

## Community Affairs Legislation Committee

### Inquiry into the Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Bill 2024

Hearing date: 1 May, 2024

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Liber Pharmaceuticals (**Liber**) is pleased to provide its response to questions taken on notice before the Community Affairs Legislation Committee's Inquiry into the *Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Bill 2024*.

### Liber's Response to Questions on Notice

#### Question 1 (Proof Hansard, p. 30.)

**Senator PRATT:** *What is the nicotine dosage in these products per vape? You might have a variety of them that have a different dose. As we've been hearing in earlier evidence, unless it's done under the supervision of a doctor and you're monitoring how much you're taking in, vaping can lead to quite elevated levels of nicotine consumption sometimes compared even to smoking. What testing have you done of these products, and how do people use them to make sure that their nicotine consumption is going down over time rather than up?*

...

**Senator PRATT:** *If we could get a copy of the consumer materials for each device, that would be great.*

**Mr Lee:** *And may I take on notice a response to that one as well?*

#### Liber's response

1. Liber has attached copies of:

Consumer Medicines Information (CMI) document.

Nicovape Q New Patient Guide.

2. What is the nicotine dosage in these products per vape?

Liber's current product is available in three concentrations: 59 mg/mL, 35 mg/mL, and 20 mg/mL.

Each Nicovape Q pod contains 1.5ml of e-liquid, which amounts to 88.5 mg, 52.5 mg, and 30 mg of nicotine per pod.

Regarding dosage, Liber has established that Nicovape Q delivers nicotine uniformly throughout the cartridge's lifecycle.

Liber will launch a new version of its Nicovape Q system at the end of May.

Liber wishes to draw the Senate's attention to a critical distinction between "dosage" and "nicotine concentration" in Nicotine Vaping Products, as "concentration" is frequently used incorrectly to indicate dosage.

- The dosage of any given NVP depends on two independent factors: the amount of nicotine in the liquid and the amount of liquid delivered in aerosol form per inhalation.
- In general, higher-powered devices deliver more aerosol per inhalation. This is why open systems (refill liquids) have predominated in markets with regulatory limits on nicotine concentration, such as the EU and the UK. In contrast, in the United States, where there are no limits, refill liquids barely feature at all in tracked retail channels and are now something of a historical technology.
- Closed-system NVPs, such as Nicovape Q, typically operate at substantially lower power and, since they deliver less aerosol mass per puff, must use higher concentrations of nicotine than open-system equivalents.

The Senate should be aware of three facts that lead from this:

- A. Higher concentrations and lower power mean that, per mg of delivered nicotine, users are exposed to substantially less mass of non-active ingredients. Lower power also means less exposure to toxic products of thermal decomposition (e.g., formaldehyde) which are generated by overheating.
  - B. Because the nicotine liquid in closed systems is contained in a tamper-free cartridge, it is safer for users and third parties than refill liquids, which may be spilled or adulterated.
  - C. Only closed systems can be fully characterised in terms of their quality since the manufacturer controls both the device and the liquid it contains. For this reason, the MHRA (to date, the only regulator that currently issues guidance on licensing NVPs as therapeutic goods) has stated that it anticipates all licensed NVPs to be closed-system products.
3. How do patients monitor how much they're actually taking in?
- The canonical finding on nicotine self-administration is that nicotine-dependent individuals achieve remarkably consistent blood levels over time through a process of automatic self-titration.
  - Additionally, one of the principal advantages of closed-pod systems (such as Liber's Nicovape Q) is that patients (and prescribers) can quite straightforwardly monitor the amount of nicotine they consume over a given period by referring to the number of cartridges they consume.
  - Liber developed Nicovape Q such that most smokers would require a maximum of one cartridge per day.
  - The updated Nicovape Q product, which will launch at the end of this month (and in time for implementation of the Bill, if passed), contains new functionality that enables users to monitor their consumption directly by connecting the device to their smartphone, by way of a simple tap. This will assist patients in stabilising their nicotine consumption and when appropriate, down-titrating their nicotine consumption under medical supervision on their way to abstinence.
4. What testing have you done of these products?
- Liber conducted a multifaceted research programme before it launched Nicovape Q. This work substantially exceeds the requirements under TGO 110 and was conducted as the first research phase in Liber's pharmaceutical development programme. Works carried out included:

- Analytic studies of harmful or potentially harmful compounds known to be present in NVP aerosols, following the US FDA's guidance.
- Molecular characterisation of e-liquid formulations, with all ingredients subjected to expert toxicological screening.
- Toxicological risk assessments of ingredients and emissions, using a conservative lifetime exposure assumption.
- Liber held a scientific advisory meeting with the MHRA, the UK's medical regulator, in which it briefed the agency on its work. Liber's programme was well received, and the MHRA advised Liber on additional work it must carry out before seeking medicinal licensing.
- Of particular note: The delivered dose from Nicovape Q product was uniform within the acceptable variation. The aerosol's emission profile does not exceed Liber's expert toxicologists' (conservative) toxicological guidance values, which are derived from multiple authoritative sources.
- Liber has all the required certifications, and total visibility of its supply chain. Liber's manufacturer conducted design validation studies to ensure the product's quality and performance.

5. Note on titration, excess nicotine, etc.

- Concerning the over-delivery of nicotine, the main risk from vaping products arises where the device and liquid combination are not controlled, as is the case with open-system vaping products. Higher-powered NVP devices typically output more aerosol per given activation, so delivered nicotine can be much higher than with a low-powered closed-system NVP device.
- Those most at risk from overconsumption are nicotine and vape-naive individuals. Nicotine-naive individuals should not be using vaping products, and the efforts to close illicit access to vaping products should significantly reduce access by this cohort of users. Further, vape-naive individuals who have become nicotine dependent and who may be prescribed vaping products, are protected through instruction/supervision by medical professionals, who may adjust the prescribed product and work with patients to ensure they are not overconsuming. The MAF's provisions achieve both.
- The literature reports minimal adverse events from NVPs, which is in line with Liber's real-life experience over the first 2 ½ years of seeing its Nicovape Q product prescribed and dispensed in Australia. Liber notes that the most recent update of the Cochrane Collaboration's annual review on NVPs found no additional adverse events compared with nicotine replacement therapy, which is itself a safe treatment. Medical oversight, product specifications, and manufacturers' user guidance will further ensure safe usage.
- While high nicotine delivery is frequently raised as a concern, Liber believes underdosing is an equal concern in treating nicotine-dependent individuals. Products that underdose leave patients unsatiated in terms of their nicotine cravings and therefore at greater risk of relapse. For smokers who have already tried and failed to stop smoking, relapse remains the typical outcome with existing therapeutic methods in subsequent attempts.
- The decline in smoking in Australia is asymmetric - the successes have mostly come in recent years from preventing uptake in young people, whereas little has improved in

cessation outcomes. Vaping products under the MAF are an important new therapeutic option in the fight against disease and death from smoking.

### **Question 2 (Proof Hansard, p. 32.)**

**Senator CADELL:** *We're going down this line very specifically. I've just come off the supermarket inquiry. Access to market is very important. What relationship does Liber have with Chemist Warehouse?*

**Mr Lee:** *Chemist Warehouse sits on our register. They're a shareholder, but they're not involved in the day-to-day running of the business—as no individual shareholder is. They have no board representation. They support the prescribed access model, as do all of our shareholders.*

**Senator CADELL:** *Do they stock other products as well as yours?*

**Mr Lee:** *They will meet any script that is presented as a pharmacist.*

**Senator CADELL:** *Do they stock other products as well as yours?*

**Mr Lee:** *I don't know what they range.*

**Senator CADELL:** *Can you find that out on notice?*

**Mr Lee:** *Yes, I'll take that on notice.*

### **Liber's response**

- Liber notes that it cannot speak directly on behalf of Chemist Warehouse and its commercial approach to stocking any products including nicotine vaping products. However, Liber does note this response from Mr Jack Gance, Chairman of Chemist Warehouse:
  - As a pharmacy, Chemist Warehouse seeks to dispense any scripts that are presented to it, including those for nicotine vaping products.
  - In this regard, as all nicotine vaping products are unlicensed, and have not been assessed by the TGA for safety and efficacy, Chemist Warehouse has elected to only hold stock of vaping products that are available for distribution through its national wholesale distributor partners.
  - Further, Chemist Warehouse does not support the presence of tobacco-affiliated vaping products through the pharmacy channel and has elected not to hold stock of any such products.
  - Where a patient presents a script for a vaping product that is not distributed by a national CSO pharmaceutical wholesaler, Chemist Warehouse pharmacies will seek to source the products, provided they are duly notified on the TGA's list of notified NVPs that are compliant with TGO 110.

### **Question 3 (Proof Hansard, p. 32.)**

**Senator CADELL:** *What I don't want to create is a new big industry that is controlled by channel to market. I have concerns over that relationship, going forward. Is smokefreeclinic.com.au owned by your Managing Director, Ryan Boulton? Is that correct?*

**Mr Lee:** *Yes.*

**Senator CADELL:** *I can go on that site and get a prescription for your products.*

**Mr Lee:** No, you can't.

**Senator CADELL:** What can I do? It says, 'Nicotine vaping prescriptions available. Local pickup 5,500 pharmacies,' on that website.

**Mr Lee:** That goes to an independent cohort of doctors with whom we have no contractual relationship.

**Senator CADELL:** So the owner of the people that make the products has a website that goes to an independent cohort of doctors who can prescribe your products?

**Mr Lee:** Correct. They can prescribe any products. The simple fact of the matter is that the reason we created smokefree was because there was a lack of education and a lack of people knowing where to go to speak to a doctor. That remains the biggest issue with the channel to date. It's not that there are not enough doctors. It's that people don't know where to go to access them.

**Senator CADELL:** How many independent doctors are on that website?

**Mr Lee:** On?

**Senator CADELL:** How many independent doctors operate via smokefreeclinic.com.au.

**Mr Lee:** That's a question for SwiftDoc, the independent platform. I would have to take that on notice, as well.

### **Liber's response**

- SwiftDoc is an independent prescribing platform that, among other things, provides smoking cessation assessments to patients.
- Neither Liber nor Mr Boulton has any direct or indirect contractual relationship with SwiftDoc or any other prescribing platform, clinic or doctor in relation to the prescribing of vaping products, or Liber's Nicovape Q products.
- SwiftDoc have advised that six doctors provide telehealth services for smoking cessation generally, including referred consultations from smokefreeclinic.com.au.

### **Question 4 - not noted in Secretariat email (Proof Hansard, p. 28.)**

**Senator URQUHART:** Sure. Can I ask that the other witnesses provide on notice what products they have currently on the market?

### **Liber's response**

- Liber currently has the following products on the market:  
Nicovape Q closed system nicotine vaping product, which comprises:
  - The Nicovape Q vaping device.
  - Nicovape Q cartridges at a nicotine concentration of 59 mg/mL (as nicotine lactate). The cartridges contain 1.5 ml of e-liquid for a total of 88.5 mg of nicotine. These cartridges are available in three flavours, classic, coolmint and cherry.
  - Nicovape Q cartridges at a nicotine concentration of 35 mg/mL (as nicotine lactate). The cartridges contain 1.5 ml of e-liquid for a total of 52.5 mg of nicotine. These cartridges are available in three flavours, classic, coolmint and cherry.

- Nicovape Q cartridges at a nicotine concentration of 20 mg/mL (as nicotine lactate). The cartridges contain 1.5 ml of e-liquid for a total of 30.0 mg of nicotine. These cartridges are available in three flavours, classic, coolmint and cherry.
- Under the new flavouring restrictions in TGO 110, Liber may not notify the TGA or import its cherry-flavoured Nicovape Q cartridges after 1 March 2024. However, as permitted by the TGA, Liber will continue to make its cherry-flavoured Nicovape Q cartridges available until 30 June 2024, or until stocks run out, whichever comes first.
- The above products will be phased out from the beginning of June 2024 and replaced with:
  - A Nicovape Q vaping device (version 2).
  - Nicovape Q50 cartridges at a nicotine concentration of 50 mg/mL (as nicotine benzoate). The cartridges contain 2.0 ml of e-liquid for a total of 100.0 mg of nicotine. These cartridges are available in three flavours: classic tobacco, coolmint and freshmint.
  - Nicovape Q35 cartridges at a nicotine concentration of 35 mg/mL (as nicotine benzoate). The cartridges contain 2.0 ml of e-liquid for a total of 100.0 mg of nicotine. These cartridges are available in three flavours: classic tobacco, coolmint and freshmint.
  - Nicovape Q20 cartridges at a nicotine concentration of 20 mg/mL (as nicotine benzoate). The cartridges contain 2.0 ml of e-liquid for a total of 100.0 mg of nicotine. These cartridges are available in three flavours: classic tobacco, coolmint and freshmint.
  - Liber elected to reduce its highest nicotine concentration cartridges to align with the TGA's proposal to restrict the maximum nicotine concentration to 50 mg/mL at the end of 2024.

## Liber's Response to Adverse Comment and other Statements

### Note to the Chair and Response to Adverse Comment (Proof Hansard, p. 25.)

It has come to Liber's attention that during his testimony before the Committee on 2 May 2024 on behalf of Vape4life, Mr Craig Jackman, abused his Parliamentary privilege by alleging, without any basis in fact, that Mr Lee lied in his article 5.3 declaration to the Committee. Furthermore, Mr Jackson insinuated that Liber operates as a front for "Philip Morris" (presumably, Philip Morris International) through its Head of External & Regulatory Affairs, Mr Stuart Prichard:

*"I believe the Committee was lied to because Liber asserted they had no association with any tobacco company yet their Head of External & Regulatory Affairs, Mr Stuart Prichard, worked for Philip Morris for over 11 years, and now Philip Morris are proved to have prescription vapes, so, I don't know, I'm not the smartest man on the planet but I can join some dots there..."*

In response, the Chair stated that the Committee would take that advice and discuss it privately.

Liber stands by and wishes to reiterate the Article 5.3 declaration of interest and statement of interest included in its submission to the Committee, which Mr Lee reaffirmed at the Senate Committee hearing.

Furthermore, Liber wishes to draw the Senate's particular attention to its disclosure in its written submission regarding Mr Prichard's employment history.

Liber has always been transparent about Mr Prichard's employment history, given the sensitivities regarding the tobacco industry and its long history of attempts to influence the regulatory framework governing the supply of tobacco products, and more recently, nicotine vaping products.

Unfortunately, this voluntary disclosure has been picked up by the media and, Liber understands, circulated on social media to insinuate or, as with Mr Jackson at the senate hearing, directly suggest that Liber is subject to an ongoing tobacco influence.

Again, for the record:

- Neither Mr Lee nor Liber has any affiliation with the tobacco industry, its affiliates, or any organisations or individuals engaged in lobbying on its behalf.
- Neither Mr Lee nor Liber has ever received funding, investment or in-kind support from the tobacco industry, either directly or through third parties who may have received funding from the tobacco industry.
- Mr Prichard's direct employment by the tobacco industry ceased in 2013. He then acted as an ad hoc consultant until 2019, when he ceased before joining Liber. Mr Prichard has no financial, personal, or other connection with Philip Morris International or any other tobacco company.

Mr Prichard, whilst very respectful of Mr Jackman's advocacy and his right to advocate, is aggrieved by the allegation that he is acting on behalf of Philip Morris. Mr Prichard respectfully requests that the Chair compel Mr Jackman to withdraw his allegation and apologise for making his statements to the Committee without any basis in fact.

Liber also notes that despite having a history of employment in senior executive roles in tobacco companies, certain other witnesses at the Senate committee have not made similar disclosures, either in their submissions or at the hearing. Liber is uniquely transparent in this regard.

### **Response to Statement made (Proof Hansard, p. 24.)**

**Senator CANAVAN:** *I want to get more of a handle on the cost-of-living impacts. This might go particularly to Mr Leary as a user.*

*You mentioned earlier that going to vapes saved you money. Can you give us a rough cost per week or so that you have saved? I think you were going through the prices at pharmacies—it sounds like these legalised vapes are very excessively priced.*

*What's the difference between them and what you were able to pay at a vape store last year, and is that a big cost-of-living impact?*

**Mr Leary:** *The irony is that, when I was a smoker, I was working at the local government in engineering and I was spending—even then, when I was working, I was poor, and it's because I was smoking.*

*When I quit smoking and started vaping—and the price of cigarettes is much higher now—I think I was spending about \$300 a fortnight, so about \$150 or \$200 a week on cigarettes.*

*Vaping, I estimated, was costing no more than \$30 a week—so probably one-sixth to 10 or 15 percent of the cost.*

*I didn't actually go and buy the pods. I got a link from the doctor to a website—I think it was Chemist Warehouse. I didn't buy it, but I researched it, and people were saying they were paying two hundred and something dollars for three or six pods.*

*They said that they'd only last them three days, so you're looking at probably \$300 or \$400 a week for the pharmaceutical alternative.*

*The pharmaceuticals are probably as expensive as or more expensive than cigarettes, whereas vaping is probably 10 to 15 percent of the cost.*

## **Liber's response**

In relation to Mr Leary's response to Senator Canavan, Liber notes the following:

- Nicovape Q is distributed by national pharmaceutical wholesalers to pharmacies, in the manner expected of all mainstream medicines.
- Liber has no commercial relationships with and does not distribute its Nicovape Q products to individual pharmacies or online distribution platforms.
- As a wholesaler-distributed medical device, the pricing to pharmacies is fixed, as is the recommended retail price (RRP) of Nicovape Q cartridges, which is \$24.99 per twin pack.
- As such, six Nicovape Q cartridges retail at no more than \$74.97, or approximately \$12.50 per Nicovape Q cartridge.
- At \$12.50 per Nicovape Q cartridge, the maximum recommended weekly usage would cost \$87.50. By way of comparison, a pack-a-day smoker at \$40 per pack of cigarettes would spend \$280, meaning that a straight transition to a Nicovape Q cartridge per day would equate to savings of almost 70%.
- Liber notes that while users may start using an entire Nicovape Q cartridge per day, it is normal to down-titrate to a lower consumption pattern over the initial few weeks of treatment. A single Nicovape Q cartridge often lasts 2 - 3 days, bringing the daily cost down to \$3 - \$4, with some patients extending them over even longer periods.
- By way of example, I (Mr Lee) spoke to a patient recently who had decades of smoking history, typically smoking 50 cigarettes per day. The patient had a history of failed quit attempts using a variety of means. She started using Nicovape Q six months ago and initially used a Nicovape Q cartridge per day. She is now six months without smoking, uses a single Nicovape Q cartridge every six days, which she has dispensed from a Chemist Warehouse pharmacy, and estimates that over that six-month period, she has saved \$8,000.
- Mr Leary stated that his prescriber gave him a link to a website, he believes to be Chemist Warehouse. However:
  1. It is not possible to purchase Nicovape Q, or any other Schedule 4 medicines, from Chemist Warehouse online, and
  2. It is very unusual for a prescriber to give a patient a link to a website where they can purchase a prescribed medicine.
- Liber believes Mr Leary's testimony underscores the importance of restricting prescription medicines to brick-and-mortar pharmacies, rather than online platforms, which may not operate in the manner expected of pharmacies, including selling products at prices well above that which patients would pay from brick and mortar pharmacies.
- It is for this reason that Liber only distributes its Nicovape Q vaping products through national CSO wholesalers, and has no commercial or distribution arrangements with online platforms or individual pharmacies.



# NICOVAPE® Q | Q SD cartridges

## Consumer Medicine Information (CMI) summary

The full CMI on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

### 1. Why am I using Nicovape Q | Q SD?

Nicovape Q | Q SD contains the active ingredient nicotine. Nicovape Q | Q SD may aid in smoking cessation by replacing the nicotine you are used to getting from cigarettes and by replicating the hand-to-mouth action associated with smoking.

For more information, see Section 1. [Why am I using Nicovape Q | Q SD?](#) in the full CMI.

### 2. What should I know before I use Nicovape Q | Q SD?

Do not use if you have ever had an allergic reaction to nicotine or any of the ingredients listed at the end of the CMI.

**Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.**

For more information, see Section 2. [What should I know before I use Nicovape Q | Q SD?](#) in the full CMI.

### 3. What if I am taking other medicines?

Some medicines may interfere with Nicovape Q | Q SD and affect how it works.

A list of these medicines is in Section 3. [What if I am taking other medicines?](#) in the full CMI.

### 4. How do I use Nicovape Q | Q SD?

Nicovape Q | Q SD is intended for use as a replacement for cigarette smoking and for the purposes of smoking cessation. Always use Nicovape Q | Q SD in consultation with your doctor or pharmacist.

More instructions can be found in Section 4. [How do I use Nicovape Q | Q SD?](#) in the full CMI.

### 5. What should I know while using Nicovape Q | Q SD?

<b>Things you should do</b>	<ul style="list-style-type: none"><li>Remind any doctor or pharmacist you visit if you have an overactive thyroid gland; high blood pressure or have had a stroke; serious liver or kidney disease; are a diabetic; a tumour of the adrenal glands; or you have a history of epilepsy or are taking medicine to control any fits or seizures.</li><li>Check with your doctor if you are pregnant or intend to become pregnant</li></ul>
<b>Things you should not do</b>	<ul style="list-style-type: none"><li>Do not stop using this medicine suddenly – you may experience nicotine withdrawal symptoms.</li><li>Do not use this medicine if you are allergic to nicotine, or any of the ingredients listed at the end of this leaflet.</li><li>Do not use this medicine if you are a non-smoker or do not have an existing nicotine dependence.</li></ul>
<b>Driving or using machines</b>	<ul style="list-style-type: none"><li>Be careful before you drive or use any machines or tools until you know how Nicovape Q   Q SD affects you. Nicovape Q   Q SD may cause dizziness in some people.</li></ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"><li>Keep Nicovape Q   Q SD cartridges sealed in the blister pack until needed and store in a cool dry place where temperature stays below 24°C and store away from moisture, heat or sunlight.</li><li>Store Nicovape Q   Q SD cartridges where young children and pets cannot reach them.</li></ul>

For more information, see Section 5. [What should I know while using Nicovape Q | Q SD?](#) in the full CMI.

### 6. Are there any side effects?

If you smoke or use any other nicotine containing product while you are using Nicovape Q | Q SD, you may suffer an overdose of nicotine. However, if used correctly, nicotine overdose is unlikely. A large overdose may present symptoms such as exhaustion, convulsions, low blood pressure, circulatory collapse and breathing difficulty. In this event, you should immediately phone the Poisons Information Centre (by calling 13 11 26), or contact your doctor, or go to the Emergency Department at your nearest hospital.

For more information, including what to do if you have any side effects, see Section 6. [Are there any side effects?](#) in the full CMI.

# NICOVAPE® Q | Q SD cartridges

Active ingredient: *Nicotine lactate*

## Consumer Medicine Information (CMI)

This leaflet provides important information about using Nicovape Q | Q SD. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Nicovape Q | Q SD.**

Where to find information in this leaflet:

- [Why am I using Nicovape Q | Q SD?](#)
- [What should I know before I use Nicovape Q | Q SD?](#)
- [What if I am taking other medicines?](#)
- [How do I use Nicovape Q | Q SD?](#)
- [What should I know while using Nicovape Q | Q SD?](#)
- [Are there any side effects?](#)
- [Product details](#)

### 1. Why am I using Nicovape Q | Q SD?

**Nicovape Q | Q SD contains the active ingredient nicotine.**

Nicovape Q | Q SD is a nicotine vaping product (NVP) which may aid in smoking cessation by replacing the nicotine you are used to getting from cigarettes and by replicating the hand-to-mouth action associated with smoking.

**Nicovape Q | Q SD may aid in smoking cessation.**

Nicovape Q | Q SD cartridges contain a dilute nicotine liquid. When used in conjunction with the Nicovape Q | Q SD device the liquid is vaporised for inhalation which replaces the nicotine you would otherwise get from smoking.

The device and the cartridge when used together are referred to as the Nicovape Q System.

Using the Nicovape Q System provides nicotine to relieve some of the unpleasant symptoms such as feeling ill or irritable that smokers often feel when they try to give up. The nicotine can also reduce your cravings for a cigarette and help you to resist the urge to smoke.

This type of treatment is called Inhaled Nicotine Replacement Therapy (INRT).

### 2. What should I know before I use Nicovape Q | Q SD?

#### Warnings

**Do not use Nicovape Q if:**

- you are allergic to nicotine, or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use this medicine.
- you do not have an existing nicotine dependence.

**Check with your doctor if you:**

- have an uncontrolled, overactive thyroid gland. Nicotine may make your symptoms worse.
- have heart or circulation problems including heart failure or stable angina or high blood pressure or have had a stroke. **If you are in hospital because of a heart attack, severe heart rhythm disturbances or a stroke,** you should try to quit smoking without using INRT unless your doctor tells you to use it. Once you are discharged from hospital, you may use INRT in consultation with your doctor.
- have any serious liver or kidney disease. You may be more prone to side effects.
- are a diabetic. If you have diabetes you should monitor your blood sugar levels more often than usual when starting Nicovape Q as you may find your insulin or other medication requirements alter.
- have been diagnosed as having a tumour of the adrenal glands (phaeochromocytoma). Nicotine may

make your symptoms worse.

- have a history of epilepsy or are taking medicine to control any fits or seizures.
- have stomach or duodenal ulcers or an inflamed oesophagus or gullet (the passage between the mouth and the stomach) because INRT can make your symptoms worse.

If you have not told your doctor or pharmacist about any of the above, tell them before you use Nicovape Q | Q SD.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section 6. [Are there any side effects?](#)

#### Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Smoking during pregnancy has risks such as poor growth of your baby before birth, premature birth or still-birth. Stopping smoking is the best way to improve both your health and that of your baby. The earlier you stop smoking, the better.

Ideally, if you are pregnant, you should stop smoking without using INRT. However, if you have tried and this hasn't worked, your doctor may recommend you use INRT to help you stop smoking. This is because it is better for your developing baby than if you carry on smoking. The decision to use INRT should be made as early on in your pregnancy as possible and you should aim to use it for only 2-3 months. Remember, the most important thing is to stop smoking. You should only use INRT if your doctor has told you to.

**Talk to your doctor if you are breastfeeding or intend to breastfeed.**

Tobacco smoke causes breathing difficulties and other problems in babies and children. Ideally, if you are breastfeeding, you should try to stop smoking without using INRT.

Nicovape Q | Q SD should not be used while breastfeeding. You should use NRT products that are taken intermittently (e.g. gum or lozenges) and breastfeed just before you take the product. This helps your baby to get the smallest amount of nicotine possible.

### 3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

**Some medicines may interfere with Nicovape Q | Q SD and affect how it works.** Other medicines may be affected by Nicovape Q or affect how well Nicovape Q | Q SD works. Your pharmacist or doctor can advise you what to do if you are using any of these medicines.

**Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Nicovape Q | Q SD.**

### 4. How do I use Nicovape Q | Q SD?

#### How much to take / use

- Follow all directions given to you by your doctor or pharmacist carefully.**
- These directions may differ from the information contained in this leaflet.
- If you do not understand the instructions on the box, ask your doctor or pharmacist for help.**
- Use the Nicovape Q System when you feel the urge

- to smoke. It should be used as a direct alternative for smoking.
- Follow the instructions provided and use Nicovape Q | Q SD until your doctor tells you to stop.

#### When to take / use Nicovape Q | Q SD

Nicovape Q | Q SD should be used when you feel the urge to smoke. It should be used as a direct alternative for smoking.

#### How to use Nicovape Q | Q SD

- Remove the coloured safety cap and mouthpiece plug from the cartridge.
- Insert the cartridge into the top of the Nicovape Q device. It will secure itself automatically via the magnets.
- For the best experience, prior to first using the Nicovape Q device, ensure the device is fully charged by using the USB-C charger provided.
- The light ring around your charge port will indicate your device's current charge level.
- The Nicovape Q device is simple and familiar to use. It requires no buttons to turn on/off and activates only when you draw through the mouthpiece.
- To start, place the mouthpiece between your lips about halfway along the mouthpiece. Ensure that the device is angled downwards during use.
- Draw firmly for 2 to 3 seconds. Aim to draw enough air through the device to fill your mouth. Then immediately inhale deeply and then exhale slowly. It's not unusual to cough when you first start, but this will ease with continued use.
- Wait at least 20 seconds before your next draw. This will allow the device to reset for the next puff and will enable you to see if your cravings have been satisfied.
- Note – a flashing white light ring means your cartridge may be empty, or there may be a connection error. Try removing the cartridge and re-inserting or replace with a new cartridge if it appears to be empty.

For further information about using the Nicovape Q device, please consult the User Guide provided with the device.

#### If you forget to use Nicovape Q | Q SD

Nicovape Q | Q SD is intended for use as a replacement for cigarette smoking and for the purposes of smoking cessation. Always use Nicovape Q | Q SD in line with the directions of your doctor or pharmacist.

If you stop using Nicovape Q | Q SD suddenly, you may experience symptoms of nicotine withdrawal. Common symptoms of nicotine withdrawal include:

- Feeling tense and irritable
- Depression
- Appetite changes
- Constipation and gas
- Insomnia
- Difficulty concentrating
- Cough and cold-like symptoms

#### If you use too much Nicovape Q | Q SD

If you think that you have used too much Nicovape Q | Q SD, you may need urgent medical attention.

If you smoke or use any other nicotine containing product while you are using the Nicovape Q System, you may suffer an overdose of nicotine. However, if used correctly, nicotine overdose is unlikely.

Symptoms of nicotine overdose include:

- Headache
- Dizziness
- Stomach upset
- Drooling
- Vomiting
- Diarrhoea
- Cold sweat
- Blurred vision
- Hearing distortion

- Confusion
- Weakness
- Fainting
- Pale skin
- Tremor

If it is a large overdose, there may be exhaustion, convulsions, low blood pressure, circulatory collapse and breathing difficulty.

#### You should immediately:

- phone the Poisons Information Centre (by calling **13 11 26**), or
- go to the Emergency Department at your nearest hospital.

#### You should do this even if there are no signs of discomfort or poisoning.

**WARNING** – children are more likely to be affected by nicotine and it could cause severe toxicity which may be fatal.

**In the event of a child playing with a new or used cartridge contact a doctor or the Poisons Information Centre (telephone 13 11 26) immediately.**

### 5. What should I know while using Nicovape Q | Q SD?

#### Things you should not do

- Do not use Nicovape Q | Q SD if you are allergic to nicotine or any of the ingredients listed at the end of this leaflet.
- Do not use Nicovape Q | Q SD if you do not have an existing nicotine dependence.
- Do not use Nicovape Q | Q SD to treat any other complaint unless your doctor or pharmacist says it is safe. This medicine is for the named patient for whom it is prescribed only.
- Do not give this medicine to anyone else even if they have the same symptoms as you.

#### It is discouraged to use Nicovape Q | Q SD in conjunction with combustible cigarette smoking.

Nicovape Q | Q SD is intended to support smoking cessation by replacing cigarettes. Dual-use is discouraged.

#### Driving or using machines

#### Be careful before you drive or use any machines or tools until you know how Nicovape Q | Q SD affects you.

Nicovape Q | Q SD may cause dizziness in some people. See: [if you use too much Nicovape Q | Q SD](#).

#### Looking after your medicine

Keep the Nicovape Q | Q SD cartridges sealed in the blister pack until needed and store in a cool dry place where the temperature stays below 24°C.

Store away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

**Keep it where young children and pets cannot reach it.** (new and used Nicovape Q | Q SD cartridges contain nicotine, which can be harmful).

#### When to discard your medicine

Do not use this medicine after the expiry date (EXP.) printed on the pack. If you use it after the expiry date has passed, it may not work as well.

Do not use if the packaging is torn, shows signs of tampering or if the blister pack is damaged.

#### Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for disposal.

Do not use this medicine after the expiry date.

### 6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

NVPs have the potential to aid with smoking cessation efforts but they may have unwanted side effects in a few people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Stopping smoking itself can cause some symptoms such as dizziness, headache, sleep disturbance, cough and cold-like symptoms. Symptoms such as depression, irritability, anxiety and insomnia may also be related to withdrawal symptoms associated with giving up smoking. You may also get more mouth ulcers than usual.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

**Do not be alarmed by the following list of side effects. You may not experience any of them.**

#### Less serious side effects

- Nausea
- Stomach upsets
- Vomiting
- Diarrhoea
- Dizziness
- Headache
- Dry mouth
- Indigestion
- Constipation
- Sleep disturbances
- Tremors
- Nervousness
- Tiredness or weakness
- Increased sweating
- Joint and muscle pain
- Shortness of breath or difficulty breathing
- Sore throat
- Initiation cough – *Short duration coughing after initial usage of Nicovape Q | Q SD. Usually resolves with continued use.*

#### What to do

Speak to your doctor or pharmacist if you have any of these less serious side effects and they worry you.

#### Serious side effects

- Fast or very irregular heartbeat
- Swelling of the face, lips, mouth or throat which may cause difficulty in swallowing or breathing. You may have a serious allergic reaction to the medicine

#### What to do

Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.

**Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.**

Other side effects not listed here may occur in some people.

#### Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems). By reporting side effects, you can help provide more information on the safety of this medicine.

**Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.**

### 7. Product details

This medicine is only available with a doctor's prescription.

#### What Nicovape Q | Q SD contains

<b>Active ingredient</b>	Nicotine lactate
<b>Other ingredients</b>	Propylene glycol Vegetable glycerin
<b>(Inactive ingredients)</b>	Flavours

Nicovape Q cartridges are available in:

- 59 mg/mL (88.5 mg total nicotine per cartridge)

Nicovape Q SD cartridges are available in:

- 35 mg/mL (52.5 mg total nicotine per cartridge)
- 20 mg/mL (30 mg total nicotine per cartridge)

**Do not take this medicine if you are allergic to any of these ingredients.**

Note – All Nicovape Q | Q SD liquids are derived from highest quality raw materials and are subjected to a rigid quality verification process prior to formulation. All of our flavours have undergone an Inhalation Toxicological Risk Assessment.

#### What Nicovape Q | Q SD looks like

Nicovape Q | Q SD cartridges are available in three (3) flavours:

- Cherry (red cap)
- Classic (gold cap)
- Coolmint (green cap)

Nicovape Q | Q SD cartridges are available in packs containing two (2) cartridges.

Nicovape Q | Q SD is not a registered medicine on the Australian Register of Therapeutic Goods (ARTG). NVPs have not been approved as smoking cessation aids in Australia. These products are considered to be "unapproved" therapeutic goods and the Therapeutic Goods Administration (TGA) has not evaluated them for quality, safety and effectiveness.

NVPs are not first-line treatments for smoking cessation. However, for people who have tried to achieve smoking cessation with approved pharmacotherapies but failed, and who are still motivated to quit smoking and have discussed NVP usage with their healthcare practitioner, NVPs may be a reasonable intervention to recommend. This needs to be preceded by an evidence-informed shared decision-making process, whereby the patient is aware of the following:

- there are no NVPs approved for the ARTG
- the long-term health effects of vaping are unknown
- possession of nicotine-containing e-liquid without a prescription is illegal
- in order to maximise possible benefit and minimise risk of harms, only short-term use is recommended
- dual use (i.e., with continued tobacco smoking) should be avoided.

#### Mandatory product warnings

- KEEP OUT OF REACH OF CHILDREN
- Avoid contact with eyes
- Avoid contact with skin

#### Who distributes Nicovape Q | Q SD

Liber Pharmaceuticals Pty Ltd  
ACN 646 586 334

Suite 8, 35 Old Northern Rd  
Baulkham Hills  
2153 NSW  
Australia

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This leaflet was prepared in October 2021.

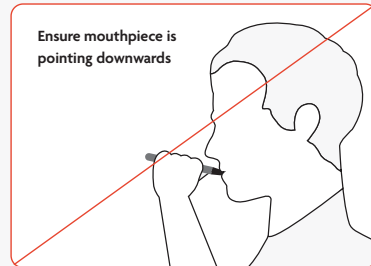
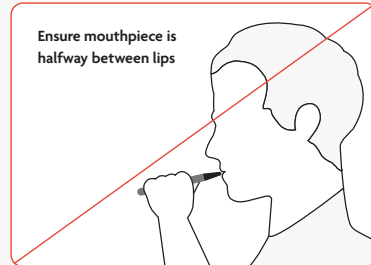
## Correct usage guidance

For each puff, draw into your mouth (up to 3 seconds) and then inhale deeply.

**Wait 20 seconds between each usage.**

If you find you are still craving after two puffs, on a third puff, try holding your breath for 4 or 5 seconds before exhaling.

**Try to take no more than ten puffs per hour for craving relief.**

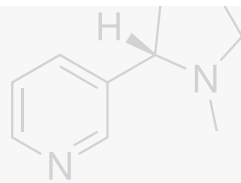


## What you need to know about consuming nicotine

Once a cigarette is lit you are forced to take 10-12 puffs until it is finished.

The Nicovape® Q system delivers nicotine quickly and consistently, just like a cigarette, but without 'forcing' you to take all your puffs in one go.

It can be used only when you feel the urge to smoke, two or three puffs at a time, and after a short period you will be able to get the same amount of nicotine as before.



Importantly, 250 of the 7,000 chemicals in tobacco smoke are known to cause serious harm.

Most of these are not found at all in the Nicovape® Q system. Where they are found, they are in minimal amounts incapable of producing a toxic effect.

**And while nicotine is addictive, it is not the cause of smoking-related diseases.**

nicovape® Q

## New patient guide

Getting started with your Nicovape® Q system

For further guidance on the Nicovape® Q system, visit

[nicovapeq.com/help](https://nicovapeq.com/help)



# Congratulations

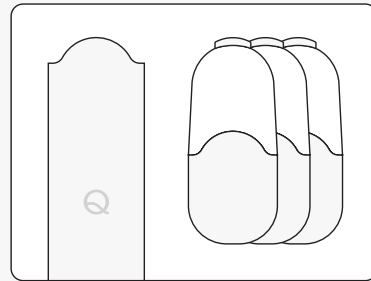
You have taken a big step towards permanently breaking your smoking habit.

Now that you're going to give it a go, follow this guide to ensure that you get the best from your Nicovape® Q system for your quitting journey.

## The Nicovape® Q system

Your Nicovape® Q system consists of a **device** and **nicotine cartridges**.

**With no buttons or settings**, it will activate automatically with each puff, and enter standby mode when not in use.

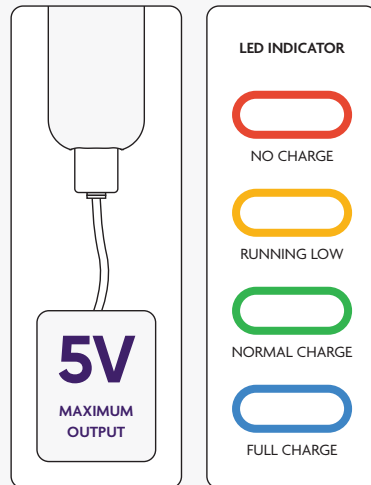


## Charging your device

Ensure you charge your Nicovape® Q device fully before use. When fully charged, it should last a full day of use.

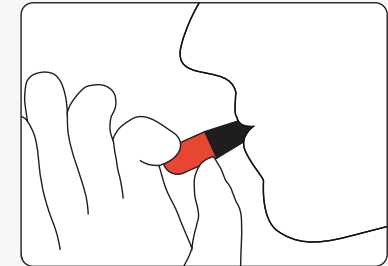
To charge the Nicovape® Q device, **only use the charging cable provided**, and check the power output of the adaptor to ensure **5v or less**.

**Please note:** Power adaptors can supply up to 20v and are **not suitable for use**.



## Priming new cartridges

1. Remove the silicone plug from the top of your cartridge and discard. **Do not remove the coloured plastic cap.**
2. **Blow gently through the cartridge into the plastic cap.** You may hear a small amount of condensation/liquid clearing from the cartridge if this is present.
3. After the cartridge has been cleared, **remove the plastic cap and discard.** You may then insert the cartridge into your device.

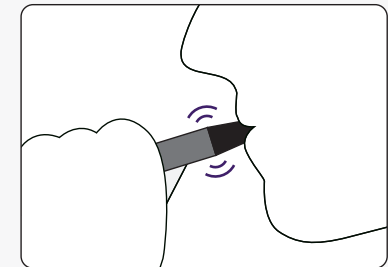


- The first puff of any NEW Nicovape® Q or Q SD cartridge **must be a firm and continuous inhalation for three (3) seconds.**

*This will eliminate any additional oversaturation of the internal wicking component and allow your Nicovape® Q or Q SD cartridge to function normally.*

- You may hear an **audible singular click/pop sound from within the cartridge** during this initial puff, which indicates your cartridge is correctly primed.

**If you do not hear a click/pop**, check to see whether the LED light on your device glows **blue** upon inhalation. If it does, your cartridge is correctly primed.



### Please note:

If you experience a lack of aerosol/vapour being drawn from the Nicovape® Q or Q SD cartridge, and/or the light around your device's charge port is flashing white after following the instructions above, the cartridge may not be correctly primed or may be subject to a connectivity issue.