Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

A Decision by the Deputy Health and Disability Commissioner

(Case 21HDC00955)

Introduction

1. This report is the opinion of Deborah James, Deputy Health and Disability Commissioner, and is made in accordance with the power delegated to her by the Commissioner.

2. The report discusses the care provided to Ms A by a pharmacy. The following issues were identified for investigation:

- *Whether Mr C provided Ms A with an appropriate standard of care on 7 April 2021.*
- *Whether Mr D provided Ms A with an appropriate standard of care on 7 April 2021.*
- *Whether the pharmacy provided Ms A with an appropriate standard of care on 7 April 2021.*

3. The parties directly involved in the investigation were:

Ms A	Consumer
Ms B	Complainant
Pharmacy	Provider/pharmacy
Mr C	Provider/pharmacist
Mr D	Provider/pharmacist/Pharmacy Manager
Mr E	Pharmacy Manager

Names have been removed to protect privacy. Identifying letters are assigned in alphabetical order and bear no relationship to the person's actual name.

4. Pharmacist Ms F is also mentioned.

Information gathered during investigation

Introduction

5. The complaint concerns a medication dispensing error that occurred on 7 April 2021 when Ms A was dispensed an incorrect strength of medication.

Background

6. Ms A, in her twenties at the time of the events, has a history of mental health difficulties, including self-harm, low mood, and suicidality. On 7 April 2021 Ms A's general practitioner (GP) prescribed her venlafaxine 37.5mg[1] and quetiapine 25mg[2] on advice from her mental health team. The venlafaxine prescription specified one tablet a day for one week, and to increase to two tablets a day if tolerating the medication.

7. Ms A's sister, Ms B, told HDC that due to concerns about Ms A's mental state and safety with medication, she had asked not to be given a large amount of medication. The prescribing doctor specified that only two weeks' supply of venlafaxine (21 tablets) should be dispensed at a time.

8. Later that day Ms A collected her medication from the pharmacy and was dispensed 21 venlafaxine 150mg tablets.

9. When Ms A returned home, she noticed that the dosage of the venlafaxine tablets she had received (150mg) was higher than was prescribed (37.5mg). She contacted Ms B, who advised her to return the medication to the pharmacy.

Pharmacy process

10. Pharmacist Mr C told HDC that the pharmacy's 'standard dispensing procedure is to process and generate labels for a prescription, then another staff member will dispense the prescription, and another pharmacist will carry out the final check to minimise dispensing errors'.

11. The pharmacy's Standard Operating Procedure[3] (SOP) states that all boxes and bottles need to be opened to ensure that they contain the correct medicine, quantity, and strength.

12. Mr C told HDC that according to the prescription audit report, Ms A's prescription was typed using his log-on at 4.26pm and then modified by pharmacist Ms F at 4.28pm. Mr C is unclear whether he or Ms F dispensed the venlafaxine medication, although he notes that his initials are on the prescription and it is his usual process to initial the prescription item when he has

[1] Venlafaxine belongs to a group of medicines known as serotonin-noradrenaline reuptake inhibitors (SNRIs) and is used to treat severe depression, anxiety, and panic disorders.
[2] Quetiapine is an atypical antipsychotic medication used for the treatment of schizophrenia, bipolar disorder, borderline personality disorder, and major depressive disorder.
[3] See relevant paragraphs from the Standard Operating Procedure at Appendix A.

dispensed it. He stated: 'If [Ms F] dispensed the medicine, I should not have initialed the third part label to indicate I had completed this step.'

13. Pharmacy Manager Mr D prepared a letter for Ms A[4] outlining that he performed the final check of the prescription — he checked that it was the correct medicine name, strength and instructions on the label, but he 'did not check the contents of the box to ensure the dispensing pharmacist had selected the correct strength of medicine'.

14. The description of the dispensing error/incident to the Pharmacy Defence Association (PDA) completed by Mr D outlined that '[v]enlafaxine was processed as 37.5mg by [Ms F] but dispensed as venlafaxine 150mg by [Mr C]'.

15. A draft apology letter, written by Mr D to Ms A, noted that their investigations showed that three pharmacists were involved in dispensing her medicine. The letter stated:

> '[The prescription] was processed through the computer by one staff member. The next pharmacist mistakenly selected the incorrect strength of medicine from the shelf, counted it and put it into a box. The final check was then performed by me.'

Contributing factors

16. Ms A's medications were dispensed in the week of the Easter holiday period. Mr C told HDC:

> '[I]t was busy on both Tuesday 6th April 2021 and Wednesday 7th April 2021 (the day that incident happened). On the 6th a total of 439 prescriptions were dispensed and 415 prescriptions on the 7th (attached). I genuinely cannot recall if it was only three of us working in the pharmacy, if this was the case, it would have put the whole team under increased stress.'

17. Mr D stated:

> '[I]it was a very stressful environment as we had two staff members call in sick that day and we had a backlog of prescriptions from the previous day. Due to [Ms A's] medications not being completed on her return I rushed to complete it for her.'

18. Mr E replaced Mr D as Pharmacy Manager in May 2021. Mr E told HDC that at the time of the dispensing error Ms F was a part-time pharmacist who had only recently joined the team, and Mr C usually worked at the pharmacy one day a week. Mr E also noted that when he started as Pharmacy Manager at the pharmacy, staffing levels were inadequate, and the premises were too small for the volume of work. He said that these issues have since been addressed.

Pharmacy follow-up actions

19. The Pharmacy Council guidelines, Competence Standards for the Pharmacy Profession (2015), state that a pharmacist[5] '[a]ccurately records details of medication incidents and actions

[4] An apology letter was written and delivered to Ms A as she declined to have telephone contact with the pharmacy after the error.
[5] Pharmacy Council Competence Standards for the Pharmacy Profession — paragraph 03.2.5.

taken, including clinical and professional interventions, to minimise their impact and prevent recurrence'.

20. After the pharmacy was notified of the error with Ms A's dispensing, the Pharmacy Manager, Mr D, completed a PDA Incident Notification Form for the event on 8 April 2021. The form gave a brief summary of what had occurred.

21. Mr D attempted to call Ms A on her mobile but was unable to establish contact. He also organised the delivery of an apology letter that he had drafted. On 13 April 2021, the pharmacy was informed that Ms A should not be contacted until further notice.

22. After the incident and the investigation, a staff meeting was held, and staff acknowledged that a dispensing error had occurred.

Responses to provisional opinion

23. Ms B, Ms A, Mr C, Mr D and the pharmacy were given the opportunity to respond to relevant sections of the provisional opinion. All parties confirmed that they had no comments to make in response.

Opinion

Introduction

24. I consider this to be a significant incident.

Mr C — breach

25. As a registered pharmacist, Mr C had a duty to provide adequate care and was responsible for ensuring that he provided services of an appropriate standard to Ms A, including complying with the professional standards set by the Pharmacy Council.

26. The Pharmacy Council of New Zealand's Competence Standards for the Pharmacy Profession (2015) provide that a pharmacist 'maintains a logical, safe and disciplined dispensing procedure'.[6]

27. In a similar case that involved a medication dispensing error, this Office stated:[7]

> 'It is a fundamental patient safety and quality assurance step in the dispensing process to adequately check the medication being dispensed against the prescription for accuracy. This involves checking that the correct medicine, dose, form, strength, and quantity is being dispensed, and checking for any interactions.'

28. Mr C told HDC that there is a possibility that Ms F was the one who 'chose the wrong strength of [v]enlafaxine'. He stated: 'However, my initials were marked by each third part label placed

[6] Pharmacy Council Competency Standard — Dispense Medicine — Paragraph 03.2.1.
[7] Case 20HDC00383.

beside each prescription item (which is my usual process when I dispense any prescription item).'

29. Mr C said that on that day he shared tasks with Ms F instead of each one starting and finishing each step of the dispensing process, as they usually do. I am concerned about the process Mr C followed. It is contrary to the pharmacy's SOP for dispensing medications, which states: 'The pharmacist must ensure the entire dispensing process occurs in a logical and orderly manner.'

30. At several stages, the pharmacy's SOP requires a check that the medication matches the prescription. More specifically, in this case, the drug, strength, and quantity of medication must be checked against the prescription when selecting the medicine from the shelf.

31. In my view, as the pharmacist dispensing the medication, it was Mr C's responsibility to perform these checks. Mr C failed to check adequately that he had chosen the right strength, and he placed the incorrect strength medication in its container.

32. Because Mr C's usual process is to initial the prescription when he has dispensed the medication, and because his initials were on the venlafaxine prescription label, I am satisfied that he dispensed the medication.

33. Mr E, the Pharmacy Manager at the time of the complaint, stated that the pharmacy did not have adequate staffing and the premises were too small at the time. I am mindful that the pharmacy was busy with a backlog of prescriptions, and it was understaffed because staff were sick that day. I acknowledge that mistakes are more likely to occur when understaffed. However, Mr C still had a responsibility to take appropriate steps to ensure the provision of safe and accurate services.

34. In selecting the wrong strength medication and not checking against the prescription adequately, and thus preparing an incorrect strength medicine to be dispensed, Mr C failed to adhere to the standards set by the Pharmacy Council of New Zealand. He also failed to adhere to the SOP. Accordingly, I find that Mr C breached Right 4(2)[5] of the Code of Health and Disability Services Consumers' Rights (the Code).

35. Notwithstanding this finding, I acknowledge Mr C for the changes he made after becoming aware of the error. These are set out in paragraphs 54 and 55.

36. Mr C expressed to HDC his sincere apologies from himself and on behalf of the team. He stated that he would have liked to have the opportunity to rectify the error and to extend their apologies to Ms A's family for the distress the error caused.

[5] Right 4(2) states: 'Every consumer has the right to have services provided that comply with legal, professional, ethical, and other relevant standards.'

Mr D — breach

37. Mr D had a duty to provide adequate care and was responsible for ensuring that he provided services of an appropriate standard to Ms A, including complying with the professional standards set by the Pharmacy Council.

38. The Pharmacy Council of New Zealand's Competence Standards for the Pharmacy Profession (2015) provide that a pharmacist[8] 'maintains a logical, safe and disciplined dispensing procedure', and 'follows relevant policies, procedures and documentation requirements for the administration of medicines'.

39. In a similar case that involved a medication dispensing error, this Office stated:[9]

> 'It is a fundamental patient safety and quality assurance step in the dispensing process to adequately check the medication being dispensed against the prescription for accuracy. This involves checking that the correct medicine, dose, form, strength, and quantity is being dispensed, and checking for any interactions.'

40. According to the SOP regarding clinical checks:

> 'Under the Pharmacy Council's Code of Ethics 2018, principles 1F, 1G and 1H, it is the pharmacist responsibility to ensure a full clinical check is done to the prescription before handing it out to the patient. The clinical check includes, but [is] not limited to, checking medication interactions, dose and frequency.'

41. At several stages, the SOP requires a check that the medication matches the prescription. More specifically, in this case, that a final check is done before handing the prescription to the patient.

42. Mr D told HDC that he was rushing to complete Ms A's prescription and did not check the contents of the box as he normally would have. As a result, he did not identify that the venlafaxine capsules were the wrong strength.

43. In his response to this Office, Mr D stated: 'I take full responsibility as the checking pharmacist for this dispensing error.'

44. Mr E, the Pharmacy Manager at the time of the complaint, stated that the pharmacy did not have adequate staffing, and the premises were too small at the time. I am mindful that the pharmacy was busy with a backlog of prescriptions and was understaffed because staff were sick that day. I acknowledge that mistakes are more likely to occur when understaffed. However, Mr D still had a responsibility to take appropriate steps to ensure the provision of safe and accurate services.

45. In not carrying out the final check sufficiently and thus allowing an incorrect strength medicine to be dispensed, Mr D failed to adhere to the standards set by the Pharmacy Council

[8] Pharmacy Council Competence Standards for the Pharmacy Profession — Paragraph 03.2.5.
[9] Case 20HDC00383.

of New Zealand, and he did not adhere to the SOP. Accordingly, I find that Mr D breached Right 4(2) of the Code.

46. Notwithstanding this finding, I acknowledge that Mr D took swift action when he became aware of the error, accepted full responsibility for the mistake, and made changes after becoming aware of the error. These are set out in paragraphs 56 and 57.

Pharmacy—other comment

47. The pharmacy had a duty to ensure that it provided services to Ms A with reasonable care and skill. This included ensuring that its staff provided safe, accurate, and efficient dispensing services.

48. Given that the days of 6 and 7 April 2021 came after the Easter public holidays, the pharmacy could have reasonably expected busy days with an increase in customers and a backlog of scripts. Added to this, two staff members called in sick on these days.

49. The Pharmacy Council has published 'Workplace pressures in Pharmacy: practical advice for pharmacists, pharmacy staff and employers.'[10] This provides guidelines on how to manage workplace stress in cases where the pressure becomes excessive or otherwise unmanageable for employees. The guide suggests solutions that include communication, prioritisation of scripts, and giving realistic waiting times.

50. In April 2021 there were no guidelines in place to assist staff to prioritise work and manage the increased workplace pressure due to script backlog and staff absences. I remind the pharmacy of the importance of having such guidelines that reflect best practice.

51. As detailed above, I have found that Mr C and Mr D breached Right 4(2) of the Code. I consider that the medication dispensing error was the result of individuals' actions and does not indicate organisational issues at the pharmacy. Further, the pharmacy was entitled to rely on Mr C and Mr D, as experienced pharmacists, to dispense accurately and adhere to the standards set by the Pharmacy Council of New Zealand and in accordance with the SOP.

52. Accordingly, I do not find the pharmacy in breach of the Code.

53. I commend the pharmacy for quickly extending the pharmacy premises and for recruiting more staff once it was known that the staffing levels were inadequate and the premises were too small for the volume of work, and the workflow was putting huge stress on the staff.

Changes made since events

Mr C

54. Mr C told HDC:

> 'As a result of this incident occurring, [the pharmacy] added a sundry label to print after each time venlafaxine is processed through the dispensary computer to alert all

[10] https://pharmacycouncil.org.nz/wp-content/uploads/2021/03/Workplacedocwebsite-1.pdf

> dispensers and checkers to ensure the correct strength is dispensed. When new team members join our team, we also alert them to be extra cautious when dispensing venlafaxine (have you picked the right strength sticker).'

55. Mr C stated: '[I have] encouraged and reminded our staff about the importance of completing what we are working on before dealing with other matters, even in situations when the dispensary is increasingly busy.'

Mr D

56. Mr D told HDC:

> '[Following the error with Ms A's prescription,] [t]he different strengths of [v]enlafaxine are now physically separated on the dispensary shelves — we have also implemented a supplementary dispensary label as attached that is produced for every venlafaxine prescription to ensure that the correct strength of [v]enlafaxine is selected.'

57. Mr D said that he has taken the dispensing error very seriously and has reflected on his whole practice. Since the incident, he has been paying extra attention when checking medications and in particular medications similar to that dispensed to Ms A. He has reinforced following each step of the SOP for checking a prescription, to ensure and prioritise patient safety despite the waiting time, as he does not want any incidents like this to occur in the future.

Pharmacy

58. Pharmacy Manager Mr E told HDC: 'Since that time the pharmacy has been extended, we now have a full-complement of staff and the workflow issues have been addressed.'

Recommendations

59. I recommend that Mr C:

a) Provide an individual formal written apology to Ms A for the breach of the Code identified in this report. The apology is to be sent to HDC, for forwarding to Ms A, within three weeks of the date of this report.

b) Complete the Improving Accuracy and Self-Checking Workbook provided by the Pharmaceutical Society of New Zealand. I recommend that he provide evidence of this and outline any further changes or improvements he has made to his practice as a result of this training, within three months of the date of this report.

60. I recommend that Mr D:

a) Provide an individual formal written apology to Ms A for the breach of the Code identified in this report. The apology is to be sent to HDC, for forwarding to Ms A, within three weeks of the date of this report.

b) Complete the Improving Accuracy and Self-Checking Workbook provided by the Pharmaceutical Society of New Zealand. I recommend that he provide evidence of this

and outline any further changes or improvements he has made to his practice as a result of this training, within three months of the date of this report.

61. I recommend that the pharmacy:

a) Undertake a random audit of the medication dispensing and checking of medication for 20 prescriptions within a one-month period to assess staff compliance with the dispensing and checking SOP, and report back to HDC with the outcome of the audit and any action plan to address the findings, within three months of the date of this report.

b) Provide yearly refresher training for its staff in relation to dispensing and checking medications and dispensing errors and provide HDC with evidence of the training plan and any learning, within three months of the date of this report.

c) Review the Pharmacy Council publication 'Workplace pressures in Pharmacy: practical advice for pharmacists, pharmacy staff and employers' and consider developing guidelines for prioritising workloads and managing workplace pressures, for inclusion in its existing SOP, within six months of the date of this report.

d) Review its SOP to incorporate all the steps taken in the Clinical and Final Check, including describing the difference between these checks. Please provide HDC with evidence of an amended SOP within six months of the date of this report.

d) Ensure that there is a process for registering and managing pharmacy complaints and incidents, and that pharmacy managers have a clear process for investigating and responding to complaints (that includes engagement with affected staff). Please provide HDC with evidence of a complaints management process within six months of the date of this report.

Follow-up actions

62. A copy of this decision with details identifying the parties removed will be sent to the Pharmacy Council of New Zealand, and it will be advised of the names of Mr C and Mr D.

63. A copy of this decision with details identifying the parties removed will be sent to Medicines Control at Manatū Hauora|Ministry of Health, and it will be advised of the name of the pharmacy.

64. A copy of this decision with details identifying the parties removed will be sent to the Pharmaceutical Society of New Zealand (College Education and Training Branch), Te Tāhū Hauora|Health Quality & Safety Commission, and the New Zealand Pharmacovigilance Centre, and placed on the Health and Disability Commissioner website, www.hdc.org.nz, for educational purposes.

Appendix A

[The pharmacy's] Standard Operating Procedure (SOP) (last reviewed 2021)

Dispensing and labelling the prescribed medicine

Overview of the dispensing process

Responsibility of: All Pharmacists

The Pharmacist must ensure the entire dispensing process occurs in a logical and orderly manner and has been undertaken in accordance with all legal and ethical requirements including NZS 8134.7:2010 Health and Disability Services Standard and according to best pharmacy practice.

…

Clinical checks

Responsibility of: All dispensing staff

Under the Pharmacy Council's Code of Ethics 2018, principles 1F, 1G and 1H, it is the pharmacist[']s responsibility to ensure a full clinical check is done to the prescription before handing it out to the patient.

The clinical check includes, but [is] not limited to, checking medication interactions, dose and frequency appropriateness, patient medication history, dispensing frequency, medication contraindications (for example allergies, pregnancy or breastfeeding).

…

Dispensing the correct medicine

Procedure to follow to ensure each medication is correctly selected and counted for dispensing

Responsibility of: All dispensing staff

SELECTING CORRECT MEDICINE

- Check you are using the right medicine and subsidised brand …
- Check that the medicine is the right strength
- Check that the medicine is in the right form
- Check the expiry date
- Leave the stock container next to the prescription for the final check.

Appendix B

Pharmacy Council of New Zealand: Competence Standards for the Pharmacy Profession (2015)

COMPETENCY O3.2 DISPENSE MEDICINES

Behaviours O3.2.1 Maintains a logical, safe and disciplined dispensing procedure

O3.2.2 Monitors the dispensing process for potential errors and acts promptly to mitigate them

O3.2.3 Identifies the interchangeability and bioequivalence of different proprietary products where applicable

O3.2.4 Adapts labelling instructions to address patient needs

O3.2.5 Accurately records details of medication incidents and actions taken, including clinical and professional interventions, to minimise their impact and prevent recurrence

O3.2.6 Maintains the medicine supply chain to ensure the quality of medicines supplied and their safe disposal

Pharmacy Council of New Zealand: Code of Ethics (2018)

Principle 1: A pharmacist makes the health and wellbeing of the patient their first priority.

Principle 1 places the health and wellbeing of patients at the centre of all pharmacy practice.

A pharmacist:

A. Fulfils their duty of care to the patient first and foremost.
B. Ensures that their duty of care is not compromised by other interests and manages potential conflicts in the interests of the patient.
C. Exercises compassion and care towards patients and the public in a culturally safe and responsive manner.
D. Supports people who are vulnerable and tailors provision of care accordingly.
E. Promotes patient health, well-being, and whānau ora.
F. Acts to prevent harm to the patient and the public.
G. Promotes the safe, judicious and efficacious use of medicines, and prevents the supply of unnecessary and/or excessive quantities of medicines, or any product which may cause harm.
H. Before recommending, supplying or promoting a medicine, complementary and/or alternative medicine or other healthcare product or service, considers available evidence,

and only supplies a product when satisfied that it is appropriate, and the person understands how to use it correctly and safely.

I. Promotes continuity of care for patients across health sectors and providers, through appropriate referral and sharing of information.

J. Recognises patients' health status, abilities, cultural and social needs and provides or facilitates access to professional services delivered by the pharmacist or other appropriate services.