Pharmacy

Pharmacist, Ms B

A Report by the

Health and Disability Commissioner

(Case 19HDC00229)

Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

Contents

Executive summary

1. A woman in her forties had a medical history that included asthma, epilepsy, and multiple ear problems. The woman underwent surgery to remove a skin growth in her left ear, and was discharged with a prescription for paracetamol and tramadol. The tramadol prescription stated that she was to take 2 tablets every 6 hours, as needed.

2. When her family members presented to the pharmacy the following day to have the prescription filled, the pharmacy was busier than usual, and only three staff members were working — including an intern pharmacist and a registered pharmacist.

3. The intern was responsible for processing the prescriptions through the computer and dispensing the medication, while the pharmacist was helping to prepare the medicines, and was responsible for completing the final and overall check. When the tramadol prescription was processed, the intern input the wrong instructions. The intern did not double check the label after printing it, and the pharmacist did not pick up the error when performing her final check.

4. The prescription was dispensed correctly for a five-day supply of tramadol to be taken every six hours. However, the tramadol instructions were labelled incorrectly as "Two capsules every **four** hours when required", instead of "Two capsules every **six** hours when required".

5. The woman took the tramadol every four hours, as stated on the label, until the following day, when she was found to be agitated, shaking, hallucinating, crying, and unable to speak. She was taken to the emergency department (ED) at the public hospital, where the labelling error on the tramadol medication was discovered. She was admitted with a primary diagnosis of an accidental tramadol overdose and kept in hospital overnight for observation.

6. This report highlights the importance of the checking process when dispensing medication.

Findings

7. The pharmacist had ultimate responsibility for performing the final check on the labelling of the tramadol, and failed to do so adequately. In addition, her incident reporting and follow-up action subsequent to her checking error were inadequate, and did not adhere to the Pharmacy Council of New Zealand's professional standards and the pharmacy's SOPs. Accordingly, the Commissioner found that the pharmacist breached Right 4(2) of the Code.

8. The Commissioner was critical of the intern's failure to check the tramadol label after printing it and before attaching it to the container, but acknowledged that he was an intern pharmacist at the time and was under the pharmacist's direct supervision.

9. The Commissioner considered that the pharmacy had taken reasonable steps to prevent the pharmacist's actions, but reminded the pharmacy of its obligation to comply with the Pharmacy Council of New Zealand's Code of Ethics when offering compensation.

Recommendations

10. The Commissioner recommended that the pharmacist arrange for an assessment through the New Zealand College of Pharmacists regarding the checking and assessment of prescriptions, and provide a written apology for her breach of the Code.

11. The Commissioner recommended that the intern review the Pharmacy Council of New Zealand's professional guidelines and identify improvements in his dispensing practice.

12. The Commissioner recommended that the pharmacy randomly audit staff compliance with its SOPs for dispensing and checking medications and incident reporting, and review with staff the Pharmacy Council of New Zealand's Code of Ethics.

Complaint and investigation

13. The Health and Disability Commissioner (HDC) received a complaint from Ms A about the services provided to her by the pharmacy. The following issues were identified for investigation:

- *Whether the pharmacy provided Ms A with an appropriate standard of care during the period of November 2018 to December 2018, inclusive.*
- *Whether Ms B provided Ms A with an appropriate standard of care during the period of November 2018 to December 2018, inclusive.*

14. The parties directly involved in the investigation were:

Ms A	Consumer
Pharmacy	Provider/pharmacy
Ms B	Provider/pharmacist

15. Also mentioned in this report:

Mr C	Pharmacy manager/owner

16. Further information was received from:

Mr D	Intern pharmacist
District Health Board (DHB)	

17. Independent expert advice was obtained from Ms Sharynne Fordyce, and is included as Appendix A.

Information gathered during investigation

Background

18. Ms A had a medical history that included asthma, epilepsy, and multiple ear problems, and had developed a cholesteatoma[1] in her left ear. Surgery to remove the cholesteatoma was performed on 21 November 2018 at a public hospital. The surgery proceeded uneventfully, and Ms A was discharged home the following day, with a prescription for postoperative analgesia.

19. The take-home prescription was for both paracetamol and tramadol,[2] and stated:

> "Drug: paracetamol 500 mg tablet
> Instructions: 2 tabs every 6 hours PRN [as needed]
> Intended Duration: Unknown
> Amount: 1 week
>
> Drug: tramadol hydrochloride 50 mg capsule
> Instructions: 2 tabs every 6 hours PRN [as needed]
> Intended Duration: Unknown
> Amount: 5 days"

Labelling error

20. On 22 November 2018, at around 11.30am, Ms A's family members presented to the pharmacy to have the prescription filled on her behalf, as she was at home resting from the operation.

21. The pharmacy told HDC that it was busier than usual on this day, with 202 prescriptions being dispensed between 8am and 12pm, compared to the usual average of 130 prescriptions during this time. When Ms A's family presented, three staff members were working — Mr D,[3] an intern pharmacist at the time, Ms B,[4] a registered pharmacist, and Mr C, the pharmacy manager and owner. Mr C told HDC that usually there are two pharmacists and two dispensary staff on at a time; however, owing to personal reasons, the second dispensary staff member did not start until later that day.

22. Mr D was responsible for processing the prescriptions through the computer and dispensing the medication. Ms B was helping to prepare the medicines, and was responsible for completing the final check before handing over to the senior pharmacist to give out the medication and counsel the consumer.

[1] An abnormal, non-cancerous skin growth that can develop in the middle section of the ear, behind the eardrum.
[2] Medication used to treat moderate to moderately severe pain.
[3] Mr D is currently registered with the Pharmacy Council of New Zealand.
[4] Ms B is currently registered with the Pharmacy Council of New Zealand. She is also a member of the Pharmaceutical Society of NZ and the Pharmacy Defence Association.

23. Mr D stated:

> "I checked the legality of [Ms A's] script which included the date, patient's name and address, doctor's name, phone number, signature and address, and the medicine's name dose and instruction. After I was satisfied the prescription was legal and clinically sound, I proceeded to type the medications according to the script … I read what I typed in my head before printing each of her medicine's labels. Once I was satisfied these were correct, I placed the labels with the prescription and went to pack her medicine along with other people's medicines. Once packed, I stuck the label onto the container with the medicine and left a flap out ready for the pharmacist to check."

24. Ms B told HDC:

> "During this incident, the intern pharmacist [Mr D] was typing and we both shared the job of preparing the medicines, which then was checked by me and handed over to the senior pharmacist to give out and counsel.
>
> …
>
> I normally start checking from the top of the prescription making my way down to the bottom. Ensuring all legal and clinical requirements are met and that the medicine I am holding is for the person stated on the prescription. On every occasion, I always check and open the box/bottle to check that it is the correct medicine, strength, dosage form and then I continue to check for instructions and cautionary label instructions."

25. The prescription presented by Ms A was dispensed correctly for the paracetamol. The quantity of tramadol was dispensed correctly for a five-day supply to be taken every six hours. However, the tramadol instructions were labelled incorrectly as "Two capsules every four hours when required", instead of "Two capsules every six hours when required".

26. Mr D told HDC that many factors may have affected his dispensing around the time of the incident. He said that he started his shift at 8am, and because the pharmacy was very busy, he was unable to take a break until 12pm. In addition, he was stressed about his intern assessment centre results. He stated: "Due to those factors, I inputted 'q4h' instead of 'q6h' by mistake during the rush." He told HDC that usually he checks the labels and medications when the pharmacy is not busy, but on the day in question he did not check the labels after printing them. He stated that like all rushes during the year, he worked according to his dispensing role as an intern, which was to do the initial check and packing so that patients could receive their medicines in a timely matter.

27. At the time of these events, the pharmacy had a standard operating procedure (SOP) for dispensing and checking a prescription. The SOP stated:

> "• When dispensing a medicine, the Pharmacist or Technician shall:
> …

- Double check the generated dispensing label(s) against the original prescription before attaching to the container, making sure that the dispensary label contains what is written on the prescription, e.g. correct medicine, dose, quantity, instructions, customers name, and prescriber.

…

- When **checking** the prescription, the Pharmacist shall:

…

- Check the appropriateness of each prescribed medicine with respect to its therapeutic use, appropriateness for the customer's parameters, e.g. age, weight, renal function, possible adverse effects, contraindications, dosage, route of administration, duration of treatment, and possible interactions with other medication(s) or food.

- Check that each medicine dispensed is correct against the medicine prescribed on the prescription. This includes checking the generated dispensary label and dispensed medicine(s) against the original prescription for the:

  - Correct customer's name;
  - Correct instructions for use;
  - Correct formulation, strength and quantity of medicine;
  - Correct prescription number;
  - Correct prescriber;
  - Correct directions, which are clear and concise.

…"

28. Mr D told HDC that at the beginning of 2018, he had read all of the pharmacy's SOPs that related to his role. Ms B told HDC that she had read the pharmacy's SOPs at the commencement of her employment in 2017, and that she was involved with updating the old SOPs to the procedures that were in place on 22 November 2018.

29. Ms A's family left the pharmacy unaware of the error with the tramadol label, and Ms A's partner proceeded to administer her the tramadol every four hours, as stated on the label. At approximately 1pm on 23 November 2018, Ms A was taken to the emergency department by her family, as they were concerned by her behaviour. She was found to be agitated, shaking, hallucinating and crying, and was unable to speak. Ms A believes that during this period, she also had a seizure, as she had awoken with a bitten tongue and blood on her bedding.

30. At the ED, the labelling error on Ms A's tramadol medication was discovered, and she was admitted with a primary diagnosis of an accidental tramadol overdose. She was kept in hospital overnight for observation.

Follow-up actions

31. Following Ms A's presentation to the ED, a doctor called the pharmacy to explain what had happened, and to advise the pharmacy of its error.

32. Team meetings were held at the pharmacy on both 23 and 24 November 2018, to discuss the dispensing error and how they were to prevent incidents like this from occurring in the future. The meetings were attended by Mr C, Ms B, and Mr D, as well as other pharmacists from the pharmacy. They discussed the importance of communicating to the patient when the practice is busy, rather than rushing, and agreed that once one pharmacist starts checking a prescription, that pharmacist should be the one to complete it, as this would reduce the chance for errors. The SOPs were updated accordingly, and put into practice on 24 November 2018.

33. On 23 November 2018, Ms B filled out an incident form outlining the telephone call from the hospital, with a brief summary of what had occurred and what was discussed at the team meeting on that day. The form stated: "We will follow up with the patient once she is out of hospital and give our apology."

34. Ms B attempted to call Ms A five times during the period of 24 and 26 November 2018, to check that she was all right and to apologise for the error that had occurred. However, Ms B was unable to reach her. Ms A told HDC that she was very unwell from the effects of the tramadol at this time, and was unable to answer the phone.

35. Ms A called back on 26 November 2018 and spoke to a pharmacist, who apologised to Ms A on behalf of the pharmacy and explained what had happened. She informed Ms A that a team meeting was held in response to the incident, and that they discussed how they would ensure that such an incident does not happen again.

36. A further call was made to Ms A by Mr C on 29 November 2018, to follow up on Ms A's health. He again apologised for the error and advised Ms A that she could contact him if she had any further concerns or issues.

37. At the time of events, the pharmacy had an SOP for the procedure to be followed after a dispensing error. The procedure stated:

> "Incident reports are working documents that must have enough information included that would allow an outsider to review and fully understand what happened, and what has been done to ensure a similar situation does not happen again."

38. The SOP also stated that a "[f]ace to face apology or a letter of apology will be written by the Pharmacist involved in the dispensary error as soon as possible …"

39. On 10 December 2018, Ms A and her partner attended the pharmacy and asked to speak to Mr C. A meeting was held, and Ms A and her partner expressed their concerns about what had happened. Mr C acknowledged their concerns, and explained that a typing error had not been picked up by the pharmacist. He discussed all of the changes the pharmacy made subsequently, such as updating the SOPs, to ensure that such an incident never happens again.

40. Ms A told HDC that at this meeting, the pharmacy did not explain to her or her partner what they meant by SOP. She stated that they thought it was medical terminology and did not understand at the time.

41. Mr C told HDC that after this discussion, Ms A's partner hinted at compensation, stating that the incident had cost them money and had been a hassle for them both. Mr C explained:

> "I therefore offered $100 as a gift to compensate for the hassle caused by the incident and to consider it as a Christmas gift to help them through the season. [Ms A's partner] asked [Ms A] if this money is enough to compensate but she wasn't sure, so he asked for $200 and stated that would make them happy. I accepted his request as patient's sanctification [sic] is our priority. They accepted the apology and also stated the situation was over and left the pharmacy happy."

Further information

The pharmacy

42. The pharmacy manager and owner, Mr C, stated on behalf of the pharmacy that it deeply regrets the mistake made in writing the incorrect instructions on Ms A's tramadol medication.

43. Mr C and Ms B acknowledged that the pharmacy did not record the error in the incident report as comprehensively as they should have, and said that they have learnt from this. They stated: "We had no detailed information at the time when we wrote the incident so we wrote to cover the detail we were informed of and what we did to change our practice and SOP."

44. In response to the incident, the pharmacy implemented the following changes, to ensure that such an event does not happen again:

- A new rule was created whereby two staff members must check the medication before giving out tramadol prescriptions;
- When dispensing tramadol, the pharmacist who checked the script will now explain the medication to the consumer, to make sure that the consumer fully understands the instructions;
- The SOPs were updated to make the new changes effective immediately.

45. The pharmacy has also employed more staff to help with busy times. Mr C stated:

> "Following the incident we have now implemented that during peak hours we have extra staff working to ease work flow and when a staff member cannot do their shift (as occurred on the 22.11.18), we now arrange for another staff to cover."

Ms B

46. Ms B stated: "[A]fter evaluating what had happened during the dispensing of [Ms A's] prescription, there may have been contributing factors to the error that occurred." She reiterated how busy the pharmacy was on this day, stating that 22 November 2018 was one of the pharmacy's busiest mornings in her memory, and that because of this, she and Mr D did not have their break until 12 noon.

47. Ms B told HDC:

> "My tiredness due to this busy morning could have affected my checking of [Ms A's] Tramadol label instructions … From my pharmacy knowledge, I am aware that the therapeutic range for Tramadol 50mg is at 2 capsules every 4 to 6 hours. Reading the label as 2 capsules every 4 hours would have therefore not set alarm bells, as I was aware that this was within the therapeutic range for Tramadol 50mg capsules. The label also stated, 'when required for severe pain' which is not indicating to give the medication regularly. Somehow my tired eyes managed to read everything else correctly and may have lost focus that it had 6 hours not a 4 hours on the prescription."

48. Ms B informed HDC that since this incident, she has made changes to her practice to avoid such an error occurring again. She stated that she now allows for a full 10-minute break where she rests away from the dispensary on busy days. She requests that a maximum 24-hour dose be written on the label for tramadol and paracetamol, and she has also educated all shop and dispensary staff not to disturb the pharmacist when the pharmacist is in the middle of checking a prescription.

49. In her response to HDC, Ms B voiced that the hospital should not have prescribed Ms A with tramadol as analgesia in the first place. She stated:

> "Tramadol is contra-indicated in uncontrolled epilepsy and the patient was non-compliant[5] with her epilepsy medication (last time dispensed 3 months prior to the incident with 2 repeats but it has been picked up one off time only). This could have contributed to the seizure the patient states occurred ..."

50. As stated above, the pharmacy's SOP provides that the checking pharmacist should check the appropriateness of each prescribed medicine with respect to its therapeutic use and the appropriateness for the customer's parameters, including any contraindications.

51. When asked what steps she took to ensure the appropriateness of the tramadol for Ms A, Ms B stated that she was not aware of this information at the time of the event. She told HDC:

> "In order to make changes to my practice, I read through Tramadol 50mg capsule data sheet and also looked into [Ms A's] history. This was to ensure that I increase my knowledge regarding this medicine and to also identify how this incident would have

[5] Ms A told HDC that she keeps a spare six-month supply of her epilepsy medication with her, as often she is unable to get to the pharmacy.

> happened. No pharmacist would wish for a patient to be harmed in any way and would try to put every possible step into their practice to avoid a future incident. Therefore, my research allowed me to identify that Tramadol is contra-indicated in uncontrolled epilepsy, and that [Ms A] was non-compliant with her epilepsy medication (according to our system)."

52. Ms B also explained that in the pharmacy's dispensing system, if there is no regular dispensing for a patient's medication, that particular medication would be shifted to the bottom of the screen. She stated that at the time of dispensing, this would have been a factor that played a part in why it was not noticed that Ms A takes epilepsy medication.

DHB

53. When asked about the appropriateness of prescribing tramadol to Ms A, the DHB provided HDC with statements from all staff members involved in prescribing her the medication both intraoperatively and postoperatively. They stated that they took into account her co-morbidities and analgesia requirements when prescribing, explaining that Ms A has a history of poorly controlled asthma, and so non-steroidal anti-inflammatory drugs (NSAIDS) were contraindicated. Opioids were also avoided owing to Ms A's high BMI and the risk they pose of sleep disordered breathing. They noted that Ms A had been seizure free for five years, and explained that the risk of seizures with a small dose of tramadol is extremely low.

54. The DHB told HDC that the prescribing of tramadol postoperatively was carefully considered and reasonable in the circumstances, and concluded:

> "[The DHB is] satisfied that the prescription on discharge was reasonable, given that: the prescription of NSAIDS was not appropriate; that an appropriate dose had been prescribed; that [Ms A] had not had any undue side effects of the tramadol that had been administered as an inpatient; that the prescription for tramadol was given should the prescription of paracetamol alone not provide sufficient pain relief; and it was prescribed at a suitable interval of 6 hourly/QID [four times each day]."

Responses to provisional opinion

55. The pharmacy was provided with an opportunity to respond to the provisional opinion, and advised that it had no comments to make. Mr D also advised that he did not wish to comment.

56. Ms B was provided with an opportunity to respond to the relevant sections of the provisional opinion, and had no comments to make. She told HDC that she has already enrolled in the recommended assessment, and that this will be completed shortly.

57. Ms A was provided with the opportunity to respond to the "information gathered" section of the provisional opinion, and her comments have been incorporated into the report where relevant.

Relevant standards

58. The Pharmacy Council of New Zealand's Competence Standards for the Pharmacy Profession (2015) state that the pharmacist:

> "Domain O1: Health and medicine management:
>
> …
>
> O1.4.1 Advocates for, and ensures patients access and receive quality services and care commensurate with their health needs
>
> …
>
> O1.4.3 Acts to optimise health outcomes by identifying and mitigating potential sources of error in service delivery
>
> …
>
> O1.4.6 Effectively uses systems to record accurate, complete and timely patient information, maintaining privacy and security of the information
>
> …
>
> Domain O3: Supply and administration of medicines:
>
> …
>
> O3.1.3 Applies knowledge in undertaking a clinical assessment of the prescription to ensure pharmaceutical and therapeutic appropriateness of the treatment and to determine whether any changes in prescribed medicines are warranted
>
> …
>
> O3.2.1 Maintains a logical, safe and disciplined dispensing procedure
>
> …
>
> O3.2.5 Accurately records details of medication incidents and actions taken, including clinical and professional interventions, to minimise their impact and prevent recurrence"

59. The Pharmacy Council of New Zealand's Code of Ethics (2018) requires that a pharmacist:

> "Principle 4F Avoids conflicts of interest by not offering, requesting, or accepting incentives, gifts, hospitality or referrals and by not entering business arrangements that may affect, or be seen to affect, their professional independence or judgement, or limit patients' free choice of who they use to provide healthcare services.
>
> …

> Principle 6C Is accountable for practising safely and providing professional services only within their own scope of practice, and for maintaining professional competence relative to this scope of practice."

Opinion: Ms B — breach

Introduction

60. As a registered pharmacist, Ms B was responsible for complying with all professional and other relevant standards. Ms B was one of three staff members working at the pharmacy on 22 November 2018, and was responsible for helping to prepare the medicines, and for completing the final check before handing over to the senior pharmacist to give out the medication and counsel the consumer.

Labelling error

61. The Pharmacy Council of New Zealand's Competence Standards for the Pharmacy Profession (2015) provides that a pharmacist "[m]aintains a logical, safe and disciplined dispensing procedure", and "[a]cts to optimise health outcomes by identifying and mitigating potential sources of error in service delivery".

62. At the time of these events, the pharmacy had an SOP for dispensing and checking a prescription. The SOP stated that when checking the prescription, the pharmacist shall:

> "Check that each medicine dispensed is correct against the medicine prescribed on the prescription. This includes checking the generated dispensary label and dispensed medicine(s) against the original prescription for the:
>
> - Correct customer's name;
> - Correct instructions for use;
> - Correct formulation, strength and quantity of medicine;
> - Correct prescription number;
> - Correct prescriber;
> - Correct directions, which are clear and concise."

63. On 22 November 2018, intern pharmacist Mr D erroneously typed "q4h" instead of "q6h" ("take every four hours" instead of "take every six hours") in the instructions on the label for Ms A's tramadol. The dispensed medicine was then checked by Ms B to ensure that it matched the prescription, as per the pharmacy's SOPs. However, the error with the instructions was not picked up during Ms B's final check, and Ms A's medication was taken home with the incorrect instructions on her tramadol container.

64. Ms B told HDC that on 22 November 2018 the pharmacy was unusually busy, and that the morning was one of the pharmacy's busiest in her memory. She stated that because of

this, she and Mr D did not have their break until 12 noon, and she believes that these factors may have contributed to the errors that occurred.

65. My expert pharmacist, Ms Sharynne Fordyce, considers that the labelling error was a moderate to severe departure from accepted practice. She advised: "Tramadol is a drug with a narrow therapeutic index, therefore dosing instructions must be accurate to prevent overdosage …"

66. Ms Fordyce stated that although the pharmacy intern would have been at the end of his training, and very close to qualifying, "[t]he qualified pharmacist, as the final checker has ultimate responsibility, and also should have been aware of the extra care needed when dispensing and checking Tramadol".

67. The error that occurred on 22 November 2018 indicates to me that Ms B's checking processes were inadequate on this occasion. While I acknowledge that the pharmacy was busier than usual, I do not consider this justifies inaccuracy. I agree that the labelling error resulted from a failure to follow the pharmacy's SOPs and the Pharmacy Council of New Zealand's Competence Standards for the Pharmacy Profession, and consider that the error represents at least a moderate departure from accepted practice.

Follow-up actions

68. The Pharmacy Council guidelines, Competence Standards for the Pharmacy Profession (2015), states that a pharmacist "[a]ccurately records details of medication incidents and actions taken, including clinical and professional interventions, to minimise their impact and prevent recurrence".

69. At the time of events, the pharmacy had an SOP for the procedure to be followed after a dispensing error. The procedure stated:

> "Incident reports are working documents that must have enough information included that would allow an outsider to review and fully understand what happened, and what has been done to ensure a similar situation does not happen again."

70. Ms B completed the pharmacy's incident form for this event on 23 November 2018, after being notified of the error by the hospital. The form discussed the telephone call from the hospital, and gave a brief summary of what had occurred and what was discussed at the team meeting that day. The form stated: "We will follow up with the patient once she is out of hospital and give our apology."

71. Ms Fordyce advised:

> "The incident form should include the people involved in the incident, the date and time the incident took place, how busy the dispensary was at the time, the harm caused to the patient and how much medication had been consumed incorrectly. The [form should also include] details of the action taken by the pharmacy and the outcome for the patient …"

72. Ms Fordyce stated that the form written by Ms B is rather scant on detail, and does not give the impression of logical processes or record-keeping. Ms Fordyce considers that because a significant number of the steps listed above do not feature on the pharmacy's incident form for this event, there has been a moderate to severe departure from accepted practice.

73. Mr C and Ms B both acknowledged that the error was not recorded in the incident report as comprehensively as it should have been, and explained that they had no detailed information at the time, so wrote to cover the detail they were informed of and what they did to change their practice and SOPs.

Conclusion

74. By failing to perform the final check on the labelling of tramadol adequately on 22 November 2018, and for the inadequate incident reporting and follow-up actions taken following the labelling error, Ms B failed to adhere to the professional standards set by the Pharmacy Council of New Zealand, and the pharmacy's SOPs. As a consequence of the error on the label, Ms A overdosed on tramadol, which had an adverse effect on her health. Ms B failed to provide Ms A with services in accordance with professional and other relevant standards, in breach of Right 4(2)[6] of the Code of Health and Disability Services Consumers' Rights (the Code).

75. I acknowledge that since these events, Ms B has undertaken many actions in order to improve her practice and to ensure that a similar incident will not happen again.

Opinion: Mr D — adverse comment

76. Mr D was an intern pharmacist at the time of these events, and was one of the three staff members working at the pharmacy on 22 November 2018, when Ms A presented to have her prescription filled. Mr D was responsible for processing the prescriptions through the computer and dispensing the medication, and erroneously input the instructions on the tramadol label as "Two capsules every four hours when required", instead of "Two capsules every six hours when required".

77. My expert advisor, Ms Fordyce, considers the labelling error on Ms A's tramadol medication to be a moderate to severe departure from accepted practice. Ms Fordyce advised:

> "Tramadol is a drug with a narrow therapeutic index, therefore dosing instructions must be accurate to prevent overdosage, and preferably include a maximum daily dose on the label … The Intern pharmacist, who processed and dispensed the prescription would have been at the end of his training, and very close to qualifying,

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

> so would have been expected to be aware of the above factors, and be acting as a qualified pharmacist, with all the care that entails."

78. However, Ms Fordyce noted that the qualified pharmacist, as the final checker, has ultimate responsibility for ensuring that the prescription has been filled correctly. I acknowledge that as an intern pharmacist, Mr D would have been under Ms B's direct supervision, and that as the qualified pharmacist and final checker, ultimately Ms B was responsible for the safe dispensing of Ms A's medication.

79. Nonetheless, I remain critical of Mr D for not checking the tramadol label after printing it and before attaching it to the container. As per the pharmacy's SOPs, the pharmacist who dispenses the medicine should:

> "Double check the generated dispensing label(s) against the original prescription before attaching to the container, making sure that the dispensary label contains what is written on the prescription, e.g. correct medicine, dose, quantity, instructions, customers name, and prescriber."

80. Mr D told HDC that usually he checks the labels and medications when the pharmacy is not busy, but on the day in question he did not check the labels after printing them. Had Mr D completed this step, as per the SOPs, the labelling error may have been picked up before the tramadol was given to Ms A.

Opinion: Pharmacy

Labelling error and follow-up actions — no breach

81. As a healthcare provider, the pharmacy was responsible for providing services in accordance with the Code. In this case, I consider that the errors that occurred did not indicate broader systems or organisational issues, and that they were entirely individual failures. Therefore, I consider that the pharmacy did not breach the Code directly.

82. In addition to any direct liability for a breach of the Code, under section 72(2) of the Health and Disability Commissioner Act 1994 (the Act), an employing authority is vicariously liable for any acts or omissions of its employees. Ms B was an employee of the pharmacy on 22 November 2018. As set out above, I have found that Ms B breached Right 4(2) of the Code, for failing to adhere to the professional standards set by the Pharmacy Council of New Zealand, and the pharmacy's SOPs.

83. However, a defence is available to the employing authority of an employee under section 72(5) if it can prove that it took such steps as were reasonably practicable to prevent the acts or omissions.

84. At the time of these events, the pharmacy had comprehensive SOPs in place for checking and dispensing medications, as well as for the procedures to be followed after an adverse

event. Both Mr D and Ms B told HDC that they were aware of these SOPs, and Ms B was also involved in updating the old SOPs to the ones in place on 22 November 2018. I note that my expert advisor, Ms Fordyce, considers that these SOPs complied with accepted practice.

85. In light of the above, I consider that the pharmacy had taken steps that were reasonably practicable to prevent Ms B's failures. Accordingly, I do not find that the pharmacy is vicariously liable for Ms B's breach of the Code.

Payment made to Ms A — other comment

86. Following the labelling error made on 22 November 2018, Ms A and her partner presented to the pharmacy and met with the pharmacy manager, Mr C. Ms A and her partner expressed their concerns about what had happened, and Mr C explained all of the changes made by the pharmacy to prevent such an event reoccurring. Mr C told HDC that Ms A and her partner then hinted at compensation. He stated:

> "I therefore offered $100 as a gift to compensate for the hassle caused by the incident and to consider it as a Christmas gift to help them through the season. [The partner] asked [Ms A] if this money is enough to compensate but she wasn't sure, so he asked for $200 and stated that would make them happy. I accepted his request as patient's sanctification [sic] is our priority …"

87. My expert pharmacist, Ms Sharynne Fordyce, advised:

> "While it is accepted practice to offer to cover any extra costs incurred by the patient, because of the error made, it is not accepted practice to offer a specific sum of money to 'compensate for the hassle caused … to consider it as a Christmas gift'. To negotiate this amount of this offer with the wronged party is even less acceptable, and is unethical and unprofessional."

88. I agree with Ms Fordyce's statement. I acknowledge that Mr C was trying to compensate for the problems caused to Ms A by the labelling incident, and I agree that covering the extra costs that may have occurred would have been appropriate in this case. However, I remind the pharmacy of its obligation to comply with the Pharmacy Council of New Zealand's Code of Ethics.

Recommendations

89. I recommend that Ms B arrange for an assessment through the New Zealand College of Pharmacists regarding the checking and assessment of prescriptions, and provide evidence to this Office, within six months of the date of this report, confirming the outcome of the assessment.

90. In response to the recommendations in the provisional opinion report, Ms B provided Ms A with a written apology for the breach of the Code identified in this report.

91. I recommend that the pharmacy:

a) Randomly audit, over a period of three months, staff compliance with its SOPs for dispensing and checking medications and incident reporting, and provide HDC with the outcome of the audit within six months of the date of this report.

b) Review the Pharmacy Council of New Zealand's Code of Ethics with all of its staff members, and provide HDC with evidence that this has been done within six months of the date of this report.

92. I recommend that Mr D review the Pharmacy Council of New Zealand's professional guidelines and identify improvements in his dispensing practice. Mr D is to provide HDC with evidence of this within four months of the date of this report.

Follow-up actions

93. A copy of this report with details identifying the parties removed, except the expert who advised on this case, will be sent to the Pharmacy Council of New Zealand, and it will be advised of Ms B's name.

94. A copy of this report with details identifying the parties removed, except the expert who advised on this case, will be sent to the Pharmaceutical Society of New Zealand, the 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: Independent advice to the Commissioner

The following expert advice was obtained from pharmacist Ms Sharynne Fordyce:

"Complaint: [the pharmacy]/[Ms A]

Reference: 19HDC00229

I, Sharynne Fordyce, have been asked to provide an opinion to the Commissioner on Case number 19HDC00229 and have read and agreed to follow the Commissioner's Guidelines for Independent Advisers.

My qualifications include a Diploma of Pharmacy, and a Masters of Clinical Pharmacy. I have worked in Retail Pharmacy for over 30 years, both in New Zealand and in England, and also work for the Wairarapa DHB.

Background of complaint:

[Ms A] had an operation at [a public hospital] on 22 November 2018, and was discharged with a prescription for Tramadol. She had the prescription filled at [the pharmacy] on the same day. On 23 November 2018, [Ms A's] family became concerned with her behaviour, as she was agitated, unable to speak, hallucinating and crying. She also believed she had a seizure during this time. She was taken to [hospital] where it was found that she had experienced an overdose of Tramadol. The instructions on the script said the medication was to be taken every 6 hours when required; however the instructions on the packet were mistyped and said every 4 hours.

1. Comment on the appropriateness of the labelling and dispensing of the Tramadol to [Ms A] on 22 November. Please specifically comment on the care provided by the individual pharmacists.

a) What is the standard of care/accepted practice?

That the label typed out and dispensed replicated the instructions written on the prescription by the doctor, for that medication, ensuring the instructions are legal, appropriate and safe for the patient. The label should be checked at least three times, by the processor (when it is entered into the computer), by the dispenser, and by the pharmacist completing the final check. At each stage the label should be checked against the prescription for accuracy, appropriateness and safety.

b) If there has been a departure from the standard of care or accepted practice, how significant a departure (mild, moderate, severe) do you consider this to be?

I would consider this to be a moderate to severe departure from the accepted practice. Tramadol is a drug with a narrow therapeutic index, therefore dosing instructions must be accurate to prevent overdosage, and preferably include a maximum daily dose on the label. There have also been a number of errors made in dispensing Tramadol in recent years, so it is a drug that should warrant extra care. The

Intern pharmacist, who processed and dispensed the prescription would have been at the end of his training, and very close to qualifying, so would have been expected to be aware of the above factors, and be acting as a qualified pharmacist, with all the care that entails. The qualified pharmacist, as the final checker has ultimate responsibility, and also should have been aware of the extra care needed when dispensing and checking Tramadol.

c) How would it be viewed by your peers?

My peers would also view this as a moderate to severe departure from accepted practice, particularly given that both computer dispensary programmes used in New Zealand carry warnings for Tramadol.

d) Do you have any further recommendations for how this aspect of care could be improved?

Greater vigilance when entering, dispensing from, and checking labels, especially with drugs such as Tramadol (noted that this has been actioned by [the pharmacy]).

2. Comment on the adequacy of the standard operating procedures (SOPs) in place at [the pharmacy] at the time of the event.

a) The SOPs available to view comply with accepted practice.

b) There is no significant departure from accepted practice.

c) My peers would agree with this statement.

d) Improvements could include a signed and dated record of all SOPs read by all staff.

3. Comment on the adequacy of the SOPs in place at [the pharmacy] that were implemented after the event.

a) The SOPs implemented after the event comply with accepted practice.

b) There is no significant departure from accepted practice.

c) My peers would agree with this statement.

d) Improvements have taken place in specifying extra care for certain drugs with a narrow therapeutic index. The list could be more comprehensive, however, rather than written exclusively to cover this event. As previously mentioned, the list of SOPs read, dated and signed by all staff needs to include the title of each SOP read, and to include all relevant pharmacy SOPs, not just the new improved ones.

4. Comment on the adequacy of the Pharmacy's incident reporting.

a) Accepted practice is to fill out an incident from as soon as notified of mistake, not just to add to patient notes. Pharmacy Defence Association (PDA) should be notified, particularly when there has been harm to the patient or they have been hospitalised, as was the case in this event. The incident form should include the people involved in the incident, the date and time the incident took place, how busy the dispensary was at the time, the harm caused to the patient and how much medication had been

consumed incorrectly. The details of the action taken by [the pharmacy] and the outcome for the patient.

b) There has been a moderate to severe departure from accepted practice as a significant number of steps listed above do not feature on [the pharmacy's] incident form for this event.

c) My peers would regard this as a moderate to severe departure from accepted practice, with the form being rather scant on detail. This form also does not give the impression of logical processes or record keeping. The severity of the situation is not alluded to in the form.

d) Improvement to this form would include following [the pharmacy] SOP for reporting of incidents, including 'working documents that must have enough information' and 'record as much information on suitable form when incident is major'. This incident was major. The SOP also stipulates a written letter of apology to be posted to the customer, which was not done in this event.

5. Any further comments.

From the dispensing figures given on the day, [the pharmacy] appeared to be busy during the time the incident took place. More staff could be appropriate to lessen the temptation to rush important processes.

While it is accepted practice to offer to cover any extra costs incurred by the patient, because of the error made, it is not accepted practice to offer a specific sum of money to 'compensate for the hassle caused … to consider it as a Christmas gift.' To negotiate this amount of this offer with the wronged party is even less acceptable, and is unethical and unprofessional."

The following further advice was received from Ms Fordyce:

"… After reading all the extra information that was sent to me, and in answer to the questions you put to me, I would like to make the following comments:

1. The Datasheet for Tramadol states 'Patients with epilepsy or those susceptible to seizures should only be treated with tramadol if there are compelling circumstances' and that tramadol is 'contraindicated in patients with uncontrolled epilepsy or epilepsy not adequately controlled by treatment.' Therefore it would appear that it was completely inappropriate for the hospital to have prescribed [Ms A] tramadol, given her history, of which they were aware.

2. The same datasheet also states that the maximum daily dose of Tramadol 'should not exceed 400mg per day.' If following the directions on [the pharmacy's] label of 100mg q4h or every four hours that gives a daily dose of 600mg, which is not within the dose guidelines. [Mr C] mentions that [Ms A] would have had time to consume 5 to 6 doses before being admitted to hospital, which would be a total of 600mg in under 24 hours.

3. [Mr C] also mentions [Ms A's] caregiver should have realised that 'when required' did not mean strictly every four hours. Unfortunately the phrase 'when required' is very open to interpretation, and depending on health literacy, and the degree of pain/stress associated with [Ms A's] operation, it is understandable that this dose was given this frequently. The change in [the pharmacy's] procedure to ensure patient counselling by a pharmacist for tramadol prescriptions is well thought out.

4. I was unaware of the time frame in which [the pharmacy] had to respond, I was working to the time frame that was available to me. It was not a deliberate move to avoid 'natural justice'.

I hope this helps answer your queries …

Kind regards

Sharynne Fordyce"

The following further advice was received from Ms Fordyce:

"… In reply to [Ms B's] reply

1) The maximum dose of tramadol is 50mg to 100mg not more than every FOUR hours as mentioned by [Ms B], but up to a daily maximum of 400mg. However in a previous letter [Ms B] mentions changes to her dispensing practice to include this daily maximum on future tramadol labels.

2) The pharmacy's last dispensing of Epilim to [Ms A] was a month's supply, dispensed nearly four months prior to the incident in question. With the number of medications [Ms A] had had dispensed from [the pharmacy] in the intervening period I would have expected the Eplim dispensing to have still been visible. However this can vary from pharmacy to pharmacy, depending on the screen size being used for this dispensing.

These would be my final comments on this response.

Kind regards

Sharynne Fordyce"