Pharmacist A

Pharmacy

A Report by the

Deputy Health and Disability Commissioner

(Case 20HDC00979)

Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

Contents

Executive summary

1. A four-week-old baby was prescribed omeprazole oral liquid (to reduce stomach acid) by her GP. The prescription was dispensed by a pharmacist.

2. Owing to a number of errors, the baby's omeprazole was contaminated with methadone. The baby was taken to hospital unresponsive but ultimately survived.

3. This report highlights the importance of adherence to professional guidelines and pharmacy standard operating procedures. In failing to adhere to the guidelines and procedures, the pharmacist did not dispense methadone safely, and failed to carry out the appropriate checks in the dispensing process, leading to the error in dispensing the baby's medication.

4. Pharmacy staff made a number of errors, and elements of the pharmacy's environment contributed to the error. The report also discusses failings in the management of the dispensing error after it was discovered.

Findings

5. The Deputy Commissioner found that by failing to dispense the methadone in a safe and appropriate way, by failing to check the final product given to the mother, and in mismanaging the dispensing error, the pharmacist did not provide services to the baby in a manner consistent with professional standards and competent pharmacist practice, in breach of Right 4(2) of the Code.

6. The Deputy Commissioner identified multiple errors in the pharmacy's dispensing practice, which amounted to a service delivery failure for which ultimately the pharmacy was responsible. Therefore, the Deputy Commissioner found the pharmacy in breach of Right 4(1) of the Code.

7. Adverse comment was made regarding a pharmacy technician's adherence to the pharmacy's SOP.

Recommendations

8. The Deputy Commissioner recommended that the pharmacist complete the "Addictions and opioid substitution therapy" course prior to providing further opioid substitution therapy services, and complete the "Improving accuracy and self-checking" workbook provided by the Pharmaceutical Society of New Zealand should the pharmacist remain actively in practice.

9. The Deputy Commissioner recommended that the pharmacy technician complete the "Improving accuracy and self-checking" workbook provided by the Pharmaceutical Society of New Zealand.

10. The Deputy Commissioner has referred the pharmacist to the Director of Proceedings for the purpose of deciding whether any proceedings should be taken.

Complaint and investigation

11. The Health and Disability Commissioner (HDC) received a complaint from Mrs B about the services provided to her baby by Pharmacist A. Pharmacist A owned the pharmacy. The following issues were identified for investigation:

- *Whether the pharmacy provided Baby B with an appropriate standard of care in June 2018.*
- *Whether Pharmacist A provided Baby B with an appropriate standard of care in June 2018.*

12. This report is the opinion of Deputy Commissioner Dr Vanessa Caldwell, and is made in accordance with the power delegated to her by the Commissioner.

13. The parties directly involved in the investigation were:

Pharmacist A	Provider/pharmacist
Baby B	Consumer
Mrs B	Complainant/consumer's mother
Provider/pharmacy	

14. Also mentioned in this report:

Technician C	Dispensary technician
Technician D	Dispensary technician

15. Further information was received from:

Technician E	Dispensary technician
Pharmacy Council of New Zealand	Regulatory body
ACC	New Zealand Crown entity
District health board	

16. Independent expert advice was obtained from a pharmacist, Ms Sharynne Fordyce (Appendix A).

Information gathered during investigation

Background

17. Baby B (aged four weeks at the time of events) was prescribed omeprazole oral liquid[1] by her family doctor for colic.[2] On 5 June 2018, Mrs B presented the repeat prescription to the pharmacy. This case concerns the dispensing of methadone,[3] which accidentally was mixed with Baby B's prescribed omeprazole.

Dispensing error on 5 June 2018

8.25am — methadone dispensing and pharmacy opening

18. The pharmacy was due to open at 8.30am. On the day of the event, the pharmacy was staffed with one pharmacist and four pharmacy technicians, who started on a staggered basis. Around 8.25am, sole charge Pharmacist A[4] arrived at work to prepare methadone for a visiting patient before the pharmacy opened and before the computers were turned on.

19. Pharmacist A told HDC that at the time of events, the pharmacy did not have a regular methadone client base. However, the pharmacy was supplying methadone to a patient for two weeks while the patient was visiting the area. The patient habitually presented to the pharmacy at 8.35am to receive his daily methadone dose. To reduce interruptions, Pharmacist A's usual process for dispensing for this patient was to measure and pour the methadone into a 30ml bottle before the pharmacy opened, so that it would be ready for consumption when the patient arrived. On 5 June 2018, the visiting patient did not present to the pharmacy at the usual time.

20. Pharmacist A poured 6ml of methadone 5mg/ml liquid into an unlabelled 30ml bottle. He told HDC that he could not enter this dispensing through the computer until the patient appeared for his "consume on premises" dose. Before completing the dispensing process and returning the measured methadone to the safe, as per Pharmacist A's usual practice, Pharmacist A was distracted and had to attend to a jammed door at the entrance of the pharmacy. He placed the unlabelled 30ml bottle containing methadone on top of the methadone prescription, and left it on the dispensary bench.[5]

21. Upon his return to the dispensary, Pharmacist A was occupied with an influx of prescriptions to dispense. The unlabelled 30ml bottle containing methadone remained on the dispensary bench.

22. The pharmacy was unusually busy that day because it was the first day back after a long weekend, and one pharmacist and one pharmacy technician were absent due to illness.

[1] Omeprazole reduces stomach acid.
[2] Colic describes the frequent or prolonged crying or fussing of an otherwise healthy baby for no clear reason.
[3] Methadone, a synthetic opioid, is a controlled drug used to help people who are addicted to opioid drugs. Some patients on a methadone treatment programme are required to consume their daily dose of oral methadone under supervision (often at a pharmacy).
[4] Pharmacist A is also the owner and a director of the company that operates the pharmacy.
[5] An area dedicated to the dispensing of prescription medications.

9.00–9.30am — movement of methadone bottle

23. Between 9.00am and 9.30am the dispensary was busy. In a note written on the day of the incident, pharmacy technician Technician D stated that she moved the bottle containing the methadone, and the prescription on which it was sitting, further to the right of the dispensary bench to give herself more working space. Technician D later stated to HDC that at the time, she was not aware of any methadone on the bench. Technician D accepts that she moved a bottle, but it appears that at the time she was unaware that it contained methadone.

24. Pharmacy technician Technician C started her shift at 9.00am. Technician C told HDC that she was never made aware of the unlabelled bottle of methadone left on the dispensary bench. Pharmacist A cannot recall whether any of the dispensary technicians working that day were aware of the bottle of methadone.

11.00am — prescription for omeprazole

25. At or around 11.00am, Mrs B dropped off Baby B's repeat prescription for omeprazole liquid. The medication had to be compounded,[6] as there were no commercially available products. Technician C made up the medication on the compounding bench,[7] which is an area separated from the dispensary bench by a large sink. While the omeprazole was still in the measuring cylinder, Pharmacist A checked that the final volume was 28ml and that the medication used was correct.

26. Technician C then inadvertently poured the omeprazole liquid into the 30ml bottle containing the methadone prepared by Pharmacist A earlier.

27. Technician C is unable to recall the area from which she picked up the bottle on the day. She considers that it would have been an instinctive action to pick up a 30ml bottle from the basket below the compounding area, rather than to reach for a bottle that was located a few steps away on the dispensary bench, where the bottle containing the methadone was last seen. It is unclear how the bottle containing methadone came within Technician C's reach.

28. Technician C told HDC that she did not rinse the bottle with water prior to filling it with omeprazole, nor was she aware that this was a requirement. However, Pharmacist A told HDC that part of a general pharmacy technician's training is that bottles should be rinsed and cleaned with water prior to use.

29. Technician C stated that the 30ml bottle used was an opaque plastic bottle without demarcation lines, making it hard to examine the contents. She recalls thinking briefly that after pouring the medication, the volume sat higher up on the neck of the bottle than usual, but because she was so busy that day, she did not question it further.

[6] Compounding is the preparation of a custom formulation of a medication to fit a unique need of a patient that cannot be met with commercially available products.
[7] An area in the pharmacy designated to the compounding of medications.

30. The bottle was then labelled and placed in the fridge, ready for collection. Technician C told HDC that the job sheet was signed off by Pharmacist A at this point, which was deemed a final check of the medication. However, Pharmacist A stated that he signed the job sheet when he confirmed that the volume of the omeprazole was 28ml when it was still in the measuring cylinder. He said that his normal checking procedure required a separate check of the final product and volume once the ingredients had been combined. Pharmacist A did not undertake this separate check.

31. The pharmacy's standard operating procedure (SOP) E17.1 provides that if a pharmacy technician is undertaking compounding, a pharmacist must check and sign off the measurement of each starting material, and the pharmacist must sign off the compounding worksheet once the compounding, labelling, and checking has been completed. SOP E14.1 requires that labels and dispensed medications should be checked against the original prescription, and that wherever possible the check should be done by a second person. The SOP states that it is necessary to "initial each item on the prescription to indicate the prescription has been checked for completeness by a pharmacist and passed for accuracy".

32. Mrs B picked up her baby's dispensed medication between 11.00am and 11.30am. Pharmacist A did not check the medication, and was not aware that it had been dispensed. Pharmacist A told HDC that he should have undertaken a final check of the medication.

11.30am–12.00pm — discovery of error

33. Between 11.30am and 12.00pm, Pharmacist A noticed that the bottle containing methadone that had been on the dispensary bench was missing. Pharmacist A told HDC that he took immediate steps to locate it. The rubbish bin was searched, and another pharmacy was contacted to see if the methadone had been delivered there as part of an order. It was at this stage that Pharmacist A began to query whether there had been a dispensing error, because during this timeframe, two items had been dispensed into a 30ml bottle — the omeprazole for Baby B, and the methadone.

Subsequent events and actions following discovery of error

34. Between 12.30pm and 1.00pm,[8] a dose of omeprazole was given to Baby B, who started to breathe abnormally, with periods of not breathing. Baby B then became unresponsive, and Mrs B began CPR and called an ambulance at 1.22pm.

35. The pharmacy told HDC that at around 12.30pm, Technician C obtained the family's landline number from Baby B's prescription and called the number. Technician C told HDC that the call went to an answerphone, and she left a voice message asking to be called back urgently.

36. In response to the provisional opinion, Mrs B provided a recording of a voicemail left on her mobile at 1.29pm by Technician C. Mrs B said that this voicemail did not show up on her mobile phone records, because she was on the phone to emergency services at the time.

[8] In response to the provisional opinion, Mrs B submitted that she gave Baby B the omeprazole closer to 1.00pm.

The voicemail makes no reference to the need for Mrs B to call back urgently. Mrs B confirmed that this was the first call she received from the pharmacy on 5 June.

37. The pharmacy told HDC that at 1.00pm, realising that no one had returned her call, Technician C contacted the medical centre to obtain Mrs B's mobile number. However, because of the family's common surname and recent address change, there was a delay in obtaining the number. Pharmacist A submitted in response to the provisional opinion that as the prescription was a repeat, the dispensing took place based on the details of the prescription that were recorded on the electronic dispensing system. Pharmacist A added that this is relevant when considering the delay in locating a phone number, as the original prescription needed to be found within the pharmacy's filing system.

38. The pharmacy stated that around 3.00pm, Technician C made a call to Mrs B's mobile number and again, the call did not go through, and Technician C left a voice message on the answerphone.

39. In response to the provisional opinion, Mrs B provided recordings of the voicemails that were left on her mobile on 5 June. In addition to the previously mentioned voicemail from Technician C at 1.29pm, there was one voicemail left by Pharmacist A (not Technician C) at 2.46pm. This voicemail requested a call back, although it did not convey any sense of urgency.

40. Mrs B told HDC that at the time she had her landline set up so that it rang through to her mobile. She added that on the day of 5 June 2018 she received only two calls from the pharmacy, at 1.29pm and 2.46pm — the two voicemails that were left.

41. Technician C told HDC that she realised that the dispensing error was an issue that required immediate attention, but she recalls that there was "no urgency" from Pharmacist A in trying to locate Baby B's family's contact details, and Pharmacist A told her that he was too busy. Therefore, Technician C dealt with the situation herself.

42. Technician C also told HDC that "no attempts were made [on 5 June 2018] by [Pharmacist A] to contact [Mrs B] himself". However, the voice recordings provided by Mrs B show that Pharmacist A did leave one voicemail at 2.46pm.

43. Pharmacist A said that he understood that Technician C wanted to assist by contacting Mrs B to explain the situation, and he considered that she would benefit from being a part of the process to rectify and address the error. Pharmacist A told HDC that in hindsight, Technician C may have interpreted this as an attempt to evade responsibility, but this was not his intention.

44. Pharmacist A explained that he believed that he and Technician C were working together to address the error and acted swiftly. He said that he appreciated the help, as the pharmacy was busy that day, and he continued to operate the dispensary as usual. Pharmacist A told HDC that any delay in contacting Mrs B was not due to a lack of acknowledgement of the urgency of the matter, but rather the difficulty in obtaining contact details. Mrs B told HDC

in response to the provisional opinion that she disagrees with Pharmacist A's statement, given the timing of the calls made, and the nature of the voicemail messages.

45. In his response to the provisional opinion, Pharmacist A reiterated that there were difficulties in obtaining Mrs B's contact details, and the phone number that was obtained for Mrs B had a different address to the address on the prescription record for Baby B. Pharmacist A stated that due to the risk that the phone number was not correct, and being conscious of Baby B's privacy, the voicemails did not contain full details of the suspected dispensing error. While Pharmacist A acknowledged that a greater sense of urgency could have been conveyed, he considered that this needed to be balanced against the risk of causing unnecessary alarm and panic. Technician C noted in her response to the provisional opinion that she wishes she could have acted with more urgency, but she was not aware that there had been an unlabelled bottle of methadone on the dispensing bench until 12.45pm that day. Technician C then waited until 1.15pm for another pharmacy technician to return from lunch to ask if she had seen the bottle, and they then acted quickly. Technician C stated that she did not know if Baby B had been given a dose, and did not want Mrs B to panic. Technician C said that she felt overwhelmed and out of her depth, but did her very best to try to locate Mrs B.

46. The pharmacy told HDC that at around 3.30pm, Mrs B telephoned Technician C and told her that Baby B had stopped breathing and was in hospital. In her response to the provisional opinion, Mrs B stated that she checked her phone in the Emergency Department at around 2.56pm, and her phone records show that she called the pharmacy at 2.57pm. Having been informed that Baby B's prescription may have been contaminated, Mrs B then handed the phone to the paediatrician, who asked Technician C what was in the bottle of omeprazole. Technician C spoke to the paediatrician with Pharmacist A standing next to her relaying his suspicion that the omeprazole liquid contained methadone.

47. Pharmacist A later called the hospital to enquire about Baby B's health. The doctor called back between 4.15pm and 4.45pm, and informed Pharmacist A that Baby B had been treated appropriately and was stable in ICU.

48. A urine sample returned a positive result for methadone, and confirmed that Baby B had suffered a methadone overdose.

49. On 7 June 2018, two days after the incident, Pharmacist A sent a written apology letter to Mrs B.

50. Pharmacist A, with the assistance of the Pharmacy Defence Association,[9] also conducted a root cause analysis assessment of the event, to understand what had caused the error and to prevent it from happening again.

[9] A non-profit, pharmacist support organisation. Membership is designed to provide assistance to pharmacists in the event of professional indemnity, public liability, and statutory liability claims.

51. Pharmacist A told HDC that after the dispensing error, the pharmacy conducted two staff meetings — one on the day of the dispensing error, and the second on 4 July 2018, facilitated by the DHB.

Standard operating procedures

52. Copies of the relevant SOPs were provided to HDC, and extracts of these are included as Appendix B.

Further Information

Baby B's mother

53. Mrs B told HDC that it took her two years to make a complaint to HDC because of the immense stress caused to her and her family by the incident.

54. Mrs B sought financial compensation from Pharmacist A as a result of the dispensing error. The claim was resolved in a confidential settlement to reflect the significant impact of the incident on the family.

55. In response to the provisional opinion, Mrs B provided further information about the impact of the methadone overdose on Baby B and their family. Mrs B explained that Baby B was in hospital for 10 days and suffered significantly. Baby B's family were told in hospital that it would be some time before they knew the effects the lack of oxygen would have on Baby B's development, and they spent a considerable amount of time not knowing if Baby B would be brain damaged. Mrs B told HDC that Baby B has experienced health problems since the overdose, and her GP considers that these can be traced back to Baby B's treatment.

Pharmacy

56. The staff at the pharmacy have taken the dispensing error extremely seriously and found the incident deeply distressing.

Pharmacist A

57. Pharmacist A told HDC that he has been deeply affected by this incident, both personally and professionally. He wishes to acknowledge the devastating impact this incident has had on the family. He has carried out further work to ensure that this type of incident does not occur again.

58. Since the incident, Pharmacist A has chosen not to work in sole practice, and always works with another person.

Technician C

59. Technician C told HDC that she acknowledges the heavy impact that this incident had on Baby B and her mother, and the trauma that Mrs B went through.

60. Technician C said that she resigned on the day of the incident because of "immense stress". She has since changed her practice, and now double checks that a pharmacist has checked her processes and scripts.

Pharmacy Council

61. The Pharmacy Council of New Zealand conducted a preliminary enquiry into this dispensing error and found no competence issues with Pharmacist A's practice.

ACC

62. After reviewing the clinical information available on file, ACC accepted that a dispensing error had resulted in the accidental ingestion of methadone by Baby B.

Ministry of Health

63. Following the incident, the Ministry of Health carried out an audit at the pharmacy. The audit report stated that procedures for dispensing controlled drugs had been tightened, and it recommended a review of the pharmacy's SOPs for dispensing incidents.

Response to provisional opinion

Mrs B

64. Mrs B was given the opportunity to comment on the "information gathered" section of the provisional opinion. Where appropriate, her comments have been incorporated above.

Pharmacist A

65. Pharmacist A accepted that he made errors that contributed to the unfortunate hospitalisation of Baby B. In particular, Pharmacist A accepted that leaving the methadone unlabelled on the bench, rather than placing it in the controlled drug safe, was unacceptable.

66. Pharmacist A also acknowledged the delay in contacting Mrs B. He said that the lag between the initial landline message being left and the multiple attempts to locate Mrs B's mobile number is unfortunate.

67. Pharmacist A noted that the provisional opinion stated that he should have spoken to the paediatrician rather than Technician C when Mrs B returned the call. Pharmacist A submitted that although Technician C did answer the phone, he was next to her and participated in the discussion. He accepts that he could have taken over the call, but said that emotions were high and time was of the essence. Pharmacist A considers that Technician C was conveying the necessary information to Mrs B and the paediatrician. Later that day, Pharmacist A contacted the paediatrician personally to check on Baby B.

68. Pharmacist A submitted that the provisional opinion was unfairly critical of the delay in an apology. He noted that he attempted to contact Mrs B the day after the event but was unable to reach her. He made a similar attempt to contact Mrs B on 7 June 2018 but again was unsuccessful. Following these attempts he drafted a written apology and significant efforts were made to deliver this, including driving to the family home. Ultimately, he delivered the letter through the hospital. This was not done in response to media attention, and the letter had been drafted much earlier.

69. Pharmacist A stated that he did not hear further from Mrs B until 2019. He noted that since that time he provided a number of additional apologies, including an offer to meet in person, but he did not receive a response to the offers.

70. Pharmacist A submitted that he and his staff did not act deliberately to cause the dispensing error. There was considerable work pressure on the staff because there were unusually high workloads and an unexpected staff shortage. This was further complicated by the malfunctioning doors first thing in the morning.

71. Pharmacist A added that the provisional report states that pharmacy technicians are directly supervised by pharmacists, and that the ultimate responsibility for the dispensing error therefore lies with him. Pharmacist A accepts that he made errors on the day in question and is responsible for these. He also acknowledged that ultimately he is responsible for all dispensing in the pharmacy. However, he believes there is a distinction in relation to the separate error made by the technician, Technician C.

72. Pharmacist A said that prior to these events he had practised safely and competently for more than 30 years, and the error occurred almost four years ago. He stated that he has continued to practise without incident or restriction since the event. This includes the period during the pandemic, which placed unprecedented stress on all the community, and especially those in the health sector. Pharmacist A said that he navigated this time without further incident. He submitted that he is a safe and capable pharmacist, and that this error was an isolated one-off incident.

73. Pharmacist A said that these events have taken their toll, and he made the decision to retire from the profession. Pharmacist A stated that despite the time since the error, he remains deeply affected. He finds himself "constantly" going back to the events of 5 June 2018 in his mind. He considers that he has engaged fully with the Pharmacy Council, with Mrs B, and now with the HDC. He said that this process has continued the pressure, and is a key reason for his decision to retire.

Pharmacy

74. The pharmacy stated that a number of the recommendations contained in the provisional opinion have been completed. For example, the pharmacy updated its relevant SOPs following the incident, and HDC's independent advisor has indicated that the changes made since the incident were appropriate. The pharmacy also advised that it has continued with its commitment to ongoing practice improvements, including in relation to compounding training.

75. In response to the recommendation of HDC's independent advisor, Ms Fordyce, that the pharmacy's SOP be updated so that the phone number of patients is recorded on prescriptions, the pharmacy advised that there are practical difficulties with this approach.

76. The pharmacy is now under new ownership.

Technician C

77. Technician C reiterated to HDC the ongoing impact that these events have had on her.

Opinion: Pharmacist A

78. As a registered pharmacist, Pharmacist A was responsible for ensuring that he provided services of an appropriate standard to Baby B, including complying with the professional standards set by the Pharmacy Council of New Zealand and the Ministry of Health.

Dispensing error — breach

Methadone dispensing

79. On 5 June 2018, Pharmacist A dispensed methadone for a patient before the pharmacy had opened and before the computers had been turned on. He dispensed the methadone into a mission bottle[10] but did not label it because he could not enter the dispensing through the computer until the patient had arrived to consume his "on premises" dose. Pharmacist A then left the bottle on the dispensary bench on top of the prescription, to attend to other matters.

80. My pharmacy advisor, Ms Sharynne Fordyce, advised that the accepted practice for dealing with methadone dispensing is to process the dose through the computer, and to generate an appropriate label, including the dose, directions, name of the patient, and the date of dispensing. Ms Fordyce stated that to her knowledge, the dispensary computer systems used in New Zealand pharmacies are capable of generating labels before the customer is present in the shop. The methadone dose would then be measured and poured into an appropriate mission bottle, and labelled and stored in the safe until needed. Ms Fordyce considers Pharmacist A's dispensing of methadone to be a severe departure from accepted practice, specifically because Pharmacist A left the bottle unlabelled, and did not store it in the safe. Ms Fordyce pointed out that if the unlabelled methadone had not been present on the bench, the incident would not have occurred.

81. I understand that the pharmacy's SOP on Controlled Drug Dispensing in place at the time did not include a requirement to store controlled drugs in the safe. After this event, the pharmacy introduced SOP D11, which states:

> "[A]ll completed controlled drug prescriptions are to be placed in a snap lock resealable plastic bag with the prescription and kept in the locked safe. The receipt with 'safe' written on it is placed on the 'completed with query's' prescriptions glass shelf above the bench."

82. While this SOP was not in place at the time of events, I note that Ms Fordyce advised that knowledge of the storage requirements for controlled drugs is an expected part of a pharmacist's practice.

83. I also note that the Ministry of Health's "New Zealand Practice Guidelines for Opioid Substitution Treatment 2014" 9.3.6 (Dispensing errors) states:

[10] A type of bottle used by pharmacists to package liquid medication.

> "Pharmacists must have procedures in place to minimise the chances of an error in dispensing. If a client receives a higher than normal dose of methadone, the potential for complications, including death, may be high."

84. It appears that Pharmacist A did not have in place procedures to minimise the risk of an event such as this. Leaving the methadone on the bench contributed to Baby B receiving a potentially deadly dose of methadone, as opposed to the prescribed omeprazole. I consider that this breached the Ministry of Health Guidelines.

85. I accept Ms Fordyce's advice in relation to Pharmacist A's dispensing of methadone. Pharmacist A was handling a controlled drug, which warranted a number of careful steps when dispensing. Pharmacist A's failure to label and store the methadone appropriately was careless and unsafe, and was the first of the errors that resulted in the dispensing error. Knowledge of the storage requirements for a controlled drug is expected of a competent pharmacist, and professional standards also required Pharmacist A to implement procedures to ensure the careful dispensing of methadone. I am critical of Pharmacist A's failure to store and process the methadone safely, which led to a devastating consequence.

Checking process for omeprazole

86. Later the same day, Mrs B arrived at the pharmacy with the prescription for omeprazole. Pharmacy technician Technician C made up (compounded) the omeprazole liquid, and Pharmacist A checked the weight, measure, batch number, and expiry dates for each of the ingredients used. Pharmacist A also checked the volume of the omeprazole liquid (28ml) when it was in a measuring cylinder. After adding the omeprazole liquid to the unlabelled methadone bottle, Technician C then placed the bottle in the fridge and subsequently gave it to Mrs B. Pharmacist A did not check the omeprazole liquid in its mission bottle before the medication left the pharmacy. Pharmacist A accepts that he should have checked the bottle prior to it being given to Mrs B.

87. I note that different accounts have been provided about the pharmacy's dispensing procedures and what constituted a final check of the product. Technician C told HDC that the job sheet was signed off by Pharmacist A when the bottle was placed in the fridge, which was deemed a final check of the medication. However, Pharmacist A stated that he did not undertake a final check of the omeprazole liquid in its mission bottle before it left the pharmacy. SOP E17.1 required the pharmacist to sign off the compounding worksheet when the compounding, labelling, and checking had been completed. SOP E14.1 on dispensing accuracy checks also required the label and dispensed medicine to be checked against the original prescription, and the prescription to be signed to indicate that a pharmacist had checked for completeness and accuracy.

88. Ms Fordyce advised that in addition to checking each ingredient used, as well as the volume, the pharmacist should check the final product against the job sheet and prescription before releasing the product to be put on the shelf (in this case the fridge) to await collection. While the job sheet was prepared and signed off at each step by Pharmacist A, he did not check the final product before it was released to Mrs B. Ms Fordyce considers that Pharmacist A's

failure to check the final product before it was released was a severe departure from accepted practice. I accept Ms Fordyce's advice.

89. I also note that Competency 03.2.1 of the Pharmacy Council's Competence Standards requires pharmacists to "[maintain] a logical, safe and disciplined dispensing procedure". Pharmacist A had a professional responsibility to take appropriate steps to ensure the provision of safe and accurate medications. It is a fundamental patient safety and quality assurance step in the dispensing and checking process to check the medication being dispensed against the prescription for accuracy, including a final inspection prior to the product being released. Pharmacist A's checking process was clearly inadequate, and an opportunity to note the increased volume in the bottle and prevent the serious incident that resulted was missed. Pharmacist A acknowledged that a final check was required, and that his failure to undertake a second check was a breach of usual practice.

Conclusion

90. In failing to dispense the omeprazole in a safe and appropriate way, and by failing to check the final product given to Mrs B, Pharmacist A did not provide services to Baby B in a manner consistent with professional standards and competent pharmacist practice. Accordingly, I find that Pharmacist A 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.

Management of dispensing error — breach

91. Pharmacist A realised the possibility of the dispensing error between 11.30am and 12.00pm. Technician C told HDC that she contacted Mrs B by calling and leaving a voicemail message on her landline at around 12.30pm. The pharmacy stated that a second call was made by Technician C to Mrs B's mobile number at around 3.00pm, when again a voice message was left.

92. Mrs B, in her response to the provisional opinion, stated that she received two calls from the pharmacy on 5 June, and any call to her landline would have been forwarded to her mobile. The voice mail recordings and phone log that Mrs B provided to HDC confirms that the two calls made by the pharmacy to Mrs B on 5 June occurred first, at 1.29pm (made by Technician C), and secondly at 2.46pm (made by Pharmacist A).

93. On this basis, there was a delay of 1.5–2 hours between Pharmacist A discovering the potential dispensing error, and the pharmacy contacting Mrs B.

94. Pharmacist A informed HDC that the delay occurred because of difficulties obtaining Mrs B's mobile number from the medical centre, as there were multiple patients with the same surname, and her address had not been updated following a recent relocation. Pharmacist A also submitted that the delays were a result of the prescription being a repeat prescription, rather than a new prescription, which meant that he was required to find the original paper prescription in order to locate Mrs B's phone number.

95. When Mrs B returned the pharmacy's calls at 2.57pm, it was Technician C who spoke to her and the paediatrician at the hospital. However, Pharmacist A submitted that he was next to Technician C during the phone call and participated in the discussion. Pharmacist A personally contacted the paediatrician to check on Baby B later that day.

96. Following the incident, Pharmacist A notified the Pharmacy Defence Association and filled out an incident notification form. He also sent an apology letter to Mrs B two days after the incident.

97. Ms Fordyce advised that after an error is detected, and when an incorrect medication is consumed, as in a case such as this, the pharmacist should telephone to check on the child and parent, and then contact the consulting doctor to alert them of the dose and strength of the medication that the child has consumed. Given the severity of the overdose, it would be appropriate to check on the child's health status with urgency and with regular follow-ups. Ms Fordyce considers that the time lag in initiating contact, the failure to contact Mrs B and the paediatrician personally, and the delay in sending an apology letter to Mrs B, together amount to a moderate departure from accepted practice.

98. I note that Ms Fordyce's advice was provided on the basis that the first call took place at 12.30pm, meaning a delay of half an hour to an hour between the error being discovered and Mrs B being contacted. On the basis of further information provided by Mrs B in response to my provisional opinion, I have found it is more likely than not that the first call took place at 1.29pm, and therefore there was a delay of 1.5 to 2 hours.

99. I note that the pharmacy's SOP C11.2 states: "When a dispensing error is made known to the pharmacy, ensure that the charge pharmacist handles the matter." The SOP also states: "If the patient has left the pharmacy and you suspect an error may have occurred act speedily to confirm/eliminate any possibility without causing unnecessary alarm." I also note that Competency 3.2.2 of the Pharmacy Council Competence Standards required Pharmacist A to "act promptly" to mitigate any errors in the dispensing process.

100. I acknowledge the standards with which Pharmacist A was required to comply, and agree with Ms Fordyce's advice. Given the severity of a methadone overdose in a young child, and the potentially life-threatening outcome, Pharmacist A should have prioritised contacting Mrs B to check on Baby B's health, and should have liaised with the paediatrician to provide details of the drug ingested.

101. I acknowledge that Pharmacist A was the only pharmacist on duty and believed he was working collaboratively with Technician C. I also acknowledge the submissions I received in response to my provisional opinion, which show that Pharmacist A did take responsibility for one of the phone calls to Mrs B, and was present during the phone call with the paediatrician. However, despite these submissions, I remain of the view that it was inappropriate for Pharmacist A to delegate responsibility to Technician C to manage the dispensing error, and this delegation went against the pharmacy's SOP. In addition, while I acknowledge Pharmacist A's submissions regarding the difficulty in contacting Mrs B, I remain critical of the significant delay of 1.5–2 hours between Pharmacist A's discovery of

the dispensing error and the first attempt to contact her. In my view, Pharmacist A's actions once he was aware of Baby B's overdose were inadequate.

102. Accordingly, I find that Pharmacist A breached Right 4(2) of the Code in failing to provide services in accordance with professional standards.

Opinion: Pharmacy

Dispensing error — breach

103. The pharmacy had a duty to ensure that it provided services to Baby B with reasonable care and skill. This included a responsibility to ensure that it had adequate policies and procedures in place to facilitate safe, accurate, and efficient dispensing, and to ensure that its staff followed those policies.

Pharmacy's SOP

104. SOPs provide important guidance to staff to support them to comply with professional and practice standards.

105. The pharmacy was unable to supply the SOP for Controlled Drug Dispensing, as it had been misplaced during a recent refurbishment. The SOP supplied by the pharmacy for Controlled Drug Dispensing (SOP D10.2) was a revised version created after the incident in July 2018. This referred to a new clause in SOP D11 stating that controlled drugs should be placed in a snap-lock bag with the prescription and stored in the locked safe. D11 also includes an additional requirement to place the receipt with "safe" written on it on the "completed with query's" prescriptions glass shelf above the bench.

106. Ms Fordyce advised that without the clause on controlled drug storage, the SOP would be considered incomplete and therefore inadequate. Such an omission would amount to a mild departure from accepted practice.

107. I agree with Ms Fordyce. Due to the potentially devastating consequences of a misplaced controlled drug, its storage requirements should have been included in the pharmacy's SOP. However, I acknowledge that Ms Fordyce also advised that knowledge of storage requirements is an expected part of a pharmacist's practice, and Pharmacist A himself advised that storing controlled drugs in the safe was his usual practice. I also note that the pharmacy updated its SOP following this incident.

108. Ms Fordyce advised that the SOP supplied for the compounding of products at the time of the incident was thorough and comprehensive, and it was within review date at the time of the incident.

Pharmacy's work environment

109. The environment in which pharmacy staff work is relevant when considering whether there were any systemic factors that influenced staff actions, including staffing levels, communication, and the pharmacy layout.

110. It was particularly busy on the day of the event. It was the first day after a long weekend, the pharmacy was short staffed, and, shortly after opening, the pharmacy entrance door malfunctioned, which distracted Pharmacist A from completing the methadone dispensing, as he had to attend to the door. Pharmacist A left the unlabelled methadone bottle on the dispensary bench, and later the bottle was moved further down the bench by Technician D.

111. While expressing sympathy for the situation, Ms Fordyce advised that during busy periods, staff should follow the process set out in the pharmacy's SOP — working systematically, focusing on the task in hand, and keeping clutter and distractions to a minimum. She highlighted that good communication and clear annotations are key to ensuring that any important messages are passed on and dealt with. Ms Fordyce identified a moderate departure from accepted practice, in that Pharmacist A was distracted, and the dispensary was full of staff "rushing around each other".

112. I agree with this advice. When a dispensary team is under pressure is when a patient's safety is most at risk. It is particularly important for a pharmacy to have in place a robust system that works efficiently when staff are under pressure, so that medications can still be dispensed safely. Ms Fordyce noted that each team member should have high situational awareness, follow the relevant SOPs, and communicate clearly with one another. In this case, there were multiple occasions on which individuals failed to follow the SOPs and/or disciplined dispensing practices:

- Pharmacist A in his dispensing of methadone and checking of omeprazole.
- Technician C in not querying the increased volume in the bottle and not involving a pharmacist in the final checking process. I note that Technician C considered that a final check had been done when the job sheet was signed off by Pharmacist A, but Pharmacist A told HDC that a final check was not completed.
- Technician D in moving the bottle to give herself more working space, suggesting that the dispensary bench was cluttered.
- Pharmacist A in not taking charge of contacting Mrs B upon discovery of the error.

113. In addition, overall there appears to have been a lack of situational awareness by all dispensary staff, and a breakdown in communication regarding the presence of a partly dispensed bottle of methadone on the dispensary bench. I consider that cumulatively, these issues amounted to a systems failure, which ultimately affected the service provided to Baby B that day.

114. In my opinion, the multiple errors identified amount to a service delivery failure, for which ultimately the pharmacy is responsible. Accordingly, I find that the pharmacy breached Right

4(1) of the Code.[11] I note that the pharmacy has taken reasonable steps to improve this issue, including increasing staffing levels, improving dispensing labelling and storage processes, and increasing the waiting time for dispensing.

Opinion: Technician C — adverse comment

115. Whilst acknowledging that it was Pharmacist A's overall responsibility to ensure that the appropriate dispensing of medications occurred, as a Level 5 qualified pharmacy technician, Technician C also had a responsibility to ensure that she took appropriate care in dispensing and compounding medications, and that she had a good knowledge of relevant pharmacy processes and SOPs.

116. On 5 June 2018, Technician C compounded Baby B's prescription. Pharmacist A checked the individual ingredients as well as the volume while it was in the measuring cylinder. Technician C then poured the mixture into a 30ml mission bottle containing methadone that had been dispensed previously by Pharmacist A, and left the bottle on the dispensary bench. Technician C told HDC that she had cleared and cleaned the compounding bench to process the omeprazole prescription, and that the compounding bench was separated from the dispensary bench by a large sink. It is unclear how the bottle came to be within Technician C's reach. Ms Fordyce advised that the area not being cleared for preparation, resulting in the unlabelled bottle of methadone being in easy reach of Technician C, was a step that led to the dispensing error.

117. After the omeprazole was mixed with the methadone, the total volume in the bottle would have been 34ml. Technician C told HDC that she noticed the increased volume of the liquid and that it sat higher up the neck of the bottle than usual, but she did not query this further. Ms Fordyce advised that Technician C's failure to comment on the increased volume was another step that led to the dispensing error.

118. The bottle was then labelled and placed in the fridge, ready for collection. I note that different accounts have been provided about the pharmacy's standard dispensing procedures and what constituted a final check of the product. Technician C told HDC that the job sheet was signed off by Pharmacist A when the bottle was placed in the fridge, which was deemed a final check of the medication. However, Pharmacist A stated that he did not undertake a final check of the product after it was poured into the mission bottle.

119. Pharmacist A told HDC that Technician C had been trained to rinse out the bottle prior to filling, and that this was an aspect of general pharmacy technician training. However, Technician C told HDC that she was unaware of this requirement. Ms Fordyce advised that while it is best practice to rinse out bottles prior to filling, such practice can be impractical, and usually bottles are stored with the lid on, as was the case in the pharmacy. Ms Fordyce

[11] Right 4(1) states: "Every consumer has the right to have services provided with reasonable care and skill."

advised that although the failure to rinse out the bottle was another step that led to the dispensing error, she does not consider this to be a departure from accepted practice.

120. It is clear that some of Technician C's actions and omissions on 5 June 2018 contributed to the error in dispensing methadone to Baby B. Ms Fordyce advised that the compound preparation of omeprazole for Baby B would be well within Technician C's scope of practice as a qualified Level 5 pharmacy technician. However, I note that while Technician C's position description states that it was her role to be responsible for prescription processing, the position description does not discuss compound preparation specifically.

121. I consider that Technician C should have taken more care to follow the pharmacy's SOPs for compounding products and dispensing accuracy checks. In particular, Technician C ought to have taken precautions to ensure that there was no product mix-up when preparing Baby B's omeprazole liquid, as required by SOP E17.1, and it would have been prudent for her to ensure that Pharmacist A had checked the final product, as required by SOP E14.1. This would have provided an additional opportunity to discover the dispensing error.

122. However, I acknowledge that pharmacy technicians are directly supervised by pharmacists, and that both the pharmacy's SOPs and professional standards recognise that ultimately pharmacists are responsible for the safe dispensing of medication. I consider that the ultimate responsibility for the dispensing error sat with Pharmacist A as the pharmacist. He held the responsibility to ensure the accurate dispensing of medicine, and should have double checked the dispensed medication.

123. I note that Technician C told HDC that she now double checks that a pharmacist has checked her processes and scripts; ensures that job sheets are signed off; and makes sure that all weights, volumes, and ingredients are checked thoroughly.

Changes and actions since incident

124. Following the incident, the pharmacy implemented a risk reduction strategy plan to ensure that an error such as this does not occur again. The following changes have been made:

a) A new system has been introduced whereby after dispensing, all controlled drugs are placed in sealable plastic bags with the prescription and receipt and stored in the safe until collection.

b) Compounding duties have been withdrawn from the dispensary technician, and all compounding must be completed by a pharmacist.

c) The pharmacy has increased waiting times for medications that involve complex compounding.

d) The pharmacy has stopped offering any opioid treatment services of any kind.

125. The pharmacy has also increased staffing levels. In addition, a minimum of two pharmacists will be working on days after a long weekend closure, such as in this incident.

126. The pharmacy has also trained a pharmacy accuracy checking technician.[12]

127. Pharmacist A has provided Mrs B with a written apology.

Recommendations

128. Pharmacist A advised in response to the provisional opinion that he was about to retire from practice. The following recommendations for Pharmacist A would have been required should he have remained actively in practice:

a) Complete the "Addictions and opioid substitution therapy" course provided by the Pharmaceutical Society of New Zealand, prior to providing further opioid substitution therapy services.

b) Complete the "Improving accuracy and self-checking" workbook provided by the Pharmaceutical Society of New Zealand, within three months of the date of this report.

129. In the provisional opinion, I made a number of recommendations to be implemented by the pharmacy. In response to the provisional opinion, the pharmacy advised that it has completed some of my proposed recommendations. The pharmacy is now under new ownership and I do not consider it appropriate to ask the new owners of the pharmacy to implement the outstanding recommendations.

130. I recommend that Technician C complete the "Improving accuracy and self-checking" workbook provided by the Pharmaceutical Society of New Zealand, within three months of the date of this report.

Follow-up actions

131. Pharmacist A will be referred to the Director of Proceedings in accordance with section 45(2)(f) of the Health and Disability Commissioner Act 1994 for the purpose of deciding whether any proceedings should be taken.

[12] A technician who is trained to check dispensed items against the prescription prior to final release to the consumer.

132. 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 Pharmacist A's name.

133. 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 (College Education and Training Branch), 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.

Addendum

134. The Director of Proceedings decided not to issue proceedings.

Appendix A: Independent clinical advice to Commissioner

The following expert advice was obtained from Ms Sharynne Fordyce:

"**Advice for 20HDC00979**

I, Sharynne Fordyce, have been asked to provide an opinion to the Commissioner on Case number 20HDC00979 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

On 5 June 2018, [Baby B] (four weeks old at the time of the events) was dispensed and administered methadone instead of omeprazole. The pharmacist involved, [Pharmacist A], explains to [Baby B's] mother how the error occurred in the following way:

We have a visiting methadone patient who obtains his 30mg dose of methadone daily from our pharmacy for 2 weeks while visiting the area. … This patient usually arrives at 8.35am for his consume on premises dose. By 9am he had not arrived so I measured his dose out and put this 6ml of methadone 5mg/ml into a 30ml bottle. As I cannot enter this dispensing through the computer until he appears for his consume on premises dose I placed this unlabelled bottle on the prescription on the bench. I should have placed a sundry label on it and returned it to the safe.

At 11.00am a technician, with appropriate compounding qualifications, made up the repeat omeprazole 2mg/ml mixture for [Baby B]. I checked that the correct quantity of omeprazole powder and sodium bicarbonate powder were being used and that the water volume to make 28ml was appropriate. I signed this off on the batch sheet that the amount manufactured was the correct strength and volume and appeared to be the correct colour. I did not observe the technician putting this compounded volume into a 30ml bottle. This prescription was checked and given out between 11.00 am and 11.30 am.

At 11.30am it was noticed that the methadone that had been on the bench was missing. We searched the rubbish but it was not there. We also contacted our other store in case it had been sent over there in error. This was not the case. We then wondered if the omeprazole mixture had been poured into this 30ml bottle and at 11.50am rang your land line and left a message for you to urgently call us. … We eventually managed to contact the answer phone on your mobile and you returned our call at 2pm advising us that the baby had had difficulty breathing and you were at the hospital.

Expert advice requested

Please review the enclosed documentation and advise whether you consider the care provided to [Baby B] by [Pharmacist A] and [the pharmacy] was reasonable in the circumstances, and why.

In particular, please comment on:

1. The dispensing and checking of the omeprazole prescription on 5 June 2018.
2. The appropriateness of the actions taken after the error was detected including incident reporting and changes made.
3. The adequacy of the relevant standard operating procedures in place at the time of the events.
4. Any other matters in this case that relate to the dispensing error that 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 do you consider this to be (mild, moderate or severe)?
c. How would it be viewed by your peers?
d. Recommendations for improvement that may help to prevent a similar occurrence in future.

Advice

1. The dispensing and checking of the omeprazole prescription on 5 June 2018.

a) The accepted practice to dispense this product would be to process the repeat and generate a job sheet with the formula of the suspension on it. The job sheet and formula would be checked by the pharmacist, including all weighings, measurings, and batch numbers and expiry dates of ingredients. The area for preparation would then be cleared and cleaned by the compounding technician. The finished product would then be put into an appropriate container (previously rinsed with water) and labelled. The pharmacist would then check the final product against the job sheet and prescription before releasing the product to be put on the shelf (in this case the fridge) to await collection by the customer.

b) There was a severe departure from accepted practice in this case. Whilst the job sheet had been prepared and signed off at each step by the pharmacist, the final product was not checked before being released to the customer, thereby missing the increased volume — 34ml — in a 30ml bottle. There would not have been a marked variation in colour, as the methadone also in the bottle was the colourless 5mg/ml strength. The other steps causing this severe departure were the area for preparation not being cleared, as the unlabelled bottle of methadone was within easy reach for the technician,

the unlabelled bottle of methadone being present at all, and the container for the final product not being rinsed out by the technician, who also did not comment on the increased volume in the bottle. As a level 5 technician this compound preparation would be well within her scope of practice.

c) This would be viewed as a serious departure from accepted practice by my peers.

d) Recommendations for improvement would include ensuring a final volume check and check of final product is always carried out with external preparations, and following the compounding SOP currently in place, which contained all the necessary steps.

2. The appropriateness of the actions taken after the error was detected including incident reporting and changes made.

a) Accepted practice would be to contact the parent of the child and, if possible, prevent any of the erroneous medicine being consumed. Then to retrieve and isolate the bottle concerned, and supply a bottle of correct medication, with a very sincere verbal apology. Filling in a PDA form and notifying PDA of the incident would then follow. If, as in this instance, the medication has been consumed, then the pharmacist would phone to check on the child and parent, and then contact the consulting doctor to alert them to what dose and strength of what medication the child has consumed. It would be ideal at this point to be able to retrieve the bottle of medication, or at least find out where it is and arrange for it to be appropriately isolated. Then notify the PDA and complete an incident form while all the steps involved in the incident are still fresh in everyone's minds. Given the severity of the reaction it would be appropriate to check on the child's health status regularly. Following the incident it would be important to have a comprehensive staff meeting, in which all aspects of the incident were discussed, and the steps to be taken to prevent reoccurrence also discussed and written down.

b) There has been a moderate departure from accepted practice. There was a time lag from when the error was detected to when the mother of the patient was contacted due to lack of patient contact details. It should have been the pharmacist who spoke to both the mother and the paediatrician regarding the error, not the dispensary technician. PDA were notified and the incident report filled out very promptly, however the apology letter took a little longer, and could be seen to have been prompted by the media article. The timing of actions in the letter does not always match that in the incident report or the root analysis. No mention is made of a staff meeting to discuss this incident.

Appropriate changes have been made to the dispensing, labelling and storage of Controlled Drug prescriptions in the revised SOP. The only mention of changes in pharmacy processes to [Mrs B] is that of standing down the dispensary technician from compounding duties. There is little mention made of [Pharmacist A's] culpability in not labelling or storing the controlled drug correctly, which is a moderate departure from accepted practice.

c) My peers would approve of [Pharmacist A's] incident notification and [the] changes to his Controlled Drug SOP, but would view the time lag involved in contacting the mother,

the technician talking to the mother and paediatrician, and the lack of minuted staff discussions after the event as moderate departures from accepted practice.

d) Recommendations for improvement would include ensuring a full debrief of all staff involved after any such incident, recording any contact phone numbers present on prescriptions for all customers and ensuring the pharmacist spoke to the appropriate people when dealing with such an incident. These points could all be included in the SOP for dealing with Incidents.

3. The adequacy of the relevant standard operating procedures in place at the time of the events.

a) The SOP supplied for Compounding Products for Individual Patients was the one in place at the time of the incident and is thorough and comprehensive, and was within review date at the time of the incident.

The SOP supplied for Controlled Drug Dispensing is a revised version of the one in place at the time of the incident, the existing one at the time having been misplaced during recent refurbishment — which seems a little surprising given that SOPs are generally stored electronically. The revised SOP has had added the requirement for storage of completed Controlled Drugs to be in the drug safe. Without this clause the SOP at the time of the incident would be deemed incomplete and therefore inadequate. (Incidentally, the MOH website allows 7 days for a midwife's controlled drug script to be dispensed from the date of prescribing, not 4 days as mentioned in the SOP.)

b) Knowledge of the storage requirements for Controlled Drugs would be an expected part of a pharmacist's scope of practice, however, whether or not it was included in the SOP. This omission from the SOP would therefore be considered a mild departure from accepted practice.

c) My peers would regard this omission as a mild departure from accepted practice.

d) Recommendations for improvement have been carried out in the revised SOP for Controlled Drug Dispensing with the addition of storage requirements.

4. In the Root Cause Analysis and his apology letter [Pharmacist A] mentions not being able to generate a label for the dispensed methadone before the customer is present in the shop. While not being familiar with the dispensary system used in [the pharmacy], I believe both dispensary computer systems in use in New Zealand pharmacies are capable of doing this. He also mentions not being familiar with Methadone Protocols, which would have little bearing on the incident that occurred.

Sharynne Fordyce

17 August 2020"

The following further advice was provided by Ms Fordyce:

"**Additional Advice on 20HDC00979 (based on new documentation)**

I, Sharynne Fordyce, have been asked to provide an additional opinion to the Commissioner on Case number 20HDC00979 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

On 5 June 2018, [Baby B] (four weeks old at the time of the events) was dispensed and administered methadone instead of omeprazole.

Enclosed please find the following documents that have not been reviewed by you previously:

1. [Pharmacist A] and [the pharmacy's] response to HDC's notification letter dated 30 October 2020 including:
   a. Attachment A — [the pharmacy's][1] 'Dispensary time zone report' on 5 June 2018
   b. Attachment B — Statement from pharmacy technician [Technician D] dated 28 October 2020
   c. Attachment C — Technician C's employment contract with [the pharmacy] signed 8 May 2017
2. Technician C's response dated 12 December 2020
3. [Pharmacist A] and [the pharmacy's] further response to HDC dated 23 December 2020 including:
   a. Dispensing 4 — Accuracy Check (E14) SOP — approved on 3 July 2020
   b. Incident Reporting (C08) SOP — approved 17 August 2018
   c. Dispensing Errors (C11) SOP — approved 17 August 2018
   d. Dispensing Near Misses (C12) SOP — approved 6 March 2020
   e. Attachment E — Photo showing compounding and dispensing areas including location of the stored mission bottles
   f. Attachment F — [Technician D's] original incident statement dated 5 June 2018
   g. Attachment G — [Technician E's] statement dated 1 December 2020

Expert advice requested

Please review the enclosed documentation and advise whether it causes you to add to or amend the conclusions drawn in your initial advice about whether the care provided to [Baby B] by [Pharmacist A] and [the pharmacy] was reasonable in the circumstances, and why.

If you have added to or amended your previous conclusions, please explain your reasons for doing so.

In particular, please also comment on:

1. The response from [Technician C] and whether it causes you to add to or amend your original advice including, but not limited to:
   a. The position of the compounding bench in relation to the dispensing bench separated by the sink (enclosed photo). [Technician C] stated if the unlabelled mission bottle was left on the dispensary bench it would not have been 'within easy reach'.
   b. [Technician C] stated that she was never made aware that only empty mission bottles found in the basket underneath the sink should be used.
2. Please review the SOPs provided and advise whether they are reasonable and adequate.
3. Please advise what is the standard practice for pharmacies around the use of mission bottles including where they are located, where they are retrieved from and whether they should be 'rinsed and dried' prior to dispensing.
4. Please advise what staff and pharmacists can do, individually and as a team, during busy periods to minimise the risk of dispensing errors.
5. The dispensing of the methadone (which went on to be used in the omeprazole dispensing) with reference to:

   a. The accepted practice for the dispensing of this form of controlled drug scenario;
   b. The handling of the methadone prescription and related unlabelled mission bottle;
   c. Any other comments/observations in relation to this dispensing.

   Where relevant, please refer to the Ministry of Health's 'New Zealand Practice Guidelines for Opioid Substitution Treatment' (2014) and any other relevant standards or guidelines.
6. From the information provided, we note there are some differing versions of the events. For this, please provide your advice in the alternative. For example, what your advice would be based on scenario (A), in contrast to your advice based on scenario (B).
7. Any other relevant matters in this case.

   For each question, please advise if applicable:

   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 do you consider this to be (mild, moderate or severe)?
   c. How would it be viewed by your peers?
   d. Recommendations for improvement that may help to prevent a similar occurrence in future.

In response to the above questions

1. I do not want to amend my original comments regarding [Technician C].

2. I have commented on the SOPs in place on the day of the incident, in my previous report, and have nothing more to add.

3. *Please advise what is the standard practice for pharmacies around the use of mission bottles including where they are located, where they are retrieved from and whether they should be 'rinsed and dried' prior to dispensing.*

   a) Standard practice around the use of mission bottles would very generally involve them being located near the 'wet' dispensing section of the dispensary, in drawers or baskets — depending on the style of the dispensary. While it is recommended good practice for the bottles to be rinsed and dried prior to dispensing, this can be impractical (particularly the drying) and as such, most bottles are stored lidded, as is shown in the photo, to ensure cleanliness.

   b) There has not been a departure from accepted practice.

   c) My peers would agree with this.

4. *Please advise what staff and pharmacists can do, individually and as a team, during busy periods to minimise the risk of dispensing errors.*

   a) Accepted practice during busy periods is to work systematically, following dispensary processes as laid out in SOPs, to keep clutter and distractions to a minimum and for each staff member to concentrate on the job they are responsible for. Good communication and clear annotations ensure any important messages are passed on and dealt with appropriately.

   b) There has been a moderate departure from accepted practice, with [Pharmacist A] being distracted by [the pharmacy] doors and the dispensary being full of staff 'rushing around each other'.

   c) My peers would agree with this but would be sympathetic to the situation, especially with staff illness adding to the stressors.

   d) It would appear that [Pharmacist A] has taken a number of steps to improve this situation, including increasing staffing levels, improving processes concerning labelling and storage, and increasing waiting time for prescriptions.

5. *The dispensing of the methadone (which went on to be used in the omeprazole dispensing)*

   a. The accepted practice for the dispensing of this form of controlled drug scenario;
   b. The handling of the methadone prescription and related unlabelled mission bottle;
   c. Any other comments/observations in relation to this dispensing.

   a) The accepted practice for dealing with a methadone prescription and dispensing is to process the dose through the computer, with appropriate labelling, including dose, directions, name of patient, date of dispensing, and generate a label. The methadone dose would then be measured and poured into an appropriate mission

bottle (amber with a Child Resistant Cap), labelled and stored in the safe until needed.

b) There has been a severe departure from accepted practice, specifically in regard to the bottle being unlabelled, and not stored in the safe.

c) My peers would regard this as a severe departure from accepted practice.

d) In Number 4 of my original advice I made mention of the ability of the two main computer systems used in NZ pharmacy, to generate a label before the customer is in the shop.

6. *From the information provided, we note there are some differing versions of the events. For this, please provide your advice in the alternative. For example, what your advice would be based on scenario (A), in contrast to your advice based on scenario (B).*

It would appear that there a number of different scenarios being described by various members of staff, with sometimes one member of staff having varying recollections of what happened on the day.

1. [Technician D] stated on 5/6/18 that she recognised an unlabelled bottle on the bench, as likely containing methadone for the morning patient, standing on a copy of the prescription. She moved this to one side, in order to clear the dispensary bench during a busy morning. Yet on 28/10/20 [Technician D] states she 'was not aware of any methadone on the bench'.

2. [Technician C] states consistently that there 'looked to be an increase in volume as it sat slightly higher in the neck of the bottle than usual'. As there are no demarcation lines on these 30ml bottles this would be the only way to register an increased volume, but she did not re-measure the omeprazole suspension.

   [Technician C] states that she only ever procured 30ml bottles from the basket under the bench, and the only way for her to have mistakenly used the methadone containing bottle was if it had been tidied away into the basket under the bench. [Technician C] also says that she cannot categorically state that she did or did not get a bottle from the basket on this occasion. It was, however, a very busy morning — one fact all staff members agree on.

3. [Pharmacist A], in his original statement, said he alerted dispensary staff to the presence of the unlabelled methadone containing bottle on the bench. Yet in his more recent statement he cannot remember if he told dispensary staff about the unlabelled bottle or not.

   [Pharmacist A] states that the delay in contacting the patient's mother was due to problems obtaining a current phone number. [Technician C] states that it was she who initiated contact with the medical centre to obtain a number as he was 'too busy' and only contacted PDA on her recommendation.

As can be seen by the above scenarios, it is difficult to apportion responsibility for individual steps that contributed to the incident, except that if the unlabelled methadone had not been present on the bench the incident would not have happened. I feel there are too many permutations to enable me to separate the scenarios cleanly into A or B and comment on the impact each one had on the outcome for the patient. Accepting that the time lapse and stress of this situation may have hindered accurate recall, these, at times, conflicting scenarios do emphasise the need to promptly and accurately record any and all dispensary incidents.

Sharynne Fordyce

10 March 2021”

Appendix B: The pharmacy's relevant standard operating procedures

SOP D10.2 — Controlled Drugs (CD) dispensing states:[1]

"— All controlled drugs are kept in the locked safe in the dispensary.
— Ensure that dispensed items are recorded and signed out of the Controlled Drug Register during the dispensing process.

See SOP D11 Controlled drugs storage, records and destruction

- … all completed controlled drug prescriptions are to be placed in a snap lock resealable plastic bag with the prescription and kept in the locked safe. The receipt with 'safe' written on it is placed on the 'completed with query's' prescriptions glass shelf above the bench.

— Ensure that the controlled drug safe is locked when dispensing has been completed."

SOP E17.1 — Compounding products for individual patients states:

"— If using a computer-generated record from TONIQ or RxONE it must include the following information:

a) Name of the preparation
b) Name and quantities of ingredients used
c) Date of preparation
d) Unique identifying number (usually the prescription number)
e) Batch number and expiry date of each ingredient
f) Expiry date of the finished product
g) A copy of the product label
h) A quality check of the finished product including the signature or initials of pharmacist checking/releasing the final product.

— Complete all required details on the compounding worksheet.
— The compounding area should only contain the materials and documentation associated with the process being carried out.
— It is important that for all steps of the preparation the compounder must take precautions to ensure there is no contamination, cross-contamination or product mix-up.
— If a pharmacy graduate, pharmacy technician or student is undertaking the compounding, the measurement of each starting material must be checked and signed off by the pharmacist.
— The pharmacist must sign off the compounding worksheet when compounding, labelling and checking is complete.

[1] The requirement in SOP D11 to store controlled drug prescriptions in snap lock bags in a locked safe was not included in the version of the SOP in place at the time of the dispensing error. This requirement was added to the SOP in July 2018.

— Dispense the prescription and package item for collection. Store in appropriate place, i.e. fridge, shelf."

SOP E14.1 Dispensing 4 — Accuracy check states:

"— Check the label and dispensed medicine against the original prescription and the stock supply used to dispense the medicine. This includes:

- Correct patient name
- Correct prescribers name
- Instructions for use
- Formulation, strength and quantity of medicine
- Open each dispensed bottle or skillet to compare contents with stock supply
- If more than one stock bottle or skillet has been used, check dispensed medicine against all sources of supply

— Self-checking is not recommended — wherever possible the check should be done by a second person.

— Initial each item on the prescription to indicate the prescription has been checked for completeness by a pharmacist and passed for accuracy. Ensure that the identity of the individual who has dispensed the prescription can be identified. This may be the same person as the final checker.

— Ensure any documentation accompanying the dispensed items (such as prescription records, counselling notes and receipts) belongs to the right patient."

SOP C08.1 — Incident Reporting states:

"— Incidents should be discussed by the manager with the staff members involved.

— Confirm that the correct action was taken, or discuss procedures that should have taken place. Make sure all required procedures are documented for future reference.

— Debrief all staff to ensure everyone knows how to deal with the situation if it reoccurs.

— Counselling may be required depending on the type of incident."

SOP C11.2 — Dispensing errors states:

"— When a dispensing error is made known to [the pharmacy], ensure that the charge pharmacist handles the matter.

See SOP C12 Dispensing near misses.

— Show concern and willingness to correct any error immediately.

— Apologise and show concern. Try and give a sensible explanation. If the error is obvious it is no use being evasive — admit the mistake.

— If the wrong drug/dose has been dispensed, ask:

  - Has any of the wrong medicine been ingested? If so the prescriber should be contacted immediately.
  - Has any harm been suffered? If so ask for details of symptoms.
  - Has any expense been incurred? If so it may be sensible at this state to say that you will cover any reasonable expenses i.e. taxi to hospital or doctor's visit. If unsure contact the Pharmacy Defence Association (PDA).

— Ensure you let the customer know that measures have been taken, and follow up promptly. If there is a delay, e.g. relevant staff member away, inform the customer.

— Fill out an incident form completing all sections and including alternative contact numbers when applicable. The pharmacist who failed to pick up the error is responsible for filling out the form and completing the documentation, the charge pharmacist then needs to check it and make sure it is complete. Also make a record in the patient notes in the computer. Using the PDA Toniq Template Ensure you record any dialogue or action taken in relation to the incident, at any stage, as it may be needed if a Health & Disability Commission[er] (HDC) complaint results.

— If the patient has left [the pharmacy] and you suspect any error may have occurred act speedily to confirm/eliminate any possibility without causing unnecessary alarm.

— The pharmacy owner should always be informed of a dispensing error within 24 hours. After the incident, all dispensary staff should have a debrief and come up with any reasons as to how the incident may have happened, and what can be done to stop such an incident from happening again."

SOP C12.1 — Dispensing near misses states:

"• Near misses are defined as any error that was detected during the checking process up to and including the point at which the medication was handed over to the patient or patient's representative. It does not include errors that are picked up during a self-check, but does include anything picked up in the final check.

- Near miss incidents should be documented in the Dispensing Near Miss Record and reviewed regularly. Our pharmacy reviews them every 2 months at dispensary meetings.
- Reviews of the Near Miss log should be held when all dispensary staff members are present, to ensure that all staff learn ways to avoid near misses by discussing and agreeing on actions to be taken. Particular practices that are changed or improved should be documented in [the pharmacy's] dispensing SOP.
- Reviews are undertaken by the pharmacist manager.
- Recording near misses may help identify patterns or trends. A record should be made of when the near misses were discussed and reviewed, and who was present. Resulting actions taken to prevent the near miss happening again should be documented.
- When a serious near miss has been discovered, ensure that all staff members are notified immediately and that proactive action is taken to avoid a similar situation.

- Near miss errors may include:
  - incorrect prescription dispensed because script was misread
  - wrong medicine selected
  - wrong quantity of medicine dispensed
  - wrong strength of medicine dispensed
  - wrong form of medicine selected
  - wrong label dispensed (incl. wrong medicine, wrong strengths, wrong instructions, wrong patient name or wrong prescriber).
  - transposed prescription labels, e.g. for wrong patient or product expired stock
  - an item missing from completed prescription, e.g. something left in fridge, or not dispensed.

The near miss record does not have to be highly detailed. A quick, simple way to record them is to have a small notebook in the dispensary. Generally a near miss will require a new label to be printed, so stick the near miss label in the notebook with the initials of the people involved, and some details of the near miss e.g. 'amoxy 125mg/5ml, should have been 250mg/5ml'. Also include the time the error occurred. This helps with the analysis of why the near misses are occurring — is it a particular time of the day or a particular person at about the same time?"

The Ministry of Health's "New Zealand Practice Guidelines for Opioid Substitution Treatment 2014" 9.3.6 (Dispensing errors) states:

"9.3.6 Dispensing errors

Pharmacists must have procedures in place to minimise the chances of an error in dispensing. If a client receives a higher than normal dose of methadone, the potential for complications, including death, may be high. With buprenorphine the risk is much lower; however, on becoming aware of a dispensing error in this case, the pharmacist must still alert the client and prescriber, following the procedure outlined below so that appropriate monitoring and actions (such as reducing or stopping the following days dose) can occur. Pharmacists should immediately report all suspected errors to the client and the prescriber or specialist service. They should inform the client of the need for urgent medical assessment, and call an ambulance if necessary."

The Pharmacy Council's Competence Standards 03.2.1 (in regard to dispensing medicines) states:

"Maintains a logical, safe and disciplined dispensing procedure."