

## **Re: Public consultation by the Therapeutic Goods Administration on access to nicotine vaping products in Australia**

My name is Jack Gance, and I write on behalf of the Chemist Warehouse group of pharmacies, for which I am the Chairman and Co-Founder.

### **About Chemist Warehouse**

Chemist Warehouse is the largest pharmacy banner group in Australia. We sell approximately 70% of NRT sold in Pharmacy in Australia and dispense approximately 25% of all prescriptions dispensed. We have over 550 Pharmacies in our group, employ over 23,000 staff including over 2,500 pharmacists and operate in Australia, New Zealand, China, and Ireland.

Chemist Warehouse is the established market leader in terms of dispensing all forms of smoking cessation tools, including:

- Traditional forms of NRT (gums, patches, sprays and lozenges);
- Prescribed pharmacotherapies including varenicline and bupropion; and
- Nicotine vaping products, or NVPs.

I attach some data that I would like held confidential.

I write this submission with a deep knowledge of the retail Pharmacy scene in Australia and other parts of the world.

As with other medicines, Chemist Warehouse only works with manufacturers that are responsible providers of medicines and medical devices.

In relation to NVPs, Chemist Warehouse has worked closely with one NVP manufacturer, Liber Pharmaceuticals, which manufactures Nicovape Q NVPs. Liber has no tobacco affiliations and does not sell its NVPs as recreational products. Nicovape Q is a product that was designed for doctors to prescribe and dispense, and we believe the Company and the product has been developed in the manner that we expect of medicines and medical devices, including appropriate product liability insurance, education for our pharmacists, and adverse event reporting mechanisms.

Chemist Warehouse has been approached by a number of other manufacturers of NVPs, but to date, has not found other NVPs that meet our threshold for medicines. In particular, Chemist Warehouse is passionate about helping Australians work to overcome their nicotine addictions and believes that there is no place for tobacco companies in Australia's pharmacy channel. In this regard, Chemist Warehouse does not dispense any NVPs that are affiliated to tobacco companies.

### **About the consultation paper**

Chemist Warehouse was invited to participate in a public consultation on proposed amendments to the existing regulatory framework governing access to NVPs.

Chemist Warehouse supports any regulations that assist the Australian Border Force, and public health bodies from preventing the import and distribution of illicit NVPs. I believe that this market is out of control and is resulting in a new generation of users becoming addicted to nicotine without ever having smoked.

Chemist Warehouse also supports, and will continue to do so, the prescribing and dispensing of NVPs for smoking cessation and believe that when used effectively under appropriate medical supervision, we are seeing patients

successfully achieve nicotine abstinence, who have previously failed to do so with many unsuccessful quit attempts.

On a personal basis, I have experienced professionals within the Chemist Warehouse groups who have managed to stop smoking using an NVP which we dispense, Nicovape, when they were previously unable to do so.

I am however concerned that certain proposed measures, particularly around the introduction of restrictions on flavours and nicotine concentration threaten to undermine the successful implementation of the Government's framework and intention to stop both illicit vaping and ultimately smoking.

In this regard, I note the following in no particular order:

- **Adoption of prescribed NVPs to date:** While Chemist Warehouse has more than 65% market share in the prescribed market of NVPs, the numbers of patients that have sought prescriptions to be dispensed suggests that the framework to date has been an abject failure.

[REDACTED]

Until the Government brings illicit use under control and educates Australians of the role of NVPs in the smoking cessation toolkit, adoption will continue to be poor and the black market will continue to thrive.

Where Chemist Warehouse has dispensed NVPs to patients over the last two years, our pharmacists have seen positive results in patients and we continue to support its use to help people stop smoking, either by itself or in conjunction with gums, patches, sprays and lozenges.

- **Nicotine concentration:** [REDACTED]

The role of dispensing pharmacists and Schedule 4 medicines is to ensure that where doctors wish to dispense medicines that have a higher risk profile, they are able to do so in a manner that prevents the wrong sort of people accessing the product.

By way of example, panadol is available over the counter, but higher strengths are only available on prescription when dispensed by the pharmacist. This is the fundamental principle governing medical scheduling and pharmacy access. Restricting nicotine concentrations to match OTC thresholds from other countries and prohibiting doctors from prescribing the medicines in the manner that they consider, in their clinical judgement to be the most effective for their patients, seems nonsensical and fails to understand the role of the pharmacist.

Accordingly, Chemist Warehouse strongly resists imposing nicotine concentration limits that preclude the dispensing of NVPs in concentrations that doctors are choosing to prescribe, and achieving success

with their patients, **UNLESS** the TGA has established a strong scientific basis around risks of using 59mg/mL concentration e-liquids for smoking cessation.

I would note that imposing such a restriction without a scientific basis will put an unfair burden on pharmacists who will need to explain to the thousands of existing patients why they are unable to continue to dispense their prescribed medicine to them.

In my 55 years of experience, I would suggest that this is a surefire way to get pharmacists who previously supported the framework to stop doing so.

The premise that 20 mg/mL is the right dose, based on the fact that 20mg/mL is the maximum permitted dose in Europe, New Zealand etc is flawed because THOSE PRODUCTS are available over the counter and in any kind of store. To set the dose of a prescription-only product based on a consumer access framework is a totally flawed concept.

Importantly, for most patients, the low dose of 20mg/mL does not satisfy their nicotine craving in the manner that a cigarette does, without constantly having to puff to try and get enough nicotine out of the NVP. Doing so is both expensive for the patient and means that they are inhaling more often than they need to, which may have long term implications. I believe that this lack of satisfaction is one of the main reasons that NRT is so unsuccessful and why so many patients relapse back to the experience of nicotine from a cigarette.

While patients may work to a 20mg/mL concentration over time under the guidance of their doctor, on their way to abstinence, removing higher concentrations is likely to result in relapse before doctors are able to stabilize their patients away from cigarettes, and unnecessarily removes tools that the doctor may otherwise effectively use with appropriate patients.

- **Flavourings:** As the starting point, Chemist Warehouse has no interest in becoming a candy store and will not carry a wide range of flavours, particularly with fancy name descriptors, like unicorn or bubblegum - these have no place in the pharmacy.

However, I believe that patients need palatable flavours to allow them to continue to adhere to remaining cigarette abstinent. Chemist Warehouse currently stocks Nicovape Q in three flavours. These flavours are consistent with other forms of NRT gums and sprays, which are also flavoured to be palatable.

While I am no scientist, I do not believe that tobacco flavour makes sense in the smoking cessation context and note that none of the other smoking cessation products that Chemist Warehouse dispenses are available in a tobacco flavour.

I am supportive of mint variant flavours and note that the Coolmint variant of NVPs that we dispense is the most popular, although all three variants are relatively close. I note that this product contains menthol, and that this is a key part of ensuring a palatable experience. I understand that the limits placed on menthol by the TGA are below the level required to provide effective flavour. I would not support these restrictions on menthol without a solid scientific basis in terms of the particular risks to prescribed patients.

If the intention is to ensure that patients continue to use NVPs in the manner in which they are prescribed, then I support a small range of flavours, comparable with that used in other forms of NRT, provided that the NVP manufacturer has done sufficient work to ensure that the flavourings do not contain ingredients that create a toxicological risk to patients.

- **The role of pharmacies in educating about NVPs:** A large part of low dispensing rates of NVPs is simply because patients do not know about the use of NVPs as a therapeutic intervention for smoking cessation, and under the existing framework, Chemist Warehouse and the other Australian pharmacies are unable to explain to them how it may help them, or where they can go to be assessed and where appropriate, prescribed NVPs.

You will be acutely aware of the key role that pharmacies increasingly play in terms of educating patients and facilitating their access to medicines and specialist clinic type treatments, working to increase awareness and access to flu-jabs, covid vaccines and a full range of other clinic type services.

The pharmacies take these roles seriously and provide a trusted source of information to patients, who visit their pharmacies far more regularly than their doctors. Chemist Warehouse is experienced in restrictions about advertising particular licensed medicines, and does not propose to promote or market individual brands, but believes that pharmacies will play a critical role in raising awareness of the therapeutic use of NVPs and when it may be appropriate for smokers and illicit vapers.

Allowing pharmacists to explain how NVPs may benefit patients in their smoking cessation goals, and assisting them in accessing trained GPs capable of assessing and prescribing NVPs will be critical in ensuring that smokers and illicit vapers can start the journey from addiction to fresh air.

- **Open system NVPs:** Chemist Warehouse has not to date stocked any open system e-liquids for dispensing into vapes for patients to mix themselves.

As a pharmacist, this approach seems nonsensical and I struggle to think of any medicine where we would provide the patient with an active ingredient and tell them to go and mix it with anything they want.

I am concerned about the unknown long term implications of inhaling nicotine, and note that since NVPs are not licensed, they have not been assessed by the TGA for safety. In this regard, Chemist Warehouse believes that it is an unreasonable risk for patients, many of whom do not understand inhalation or nicotine, to be able to mix their own liquids with whatever other ingredients they wish, and use them in whatever powered device they wish.

To the extent that the TGA is concerned about flavouring, I fail to understand how open system NVPs can operate within a framework in which the TGA expects to meaningfully restrict flavours. I also note that the flavourings themselves are also unregulated, so won't this result in the continued presence of bright and candy coloured flavour bottles, marketed to children?

We also believe that providing people with large bottles of liquid nicotine is likely to increase risks of poison through ingestion, as well as liquids being used by persons other than the prescribed patient.

I understand that the TGA proposes to ban single use disposable vapes. We support that, however if that extends to a closed pod, like the Nicovape system we strongly oppose such a restriction because ONLY by having a pod, that is sealed and has ingredients that are tested and designed for safe vaping in a measured form can you ensure that the patient is getting exactly what the Doctor prescribed.

In terms of the cost savings associated with open systems, I leave that with the TGA, but note that if a pack-a-day smoking patient is using an NVP cartridge every two or three days, the cost to them each day has fallen from more than \$50 to about \$5. This is an acceptable compromise in my mind for ensuring that patients are not exposed to the additional risks of open systems.

- **Diversion risks:** The TGA has made reference to the risk of diversion of prescribed NVPs to others, particularly the young. I would humbly submit that seeking to avoid this is the very reason that higher scheduled medicines are dispensed by pharmacists, when they have been prescribed by doctors as necessary for their patient's treatment. We regularly dispense other medicines with high risk of diversion including medicinal cannabis and opiates, and our pharmacists play an important role in ensuring that patients are clear about the use and consequences of diverting their prescriptions.

Chemist Warehouse is not aware of any diversion of NVPs that we have dispensed over the last two years.

Patients have no need to divert nicotine vapes because any person who needs a nicotine vape to replace cigarettes can arrange a bulk billed telehealth consultation to access it themselves at no cost to them.

In my opinion, diversion is not an issue while people who want to recreationally vape have much simpler access to much more attractive products through the illicit market. Further, if diversion were to prove to be an issue at some point in the future, the solution will not be to prohibit the medicine from being prescribed in the manner that the doctor feels most appropriate. I am not aware of any other medical intervention that has been treated as such.

I am available at any time to discuss any of the points above. I am also available to give an industry perspective on any issues that the TGA is considering. I am a strong advocate of people stopping smoking and can assure the TGA that this is the reason that I am so passionate about this matter.

Attached is actual sales data for sales or dispensing

over the last 12 months from Chemist warehouse and My Chemist stores in Australia. The data is sensitive and confidential and as discussed I and is not to be published or disclosed outside of the TGA.

I would appreciate any feedback.

Regards



Jack Gance MBA PhC MPS GAICD

Chairman and Co Founder

Chemist Warehouse Group