NSW Health

Pharmacy Inspection Audit Tool

eCigarette Compliance Program

Version 2.0 - Updated September 2024

NSW GOVERNMENT

Overview

The Pharmaceutical Services Unit has developed an eCigarette Compliance Program to monitor and support the regulatory compliance of key stakeholders, such as pharmacies, involved in the lawful supply of vaping products.

The objectives of the program are to:

1. Foster a culture of compliance through ongoing support to prevent unintentional beaches and encourage adherence to best practice standards.
2. Ensure vaping products supplied by pharmacies comply with legislation and are used as intended.
3. Identify, address and mitigate risks in the lawful supply of vaping products.
4. Oversee the supply chain to identify trends to prevent non-compliant stock being supplied to the public or legitimate products entering the illicit market.

A key strategy to support the program's objectives is the pharmacy inspection program. This program involves specialised compliance officers conducting routine inspections of pharmacies across NSW. The inspections will focus on assessing product compliance, storage, and sale practices, while ensuring adherence to the regulatory requirements for Schedule 3 and Schedule 4 vaping products.

To facilitate a thorough and consistent review of pharmacies an audit tool has been developed. The audit tool is divided into 4 sections:

1. **General information** – records information collected by the inspectors prior to the inspection.
2. **Observational audit** – records information collected by the inspectors during the visual inspection of the pharmacy and the vaping products on-hand.
3. **Interview questionnaire** – records the information collected during the on-site interview with the pharmacist.
4. **Post-inspection review** – records the information collected from dispensing reports, and other records collected during the inspection process.

The data collected will be used to evaluate compliance with regulations and adherence to best practice standards. The collection, use and disclosure of the information will be in accordance with privacy laws.

A summary of the inspection, including key findings, corrective actions to address non-compliance, and recommendations to support best practice, will be provided in a report to the pharmacy.

Audit Questions

1. General Information

1. Date of Inspection

2. Name of inspector/s conducting the inspection
   List the lead inspector's name first.

3. Pharmacy Name

4. Name of pharmacy proprietor/s

5. Pharmacy address

6. Pharmacy phone number

7. Pharmacy email address
   Confirm preferred email address with pharmacist to receive correspondence relating to the inspection.

8. Pharmacy licence number

9. Pharmacy Retailer Identification Number (RIN)

10. Time of entry

11. Time of exit

12. Document any other relevant general information.

2. Observational Audit

13. List the vaping products currently stocked by the pharmacy and the current stock on hand.

    A current inventory report can be used if available, and the SOH recorded on the inventory report. Include brand name, concentration, vaping good type (i.e. substance/device), pack size and number of units on hand of any product that does not appear on the inventory report.
    Records as: <BRAND><FORM><NICOTINE BASE CONCENTRATION><FLAVOUR><NUMBER OF PACKS><PACK SIZE>

14. Are all vaping products sold from the pharmacy listed on the TGA list of notified vapes?
    - Yes
    - No

15. Enter the details of non-compliant stock.

    Include product name, strength, flavour, quantity and reason for non-compliance.

16. Does the packaging include information in English?
    - Yes
    - No

17. Are all the vaping products packaged in plain pharmaceutical packaging?
    - Yes
    - No

18. Are the vaping products packaged in child-resistant packaging?
    - Yes
    - No
    - Unsure

19. Does the label/information sheet include an ingredient list?
    - Yes
    - No

20. Does the label/information sheet include the nicotine base concentration (mg/mL)?
    - Yes
    - No

21. Does the concentration of nicotine base exceed 100mg/mL?
    - Yes
    - No

22. Do the vaping products supplied as S3 medicines contain a nicotine concentration greater than 20mg/mL?
    - Yes
    - No
    - N/A – pharmacy does not supply S3 vaping products.
23. Do the vaping products include any prohibited ingredients?
    Prohibited ingredients include: acetoin, benzaldehyde, cinnamaldehyde, diacetyl, diethylene glycol, ethylene glycol, pentane-2,3-dione (2,3-pentanedione or acetylpropionyl), vitamin E acetate (dl-alphatocopheryl acetate)
    - Yes
    - No
24. Are the warning statements included on the label/information sheet?

    KEEP OUT OF REACH OF CHILDREN

    Prescription only medication (for all nicotine containing vapes that contain >20mg/mL of nicotine)
    Pharmacist only medication (for all nicotine containing vapes that include ≤20mg/mL of nicotine)
    Avoid contact with eyes (not required for zero-nicotine containing vapes)
    Avoid contact with skin (not required for zero-nicotine containing vapes)
    - Yes
    - No
25. Are flavours other than mint, menthol and tobacco available for supply?
    - Yes
    - No
26. Are all vaping products stored behind the counter?
    - Yes
    - No
27. Are there any vaping products available for self-selection?
    - Yes
    - No
28. Are vaping products visible to the public from inside or outside the premises?
    - Yes
    - No
29. Are vaping products only sold from one point of sale?
    - Yes
    - No
30. Are vaping products included in pharmacy's shopper loyalty program?
    - Yes
    - No

31. Is there any evidence of advertising of vaping products?
    - Yes
    - No

32. Is there any evidence of compounding of vaping products?
    .
    - Yes
    - No

33. Document any other relevant observations below.
    e.g. excessive stock of vaping products, storage location of vaping goods

3. Interview Questionnaire

34. Name of the pharmacist being interviewed.

35. Designation of the pharmacist being interviewed.
    - Proprietor
    - Pharmacist in charge
    - Duty pharmacist

36. How does the pharmacy source vaping products?
    - Wholesaler
    - Australian sponsor
    - Pharmacy buying group
    - Import directly from overseas
    - Other _____

37. Enter the pharmacy supplier details below.

38. For pharmacies that import vaping products - Does the pharmacy hold the relevant permit and licence from ODC?
    - Yes
    - No
    - N/A – pharmacy does not import vaping products

39. How are vaping products supplied by the pharmacy?
    - S4 – prescription only
    - S3 – pharmacist only
    - Both S3 and S4 supply

40. Does the pharmacy have any arrangements with online vape providers to supply vaping products?
    - Yes
    - No

41. Enter the details of affiliated online vaping businesses.

42. Is the pharmacy involved in the compounding of vaping products?
    - Yes
    - No

43. Does the pharmacy have approval to compound vaping products?

    Pharmacies must obtain 41RC consent from the TGA to compound vaping goods.
    - Yes
    - No

44. Does the compounded product comply to TGO110?
    - Yes
    - No

45. What staff are involved in the supply of S3 vaping products?
    - Pharmacists only
    - Intern pharmacists
    - Pharmacy assistant/technician
    - N/A – pharmacy does not supply S3 vaping products

46. Are intern pharmacists supervised by a pharmacist when supplying S3 vaping products?
    - Yes
    - No
    - Sometimes

47. How do you label S3 vaping products?
    - Label includes pharmacy name
    - Label includes pharmacy address
    - Other _____

48. Describe the process you follow when supplying S3 vaping products?

If available, request a copy of the pharmacy's documented procedure.

- Indication confirmed with patient (i.e. smoking cessation or nicotine dependence)
- Age confirmed with patient
- ID checked for identity/age
- Informed consent obtained – including from carers
- Inform patient that the vaping good is an unapproved therapeutic good
- Other _____

49. What advice do you provide to the patient about the safe use of vaping products?

If available, request of any written information provided to the patient and/or any clinical guidelines pharmacists use to guide their practice.

- Dose and frequency
- Duration of therapy
- Titration plan
- Alternative cessation supports or therapies
- Interaction with other medications
- Other _____

50. Do you provide the patient with contact details about smoking cessation support services?

If available, request a copy of any related written information sources provided to patients.

- Yes
- No
- Sometimes

51. How do you calculate appropriate supply quantities?

52. What process does the pharmacy have in place to ensure that vaping products are only supplied once a month to each patient?

53. What process do you follow if a patient reports an adverse event in relation to a vaping substance?

54. What process do you follow if you identify, or are notified about, a faulty or defective vaping device?

55. Do you validate that unregistered vaping products have been prescribed via an authorised pathway (i.e. AP/SAS)?
    - Yes
    - No
56. Do you submit an SAS Cat C notification when supplying S3 vaping products for each patient?
    - Yes
    - No
57. Does the pharmacy mail any vaping products to patients?
    - Yes
    - No
58. How does the pharmacy verify the identity and age of patients receiving vaping products by mail?

59. Document any other relevant information obtained during the interview.

4. Post Inspection Review

60. Was there evidence of excessive quantities of vaping products in the pharmacy?

    If stock on hand exceeds estimated monthly usage it is considered excessive (Refer to Q13 and dispensing data or sales records)
    - Yes
    - No
61. Is there evidence of over-prescribing of vaping goods

    Prescribing more than one pod or cartridge per day for a patient is considered excessive.
    - Yes
    - No
62. Is there evidence of over-supply of vaping goods?

    Oversupply is defined as dispensing more than a one-month supply at a time or re-supplying at a frequency that results in the patient accumulating more than a two-month supply of vapes at home.
    - Yes
    - No
63. List any unusual prescribing patterns identified in the review.

64. Document any other relevant information identified in the post-inspection review.