxicology data.
    - On the clinical side they [MHRA] are looking to pharmacokinetic trials and literature reviews.
    - Holds there is sufficient evidence to approve an NVP as a medicine, if manufacturers can demonstrate their product delivers nicotine effectively.

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s.47 [redacted]

TGA - [redacted] notes time remaining and suggests the meeting address the proposed questions to TGA.

TGA - [redacted] addresses Question from Liber:

- Is TGA contemplating non-sterile requirements for NVPs registered on the ARTG?

TGA -

- If labelling the product as sterile, there will be sterile requirements for the finished product manufacturer.
- If not claiming sterility, it will be formulation dependent, and we would take advice as to microbial growth and I believe it's in propylene glycol.

TGA- [redacted] addresses Question from Liber:

s.47 [redacted]

TGA –

- We will provide written advice in response to that, but in general, there is a requirement to have a product currently inhalation liquids products on their GMP clearance specified as for inhalation.

TGA - [redacted] addresses Question from Liber:

- Would TGA consider a non-clinical program, like that endorsed by MHRA, that limits the use of animal studies according to the principles of the 3Rs by conducting thorough product analytical characterization, liquid formulation and impurities, device components extractables and leachables, aerosol composition analysis, desk-based toxicology (literature and in silico) approaches to characterize toxicological (acute and long-term) health risks from inhalation of the production components and aerosol mixtures, in vitro studies to evaluate potential biological significance of significant toxicological concerns identified in the desk-based assessments (e.g., genotoxicity, mutagenicity, cytotoxicity) and a risk-benefit analysis to weigh the potential identified health risks with the benefits of marketing the product in the population of adult smokers.

TGA - We generally agree with the proposed non-clinical program for this product.

- Safety review should address all relevant endpoints particularly the local tolerance of the formulation via the inhalational route.
- Propose that this would be looked at via either an animal study - an appropriate published data or literature using the formulation would be appropriate as well.
- Other relevant endpoints that should be addressed include general toxicity, reproductive and developmental toxicity, carcinogenicity and genotoxicity - an appropriate study or published literature would be acceptable for these.

TGA - [redacted]

- Any questions from the Sponsor?

Sponsor- Richard Lee

- The two teams will need to get into the detail in future meetings. We don't have more particular questions right now.
- Liber hopes to use this meeting to open dialogue.
- Very complicated process due to the lack of precedent.
- Liber wants to address all concerns upfront.

TGA - [redacted]

- This is an ongoing process - ongoing dialogue will be welcomed by TGA
- The technology is new, but the concept of NRT is not new to TGA and TGA have a lot of experience evaluating NRT medicines.

TGA - - [redacted] addresses Question from Liber:

- Does TGA consider that there is a plausible route for a provisional determination? Dr Bagul provides response:
- TGA cannot advise what is provisional or not at this meeting without the relevant Delegate(s). Sponsor should review guidance on TGA website to understand the eligibility criteria. Nobody in this meeting is a decision-maker (for provisional determination).

Sponsor - Richard Lee

- So noted.

TGA - - [redacted] addresses Question from Liber:

- Does TGA consider MHRA's approach to efficacy (for NVPs) as appropriate for product registration in Australia?

  Dr Bagul provides response:

  - Acknowledge MHRA is a comparable overseas regulator.
  - TGA is aligned with the EU for guidance and scientific guidelines.
  - We are happy to have further dialogue on the clinical side, but at the moment we are not fully aligned with the MHRA approach for efficacy.
  - We agree there is a phase 1 study but want to see a head-to-head double blind Phase III study with TGA approved NRTs as per EU guidance.

Sponsor - Richard Lee

- Liber's Consultants have considerable experience working with UK/EU regulators

TGA - - [redacted] notes:

- TGA welcomes international collaboration, new ways of working and understanding of the subject matter expertise.
- All of the NRT on the market have been approved with the current process. If Liber can demonstrate why their product should not be evaluated as NRT this will be considered and reviewed.
- TGA can outline our assumptions for a safety and efficacy study in writing.

Sponsor- Richard Lee

- Noted.

TGA - [redacted] addresses Question from Liber:

- What additional study will TGA envision taking place after provisional determination? [redacted] provides response:
  - This is subject to a Delegate's approval of provisional determination.
  - A head to head clinical trial with an ARTG registered NRT and/or placebo for smoking cessation, would be required efficacy.

TGA - [redacted] opens the forum to questions.

TGA - [redacted]

- What is happening in the UK marketplace?
- Guidance has been out for 4 years and there are no products in the marketplace.
- Is this correct? Why that is the case.?

Sponsor - [redacted]

- Due to the consumer market thriving in the UK, there is no commercial impetus for a manufacturer to pursue market authorisation. It hasn't been considered commercially advantageous in that particular market context.
- PHE in February this year in their update on NVPs in the marketplace stated that the lack of a medicinal product in the UK market is a situation that needs to be urgently reviewed.

TGA - [redacted]

- Is this related to the volume of non-registered products in the market?

Sponsor - [redacted]

- Yes. To be clear, because the market is already thriving with products regulated under the consumer regulations or the TPD, it simply hasn't been viewed as commercially feasible by the industry.

TGA - [redacted] -

- At prior meeting there were three strengths of this product. Is that still the case?
- It is our intention to work with a single strength product at launch. There is one strength and 3 flavour SKUs.

Sponsor - Richard Lee

- We have issued notes in our submission to the delegate both in relation to the initial framework [re-scheduling] and TGO 110, as to why we have pursued that single strength approach as opposed to varying strengths.

- Can share that information again. We'll send that through.

Sponsor - [redacted]

- The literature shows that efficacy is found in closed-system products at around the strength we are marketing the product, and less so from lower strength products.
- We believe this mirrors the latest understanding of lower strength NRT products in dependent smokers.

Sponsor - s.47 [redacted]

- There has been recognition that products that deliver nicotine more effectively are more successful in getting people away from combustible cigarettes.
- It has been recognised by FDA and by PHE that low nicotine products are a barrier to getting people to quit smoking because they don't replace the nicotine that people get from combustible cigarettes.
- A high strength product proposition is more likely to be helpful in getting people away from cigarettes.

TGA - [redacted] **-**

- We can take this in another meeting. Have concerns about moving from one addiction to another addiction.
- Want to see what the pathway away from nicotine addiction is and I don't see it in this product. Thanks for today's presentations and thanks to my colleagues.

Sponsor - Richard Lee

- Thanks to you and the team, we look forward to ongoing dialogue with TGA.

Meeting closed.

Australian Government

Department of Health and Aged Care

Ref No: MC24-011927

Correspondence Background Brief
Minister Butler

Subject	**Request for CEO Liber Pharmaceuticals to discuss vaping cessation program, and concern about no legislative requirement to collect data on vaping sales (Steggall MP obo Lee).**

Summary of Issues

- Ms Zali Steggall MP (Member for Warringah) expresses two concerns in her correspondence:
    - the absence of a legislative requirement to collect data from vape sales, as reflected by Ms Steggall during the Parliamentary Debate (26 and 27 June 2024) of the *Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Bill 2024*
    - in the context of the 1 October 2024 changes, there being no requirement for pharmacists to provide information about vaping cessation to patients at the point of sale (this is clarified in the response letter).
- Ms Steggall notes Mr Richard Lee (CEO, Liber Pharmaceuticals) would welcome an opportunity to discuss with the Minister: vaping cessation programs; how the framework for the recent vaping reforms is perceived by the pharmacy channel; and the supply chain needs prior to changes coming into effect from 1 October 2024.
    - Liber Pharmaceuticals is an Australian owned and operated company producing and supplying Nicotine Vaping Products.
    - Liber Pharmaceuticals has published a statement of independence stating the organisation has no affiliation with the tobacco industry, their affiliates, or any organisations or individuals engaged in lobbying on their behalf.
- The draft response to Ms Steggall MP provides an overview of the Government's actions to implement the vaping reforms, clarifies that the provision of cessation information is a requirement of pharmacist supply, and highlights that the Government has commissioned the Pharmaceutical Society of Australia (PSA) to deliver training and education for pharmacists. The response notes that we (Department and TGA) are exploring options for monitoring of the reforms.

Background

- The Government announced (Minister Butler, 2 August 2024) an additional $1.39 million (GST exclusive) to PSA for the delivery of additional training and educational materials, building on existing work to update clinical guidelines for pharmacists in time for 1 October implementation.
- Through Budget 2023-24, more than $29.5 million has been invested in cessation initiatives to help people quit vaping and smoking, this includes a national online cessation platform, newly developed My QuitBuddy mobile app, scaling up state and territory Quitline services, and updating clinical guidance to support the health workforce.
- As at 31 July 2024, Liber Pharmaceuticals has 17 products on the Therapeutic Goods Administration's list of notified vapes.

Sensitivity

- Despite Liber Pharmaceuticals' stated independence from the tobacco industry, public officials must be aware that interactions with industry must be balanced against the obligations on public officials under Article 5.3 of the World Health Organization WHO Framework Convention on Tobacco Control FCTC, which extend to new and emerging products, such as e-cigarettes. Guidance for public officials is available here.

Consultation

- Health Products Regulation Group was consulted for input to the response letter and briefing.

Contact Officer:	*Karlie Brown*	*Assistant Secretary, Tobacco and E-Cigarette Control Branch, Population Health Division*	Ph: (02) 5132 0972 Mobile: s.22
Clearance Officer:	*Trish Clancy*	*First Assistant Secretary, Population Health Division*	Ph: (02) 5132 7138 Mobile:

s.22 [redacted]

From: Richard Lee s.22 [redacted]

Sent: Monday, 18 November 2024 12:09 PM

To: s.22 [redacted] @health.gov.au>; s.22 [redacted]

Subject: Re: Therapeutic vaping - POS advertising in pharmacy

[redacted]

REMINDER: Think before you click! This email originated from outside our organisation. Only click links or open attachments if you recognise the sender and know the content is safe.

[redacted]

s.22 [redacted]

Good morning. I am aware that you are not likely the right person to send this to, but was wondering if you could guide me as to who is.

I have attached a letter that we have been asked to send on behalf of a number of our pharmacy banner partners seeking clarity on POS materials encouraging patients to engaged with pharmacists in the manner envisaged by Minister Butler.

Happy for you to forward to appropriate parties within the TGA, or for a contact better suited to dealing with this.

Thanks and regards

Richard

Richard Lee
Chief Executive Officer

s.22

www.liber.com.au

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Liber Pharmaceuticals Ltd
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Suite 8, 35 Old Northern Road, Baulkham Hills
NSW 2153 Australia
Ph: 1300 642 682
liber.com.au

18 November 2024

Strictly private and confidential

To whom it may concern

Dear Sir/Madam

Re: Pharmacy guidance: Initiating patient discussions about therapeutic vaping

Since Minister Butler's announcement of changes to the regulatory framework governing access to vapes for therapeutic purposes at the end of June, there has been a fundamental shift in the initial point of contact for consumers. The Minister was clear in his approach, redirecting interested patients to pharmacies in the first instance to have an initial conversation about therapeutic vaping, allowing pharmacists to determine whether low concentration (S3) vapes were appropriate, and to direct patients to appropriate prescribers, whether GPs or nurse practitioners.

Minister Butler's address to the PSA's National Conference in August 2024 reinforced this approach, noting that *"pharmacists are absolutely the right people to be having those [quitting smoking/vaping] conversations with people."*

Liber is the market leader in the provision of therapeutic vapes, and its Nicovape Q products have been dispensed in almost 4,000 pharmacies since 1 October 2024. We currently work closely with the 15 major pharmacy banner groups, the 3 CSO wholesalers, and the largest guying group for independent pharmacies.

Interestingly, Liber's view is quite different from that presented on last night's 60 Minutes special, and continued across the FairFax Media publications this morning. Now that the framework has been implemented, and guidance by the TGA and the PSA published, the pharmacy supply chain has had time to digest the risk profile associated with S3 supply of vapes and the ongoing dispensing of S4 vapes. It is our view that the majority of the banners are not opposed to the Government's amendments.

Indeed, over the next 3-6 months, pharmacies will increasingly have their operating procedures, stocking strategies and training in place to support the Government's intentions. A number of pharmacy banners are now seeking to proactively encourage patients to have a discussion about their smoking cessation needs, and Liber believes that this will naturally gain momentum into 2025.

However, many are struggling to understand what they are permitted to do to encourage people to do exactly what Minister Butler has encouraged, and speak to their pharmacists to understand what therapeutic vaping is, and whether it may benefit them. These conversations, which are critical to create confidence in consumers that a legal and appropriately supervised therapeutic access pathway exists, will be critical to support the Government's enforcement efforts against the illicit market.

Liber has received a number of enquiries from pharmacists and pharmacy banners seeking clarity on how they may proactively encourage people towards having these conversations.

The bulk of queries to date relate specifically to posters at the PoS and what language is, or is not, permissible in that setting. These enquiries often point to the Guild's 'Say no to vaping' efforts, and posters that they are able to download telling patients that their pharmacy has chosen not to supply "over the counter" vapes.

To support banner-wide rollouts of education and training materials and supporting collaterals, we would like to clarify what content would be acceptable for posters at the PoS. Without being able to encourage patients to start conversations, in the manner explained by Minister Butler, the pharmacy banners will by and large remain passive, and the market perception will be that no pharmacies are supporting the new framework.

Understanding that any potential posters used in pharmacy would need to be brand agnostic and focus upon delivery of a healthcare service, we have drafted a number of options as Appendix A for TGA review. These are an aggregation of feedback we have had from pharmacy banners. The TGA may wish to respond to the market generally through market guidance, or alternatively, directions for us to share with our pharmacy partners to ensure that they can have an open line of communication to clarify that any POS materials are compliant.

We do note that timing and a fast response on this matter is likely to be critical. S3 access has now been available for six weeks, and media stories like last night's 60 Minutes undermine the credibility of the Government's new framework.

Pharmacy banners are closed to having finalised their 1H 2025 strategies, and unless guidance is rapid, will not consider implementing proactive strategies until 2H 2025. Liber believes that will be counterproductive and will have significant implications for both enforcement efforts and the Government's intention to transition patients who may benefit to medically supervised access.

I am happy to get onto a call if that helps to see how best we can support the TGA in providing quick and clear market guidance to those banners that continue to support the Government and the TGA's approach.

Yours sincerely

s.22 

Richard Lee
CEO and Managing Director

FOI 27-3600 - Document 8

Appendix 1: Sample posters for use in pharmacy settings

NEED HELP TO QUIT SMOKING?

TALK TO OUR PHARMACIST ABOUT OPTIONS TO HELP YOU QUIT

NEED HELP TO QUIT VAPING?

TALK TO OUR PHARMACIST ABOUT OPTIONS TO HELP YOU QUIT

DO YOU KNOW SOMEONE HOOKED ON CIGGIES?

TALK TO OUR PHARMACIST TO FIND OUT HOW WE CAN SUPPORT THEM

DO YOU KNOW SOMEONE HOOKED ON VAPES?

TALK TO OUR PHARMACIST TO FIND OUT HOW WE CAN SUPPORT THEM

FOI 27-3600 - Document 8

THERE ARE NEW GUIDELINES FOR ACCESSING THERAPEUTIC VAPING PRODUCTS

TALK TO OUR PHARMACIST IF YOU HAVE QUESTIONS

DO YOU HAVE QUESTIONS ABOUT MANAGING NICOTINE DEPENDENCE?

OUR PHARMACISTS ARE AVAILABLE TO HELP YOU UNDERSTAND THE OPTIONS

THERE ARE MORE OPTIONS TODAY THAN EVER TO HELP YOU QUIT SMOKING

TALK TO OUR PHARMACIST ABOUT OPTIONS TO HELP YOU QUIT

SMOKING HURTS YOUR WALLET AND HARMS YOUR HEALTH

TALK TO OUR PHARMACIST ABOUT OPTIONS TO HELP YOU QUIT

FOI 27-3600 - Document 8

DO YOU KNOW WHAT'S IN ILLICIT VAPES?

NEITHER DO WE

TALK TO OUR PHARMACIST ABOUT OPTIONS TO HELP YOU QUIT

HAVE YOU BEEN USING AN ILLICIT VAPE AND HAVE A COUGH OR A HEAVY CHEST?

TALK TO OUR PHARMACIST ABOUT OPTIONS TO HELP YOU QUIT

NEED HELP WITH VAPING?

CHAT TO OUR PHARMACIST TODAY

"Vapes are now available in pharmacies without a prescription"
– *ABC News*

TALK TO OUR PHARMACIST ABOUT OPTIONS TO HELP YOU STOP SMOKING

FOI 27-3600 - Document 8

From 1 October 2024 pharmacists may supply vapes with a nicotine concentration of 20mg/mL or less to people 18 years or over without a prescription

– Therapeutic Goods Administration

subject to certain conditions and state and territory law.

TALK TO OUR PHARMACIST TO UNDERSTAND HOW THIS MAY AFFECT YOU

Pharmacists can supply vapes where it is clinically appropriate to patients who:

1. are 18 years or over
2. require a nicotine concentration of 20mg/mL or less
3. provide informed consent, which includes informing the patient or patient's carer that the therapeutic good is not a listed good or registered good.

– Therapeutic Goods Administration

TALK TO OUR PHARMACIST TO UNDERSTAND HOW THIS COULD HELP YOU

s.22 [redacted]

From: Richard Lee s.22 [redacted]

Sent: Tuesday, 28 January 2025 11:23 AM

To: s.22 [redacted] @Health.gov.au>

Cc: [redacted] Minister Butler <Minister.Butler@Health.gov.au>;

Minister.Butler.Meetings <Minister.Butler.Meetings@Health.gov.au>

Subject: Re: Therapeutic vaping - 2025 update

REMINDER: Think before you click! This email originated from outside our organisation. Only click links or open attachments if you recognise the sender and know the content is safe.

s.22 [redacted]

Good morning and I hope you are keeping well.

We spoke in August last year about the state of the vaping market and shared thoughts on ensuring the pharmacy supply chain was able to meet the likely needs arising from the legislative changes that had been implemented.

Please find attached a short update note, and certain recent events that we at Liber have noticed that may be of interest to the Minister in terms of his ongoing assessment of the implementation of last year's legislative changes.

I should be grateful, at your convenience, for the opportunity to provide you, or the Minister, a short briefing of the details around these issues.

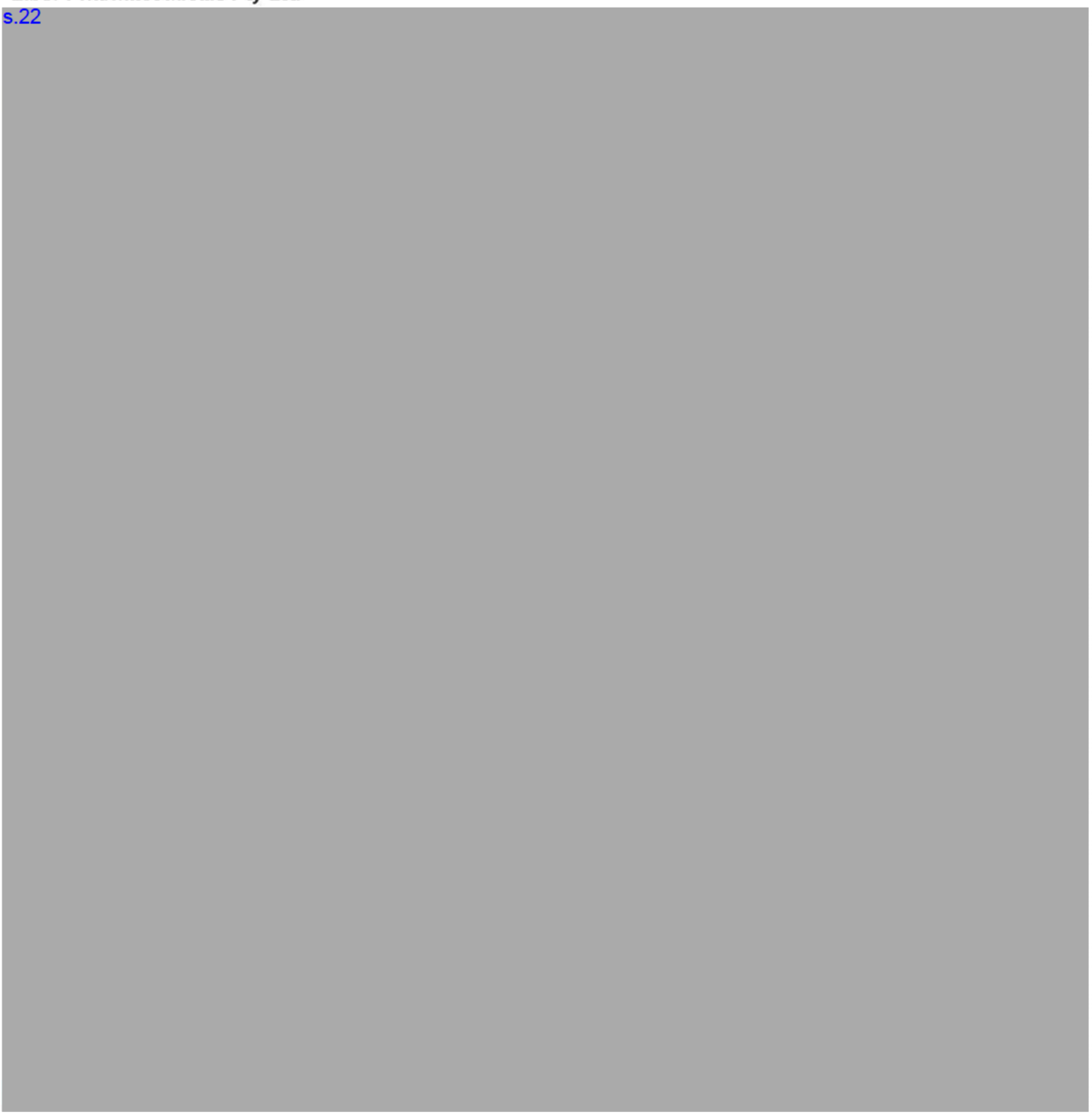
Kind regards

Richard

Richard Lee
Chief Executive Officer

Liber Pharmaceuticals Pty Ltd

s.22



FOI 27-3600 - Document 9

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Jan 28, 2025

The Honourable Mark Butler
Minister for Health and Aged Care
Parliament House
Canberra 2600

Dear Minister Butler

Re: Therapeutic vaping 2025: Market update

As we push into 2025, Liber Pharmaceuticals, as the largest provider of TGO 110 compliant vaping products, has paused to take stock on the current state of the vaping market in Australia. As the dominant manufacturer, with relationships with the three national pharmaceutical wholesalers, and substantially all of the leading national pharmacy banners, we are uniquely placed in terms of our access to market data, unlike many of those who have made claims to discredit the Government's efforts.

I should be grateful for the opportunity to brief your team on four key matters that I believe may be of use to your ongoing assessment of the regulatory changes coming into the election:

1. **Positive progress in establishing the pharmacy supply chain for therapeutic vaping:** Since the implementation of the new framework, more than 3,700 pharmacies across Australia, representing almost 70% of all pharmacies, have dispensed Liber's vaping product, Nicovape Q - the pharmacy channel is not opposed to the new framework.

   Now that the market has had several months to digest the new framework, our work with the pharmacy supply chain gives us confidence that it can meet the demands required to transition over a million smokers and vapers to legal access.

   We would be grateful for the opportunity to share insights and market data on the increasing numbers of pharmacies that have committed to educating their pharmacists on their role directing patients to prescribers, rather than replacing them.

2. **Pharmacies need to tell patients that they are open to discuss therapeutic vaping:** Liber believes that the single biggest issue hindering adoption of the Government's framework is a significant lack of consumer awareness about the legal access pathway.

   Pharmacies who are willing to supply therapeutic vapes are not legally permitted to advertise that fact, whether in store or otherwise. Further:

- The TGA has issued no guidance on what pharmacies can use to inform patients about their ability to carry out vaping assessments or dispense TGO 110 compliant products; and
- The Pharmacy Guild's "Say no to OTC vapes" poster campaign means that the only mention by pharmacies to the public on therapeutic vaping is where it is NOT available.

Liber believes that this issue could be simply remedied through refinement of existing DoH resources, but must be urgently done to allow pharmacies to drive the transition to therapeutic access to vapes.

3. **New illicit market threat:** There is a new brand of illicit vapes, Ali Barbar, being widely sold in Australia. Indeed, we have photos of 25,000 puff Ali Barbar devices brazenly sold above the counter in vape stores in Melbourne for $40.

s.37 [redacted]

4. **Tobacco-affiliated companies rearing their head again in the therapeutic space:** We have noted several new initiatives by tobacco-owned vaping brands in terms of below cost pricing and pharmacy incentive programmes aiming to further cement tobacco-owned brands within the legal channel. Both approaches are materially different to previous efforts, and have the potential to undermine legal access.

I would be grateful for an opportunity at your convenience to give you a briefing on these issues.

Yours sincerely

s.22 [redacted]

Richard Lee

CEO and Managing Director
Liber Pharmaceuticals

From: s.22
To: ; mdconsent@health.gov.au;
Cc:
Subject: RE: Content Manager Corporate Document : D25-2728270 : Request for Information: Preliminary assessment - Liber Pharmaceuticals: Application for Consent for Non-compliance (s14A and s41MA) - Email 24-06-2025 15:31:38 (0) NVP Compliance [SEC=OFFI [SEC=OFFI
Date: Wednesday, 25 June 2025 7:46:08 AM
Attachments: image001.png
image002.png
image004.png

---

s.22

FYI Q7 in the RFI D25-2728270 has requested information on their 41MA application. Hopefully, this will provoke some clarity from Liber around this.

s.22
Vaping Regulation and Reporting Section
Vaping Implementation and Enforcement Branch
(Working Mon-Thur: 0700-1430)

Regulatory Practice and Support Division | Health Products Regulation Group
Australian Government, Department of Health, Disability and Ageing

This email comes to you from Ngunnawal country
Location: Gulgana Building, 27 Scherger Dr, Fairbairn
PO Box 100, Woden ACT 2606, Australia

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From: @Health.gov.au>
Sent: Tuesday, 24 June 2025 4:21 PM
To: @health.gov.au>; mdconsent@health.gov.au; @health.gov.au>
Cc: @Health.gov.au>
Subject: RE: Content Manager Corporate Document : D25-2728270 : Request for Information: Preliminary assessment - Liber Pharmaceuticals: Application for Consent for Non-compliance (s14A and s41MA) - Email 24-06-2025 15:31:38 (0) NVP Compliance [SEC=OFFI [SEC=OFFI

Dear

Thank you for sharing the information regarding Liber — much appreciated. I've included in this email chain for visibility.
As I understand it, Liber intends to withdraw the consent applications submitted under sections 41MA and 41MAA.
could you please confirm if this is correct.

Cheers, [redacted]

From: [redacted]@health.gov.au>
Sent: Tuesday, 24 June 2025 3:45 PM
To: [redacted]@Health.gov.au>; mdconsent@health.gov.au
Cc: [redacted]@health.gov.au>
Subject: Content Manager Corporate Document : D25-2728270 : Request for Information: Preliminary assessment - Liber Pharmaceuticals: Application for Consent for Non-compliance (s14A and s41MA) - Email 24-06-2025 15:31:38 (0) NVP Compliance [SEC=OFFI [SEC=OFFICIAL

s.22 [redacted]

FYI. I have completed our preliminary assessment of the s14 consent application by Liber Pharmaceuticals. I have sent a request for information (D25-2728270) based on this assessment.

Happy to discuss further if that would assist your area.

Kind regards

s.22 [redacted]
Vaping Regulation and Reporting Section
Vaping Implementation and Enforcement Branch
(Working Mon-Thur: 0700-1430)

Regulatory Practice and Support Division | Health Products Regulation Group
Australian Government, Department of Health, Disability and Ageing
[redacted]

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------< Content Manager Record Information >------

Record Number: D25-2728270
Title: Request for Information: Preliminary assessment - Liber Pharmaceuticals: Application for Consent for Non-compliance (s14A and s41MA) [SEC=OFFICIAL] - Email 24-06-2025 15:31:38 (0) NVP Compliance

From: s.22
To: [redacted]@health.gov.au
Cc: [redacted]
Subject: Re: consent to supply applications - 41MA & 41MAA [SEC=OFFICIAL]
Date: Thursday, 3 July 2025 9:26:07 AM
Attachments: image001.png
image001[30].png
image002[41].png
Liber - letter to TGA - consent for non-compliance.pdf

REMINDER: Think before you click! This email originated from outside our organisation. Only click links or open attachments if you recognise the sender and know the content is safe.

Dear [redacted]

Thanks for your message. I confirm that the draft consent applications may be withdrawn.

I further note that, because we were unable to link to non-compliance with the MDSO in the online system, our application for s41MA consent was made in writing (letter directed Ashley MacLachlan-Bent) on 4 June 2025 - copy attached.

Regards
[redacted]

s.22

Liber Pharmaceuticals Ltd
s.22

www.liber.com.au

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From: mdconsent@health.gov.au <mdconsent@health.gov.au>
Date: Thursday, 3 July 2025 at 9:01 am
To: [redacted]@liber.com.au s.22
Subject: re: consent to supply applications - 41MA & 41MAA [SEC=OFFICIAL]

Dear [redacted]

Following your correspondence with [redacted] (attached) regarding the withdrawal of consent to supply applications under sections 41MA and 41MAA of the *Therapeutic Goods Act 1989* (the Act), please note that five applications from Liber Pharmaceuticals Pty Ltd are currently in draft status. These applications are listed in the table below.

Name	Title	Sponsor	Submitting Category	CRM Status	Is Created from Portal?	Created On
CTS-2025-01871	NVQ 2 - Consent for Non-compliance	Liber Pharmaceuticals Pty Ltd	Device(s) NOT included in the ARTG or Application(s) for Inclusion	Draft	Yes	3/06/2025 15:45
CTS-2025-01860	NVQ2 - Test for TBD	Liber Pharmaceuticals Pty Ltd	Device(s) NOT included in the ARTG or Application(s) for Inclusion	Draft	Yes	19/05/2025 13:47
CTS-2025-01841	NVQ2 - Test	Liber Pharmaceuticals Pty Ltd	Device(s) NOT included in the ARTG or Application(s) for Inclusion	Draft	Yes	8/04/2025 16:04
CTS-2025-01840	NVQ2 - 2025 exemption DRAFT	Liber Pharmaceuticals Pty Ltd	Device(s) NOT included in the ARTG or Application(s) for Inclusion	Draft	Yes	8/04/2025 15:06
CTS-2025-01777	NVQ2 - 2025 exemption	Liber Pharmaceuticals Pty Ltd		Draft	Yes	20/02/2025 16:47

Could you kindly confirm whether Liber Pharmaceuticals Pty Ltd consents to the withdrawal of these draft applications made under sections 41MA and 41MAA of the Act?

Kind regards,

s.22

Devices Application and Triage Section | Medical Devices Authorisation Branch
Medical Devices and Product Quality Division

Email: mdconsent@health.gov.au

Australian Government, Department of Health, Disability and Ageing
Therapeutic Goods Administration
PO Box 100, Woden ACT 2606
www.tga.gov.au

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From: s.22
To: mdconsent@health.gov.au; NVP Compliance
Cc: s.22 ; TGA Accounts Receivable; mdconsent@health.gov.au
Subject: Re: RE Unable to respond before 29 May: Liber Pharmaceuticals - Application s14 Consent to export goods [SEC=OFFICIAL]
Date: Thursday, 4 June 2026 9:31:09 AM
Attachments: image001.png
image002.png
image003.png
image004.png
image006.png
image007.png
image008.png
image001[30].png
image002[15].png

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Dear

Thank you for getting in touch on this matter.

I confirm that the goods subject to the s14/14A application currently under consideration do not contain therapeutic vaping devices or therapeutic vaping accessories.

Thanks also regarding your guidance on the draft CtS applications — these have now been deleted.

Regards

s.22

Liber Pharmaceuticals Ltd
s.22

www.liber.com.au

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From: mdconsent@health.gov.au <mdconsent@health.gov.au>
Date: Thursday, 4 June 2026 at 8:52 am
To: @liber.com.au>; NVP Compliance <NVPCompliance@health.gov.au>
Cc: @health.gov.au>; Richard Lee @liber.com.au>; TGA Accounts Receivable <accountsrec@health.gov.au>; mdconsent@health.gov.au <mdconsent@health.gov.au>

Subject: RE: RE Unable to respond before 29 May: Liber Pharmaceuticals - Application s14 Consent to export goods [SEC=OFFICIAL]

OFFICIAL

Dear [redacted]

Further to your recent emails to our colleagues in the Vaping Implementation and Enforcement Branch, we understand that you do not require consent to supply (CtS) under sections 41MA and 41MAA of the *Therapeutic Goods Act 1989* (the Act) for the export of therapeutic vaping kits, as they do not contain therapeutic vaping devices or therapeutic vaping accessories.

Our records indicate that you currently have four CtS applications under sections 41MA and 41MAA of the Act in draft status:

Application Number	Title	Date Created	Status
CTS-2025-01871	NVQ2 – Consent for Non-compliance	3 June 2025	Draft
CTS-2025-01860	NVQ2 – Test for TBD	19 May 2025	Draft
CTS-2025-01841	NVQ2 - Test	8 April 2025	Draft
CTS-2025-01840	NVQ2 - Test	8 April 2025	Draft

If you do not intend to progress these applications for formal TGA review under sections 41MA and 41MAA of the Act, please consider deleting the draft applications.

For further information about deleting draft CtS applications, please refer to the guidance document: Completing an application for consent to import, supply, or export medical devices that do not meet the Essential Principles, particularly the information on page 10.

I have also included an excerpt below from the guidance document below for your reference.

Application Draft tab

- The 'Draft' tab **(Figure 4)** contains all your consent applications that are in draft and not yet submitted by your organisation.
- Click on the down-arrow on the right side of the relevant application.
- Select whether you want to:
  - Edit the draft application.
  - Preview the draft application.
  - Delete the draft application.

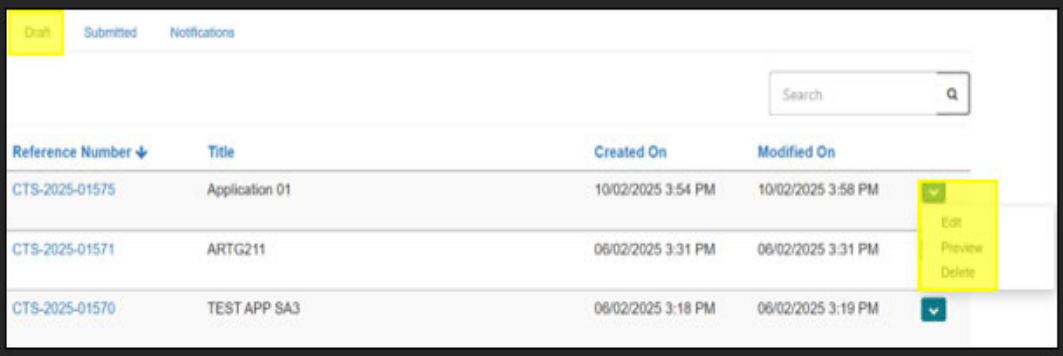


Figure 4

Delete draft applications

- Applications in the 'Draft Consent Applications' **(Figure 5)** view can be deleted permanently.
- To delete an application:
  - Click the down-arrow on the right side of the relevant application.
  - Select 'Delete'.
  - A prompt will appear to confirm your action.
  - Select 'Delete' to permanently delete the application.
  - Select 'Cancel' if you do not wish to delete the application.

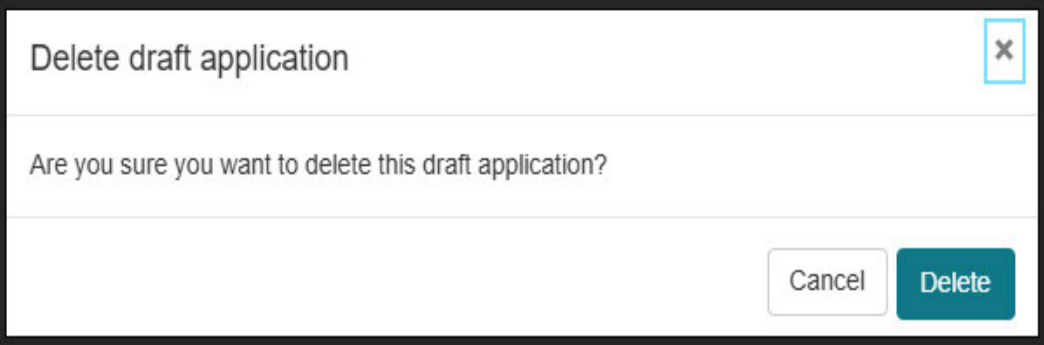


Figure 5

Please contact us if you have any questions.

Kind regards,

s.22

Devices Application and Triage Section | Medical Devices Authorisation Branch
Medical Devices and Product Quality Division

Email: mdconsent@health.gov.au

Australian Government, Department of Health, Disability and Ageing
Therapeutic Goods Administration
PO Box 100, Woden ACT 2606
www.tga.gov.au

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From: s.22 [redacted]@liber.com.au>
Sent: Wednesday, 27 May 2026 11:13 AM
To: NVP Compliance <NVPCompliance@health.gov.au>
Cc: [redacted]@health.gov.au>; [redacted]@liber.com.au>; [redacted]@liber.com.au>; TGA Accounts Receivable <accountsrec@health.gov.au>; mdconsent@health.gov.au
Subject: Re: RE Unable to respond before 29 May: Liber Pharmaceuticals - Application s14 Consent to export goods [SEC=OFFICIAL]

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Dear [redacted]

Just re-reading my response, to clarify the additional information provided:

1. The Relevant Goods do not include any therapeutic vaping packs, i.e., do not contain devices, but that our products are in twin or seven packs, which constitute therapeutic vaping kits. As such, the products that we are exporting are not usable in the form that they are being exported.
2. On the basis that there are no devices contained in the proposed shipment, we will not be making an application under s41/41A.

I am available at any time should you wish to discuss.

Regards

[redacted]

s.22 [redacted]

Liber Pharmaceuticals Ltd

[redacted]

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From: s.22 [redacted]@liber.com.au>
Date: Wednesday, 27 May 2026 at 10:56 am
To: NVP Compliance <NVPCompliance@health.gov.au>
Cc: [redacted]@health.gov.au>; [redacted]@liber.com.au>; [redacted]@liber.com.au>; TGA Accounts Receivable <accountsrec@health.gov.au>; mdconsent@health.gov.au <mdconsent@health.gov.au>
Subject: Re: RE Unable to respond before 29 May: Liber Pharmaceuticals - Application s14 Consent to export goods [SEC=OFFICIAL]

Dear [redacted]

Many thanks for your prompt response to our application. We note your advice that you are unable to provide a decision regarding our application prior to 29 May 2026.

Additional information

1. No devices are included with the cartridges being exported, the individual cartridges are contained in retail packs of 2 and 7 cartridges respectfully, as indicated in Annexure A to our application letter.
2. A related application under sections 41MA and 41MAA of the Act is not required in conjunction with the s14/14A application.

Please let me know if you require any further information to progress our application.

Regards

[redacted]

s.22 [redacted]

Liber Pharmaceuticals Ltd
s.22

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From: NVP Compliance <NVPCompliance@health.gov.au>
Date: Wednesday, 27 May 2026 at 9:26 am
To: s.22 @liber.com.au>
Cc: @health.gov.au>; @liber.com.au>; @liber.com.au>; TGA Accounts Receivable <accountsrec@health.gov.au>; mdconsent@health.gov.au <mdconsent@health.gov.au>
Subject: RE Unable to respond before 29 May: Liber Pharmaceuticals - Application s14 Consent to export goods [SEC=OFFICIAL]

OFFICIAL

Dear

Thank you for your covering letter and application under Section 14 of the *Therapeutic Goods Act 1989* (**the Act**) of 25 May 2026, for consent to export nominated therapeutic vaping substance accessories (**pods**) listed in Annexure A to the covering letter, that do not meet applicable standards (TGO110). I note from your remittance advice that the fees for this application have been paid.

Unable to respond within requested timeframe

You have advised at 2.7 of your application that the goods are currently scheduled for export on 29 May 2026. We have identified significant potential issues with export of the pods in the described circumstances. We are currently investigating these issues. Accordingly, we are unable to provide a response before your proposed export on 29 May.2026. Please be aware that while the TGA will endeavour to provide a response to your application within a reasonable time, there is no statutory timeframe for consideration of these applications.

Regulatory context prior to a decision

Liber should not export the goods until the TGA has considered your application and provided you with a final decision on this application. I note in this context you advise at 2.5 that you have s.47 of these goods, this may be considered a commercial quantity of vaping goods.

In the absence of a decision on your application, you should be aware that exportation or undertaking steps to facilitate exportation (including supply to, or possession, by a third party) may be unlawful, including but not limited to, potential offences or contraventions in relation to:

- Supplying a commercial quantity of vaping goods to a third party, possession of commercial quantity of vaping goods by a third party and associated supply of commercial quantity of vaping goods if passed on to another party within Australia (sections 41QB and 41QC of the Act).
- Export of therapeutic goods not included on the register or the subject of an applicable exemption (sections 19B and 19D of the Act).
- Export of therapeutic goods not complying with applicable standards without the consent of the Secretary (sections 14 and 14A of the Act).

These may apply to Liber, logistics and transport services and the exporter of the pods. These may also potentially extend to include executive officers of these entities.

Additional information

It would assist our investigations if you would respond to these questions.

1. Are any of the nominated pods in Annexure A to your covering letter, included in therapeutic vaping kits or therapeutic vaping packs?
2. Have you or are you contemplating, a related application under sections 41MA and 41MAA of the Act, for export of therapeutic vaping devices that do not comply with applicable standards (the essential principles or the MDSO)?

Please contact me through this email address if you have any questions about this information.

The TGA will contact you with a decision on your application or advice on export of these goods once our investigations are completed.

Kind regards

s.22
Vaping Regulation and Reporting Section
Vaping Implementation and Enforcement Branch
)

Regulatory Practice and Support Division | Health Products Regulation Group
Australian Government, Department of Health, Disability and Ageing

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Location: Gulgana Building, 27 Scherger Dr, Fairbairn
PO Box 100, Woden ACT 2606, Australia

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OFFICIAL

From: [redacted]@liber.com.au>
Sent: Monday, 25 May 2026 4:51 PM
To: TGA Accounts Receivable <accountsrec@health.gov.au>
Cc: NVP Compliance <NVPCompliance@health.gov.au>; [redacted]@health.gov.au>; [redacted]@liber.com.au>; [redacted]@liber.com.au>
Subject: Liber Pharmaceuticals - Application s14 Consent to export goods

REMINDER: Think before you click! This email originated from outside our organisation. Only click links or open attachments if you recognise the sender and know the content is safe.

Dear TGA Accounts team,
I have attached an application for consent to supply under s14. We will submit the payment via the TBS portal shortly. Many thanks.
Copy to: s.22 [redacted] - for your awareness, please see our letter attached in support of our s14 application for consent to export goods.
Please let me know if you have any questions or require further information. We are available to discuss at any time.
Regards
[redacted]

s.22 [redacted]

Liber Pharmaceuticals Ltd
s.22 [redacted]

www.liber.com.au

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