eCigarette Compliance Program



Pharmacy inspection factsheet and self-assessment

Introduction to the eCigarette Compliance Program

The national vaping reforms aim to protect the public, particularly young people, from vapingrelated harms while ensuring regulated vaping goods are accessible as a tool for smoking cessation and the management of nicotine dependence.

NSW Health is committed to supporting the reforms and has implemented several strategies to achieve this. A key strategy is the implementation of an eCigarette Compliance Program, which aims to monitor and support the regulatory compliance of wholesalers, pharmacists and prescribers involved in the lawful supply of vaping goods in NSW.

How will the program support pharmacies?

To support pharmacies in maintaining legal and responsible practices regarding the supply of vaping goods, a specialised compliance team will perform regular inspections of pharmacies across NSW.

These inspections will assess compliance, storage, sale and supply practices of vaping goods to ensure Schedule 3 (S3) and Schedule 4 (S4) regulatory requirements are being met.

What to expect during the inspection

The inspection process will include:

- a visual inspection of the pharmacy and vaping goods currently in stock
- an interview with a pharmacist to understand practices related to the procurement, dispensing, and supply of vaping goods
- a review of relevant documents, including dispensing reports, and purchasing records
- verbal guidance on corrective actions to address minor breaches that can be quickly resolved, or for more serious issues that require immediate action.

What to expect after the inspection

The compliance team will review the information collected during the inspection and compile a report of:

- key findings of the inspection, including areas of non-compliance
- corrective actions to address non-compliance
- recommendations for the pharmacy to consider that support best practice.

Pharmacy self-assessment

This self-assessment tool can be used to review how well your pharmacy complies with regulations related to the storage and supply of vapes:

Are all vaping goods sold listed on the TGA's list of notified vapes?

Are all vaping goods stored behind the counter and not available for self-selection by consumers?

Are all vaping goods stored out of sight and not visible to the public from inside or outside the pharmacy?

Are there any advertisements for vaping goods displayed inside or outside the pharmacy?

Are vaping goods with a nicotine concentration greater than 20mg/mL only supplied on prescription?

Are all vaping goods supplied via an established pathway i.e. Authorised Prescriber (AP) scheme or Special Access Scheme (SAS)?

Are there processes in place to ensure that requirements for S3 supply of vaping goods are met, including:

- confirmation that the vaping goods are used for the management of nicotine dependence or smoking cessation
- confirmation that the patient is over 18 years of age
- sighting evidence of age and ID from the patient
- obtaining informed consent from the patient
- submission of an SAS Category C notification within 28 days of supply

Are there processes in place to ensure that S3 supply is restricted to:

- a quantity that does not exceed one month supply
- one supply per month, per patient

Are there processes in place to ensure that patients are informed of the following:

- the availability of alternative smoking cessation supports and therapy
- appropriate dose and frequency instructions depending on the patient's age, weight and severity of condition
- a suitable titration plan and advice on the duration of therapy
- possible drug interactions with the patient's current medications
- the contact details of smoking cessation support services
- that vaping goods available in Australia are unregistered and have not been tested by the TGA for safety, quality or efficacy.

Are there processes in place to ensure adverse effects and faulty vaping goods are reported to the TGA and sponsor of the vaping good?

More information

Please visit the Pharmaceutical Services Unit <u>Nicotine vaping goods</u> webpage or contact the eCigarette Compliance Team via email at: <u>MOH-PharmaceuticalServices@health.nsw.gov.au</u>