Pharmacist, Mr C

Pharmacy Owner

Pharmacist, Mr D

A Report by the

Deputy Health and Disability Commissioner

(Case 21HDC00539)

Health and Disability Commissioner

Te Toihau Hauora, Hauātanga

Contents

Executive summary

1. This report concerns a pharmacist's failure to check a medication adequately before it was given to a consumer. The incorrect medication had been selected and prepared by an intern pharmacist before it was provided to the pharmacist for checking. The report highlights the importance of pharmacists undertaking adequate checks when dispensing medications.

Findings

2. The Deputy Commissioner considered that by failing to complete the final check of the medication adequately and not identifying the medication error, the pharmacist did not follow the pharmacy's Dispensing Standard Operating Procedure (SOP) or the Pharmacy Council of New Zealand Competence Standards (2015) correctly. Further, by failing both to record the error on the woman's patient file adequately and provide a written apology to her upon becoming aware of the error, the pharmacist did not follow the pharmacy's Managing Dispensing Errors SOP. Accordingly, the Deputy Commissioner found the pharmacist in breach of Right 4(2) of the Code for failing to provide services in accordance with professional standards and the pharmacy's SOPs.

3. The Deputy Commissioner made adverse comments about the respective owners of the pharmacy, including that the woman was not given a time frame on when follow-up, a formal apology, or further communication would occur, and that the SOP for Managing Dispensing Errors was inadequate. The SOP did not stipulate clearly how or when the provision of an apology should occur following a dispensing error, or when a consumer could expect a formal response to their complaint. The Deputy Commissioner also criticised the lack of discussion in the Root Cause Analysis about how to improve the management of pressure, workflow and distractions in the dispensary when it is busy.

4. The Deputy Commissioner made adverse comment about the intern pharmacist for failing to select the correct medication and failing to check the dispensed medication against the prescription, resulting in the incorrect medication being given to the pharmacist to check.

Recommendations

5. The Deputy Commissioner recommended that the pharmacy consider combining the Managing Dispensing Errors and Customer Complaints SOP; conduct staff training on the dispensing and checking SOP and undertake a random audit of the dispensing and checking of medication to assess compliance with the dispensing and checking SOPs; and use an anonymised copy of this report for education across the business.

6. The Deputy Commissioner recommended that the pharmacist provide a written apology for the failings identified in this report. In addition, the pharmacist has provided evidence to HDC that he has completed the Improving Accuracy and Self-Checking Workbook provided by the Pharmaceutical Society of New Zealand, which was an earlier recommendation.

7. The Deputy Commissioner recommended that the intern pharmacist provide a written apology for the failures identified in this report, and that he undertake further training on the pharmacy's SOPs, in particular the Dispensing SOP, and provide HDC with a reflection

on his learnings. In addition, it was recommended that the intern complete the Improving Accuracy and Self-Checking Workbook provided by the Pharmaceutical Society of New Zealand.

Complaint and investigation

8. The Health and Disability Commissioner (HDC) received a complaint from Ms B about the services provided to her late mother, Mrs A, by Mr C[1], the pharmacy owner[2] and pharmacist Mr D in 2020. The following issues were identified for investigation:

- *Whether Mr C provided Mrs A with an appropriate standard of care between 1 Month1[3] and 30 Month3 (inclusive).*
- *Whether the pharmacy owner provided Mrs A with an appropriate standard of care between 1 Month4 and 1 Month6 (inclusive).*
- *Whether Mr D provided Mrs A with an appropriate standard of care between 1 Month1 and 18 Month5 (inclusive).*

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

10. The parties directly involved in the investigation were:

Ms B	Complainant/consumer's daughter
Mr C	Provider/owner of the pharmacy
Pharmacy owner	Provider/owner of the pharmacy
Mr D	Provider/pharmacist

11. Further information was received from the district health board (now Te Whatu Ora) and intern pharmacist Mr E.

12. Independent advice was obtained from pharmacist Ms Catherine Keenan (Appendix A).

13. I extend my condolences to Ms B and Mrs A's family and friends.

[1] The pharmacy was owned and operated by Mr C as a sole trader.
[2] The ownership of the pharmacy was transferred to the current owner of the pharmacy.
[3] Relevant months are referred to as Months 1–6 to protect privacy.

Information gathered during investigation

Introduction

14. Mrs A (aged in her sixties at the time of these events) had several co-morbidities for which she was on regular long-term medication, including mycophenolate (CellCept)[4] 500mg twice daily.

15. On 22 Month1, Mrs A collected the third repeat of her CellCept prescription from the pharmacy. The pharmacy was able to dispense only 20 tablets, and the remainder of the prescription was made up as "owing" (meaning that the remaining 100 tablets would be available for collection once available). Mrs A's daughter, Ms B, returned on 10 Month2 to collect the remaining 100 tablets, but Mrs A was incorrectly dispensed 100 tablets of cyclosporin[5] 50mg. The medication was processed and dispensed by an intern pharmacist,[6] Mr E, and was checked by the Pharmacist in Charge, Mr D. Mr E was working under the supervision of Mr D at the time.

16. Mrs A took the incorrect medication for approximately 17 days. When Mrs A presented to hospital complaining of back pain, it was discovered that she had been dispensed cyclosporin incorrectly. Hospital staff advised the pharmacy of the error on 29 Month2.

17. Mrs A was discharged from hospital on 6 Month3 but became unwell again and was re-admitted to hospital on 11 Month3. Sadly, Mrs A died on 2 Month4 of heart failure.

18. At the outset, it is important to note that it is not the role of this Office to determine cause of death, and I am unable to comment on any possible link between the dispensing error and Mrs A's death.

Pharmacy

19. The pharmacy was owned and operated by Mr C as a sole trader. The ownership of the pharmacy was transferred to the current owner of the pharmacy (pharmacy owner).

Mr D

20. Mr D obtained a Bachelor of Pharmacy and is registered with the Pharmacy Council of New Zealand (PCNZ). At the time of these events, he was the Pharmacist in Charge at the pharmacy. The pharmacy's job description for Pharmacist in Charge states that direct reports may include intern pharmacists, pharmacy technicians and pharmacy assistants. The job description states that "[t]he Pharmacist in Charge is the most senior pharmacist on duty and assumes responsibility for the supervision and functioning of the pharmacy".

[4] A medication used to help prevent the body from rejecting an organ transplant or to treat some inflammatory conditions.
[5] A medication used to help prevent the body from rejecting an organ transplant or to treat some inflammatory conditions.
[6] A pharmacist who has graduated from a Bachelor of Pharmacy programme and is practising under the supervision of an experienced pharmacist to meet the requirements for pharmacist registration.

Mr E

21. At the time of these events, Mr E was an intern pharmacist working under supervision.

22. The pharmacy's job description for an intern pharmacist states that the key responsibilities of an intern pharmacist include "assist[ing] the pharmacist with the operation of the dispensary, including dispensing, administrative duties and managing stock".

Dispensing 22 Month1

23. On 22 Month1, Mrs A presented to the pharmacy to collect the third repeat[7] of her CellCept medication. However, there were only 20 tablets available in the pharmacy, so the remainder (100 tablets) were marked as "owing", to be collected once they became available.

Dispensing 10 Month2

24. Ms B attended the pharmacy on 10 Month2 to collect Mrs A's owing 100 tablets of her CellCept medication.

25. The "Owing Dispensed Form"[8] showed that 100 tablets of CellCept were dispensed by Mr E at 10.32am. Mr E told HDC:

> "I processed it on the computer, produced a label, selected and labeled the medication for [Mr D] to check. [Mr D] then checked the medication before returning to the prescription he was doing. I asked the patient picking up the medications if anything had changed or if they had any questions. They did not. I also apologised for not having all the medications available at the original repeat dispensing time."

26. Mr D told HDC that Mr E processed the script on the computer, produced a label, selected, and then labelled the medication. Mr D said that he conducted the final check. He stated: "My final check was incorrect. Although I do not recall the error specifically, I believe I likely confused the brand name with the drug name."

27. The medication label stated that it was mycophenolate mofetil (CellCept) 500mg. However, Ms B provided HDC with a photograph of the medication that was given to Mrs A. The medication box is clearly marked "Neoral 50mg Cyclosporin" (with the medication label stating mycophenolate mofetil 500mg). Instead of the 100 tablets of CellCept, Mrs A had been incorrectly dispensed 100 tablets of cyclosporin.

28. Ms B told HDC that Mrs A did not notice that the medication was incorrect, and she continued to take the medication she believed to be CellCept for approximately 17 days.

Discovery of dispensing error and subsequent events

Admission to hospital

29. On 27 Month2, Mrs A attended a neurology review at hospital complaining of severe back pain. It was discovered by the hospital that she had been incorrectly dispensed cyclosporin.

[7] Previously dispensed on two occasions as per the original prescription instructions.
[8] Produced on 22 Month1.

Staff at the hospital pharmacy notified the pharmacy of the dispensing error on 29 Month2, and the pharmacy told HDC that this information was passed on to Mr D.

30. Mrs A was admitted to the Neurology Department and underwent various investigations before she was discharged home on 6 Month3. On 11 Month3, Mrs A was readmitted to hospital and subsequently suffered a heart attack. Sadly, she passed away.

Notification of error

31. The pharmacy told HDC that following notification of the error on 29 Month2, Mr D and another pharmacist discussed appropriate next steps, including asking a pharmacy technician (who was fluent in Mrs A's language) to contact Mrs A. The pharmacy said that the pharmacy technician apologised to Mrs A for the error on behalf of the pharmacy and offered to speak to Mrs A's doctor directly to discuss the matter and provide the contact details of the pharmacy. The pharmacy told HDC: "After the patient had been verbally apologi[s]ed to and subsequently accepted the apology, the pharmacy had assumed the matter was closed."

32. In response to the provisional opinion, Ms B told HDC that she recalls the pharmacy technician calling Mrs A while she was in hospital and apologising for the error and asking Mrs A to return the medicine. Ms B said that the pharmacy technician did not explain the difference between the medication that was given to Mrs A in error and her normal medication; why Mrs A had been given the wrong medication; and/or what impact it might have on Mrs A's health. Ms B stated that she felt that the apology was "not … sincere" and that Mrs A did not accept the apology at that time. Ms B said that Mrs A was very concerned about the effect that the incorrect medication might have on her health.

33. Mr D told HDC that upon learning of the error, he updated Mrs A's file and made a note stating that there had been a dispensing error on 10 Month2 and that he should be advised immediately if the pharmacy was contacted about the error. However, the pharmacy confirmed that this was not in fact recorded on Mrs A's patient file until 17 Month4. Mr D told HDC that the day after the dispensing error was discovered, he held a dispensary staff meeting where the error was discussed along with "ways to safeguard against others in the future", and that this included a collaborative Root Cause Analysis. However, this was not documented in a formal Root Cause Analysis form, but rather as meeting minutes that were implemented and reviewed.

34. On 17 Month4, Ms B contacted the pharmacy to advise it of Mrs A's death. The pharmacy told HDC that another Charge Pharmacist (who was fluent in Ms B's language) called Ms B. The pharmacy stated:

> "[Another Charge Pharmacist] apologised and asked if [the pharmacy] could offer any assistance. He also explained the meetings and processes that had been put in place to decrease the chance of an error reoccurring. [The Charge Pharmacist] offered to meet with [Ms B], either at the pharmacy or a place of her choosing. [Ms B] explained she was grieving and therefore did not want [the pharmacy] to contact her — she would reach out when ready."

35. The pharmacy told HDC that on 11 Month5 and 18 Month5, the pharmacy attempted to call Ms B but was unable to reach her. The Charge Pharmacist who had called Ms B on 17 Month4 left a message on Ms B's voicemail system, explaining that the pharmacy wished to apologise "when she was ready to talk", and left Ms B with a direct contact number to return the call when she was ready. However, Ms B did not contact the pharmacy.

36. On 25 Month5, the Charge Pharmacist wrote to Ms B to apologise for the error. The pharmacy told HDC that a formal written apology was not provided to Ms B earlier as pharmacy staff had been waiting to hear from Ms B when she was ready to speak with them, and as they had wished to meet with Ms B in person.

37. In response to the provisional opinion, Ms B said that she does not have a "deep impression" of the pharmacy asking for a meeting with her. She stated: "I was very sad at the time, and I wanted to seek [HDC's] help first, but for sure they haven't contacted me in the past two years."

Contributing factors

38. Mr E and Mr D both told HDC that it was particularly busy in the pharmacy at the time of the medication being dispensed. Mr E said that one of the pharmacists was on a lunch break, leaving only himself and Mr D in the dispensary. The pharmacy provided HDC with documentation that showed that there were two pharmacists and two technicians working on 10 Month2, and that over the course of the day the pharmacy processed 361 scripts.

39. The pharmacy told HDC that in the 15 minutes prior to dispensing Mrs A's medication, roughly 20 items were dispensed.

40. The pharmacy also told HDC that it considered the potential causes of the dispensing error, including that "because the medications are used for the same purposes they were initially mixed up … [a]s the medications are also both contained in large foil packaging". The pharmacy said that this combined with the busy period in the dispensary may have contributed to the errors in dispensing and checking the medication.

Standard Operating Procedures

41. Standard Operating Procedures (SOPs) are documents that describe standard procedures and actions to be taken by staff when performing their duties. The pharmacy told HDC that all pharmacists are given an induction into the dispensaries, which is covered in its HR/ Induction process, and filed on the relevant staff file. The pharmacy said that both Mr E and Mr D followed all steps in the relevant SOPs when dispensing Mrs A's medication.

42. The pharmacy stated that all SOPs have a set review date and a schedule of review, and that all previous versions of SOPs are retained in one folder.

Dispensing SOP

43. The pharmacy had a Dispensing SOP (relevant sections outlined in Appendix B) that outlined its usual process for dispensing and checking medication. The SOP includes a procedural outline of receiving prescriptions; legalities and authenticity of prescription; processing

prescriptions in RxOne (the dispensing platform); dispensing medication; E-prescribing; and checking medication. The pharmacy told HDC that each step in the SOP has a list of criteria that need to be satisfied before moving on to the next step.

44. The pharmacy said that Mr E completed all steps in this process, except the "checking the dispensed medication"[9] section, which was completed by Mr D.

Dispensing Owings SOP

45. The pharmacy had a Dispensing Owings SOP that outlined its usual process for dispensing "owing" medications. The pharmacy told HDC that Mr E completed Step 8 of the process (the only step necessary) by processing the repeats/owing form, and that Mr D undertook the "check" as per the usual repeat process as outlined in the Dispensing SOP.

Repeat Dispensing SOP

46. The pharmacy had a Repeat Dispensing SOP (relevant sections outlined in Appendix B) that outlined its usual process for repeat dispensing.

47. The pharmacy told HDC that Mr E completed all steps in the process[10] except for the "checking the dispensing medication" step, which was completed by Mr D.

Managing Dispensing Errors SOP

48. The pharmacy had a Managing Dispensing Errors SOP (relevant sections outlined in Appendix B), which outlined steps to be taken in response to a dispensing error. The SOP outlines that the "responsible person(s)" includes "all pharmacists" and "intern pharmacists". The pharmacy told HDC that although the provision of an apology was included in the SOP, it did not include a timeframe for when an apology should be provided. The pharmacy stated:

> "At the time, we had made it known that investigation and an apology would be given (as appropriate) within 1 to 3 days of notification, but this was not documented at that time."

49. This SOP also stipulated that the incident should be logged, and it directed staff to the relevant SOP on how to log an incident report.

50. The pharmacy told HDC that it was the responsibility of the Pharmacist in Charge to document the error on the patient record.

Recording, Reviewing Near Misses SOP

51. The pharmacy told HDC that each store undertakes its own "near miss" review monthly, which is shared with the professional services team on a quarterly basis. The pharmacy said that this information is then collated, analysed and used for shared learnings across the

[9] Numbers 34–41 in the Dispensing SOP.
[10] Numbers 8–16 in the Repeat Dispensing SOP.

company. The pharmacy stated: "Each dispensary does their own internal assessment and reviews (as per Medsafe guidelines)."

Other relevant standards

52. The PCNZ's Competence Standards for the Pharmacy Profession (2015) provides that a pharmacist "[m]aintains a logical, safe and disciplined dispensing procedure", and "[f]ollows relevant policies, procedures and documentation requirements for the administration of medicines".[11]

Further information

Ms B

53. Ms B expressed her pain at losing her mother, and her disappointment at what she expressed as the attitude of the pharmacy following the error.

Mr D

54. Mr D told HDC that as the manager of the pharmacy at the time of the events, he had oversight of Mr E. Mr D stated:

> "At the time, [Mr E] was an experienced intern, and was only one month away from sitting his final exams. [Mr E] carried out tasks in line with [the pharmacy's] relevant SOPs, under the supervision of one of the 5 pharmacists who were working with [Mr E]."

The pharmacy

55. The pharmacy does not consider that the delay in providing Ms B with a written apology was due to the relevant SOP not containing a timeline for this to occur. The pharmacy told HDC that staff acted appropriately in regard to the apology, in that they verbally apologised to Mrs A and waited for her to contact the pharmacy again if she wished.

56. The pharmacy stated:

> "All staff at the Pharmacy wish to express their deepest condolences for the loss of [Mrs A] — [Ms B's] mother. A snapshot of the pain suffered by [Mrs A's] family as a result of her loss is captured in the correspondence received to date. The Pharmacy wishes to acknowledge this. It is accepted that the Pharmacy has made an error when dispensing [Mrs A's] prescription for Mycophenolate. Another immunosuppressant, ciclosporin, was accidentally dispensed instead. The Pharmacy accepts this error is a departure from acceptable standards. It has offered its apology for the lapse and has taken adequate steps to ensure it does not recur."

57. The pharmacy told HDC that the day after the dispensing error was discovered, Mr D held a dispensary staff meeting in which the error was discussed, along with ways to safeguard against other errors in the future. The pharmacy also said that after the error was identified, the pharmacist in charge of quality improvement was sent to the pharmacy to assist in

[11] See: https://pharmacycouncil.org.nz/wp-content/uploads/2021/03/CompStds2015Web-1.pdf.

managing the error. The pharmacy company said that management had regular updates on how the incident was progressing.

Responses to provisional opinion

Ms B

58. Ms B was given the opportunity to respond to the "information gathered" section of the provisional report. Where appropriate, her comments have been incorporated into this report. In addition, Ms B told HDC:

> "I believe the pharmacy must take [responsibility for the dispensing error]. The fact that pharmacies handle [many] prescriptions a day is not an excuse for them to prescribe the wrong medicine. They must know that they have a great responsibility. One medicine may kill a person and destroy a family … Nothing is more precious than life."

Mr D

59. Mr D was given the opportunity to respond to the provisional opinion. He accepted the findings in the provisional report. Mr D's lawyer provided the following statement on Mr D's behalf:

> "[Mr D] takes the error seriously and acknowledges the pain experienced by [Mrs A's] family. [Mr D] has undertaken significant reflection and development in the time since the error occurred. As part of this, in 2021 [Mr D] completed the Improving Accuracy and Self-Checking Workbook provided by the Pharmaceutical Society of New Zealand … [Mr D] found the workbook to be useful and has implemented the skills learned into his practice … [Mr D] is willing to provide a written apology to [Ms B] and will do so within three weeks of the final report."

60. Mr C, the pharmacy owner and Mr E were also given the opportunity to comment on relevant sections of the provisional opinion but had no further comments to add.

Opinion: Mr D — breach

Introduction

61. Mr D was the Pharmacist in Charge at the pharmacy on 10 Month2. As outlined in the job description for "Pharmacist in Charge", Mr D was responsible for the oversight of other pharmacists, including the "checking" of dispensed medications.

62. As part of my assessment of the care that Mr D provided to Mrs A, I obtained independent advice from pharmacist Mrs Catherine Keenan.

Dispensing error — 10 Month2

63. The Pharmacy Council of New Zealand (PCNZ) Competence Standards for the Pharmacy Profession (2015) provides that a pharmacist "[m]aintains a logical, safe and disciplined

dispensing procedure", and "[f]ollows relevant policies, procedures and documentation requirements for the administration of medicines".

64. On the day of the dispensing error, intern pharmacist Mr E processed and prepared Mrs A's medication, and Mr D was responsible for the final check before the medication was handed over. Mr D checked the medication but failed to identify that Mr E had mistakenly selected 100 cyclosporin 50mg capsules instead of the owing 100 mycophenolate 500mg tablets.

65. The "Checking the Dispensed Medication" section of the Dispensing SOP states that the checking pharmacist must confirm that the patient and medication details are correct, including the medication and strength; ensure that there are no interactions or contraindications; ensure that the medication dispensed is therapeutically appropriate (including checking the correct dose and correct dosage form), and that any errors are corrected by the checking pharmacist "prior to handing the medication out to the patient". The Dispensing SOP also states that when the pharmacist is satisfied that the dispensed medication is correct, they will initial the bottom left corner of the dispensing label.

66. Mr D told HDC that the pharmacy was particularly busy on 10 Month2, and that Mr E served Ms B. Mr D said that he completed the final check once Mr E had completed the dispensing steps. Mr D told HDC: "My final check was incorrect. Although I do not recall the error specifically, I believe I likely confused the brand name with the drug name."

67. Mrs Keenan advised that the dispensing error constitutes a severe departure from accepted standards. She said that as Mr D was responsible for completing the final check, "ultimate accountability is on him for not fulfilling this step adequately".

68. I agree. I am critical that Mr D did not complete the final steps of the Dispensing SOP process adequately and failed to identify the error. I acknowledge that the environment in the dispensary on the day in question was busy, and that only Mr D and Mr E were present in the pharmacy when the error occurred. However, I do not consider that this mitigates Mr D's responsibility for the error.

Recording of error

69. Mr D was notified of the dispensing error on 29 Month2. The pharmacy told HDC that it was the responsibility of the Pharmacist in Charge to document the error on the patient record.

70. Mr D told HDC that he made a note in Mrs A's patient record that there had been a dispensing error on 10 Month2 and that he was to be alerted if the pharmacy was contacted about the error. However, this was in fact not recorded until 17 Month4.

71. Mrs Keenan noted that no documentation of the error occurred on 29 Month2 (when the pharmacy was first made aware of the error). She advised that she would expect this information to be recorded in the "events" or patient notes on the RxOne system, and that the failure to document this following the discovery of the error constitutes a moderate departure from accepted practice, as it meant that no follow-up was flagged in the system.

72. I agree. I am concerned that as the Pharmacist in Charge, Mr D did not record the error in Mrs A's patient file immediately following notification by the hospital.

Apology

73. Sadly, Mrs A died before receiving a written apology.

74. Mrs Keenan stated that due to the serious nature of the error, the failure to provide Mrs A with a formal apology was a moderate departure from the accepted standard of care. She advised: "[A] written formal apology should occur in these situations and a staff member could have done this in [Mrs A's] native language."

75. I agree. I acknowledge that a formal written apology was provided to Ms B via email on 25 Month5 (approximately three months after the dispensing error). The apology contained an explanation for the delay, stating that it had not been sent as Ms B had indicated that she was not in the right mindset to speak to staff at the pharmacy. The pharmacy also told HDC that the delay in providing the written apology to Ms B was because they wanted to meet with her to discuss the matter in person.

76. As Mr D was the Pharmacist in Charge at the time the error occurred, and the SOP stipulated that it was the responsibility of all pharmacists to provide the apology, I am critical that Mr D did not provide Mrs A with a written apology upon becoming aware of the dispensing error.

Conclusion

77. As the Pharmacist in Charge, Mr D was responsible for ensuring that he provided services of an appropriate standard to Mrs A, including complying with the pharmacy's SOPs and professional standards set out by the Pharmacy Council.

78. In my view, by failing to complete the final check of the medication adequately (in that he did not identify the medication error), Mr D did not follow the Dispensing SOP or the PCNZ Competence Standards (2015) correctly. Further, by failing both to record the error on Mrs A's patient file adequately and to provide a written apology to Mrs A upon becoming aware of the error, Mr D did not follow the Managing Dispensing Errors SOP. Accordingly, I find that Mr D breached Right 4(2) of the Code of Health and Disability Services Consumers' Rights (the Code) in failing to provide services in accordance with professional standards and the SOPs.

Opinion: Mr C — adverse comment

Introduction

79. Mr C owned and operated the pharmacy as a sole trader from 1 Month1 to 30 Month3. Mr C owned the pharmacy when the dispensing error occurred on 10 Month2.

80. On 10 Month2, Mr E processed Mrs A's owing medication in the computer system and dispensed the incorrect medication. Mr D completed the check of the medication prior to it being handed over to Ms B (who collected it for her mother). Mr D failed to identify that Mrs A had been mistakenly dispensed 100 cyclosporin 50mg capsules instead of the owing 100 mycophenolate 500mg tablets.

81. As part of my assessment of this complaint, I obtained independent advice from pharmacist Mrs Catherine Keenan (Appendix A).

Management of dispensing error apology

82. The pharmacy was alerted to the dispensing error by the hospital on 29 Month2. A verbal apology was offered by a staff member at the pharmacy who spoke Mrs A's native language. Mrs Keenan advised that a verbal apology in a timely manner is accepted practice and would be viewed favourably. I agree.

83. The pharmacy said that when the staff member apologised to Mrs A, she offered to call Mrs A's doctor and provided the contact details of the pharmacy. The pharmacy told HDC: "After [Mrs A] had been verbally apologi[s]ed to and subsequently accepted the apology, the pharmacy had assumed the matter was closed."

84. Mrs Keenan was concerned that Mrs A was not provided with a time frame on when follow-up, a formal apology, or further communication would occur. Mrs Keenan advised:

> "Accountability is important and can give comfort to the customer that further information will be forthcoming and that the issue is being taken seriously. In this situation the accountability was put back on the patient to follow up if 'something happened'."

85. Mrs Keenan advised that the SOP for Managing Dispensing Errors was inadequate as there was no timeframe to ensure accountability after hearing or documenting the error for the first time. She stated that there should be a step that indicates a timeframe (eg, 7–10 working days) to give a formal response to the consumer, and also a step that asks the consumer what they would like to happen in the first instance. She said that the SOP needed to make the full process very clear for when verbal and formal apologies are given, and the timeframes for each. Mrs Keenan advised:

> "Waiting for contact from the patient to initiate the next steps, rather than following up with at least some more formal response is, in my opinion, a mild departure from accepted practice."

86. I agree. While I consider that the provision of an apology was the responsibility of individual staff members, I am concerned that the SOP did not stipulate clearly how or when this should occur or specify a timeframe for when a consumer could expect a formal response to their complaint. I note that the pharmacy has now inserted timeframes into this SOP, and I remind Mr C of the importance of having a clear and robust policy for managing dispensing errors.

Support provided to staff

87. On 30 Month2, a staff meeting took place to discuss the dispensing error. Mrs Keenan advised that this is accepted practice and would be viewed favorably by peers. She stated:

> "Discussions have included steps to take to ensure items are separated on the shelf and an extra check being made on Cytotoxic/narrow therapeutic index medications. Providing evidence of this with photos of the shelves and extra signatures on prescriptions/documents would give comfort to the customer concerned. Giving all staff an opportunity to discuss the impact of the error on their own wellbeing in a safe and non-judgmental way is extremely important in these circumstances."

88. The pharmacy told HDC that this meeting constituted its Root Cause Analysis. The meeting minutes mention "busyness" in the dispensary and pharmacy. However, there is no mention of what support has since been provided to staff members, particularly those who were affected by the dispensing error. Nor was there any mention of how pressure, workflow and distractions can be better managed when it is busy. Mrs Keenan considered this a mild departure from accepted standards. She advised:

> "[W]hile I understand these discussions can be difficult and time intensive, it does go towards providing a safe and more enjoyable workplace culture if staff feel supported and encouraged to speak up."

89. I accept Mrs Keenan's advice. I acknowledge that since these events, the pharmacy has reflected on its staff support.

Conclusion

90. I have made some criticisms about the care provided to Mrs A by the pharmacy. In particular, that Mrs A was not provided with a time frame on when follow-up, a formal apology, or further communication would occur, and that the SOP for Managing Dispensing Errors was inadequate. In addition, there was a lack of discussion in the Root Cause Analysis about how pressure, workflow and distractions can be better managed in the dispensary when it is busy. While I have identified some shortcomings in the care provided by the pharmacy, I do not consider that they amount to a breach of the Code. However, I encourage the pharmacy to reflect on my comments and those of my advisor.

Opinion: Mr E — adverse comment

91. On 10 Month2, Mr E was an intern pharmacist at the pharmacy working under the direct supervision of Mr D. Mr E was an experienced intern and was only one month away from sitting his final exams. The pharmacy's job description for an intern pharmacist stated that the key responsibilities included "assist[ing] the pharmacist with the operation of the dispensary, including dispensing, administrative duties and managing stock".

92. Mr E served Ms B when she presented to pick up Mrs A's "owing" CellCept medication on 10 Month2. The pharmacy told HDC that Mr E completed the following steps as per the SOP:

- All steps in the Dispensing SOP (except for the checking).
- Steps 8–16 in the Repeat Dispensing SOP.
- Step 8 (the only step necessary) of the Dispensing "owings" SOP, which included processing the repeats/owing form.

93. Mr E stated that it was busy in the dispensary at the time of dispensing Mrs A's medication. He said that he processed the prescription on the computer, produced a label, and selected and labelled the medication for Mr D to check.

94. Mr D had ultimate responsibility for checking the medication before it was given to Ms B. However, Mr E also failed to follow the Dispensing SOP adequately — in particular, part 26 and part 31 of the SOP. Mr E failed to select the correct medication, and he failed to check the dispensed medication against the prescription adequately.

95. My independent advisor, pharmacist Mrs Catherine Keenan, advised that "[s]ome responsibility must also go on [Mr E] for selecting the wrong medicine and labelling it".

96. I accept Mrs Keenan's advice. I am critical that Mr E failed to select the correct medication and failed to check the dispensed medication against the prescription, resulting in the incorrect medication being given to Mr D to check. I encourage Mr E to reflect on my comments and those of my advisor.

Opinion: The pharmacy owner — adverse comment

97. The pharmacy owner took over ownership of the pharmacy from Mr C on 1 Month4 and, as such, is responsible for the actions of the pharmacy from that date onwards.

98. On 17 Month4, Ms B contacted the pharmacy to advise it of Mrs A's death. The pharmacy told HDC that the Charge Pharmacist apologised and asked if they could provide any assistance to Mrs A's family. The Charge Pharmacist also explained the meetings and processes that had been put in place to decrease the chance of an error reoccurring and offered to meet with Ms B. Attempts were made to contact Ms B on 11 and 18 Month5, and on 25 Month5 the Charge Pharmacist wrote to Ms B to apologise for the error.

99. The pharmacy told HDC that it does not consider that the delay in providing Ms B with a written apology was due to the relevant SOP not containing a timeline for this to occur. The pharmacy stated that it acted appropriately in regard to the apology, in that it verbally apologised to Mrs A and waited for her to contact the pharmacy again if she wished.

100. I note that HDC's independent advisor, Mrs Catherine Keenan, considers that whilst the initial follow-up was poor, once the pharmacy had been informed of Mrs A's death, "they appear to have stepped up their response". However, Mrs Keenan advised that the SOP for Managing Dispensing Errors was inadequate, as there was no mention of time frames to ensure accountability, and no step to ensure that the incident was resolved fully in the eyes of the consumer.

101. Mrs Keenan reviewed updated versions of the SOP and commented that the SOP still did not include time frames to ensure that consumers affected by errors were kept informed of any investigation in a timely manner. Mrs Keenan advised that a step should be added to indicate a time frame (eg, 7–10 working days) in which to give a formal response to the consumer, and also a step to ask what the consumer would like to happen in the first instance. Mrs Keenan said that the SOP needed to be very clear on the full process for when verbal apologies and formal apologies are given, and the time frames for each. She stated:

> "Waiting for contact from the patient to initiate the next steps, rather than following up with at least some more formal response is, in my opinion, a mild departure from accepted practice."

102. While I consider that the provision of an apology was the responsibility of individual staff members, I am concerned that the SOP did not stipulate clearly how or when this should occur or specify the time frame for when a consumer could expect a formal response to their complaint. I note that the pharmacy has now inserted timelines into this SOP, and I remind the pharmacy of the importance of having a clear and robust policy for managing dispensing errors.

Changes made

The pharmacy

103. The pharmacy told HDC that it made the following changes as a result of these events:

- A new system was implemented, requiring that all high-risk medications are subjected to a second pharmacist check, in addition to a dispensing check.
- Prompts have been set in the dispensing software to remind all team members of the extra steps as described above.
- Owing medications are now confirmed with the patient or person picking up medication on their behalf. This includes clarifying what they are taking, what it looks like, and how it should be taken — particularly if there has been a change in medication.
- The medications mycophenolate (CellCept) and cyclosporin have been physically separated on the shelves to prevent staff members from mistakenly selecting the wrong medication.

- Warning signs have been added to the shelves for similar-sounding medications (Look Alike Sound Alike — LASA medications) to prompt dispensing staff to double check the medication they have selected.
- Staff have been provided with additional training in relation to the above changes.
- External advice was sought on changes to the SOP for incident reporting.
- Clear timelines have been inserted into the SOPs. In particular, the pharmacy has updated its Managing Dispensing Errors SOP to include timelines for a response. This was published via the pharmacy owner's Professional Services Update in March, and this was provided to HDC.
- An internal procedure was developed to record and report on near misses in an easy and electronic way. This information was provided to HDC.
- The Root Cause Analysis process was formalised, and education was provided to staff on how to conduct a Root Cause Analysis. A professional services bulletin was issued on 1 Month5 to be used in the case of a serious dispensing or other error, and this document was provided to HDC.
- The pharmacy told HDC that it is committed to ensuring that errors are as limited as possible, and it continues to work alongside PDA to better its practices.

104. The pharmacy provided HDC with staff meeting minutes and evidence of staff training that show the ongoing implementation of the above changes.

Mr D

105. Mr D told HDC that he made the following changes as a result of these events:

- He reflected on the dispensing error and how it has affected him personally. Mr D provided this reflection to HDC.
- He discussed the error, and ways to deal with the error, with PCNZ.
- When dispensing, he now asks for a second set of eyes on all medication checks. Mr D told HDC: "This is helping me to build back up my confidence after the dispensing error and provides an additional check on medications before they reach a patient."
- He created and implemented a new dispensary meeting minutes template, which was implemented in all the company's pharmacies. The template was provided to HDC.
- He organised the installation of automated dispensing machines in other pharmacies within the company. This change aimed to reduce the workload for the individual pharmacist and reduce the likelihood of error.
- He changed roles within the pharmacy company and has "undertaken significant reflection and development in recent months, as demonstrated in his response to the HDC".

Recommendations

106. In light of the significant reflections and changes made by both the pharmacy and Mr D, I now recommend the following:

The pharmacy

a) Consider combining the Managing Dispensing Errors and Customer Complaints SOP with clear guidance for staff on how to manage and respond to dispensing errors, and report back to HDC within six months of the date of this report, with information about why this has or has not been implemented.

b) Conduct staff training on the dispensing and checking SOP and undertake a random audit of the dispensing and checking of medication of 20 prescriptions over a two-month period, to assess the compliance with dispensing and checking SOPs. The pharmacy is to report its findings to HDC within three months of the date of this report, along with any action plan to address any findings.

c) Use an anonymised copy of this report for education across all pharmacies in the company. The pharmacy is to report back to HDC with evidence that this has occurred, within six months of the date of this report.

Mr D

a) Provide a written apology to Ms B for the failures identified in this report. The apology is to be provided to HDC within three weeks of the date of this report, for forwarding to Ms B.

b) In my provisional report I recommended that Mr D complete the Improving Accuracy and Self-Checking Workbook provided by the Pharmaceutical Society of New Zealand and provide evidence of his completion of this to HDC. In response to the provisional report, Mr D provided evidence of his completion of this workbook in 2021. Accordingly, this recommendation is no longer required.

Mr E

a) Provide a written apology to Ms B for the failures identified in this report. The apology is to be provided to HDC within three weeks of the date of this report, for forwarding to Ms B.

b) Undertake further training on the pharmacy SOPs, in particular the Dispensing SOP, and provide HDC with a reflection on his learnings. This information is to be provided to HDC within three months of the date of this report.

c) Complete the Improving Accuracy and Self-Checking Workbook provided by the Pharmaceutical Society of New Zealand. Mr E is to provide evidence of his completion of this within six months of the date of this report.

Follow-up actions

107. A copy of this report with details identifying the parties removed, except the independent advisor on this case, will be sent to the Pharmacy Council of New Zealand, and it will be advised of Mr D's name.

108. A copy of this report with details identifying the parties removed, except the independent advisor on this case, 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: Independent clinical advice to Commissioner

The following independent advice was obtained from pharmacist Mrs Catherine Keenan:

"1st October 2021

Expert Advice Report

I have been asked to provide an opinion to the Commissioner on case number C21HDC00539. I have read and agree to follow the Commissioner's Guidelines for Independent Advisors, and I am not aware of any conflicts of interest.

Expert advice requested (in letter sent via email)
Please review the enclosed documentation and advise whether you consider the care provided to [Mrs A] by [the pharmacy] was reasonable in the circumstances, and why.

In particular, please comment on:

1. The adequacy and appropriateness of the services provided by [pharmacy] staff on 22 [Month1] and 10 [Month2], including in relation to the processing, checking, and dispensing of [Mrs A's] prescription. Where you identify any departures from accepted practice, please specify as appropriate whether you consider individuals responsible for such departures.
2. [The pharmacy's] management of the incident and follow-up actions taken including the adequacy of the incident reporting.
3. The adequacy/appropriateness of [the pharmacy's] SOPs.
4. Any changes [the pharmacy] has undertaken since these events, and whether you consider any further changes may be appropriate.
5. Any other matters you consider warrant comment.

For each question, please advise:

a. What is the standard of care/accepted practice?
b. If there has been a departure from the standard of care or accepted practice, how significant a departure (mild, moderate, or severe) do you consider this to be?
c. How would it be viewed by your peers?
d. Recommendations for improvement that may help to prevent a similar occurrence in future.

If you note that there are different versions of events in the information provided, please provide your advice in the alternative. For example, whether the care was appropriate based on scenario (a), and whether it was appropriate based on scenario (b).

The Commissioner is subject to the Privacy Act 1993 and the Official Information Act 1982, and your advice may be requested and disclosed under those Acts.

Having read over the documents provided by [the] investigator from the office of the Health and Disability Commissioner, I can provide the following information.

1. The adequacy and appropriateness of the services provided by [pharmacy] staff on 22 [Month1].

[Mrs A] has presented at [the pharmacy] on 22 [Month1], to collect her repeat for Mycophenolate 500mg tablets, along with other items that she also had repeats for. The pharmacy was only able to supply 20 of the Mycophenolate 500mg tablets as they did not have enough tablets in stock to give the full amount. This was documented in the patient file and on the label for the patient's benefit.

This is standard dispensing practice and often stock can run low for certain medications in a busy dispensary. There is no indication on how the patient was informed of the owing besides it being on the label. All medication dispensing on this date appears to be in line with [the pharmacy's] SOPs at that time, for dispensing, repeats, owing and cytotoxic medications. There is no departure from the standard of care or accepted practice on this day. Owing medications and communicating this to patients is relatively common in a pharmacy dispensary and would be viewed as normal practice by pharmacy peers.

Recommendations:
Ensuring there is adequate stock on hand to cover future dispensing of such important medications, would be a recommendation for the future. It seems that [Mrs A] had been regularly on this medication for some time from [the pharmacy]. Also, if resources allowed, perhaps offering to deliver medications that are owed — giving the dispensary staff more time to pack and check these medications and not having to do them under urgency if the patient comes into [the pharmacy] at a busy time.

2. The adequacy and appropriateness of the services provided by staff on 10 [Month2].

[Mrs A] (or her representative) has presented at [the pharmacy] on 10th [Month2] to obtain the 'owing' of 100 Mycophenolate 500mg tablets. There is no mention of how [Mrs A] (or her representative) requested this owing i.e., presented the previous box, asked verbally, or provided some other form of documentation.

The dispensary staff have then processed the owe supply as per their dispensing process. From the information provided to me, [Mr E], the intern pharmacist has processed (run through the computer) the owe and dispensed it (put the label on the product ready for checking Steps 26 to 30 of SOP at that time). The item was then checked by [Mr D] and released to the patient. There is no mention of how the medication was presented to [Mrs A] or who gave the medication to the patient, so I am unable to comment on the adequacy of this part of the service or if it followed the SOP.

The wrong medication was dispensed to the patient. The patient was dispensed 100 Cyclosporin 50mg capsules. This is a severe departure from accepted practice. The

wrong medication was selected by one staff member ([Mr E]) and then incorrectly checked by a second staff member ([Mr D]). The patient received a medication that had not been prescribed to her and would be viewed by pharmacy peers as inadequate service. The accepted practice is that a patient receives the correct medication that has been prescribed for them, and that it is appropriate and safe for them to take it.

The SOP states that the pharmacist does the final check. This has been done by [Mr D], so the ultimate accountability is on him for not fulfilling this step adequately. Some responsibility must also go on [Mr E] for selecting the wrong medicine and labelling it (not checking the medicine he was labelling as should be mentioned in SOP).

There is mention of it being a particularly busy dispensary and this incident happened at a busy time of day. While pressure can come on to the dispensary staff, training and procedures should ensure that no short cuts are taken, and distractions are minimised.

Distractions, workflow, workspace, and personal state (hunger, tiredness, stress) can all add to steps in the SOP being missed. There is a comment from both staff members involved in the incident that other staff had gone to lunch, and they were the only 2 staff in dispensary. It appears [Mr E] has asked [Mr D] to check this owing while he was in the middle of checking another prescription. This is not best practice. If there is a sole charge pharmacist at any time in the dispensary, other staff must be mindful of the safest way of checking and allow the pharmacist adequate time and space to do this.

The report on the environment in the dispensary at the time mentions 'a particularly busy day in [the pharmacy]' and that the pharmacist 'does not recall the error specifically. He believes he likely confused the brand name with the drug name'. This is a severe departure from accepted practice.

3. The pharmacy's management of the incident and follow-up actions taken, including the adequacy of the incident reporting.

There appears to be conflicting accounts from the documentation of how [the pharmacy] was notified of the error. The complaint to HDC by [Ms B] and the letter from [the lawyer] dated 17 June 2021 both state that the hospital pharmacy notified [the pharmacy]. However, the PDA report in [Month4] states that while the hospital pharmacy noticed the error — '[the pharmacy] was then called by the patient'. Whichever way it occurred; [the pharmacy] found out about this error on 29th [Month2].

The staff at [the pharmacy] have then been in touch with the patient straight away. [A staff member] who could speak in [Mrs A's] native language contacted her to discuss the situation. A verbal apology was given, and the staff member enquired about [Mrs A's] wellbeing. [Mrs A] indicated she was not feeling well at all and was in discussions with her doctor/s. The staff member has given the contact details of [the pharmacy] team to contact them if any ongoing issues. A verbal apology in a timely manner is accepted practice and would be viewed favourably by pharmacy peers.

No time frame was given to [Mrs A] on when any follow up, formal apology or further communication would happen. This is a moderate departure from accepted practice. Accountability is important and can give comfort to the customer that further information will be forthcoming and that the issue is being taken seriously. In this situation the accountability was put back on the patient to follow up if 'something happened'.

There does not appear to be any documentation of the error in the patient file on the 29th of [Month2]. This could be recorded in the 'events' or patient notes on RxOne. This meant no follow up was flagged in the system. This is a moderate departure from accepted practice. There should have been documentation in patient file to reflect on and a report sent to PDA at this time.

PDA report:
This was not done until 17th [Month4] which was 2 months after the dispensing error had been discovered and [the pharmacy] notified. Due to the serious nature of the dispensing error, this is a moderate departure from accepted practice. The SOP states a report will be done; however, no time frames are put in the SOP. Filing this report within a few days of the error being discovered would have meant a root cause analysis by both staff members involved ([Mr D and Mr E]) could have been initiated.

The completion of a root cause analysis by both staff members for the date and time of the error would've been helpful in this situation. Such a process allows the individuals to reflect on the work environment (space, noise, colleagues, customers), distractions (chatter, mobile phones, racing thoughts) and personal state (hunger, tiredness, stress, lack of training) to ascertain what other things need to be investigated or changed to improve the dispensing process.

Formal apology:
A formal written apology to the patient affected, [Mrs A], was never given. Due to the serious nature of the error, this is a moderate departure from accepted practice. Pharmacy peers would expect that even though English was [Mrs A's] second language, a written formal apology should occur in these situations and a staff member could have done this in [Mrs A's] native language.

A formal written apology was sent to [Ms B] via email on 25th [Month5]. This does state that there was a delay in sending the formal written apology due to [Ms B] mentioning 'you were not in the right mindset to speak to us about [Mrs A]'. It is my opinion that in this circumstance a formal written apology, delayed by 3 months, is a moderate departure from accepted practice. Pharmacy peers would also expect that a formal apology is given when a dispensing error occurs, in a kind and timely manner.

Staff meetings:
A staff meeting was held on 30 [Month2] to discuss this error, among other things, as can be seen from the documentation of that meeting. This is accepted practice and would be viewed favourably by pharmacy peers. Discussions have included steps to take

to ensure items are separated on the shelf and an extra check being made on Cytotoxic/narrow therapeutic index medications. Providing evidence of this with photos of the shelves and extra signatures on prescriptions/documents would give comfort to the customer concerned.

Giving all staff an opportunity to discuss the impact of the error on their own wellbeing in a safe and non-judgemental way is extremely important in these circumstances. While 'busyness' in the dispensary, and pharmacy in general, is mentioned numerous times in documents associated with the complaint, there is no mention of what support has been given to staff members affected by the error and how pressure, workflow and distractions can be managed when it is busy.

This is a mild departure from accepted practice and while I understand these discussions can be difficult and time intensive, it does go towards providing a safe and more enjoyable workplace culture if staff feel supported and encouraged to speak up.

(I note further documentation provided to me in November 2021 shows such reflection has taken place and is admirable. While difficult, it is surely helpful for all staff to be able to share their experience.)

The follow up on the initial error was poor. Once [the pharmacy] were informed of the death of [Mrs A], they appear to have stepped up their response. This includes using a legal team for communications with the patient's family. I am not tasked with reporting on the clinical aspects of this case. In my opinion there should have been more rigorous discussions and reporting done around the initial error when the parties concerned were notified about it in [Month2].

4. The adequacy and appropriateness of [the pharmacy's] SOPs.

[The pharmacy] has comprehensive SOPs for dispensing including the repeat SOP and Cytotoxic SOP. These standard operating procedures cover all aspects of the dispensing process. There is no date of when they were written and when they will be reviewed. This information may be kept on a separate schedule and was not provided to me. If these SOPs were followed step by step, then it would be difficult to make an error. I note that since the incident an extra step has been put into the Dispensing SOP. This is number 39 — to have a second pharmacist perform a second check for Cytotoxic/ narrow therapeutic index medications. This will give further confidence in the checking procedure for these medicines.

While the SOPs are comprehensive, there seem to be steps in the SOPs that were not followed by the staff. Perhaps further training and internal auditing will ensure that all steps are followed. This would be acceptable practice in any dispensary and evidence of such training and/or internal audit would surely give comfort to the family of [Mrs A].

The SOP for Managing Dispensing Errors does give full steps to follow. This SOP does appear to be inadequate as there is no mention of time frames to ensure accountability.

There is no step included to allow for follow up to ensure the incident is fully resolved in the eyes of the patient.

I would recommend that time frames be added in to ensure there is accountability and follow up on errors/incidents. This would be for Step 8 and Step 10. Best practice is to respond to any incident/error within 7 days, outlining any next steps being taken by [the pharmacy]. The procedure states that a PDA report form must be done but does not state 'by when'. If a PDA form is not being done for all errors/incidents, then this should be in the SOP.

There is mention of giving the customer a copy of Consumers' Rights (HDC) in this SOP. A recommendation would be to have these available in multiple languages and have the link to the PDF documents for 'Your rights in different languages' included in the SOP for reference:

https://www.hdc.org.nz/your-rights/your-rights-in-different-languages/

There has been an updated SOP on Managing Dispensing errors, but this still does not appear to have any time frames added in. This would add some accountability to the process to ensure patients affected by the errors are kept informed of any investigation in a timely manner.

5. Any changes [the pharmacy] has undertaken since these events, and whether any further changes may be appropriate.

Cytotoxic dispensing:
[The pharmacy] has instigated a second pharmacist check on all Cytotoxic medicines and Medicines with a narrow therapeutic index. Evidence of this (via photographs) would give staff and customers comfort that this is now an enforced part of the dispensing process. This, along with separating items on the shelves and labelling the shelves with extra cautionary warnings, will go a long way to ensuring such an error does not happen again.

Keeping a 'near miss' log, reflecting on this regularly and putting any steps in place to mitigate errors are all practices that are mandatory in pharmacy in NZ. These practices are audited by Medsafe on a regular basis. This appears to be happening at [the pharmacy] and is good, accepted practice. The reporting of this to staff is collated with all other [pharmacies in the group].

Owed medications:
Medication balances owed to a patient are now confirmed with the patient or person picking up the medication on their behalf. This includes clarifying what they are taking, what it looks like and how it should be taken. This is accepted practice in all NZ pharmacies and evidence of this would give comfort to customers and [Mrs A's] family.

Personal reflection:
Each staff member involved has given an account of what happened at the time and attempted to provide an explanation for the incident. While difficult, this is good practice and could be helpful for the family involved to see the process going forward and how it has affected the staff as well.

Staff training:
Staff training appears to be ongoing and is documented and signed by all parties. This is accepted practice. Follow up staff training has been comprehensive and involved all staff.

Incident reporting:
There is mention that the SOP for Incident reporting is being reviewed. All SOPs should have dates on them for when they are written and when they are reviewed. This may be kept on a separate document, and this was not provided to me, so it appears that there is no review date for SOPs.

* I note that in further documentation sent to me regarding updated procedures, some SOPs appear to have dates on them, and review dates included. This would be advisable for all the SOPs, although this may be kept electronically. The SOP should have the date it has been reviewed and the next date for review.

The incident reporting SOP needs to make it very clear what the full process is and when verbal apologies are given, when formal apologies are given and time frames for each. There also needs to be accountability included as to who is following up and by when. Documentation in the patient file for all incidents/errors that leave [the pharmacy] should be compulsory. Staff training on the new SOP should be extensive and documented.

Responding to errors in a timely manner:
This did not happen in the case of the initial dispensing error and should become part of the new process for reporting incidents in the future, by having set time frames in the SOP.

Obtaining information from PDA about Root Cause analysis and how such a process can aid pharmacy staff would be recommended. This allows individuals to really break down the process that led up to the error and highlight any areas of concern, whether that be workplace issues or personal issues. Such analysis does show customers how seriously errors are taken.

Internal audit and documentation of checking process:
I would recommend that the dispensary team regularly do an internal audit to check all steps in the SOP are being followed. This would be particularly helpful with new staff members or if staff have come back from extended leave or are newly qualified.

6. Any other matters

This has been a harrowing and upsetting event for all concerned. Nobody comes to work expecting to make a mistake or error in dispensing. Unfortunately, the consequences of mistakes can be physically and mentally damaging. I certainly have some empathy for the dispensary staff, and I do hope that by reflecting on this mistake it will improve their practice in the future.

I am saddened to hear that [Mr D] has stepped away from a role in the dispensary. I can understand this would be a very stressful experience and he would have lost his confidence. I do hope he is able to see a way back to being a dispensing pharmacist, with guidance and support in the future.

Near Miss log and reports:
I note that the Near Miss report is a Shared Group Learnings report and is a list from all [pharmacies in the] group. I wonder if each store does their own reporting and reflection on the near misses that relate to that particular dispensary?

Whilst learnings can be identified when reading a report like this, having more specific reporting pertaining to their dispensary, that staff discuss would perhaps be more beneficial. Teams are then able to 'drill down' into whether circumstances that particularly relate to their workplace are coming into play. These can be things like lean process, workflow, staff numbers, lack of training, distractions, and customer demand. Actions taken in one store may not be of any significance to another store when the human element is brought into play.

Regards

Mrs Catherine Keenan
Pharmacist/Owner
Vivian Pharmacy Ltd
95 Vivian Street
P.O. Box 870
NEW PLYMOUTH"

The following further advice was received from Mrs Keenan on 15 May 2022:

"Having read through the documentation that has been sent from the Health and Disability Commissioner for reference 21HDC00539 I have the following comments to make.

There have been numerous iterations of the 'Managing Dispensing Errors' SOP. Even on Version 4 of this document there is no mention of a time frame to get back to the patient after hearing or documenting the error for the first time. I feel there should be a step that indicates a time frame (e.g., 7–10 working days) to give a formal response to the client and a step that asks the patient what they would like to have happen in the first instance.

The business does not have to agree to the request by the patient, but they should seek this information from the client when the error is first discovered. Then a response can be considered and delivered in the time frame indicated in the SOP. This can give the patient a voice in the first instance and often reduces the chances of a complaint escalating.

I note that the 'Customer Complaint' SOP does mention about a time frame and getting back to the client with an outcome. Perhaps these two SOPs could be combined? I understand sometimes the discovery of a dispensing error may not escalate to a complaint (just documented for information), however a response to the client should still be done and within a certain time.

I was encouraged by the information on the documenting of Near Misses. I see there is a clear process for this in each store which is then fed into a central reporting system. Learning from Near Misses is vitally important for day-to-day management of 'best dispensing practice'.

I wonder how easy it is to document these Near Misses at the time of their occurrence, considering this is a busy dispensary and the recording of these requires setting time to do the data entry and recording.

Regular meetings about near misses and how to avoid is also encouraging.

The Professional Services Update sent out to staff is excellent, easy to read, and gives a good example that staff can relate to and learn from. This would encourage staff to speak up if they felt a situation was not safe or not working.

There is genuine remorse and sadness for what has happened to [Mrs A] and the reflections from the staff show that there has been learning from this situation.

Response to questions in email from HDC:

Whether there is mention of how [Mrs A] or her representative requested the owing prescription on 10 [Month2] (i.e., presented the previous box, asked verbally, or provided some other form of documentation).

There is no recall from [the pharmacy] on how this occurred so I can provide no further comment on this part of the service.

Whether there is mention of how the medication was presented to [Mrs A] or who gave the medication to the patient (as you were unable to comment on the adequacy of this part of the service or if it followed the SOP).

There is no recall from [the pharmacy] on how this occurred so I can provide no further comment on this part of the service. In some pharmacies, handing out the medication to the patient is another point where the medication can be checked for accuracy — if this is done by dispensary staff to the patient themselves.

> The conflicting accounts from the documentation of how [the pharmacy] was notified of the dispensing error.
>
> There is clear information and clarity now that the Hospital Pharmacy staff were the ones to alert [the pharmacy] to the dispensing error.
>
> The date of writing of all SOPs, and the date for next review.
>
> This appears to follow a documented process for each store. I understand there is a schedule for each store, that shows when SOPs are up for review. The dates do not appear on the forms as they will be a template from head office and each store could have a different review date and publishing date. If this meets audit requirements, then I am satisfied this is appropriate and evidence can be provided that reviews occur, and dates are documented and available.
>
> Whether each [pharmacy in the group] does their own reporting and reflection on the near misses that relate to that particular dispensary.
>
> The documents state that this happens and there is a SOP to indicate how this is done. I am mindful that going back into the dispensing software to note a Near Miss can be time consuming, especially in a busy dispensary. If the dispensing team feel this system works well and does not impact workflow too much, then I am satisfied with the explanation. I see from regular meeting notes that the LASA medicines and near misses have been top of mind and widely discussed which is pleasing."

The following further advice was received from Mrs Keenan on 6 August 2022:

> "This was my response in the initial advice.
>
> The staff at [the pharmacy] have then been in touch with the patient straight away. [A staff member] who could speak in [Mrs A's] native language contacted her to discuss the situation. A verbal apology was given, and the staff member enquired about [Mrs A's] wellbeing. [Mrs A] indicated she was not feeling well at all and was in discussions with her doctor/s. The staff member has given the contact details of [the pharmacy] team to contact them if any ongoing issues. A verbal apology in a timely manner is accepted practice and would be viewed favourably by pharmacy peers.
>
> No time frame was given to [Mrs A] on when any follow up, formal apology or further communication would happen. This is a moderate departure from accepted practice. Accountability is important and can give comfort to the customer that further information will be forthcoming and that the issue is being taken seriously. In this situation the accountability was put back on the patient to follow up if 'something happened'.
>
> Now that there are time frames in the procedures, and it aligns with the Code of Health and Disability Services Consumers' Rights, this is an acceptable outcome.

I agree that I have used the word 'respond' to the complaint, rather than 'acknowledge' and stated 7 days, rather than the 5. This would cause me to rethink the departure from accepted practice to now be mild instead of moderate.

Waiting for contact from the patient to initiate the next steps, rather than following up with at least some more formal response is, in my opinion, a mild departure from accepted practice.

I appreciate the steps that [the pharmacy] have taken in this regard. Their improvement of the SOPs and recording of Near Misses will no doubt add to the smooth and effective running of their dispensary."

Appendix B: The pharmacy SOPs

"Dispensing SOP

Processing prescriptions in RxONE

18. Enter the patient name

…

20. Enter medication details.
    - Choose correct form
    - Choose correct strength
21. Enter the quantity of medication required.
    - If full quantity is unavailable ensure that the owing procedure is followed

…

23. Press the *Finish* button to generate labels and repeats, generate multiple labels where appropriate.
24. Stamp the prescription with [the pharmacy] stamp that is set to the current date.
25. Annotate each medicine on the prescription.

Dispensing medication

26. Select the medication from the appropriate location in the dispensary, or extemporaneously compound using the original prescription.
    - Ensure the correct:
        - Active ingredient
        - Strength
        - Dosage form
        - Brand (if not interchangeable)

…

28. Count or measure the correct quantity of medication and place in an appropriate container.
29. Place the label on the container.
    - Label should be:
        - Straight
        - Centered
        - Clean
        - Legible
        - Does not cover batch or expiry on original packaging if applicable

…

31. Check the dispensed medication against the original prescription.

…
    - Medication;
    - Strength;
    - Quantity;
    - Dosage form;
    - Brand

…

- Sign right hand side of the stamp on the prescription to indicate that the dispensed medication has been checked against the prescription.

32. If non-pharmacist dispensing — place the medicine, prescription, healthcare cards, and any prescription owing forms in the prescription basket and place in the designated prescription checking area located on the dispensary bench.

…

Checking the dispensed medication

34. The pharmacist will confirm the following details are correct:
    - Patient;

…

    - Medication;
    - Strength;
    - Quantity;
    - Dosage form;
    - Brand;

35. Pharmacist will ensure that there are no interactions or contraindications.
36. Pharmacist will ensure that the medication dispensed is therapeutically appropriate.
    - Correct dose;
    - Correct dosage form;
    - Correct medication for the indication.

37. Any errors will be corrected by the checking pharmacist prior to handing the medication out to the patient. All near misses are to be recorded electronically. See SOP *P5.3 — Recording, Reviewing Near Misses.*
38. When the pharmacist is satisfied that the dispensed medication is correct they will initial the bottom left corner of the dispensing label."

"Repeat Dispensing SOP

Processing repeat prescriptions in RxONE

…

8.Enter the patient name

…

9. Select the repeat prescriptions the patient would like dispensed from the patient history screen and click *Next.*
10. Confirm the following details for each repeat prescription processed:
    - Medication;
    - Medication strength;
    - Medication dosage form;
    - Quantity;

      …
    - Medication and dosage are therapeutically appropriate.

…

14. Press the *Finish* button to generate labels and certified repeat copies.
15. Certified repeat copy is signed and dated by the pharmacist.

…

16. If a sole pharmacist on duty is to leave the premises to use the bathroom facility, then they must inform other key dispensary and retail staff of their absence. No repeats are to be given out until the sole charge pharmacist returns."

"Managing Dispensing Errors SOP

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2. At all times remain calm, empathetic and co-operative. Show concern and willingness to correct any error.

3. Determine the following:

- Has any of the incorrect medication been used?
- Has any medication been missed?
- Has any harm been suffered?
- Has any expense been incurred?

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5. Give the customer a copy of Consumer's Rights (HDC) so they are aware of their rights for raising a complaint.

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7. Show empathy with the patient. This gives them the opportunity to vent their feelings, so you might learn where you truly stand.

8. Advise that you will investigate how this occurred and take action to tighten procedures. Obtain a phone number and show an interest in the welfare of the patient.

9. Contact the Dispensary Area Manager so they are aware of the error.

10. Fill out all details on the PDA approved Dispensing Incident Form. Print, do not handwrite the form.

11. PDA Incident form is available for download from PDA's website

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12. LOG THE INCIDENT ON THE VPN.

- See SOP *P5.9 — Logging an incident report*
- Include all relevant details pertaining to the incident. These notes may be extremely important in any subsequent defence of a claim.
- Make a copy for your own personal record.
- Make a note in the patient's dispensing history.

13. Notify [the pharmacy] Owner AND [the pharmacy] Manager and dispensing pharmacist if relevant.

…

15. The dispensing pharmacist must notify Pharmacy Defence Association (PDA) and report the problem. You will be advised of what further action to take.

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- It is important that you report any incident where the wrong drug or wrong dose has been ingested, as a claim could be lodged at some further date.

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20. Filled out Incident forms are printed and kept in the 'Quality Improvement' folder under 'Incident/Error' tab."