Pharmacy

Pharmacist, Mr B

A Report by the

Deputy Health and Disability Commissioner

(Case 17HDC00538)

Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

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Executive summary

1. On 21 March 2017, Ms A and her daughter, Miss A (eight years old at the time of these events), consulted an optometrist, Ms C. At the end of the consultation, Miss A was prescribed "[a]tropine drops 0.01%, 1 drop both eyes at night, 3 months supply".

2. On 26 March 2017 (a Sunday), Ms A went to the pharmacy to have Miss A's prescription for atropine 0.01% dispensed. Pharmacist Mr B[1] was the only pharmacist working on this day, and he completed the processing and dispensing of the prescription.

3. Mr B told HDC that during the dispensing "the strength of the prescription was curious to [him]" and he made attempts to verify the strength prior to dispensing. He did not, however, verify his concerns about the prescription with the prescriber, as the [optometry clinic] was closed during the weekend. Mr B said that he "offered to return the prescription to [Ms A] if she was not comfortable proceeding with the dispensing". Mr B then dispensed atropine 1% instead of the prescribed 0.01%.

4. On the evening of 26 March 2017, Ms A followed the prescription instructions and administered Miss A one drop of atropine per eye. Ms A told HDC that "[she] looked [at] the label on the bottle and read 'atropine 1% eye drops'". Ms A said that she "remembered [reading] the prescription [as] 'atropine 0.01%'" and became confused and concerned.

5. The following morning, Ms A rang the pharmacy and spoke to Mr B. She expressed her concern that the prescription said 0.01% instead of 1%. Mr B telephoned the optometry clinic and was told that the strength he had dispensed was incorrect.

6. Mr B called back Ms A to explain the situation. He recalled that he asked whether the medication had been used and advised Ms A to monitor Miss A closely and to contact him if she required any further assistance. Mr B did not specifically ask whether there had been any adverse effects from the atropine.

7. Mr B advised that he posted and faxed the prescription to another pharmacy (Pharmacy 2)[2] and then deleted the dispensing record from the dispensary software.

Findings

8. Mr B did not comply with a number of the pharmacy's SOPs as well as the Pharmacy Council of New Zealand's *Code of Ethics*. Mr B failed to provide services to Miss A with reasonable care and skill for a number of reasons, and was found in breach of Right 4(1) of the Code of Health and Disability Services Consumers' Rights (the Code).[3]

9. The pharmacy was not found vicariously liable for Mr B's breach of Right 4(1).

Recommendations

10. It is recommended that Mr B review the Pharmacy Council of New Zealand's professional guidelines and identify improvements in his dispensing practice. As part of this, Mr B

[1] Mr B is also the Dispensary Manager at the pharmacy.
[2] A registered pharmacy, specialising in pharmaceutical compounding.
[3] Right 4(1) states: "Every consumer has the right to have services provided with reasonable care and skill."

should undertake continued education on pharmaceutical products by keeping a written log of the Pharmacy Council of New Zealand's "Safety Alerts".

11. It is recommended that the pharmacy:

a) Randomly audit, over a period of three months, its staff compliance with its "Dispensing 2 — Prescription assessment and clinical check".

b) Incorporate into dispensary meetings, discussions around Pharmacy Council of New Zealand and/or Pharmacy Defence Association safety alerts and/or communications.

Complaint and investigation

12. The Health and Disability Commissioner received a complaint from Ms A about the services provided to her daughter, Miss A, by a pharmacist, Mr B, at the pharmacy. The following issues were identified for investigation:

- *Whether pharmacist Mr B provided Miss A with an appropriate standard of care in March 2017.*
- *Whether the pharmacy provided Miss A with an appropriate standard of care in March 2017.*

13. An investigation was commenced on 18 July 2017. This report is the opinion of Meenal Duggal, Deputy Commissioner, and is made in accordance with the power delegated to her by the Commissioner.

14. The parties directly involved in the investigation were:

Miss A	Consumer
Ms A	Complainant
Mr B	Pharmacist/provider
Pharmacy	Pharmacy/provider

15. Information was reviewed from:

Optometry clinic	Provider
Ms C	Optometrist
Optometry student	

16. Independent expert advice was obtained from a pharmacist, Ms Sharynne Fordyce.

Information gathered during investigation

Background

17. On 21 March 2017, Ms A and her daughter, Miss A (eight years old at the time of these events), consulted an optometrist, Ms C. The clinical notes from this appointment state that Miss A was referred to the clinic to "discuss myopia control options". Various options were discussed, and the decision was to proceed with 0.01% atropine eye drops. At the end of the consultation, Miss A was prescribed "[a]tropine drops 0.01%, 1 drop both eyes at night, 3 months supply".

Dispensing on 26 March 2017

18. On 26 March 2017 (a Sunday), Ms A went to the pharmacy to have Miss A's prescription for atropine 0.01% dispensed. Mr B was the only pharmacist working on this day, and he completed the processing and dispensing of the prescription.

19. Mr B told HDC that during the dispensing "the strength of the prescription was curious to [him]". He said that he used the dispensary software, MIMS,[4] and the pharmacy's medicine supplier's website to search for formulations of atropine that were available commercially. Mr B added that he was unable to consult with another dispensary staff member regarding the strength being prescribed, as none were working at the time.

20. Mr B explained that the optometry clinic opened between Monday and Friday only, and he knew that he would not be able to clarify the prescription with the prescriber on that day. Mr B said that nevertheless he tried to contact the clinic but, "as expected", there was no answer. He added that there was no option to leave a voice message. Mr B concluded:

> "[T]here were no further avenues available to me for investigation [and] based on the information I had available, I made a judgement call in good faith that the prescriber had inadvertently written the strength as 0.01% so I processed the prescription as 1% eye drops."

21. The pharmacy's "Dispensing 2 — Prescription assessment and clinical check" standard operating procedure (SOP) requires the pharmacist to "investigate and confirm any changes or differences with the patient and/or the prescriber as appropriate".

22. Mr B recalled conveying to Ms A that "only 1% eye drops were available, that [he] could not find any source of information that indicated the use of a 0.01% eye drop, and that [he] believed there may have been a mistake in prescribing". Specifically, Mr B recalled showing Ms A the prescription, noting where the prescription read 0.01% and suggesting that it should perhaps read 1%, and describing the possible mistake in prescribing as a "computer typo". He added that he "offered to return the prescription to [Ms A] if she was not comfortable proceeding with the dispensing". Mr B told HDC that Ms A had "no apparent concerns" at the time of dispensing. Ms A told HDC that she is "very confident" that Mr B did not mention a computer typo to her prior to dispensing atropine 1%.

[4] A medicine information resource.

Discovery of error

23. On the evening of 26 March 2017, Ms A followed the prescription instructions and administered Miss A one drop of atropine per eye. Ms A told HDC that "[she] looked [at] the label on the bottle and read 'atropine 1% eye drops'". Ms A said that she "remembered [reading] the prescription [as] 'atropine 0.01%'" and became confused and concerned.

24. The following morning, Ms A rang the pharmacy and spoke to Mr B. She said that she "explained the story" and expressed her concern that the prescription said 0.01% instead of 1%. She wanted to confirm that she had been given the correct dose. Ms A stated that during the telephone call Mr B told her that only atropine 1% was "on the market", and he believed that the 0.01% had been written by mistake. Ms A said that she was "really concerned" and asked Mr B to contact the prescriber.

25. Mr B's recollection of the telephone call is different. He told HDC that Ms A expressed doubt about the decision to proceed with the dispensing made the previous day. She used the word "ineffective" and asked if Mr B was certain the atropine dispensed was the correct strength for Miss A. Mr B conveyed to Ms A the same information as the day before — that "this was the only option available" — and assured her that he would "continue to try [to] get in touch with the initial prescribing doctor".

26. Mr B was not able to get in contact with the prescriber, Ms C, but he spoke to another "female member of staff", who advised him that the strength he had dispensed was incorrect. Mr B stated that he called back Ms A immediately to explain the situation. Mr B recalled that in one of their conversations, he asked whether the medication had been used, and Ms A replied "once". Mr B advised Ms A to monitor Miss A closely and to contact him if she required any further assistance. Mr B did not specifically ask whether there had been any adverse effects from the atropine, and Ms A did not mention that Miss A had suffered any side effects.

27. The pharmacy's "Dispensing errors" SOP requires the pharmacist to ask "has any of the wrong medicine been ingested?" and "has any harm been suffered?".

28. Mr B advised that he posted and faxed the prescription to Pharmacy 2 and deleted the dispensing record from the dispensary software because "otherwise the medicine would have been claimed for a payment from the government". Mr B told HDC that, in hindsight, he accepts that he should have changed the prescription code to "not subsidised" in the dispensary system. The system would then have retained a record of the dispensing, with no subsidy being claimed. He acknowledged that he should have kept a copy of the prescription as well.

29. When completing an incident report, the pharmacy's "Incident reporting" SOP requires that "all correspondence, documentation of procedure review and copy of relevant prescription etc. is to be attached to the paper copy of the incident form and filed".

30. Mr B said that he cannot recall whether he asked for the atropine 1% to be returned, and acknowledged that this would be standard practice following a dispensing error. He explained that his priority at the time was to ensure that Miss A received the correct medication. Mr B told HDC that "there is some uncertainty about what has happened regarding these drops". Ms A told HDC that she was not asked to return the atropine 1%.

31. The pharmacy's "Dispensing errors" SOP requires that the pharmacist "replace the incorrect item as soon as possible" and "retain the evidence (quarantined) if possible". In addition, the "Incident reporting" SOP requires that the pharmacist "take steps to minimise further harm".

32. Mr B completed an incident report for the error and documented the relevant SOPs that applied.

Subsequent events

33. Ms A told HDC that when Miss A came home from school on 27 March 2017, she reported blurred vision and sensitivity to light. Ms A said that when she examined Miss A's eyes, she observed that the pupils were very dilated. Ms A was advised that the incorrect dose would not cause any long-term damage.

Further information — Mr B

34. Mr B sincerely apologises for his lack of knowledge around the use of 0.01% atropine and his subsequent miscommunication about atropine strengths prescribed in New Zealand. Mr B is also sorry that Miss A experienced adverse effects from using the incorrect atropine eye drops.

35. As part of Mr B's role as Dispensary Manager, he is responsible for maintaining and reviewing SOPs. Mr B told HDC that, as a result of the error, changes have been made to the "Dispensing 2 — Prescription assessment and clinical check" and the "Incident reporting" SOPs.

36. Mr B acknowledges that this case demonstrates that it is not always feasible to provide a patient with his or her prescribed medications as soon as possible, particularly where there is a query or issue with the prescription. Mr B states that it is now standard protocol that when a prescriber cannot be contacted for a prescription query, the prescription will not be dispensed until the pharmacist is satisfied that the problem has been resolved appropriately.

Further information — the pharmacy

37. The pharmacy wishes to apologise to Miss A and her family. It feels deeply responsible for the incident.

38. A number of meetings have been held with all staff at the pharmacy since the incident to discuss areas of improvement. The dispensary team has been made aware of the incident, discussed possible elements that could have contributed to the incident, and reviewed the relevant SOPs. The need to keep up to date with medication changes and practices has also been emphasised.

Responses to provisional opinion

39. Ms A was provided with an opportunity to comment on the "information gathered" section of the provisional opinion. She advised that she had no further comment to make.

40. Mr B was provided with an opportunity to comment on the provisional opinion. He advised that he accepts that he has breached Right 4(1) of the Code, and he accepts all the recommendations made. He stated that he takes full responsibility for the error he made.

41. The pharmacy was provided with an opportunity to comment on the provisional opinion. It advised that it had no comment to make.

Opinion: Mr B — breach

42. As a registered pharmacist, it was Mr B's responsibility to ensure that he provided services to Miss A with reasonable care and skill.

Atropine knowledge

43. My expert, Sharynne Fordyce, considered that Mr B's lack of knowledge around atropine 0.01% "would not be regarded too severely by his peers". However, she noted that upon typing "atropine drops 0.01% in NZ" into an online search engine, the first page of results showed two references from the Pharmacy Defence Association and one from the Pharmac Subcommittee on Ophthalmology, all of which dealt with this strength of atropine in New Zealand. Ms Fordyce noted that when conducting a general search of the internet, "professional judgement can be used to distinguish between reputable sources of information", and that "not searching the internet more thoroughly to obtain more definitive information would be regarded as not very thorough".

44. Whilst I acknowledge Mr B's statement that he took steps to research atropine 0.01%, I do not accept that there were "no further avenues available [to him] for investigation".

Discussion prior to dispensing

45. Ms Fordyce considers that the discussion Mr B had with Ms A prior to the dispensing of atropine 1% was inappropriate. Ms Fordyce stated:

> "The only discussion with the customer should have stated doubt over the strength required, the need to contact the prescriber to confirm, and whether [Ms A] wanted to leave the prescription at the pharmacy to await confirmation of the dose on Monday morning, or take the prescription, undispensed, away with her."

46. Mr B's recollection that he "offered to return the prescription to [Ms A] if she was not comfortable proceeding with the dispensing" is concerning. Ms Fordyce noted that "a judgement call in good faith is no substitute for accepted practice. Neither is giving the customer the option of either taking a different strength to the one prescribed or delaying the dispensing." Ms Fordyce considers the discussion to be a "severe departure from the accepted practice". I agree with Ms Fordyce. The decision to dispense a prescription rests with the pharmacist, and should not be one for the consumer to make.

Dispensing

47. Ms Fordyce advised that the "accepted practice when in doubt about a prescription is to contact the prescriber in the first instance". As the strength could not be verified, Ms Fordyce considers that the dispensing should have been deferred until the prescriber could be contacted. She concluded that the steps taken prior to the dispensing of atropine, as outlined below, would be considered a "severe departure from accepted practice".

48. I note that the Pharmacy Council of New Zealand's *Code of Ethics (2011)* provides that:

> "Where you have reasonable grounds to consider that a prescription contains any error, omission, irregularity or ambiguity or is not legitimate, or that a prescribed medicine could be detrimental to a patient's health, consult with the prescriber and document the details and outcome."

49. Ms Fordyce advised that the decision to dispense atropine 1% was inappropriate. Mr B lacked knowledge regarding varying strengths of the drops, was unable to confirm the prescription with the prescriber, and the atropine dispensed was a significantly different strength to that which was prescribed. Ms Fordyce considers that Mr B's decision to dispense atropine 1% was a "moderate/severe departure" from accepted practice.

50. The most appropriate course of action as viewed by Mr B's peers and the Pharmacy Council's *Code of Ethics* was to defer dispensing until the strength could be confirmed, and I am critical that Mr B did not do so. I acknowledge that Mr B made an attempt to contact the prescriber, and he was aware that the prescriber would not be available on a Sunday. Having been unsuccessful in finding clarity around Miss A's prescription and knowing that the only atropine available for dispensing was 100 times stronger than what had been prescribed, I am very critical that Mr B decided to dispense the medication.

Actions taken after error discovered

51. Ms Fordyce advised that after discovering the error, accepted practice would have been for Mr B to have offered to uplift the eye drops from Ms A immediately, ask whether Miss A had suffered any ill effects, and provide counselling to reassure Ms A that there would be no long-lasting ill effects. Ms Fordyce considered Mr B's level of advice and counselling to be a "moderate departure from accepted practice". Ms Fordyce also expressed concern that Mr B waited until Ms A telephoned before contacting the prescriber on Monday morning.

52. I note that the pharmacy's SOPs support Ms Fordyce's opinion. The SOP specifically requires the pharmacist to "replace the incorrect item as soon as possible", "retain the evidence (quarantined)", and ask whether any harm has been suffered.

53. Ms Fordyce also noted that deleting the dispensing record and not keeping a copy of the prescription would be deemed "very unwise" by Mr B's peers. She advised that this would be considered a "severe departure from accepted practice". I also note that the pharmacy's SOP requires the prescription to be attached to the incident form.

54. I accept Ms Fordyce's advice and consider that the actions taken by Mr B after the error was discovered were inadequate.

Conclusion

55. I am critical that Mr B did not comply with a number of the pharmacy's SOPs as well as the Pharmacy Council of New Zealand's *Code of Ethics*. In my view, Mr B failed to provide services to Miss A with reasonable care and skill for the following reasons:

- Mr B dispensed atropine 1% — 100 times the strength of the prescribed medication (0.01%) — without first verifying his concerns about the prescription with the prescriber.
- Mr B's counselling of Ms A before the dispensing and after the error was discovered was inadequate.
- Mr B deleted the dispensing record, and he did not keep a copy of the prescription.

56. As such, I consider that Mr B breached Right 4(1) of the Code.

Opinion: Pharmacy — no breach

57. As a healthcare provider, the pharmacy is responsible for providing services in accordance with the Code. In this case, I consider that the errors that occurred did not indicate broader systems or organisational issues. Therefore, I consider that the pharmacy did not breach the Code directly.

58. In addition to any direct liability for a breach of the Code, under section 72(2) of the Health and Disability Commissioner Act 1994 (the Act), an employing authority is vicariously liable for any acts or omissions of its employees. A defence is available to the employing authority of an employee under section 72(5) if it can prove that it took such steps as were reasonably practicable to prevent the acts or omissions.

59. In March 2017, Mr B was an employee of the pharmacy. As set out above, I have found that Mr B breached Right 4(1) of the Code.

60. Ms Fordyce advised that the pharmacy had adequate SOPs. When Mr B completed the incident report for the error, he documented the relevant SOPs, indicating that he was aware of them. Further, as Dispensary Manager it is part of Mr B's job description to maintain and review SOPs. As such, I consider that the pharmacy took reasonably practicable steps to prevent the acts and omissions that led to Mr B's breach of the Code. Accordingly, I do not consider that the pharmacy is vicariously liable for Mr B's breach of Right 4(1).

Recommendations

61. I note that Mr B has already provided a written apology letter to Ms A, which will be forwarded to her.

62. I recommend that Mr B review the Pharmacy Council of New Zealand's professional guidelines and identify improvements in his dispensing practice. As part of this, Mr B should undertake continued education on pharmaceutical products by keeping a written log, over a period of three months, of the Pharmacy Council of New Zealand's "Safety Alerts", and provide HDC with a copy of this within four months of the date of this report. The log should outline the risks identified in the safety alert and the steps to be taken by the pharmacist to minimise harm to the consumer.

63. I recommend that the pharmacy:

a) Randomly audit, over a period of three months, its staff compliance with its "Dispensing 2 — Prescription assessment and clinical check", and provide HDC with the outcome of that audit within six months of the date of this report.
b) Incorporate into dispensary meetings, discussions around Pharmacy Council of New Zealand and/or Pharmacy Defence Association safety alerts and/or communications,

and provide HDC with copies of dispensary meeting agendas/minutes as evidence, within six months of the date of this report.

Follow-up actions

64. 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 to the district health board, and they will be advised of Mr B's name.

65. A copy of this report with details identifying the parties removed, except the expert who advised on this case, will be sent to the Pharmaceutical Society of New Zealand, the Health Quality and Safety Commission, and the New Zealand Pharmacovigilance Centre, and placed on the Health and Disability Commissioner website, www.hdc.org.nz, for educational purposes.

Appendix A: Independent advice to the Commissioner

The following expert advice was obtained from pharmacist Sharynne Fordyce:

"I, Sharynne Fordyce, have been asked to provide an opinion to the Commissioner on Case number 17HDC00538 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 locum for the Wairarapa DHB.

Expert Advice Requested
Please review the enclosed documentation and advise whether you consider the care provided to [Miss A] by [Mr B] was reasonable in the circumstances, and why.

In particular, please comment on:

1. The adequacy of [Mr B's] knowledge around dispensing atropine 0.01%.

2. The adequacy and appropriateness of the steps taken by [Mr B] prior to the dispensing of atropine.

3. You will note that it is disputed whether [Mr B] told [Ms A] that he believed there was a 'computer typo' and offered to return the prescription to [Ms A] if she was not comfortable proceeding with the dispensing.

   (a) If your advice relies on this fact, please provide your comments in the alternative.

   Please also comment on the appropriateness of a pharmacist having such a discussion with a customer.

4. The appropriateness of [Mr B's] decision to dispense atropine 1%.

5. The adequacy and appropriateness of the actions taken by [Mr B] once the dispensing error had been detected including (but not limited to):

   (a) Not quarantining atropine 1%;

   (b) The level of counselling/advice provided to [Ms A];

   (c) Deleting the dispensing record.

6. The adequacy of [Mr B's] incident reporting.

7. The adequacy of the relevant standard operating procedures in place at the pharmacy.

8. Any other matters in this case that you consider warrant comment.

For each question, please advise:

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

(b) If there is 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.

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).

Documents provided

1. Letter of complaint dated 27 March 2017 and telephone note dated 4 July 2017.
2. [Mr B's] response dated 6 April 2017.
3. [Lawyer's] covering letter dated 14 August 2017 enclosing:
4. [Mr B's] further response dated 26 July 2017.
5. [The pharmacy's] response dated 26 July 2017.
6. Incident Report Form.
7. Standard Operating Procedures.

Background

On 21 March 2017, [Ms A] and her daughter [Miss A] (eight years old) presented to [an optometry clinic] for an optometry consultation[1]. The clinical notes state that [Miss A] was referred to the clinic 'to discuss myopia[2] control options'. At the end of the consultation, [Miss A] was prescribed 'Atropine drops 0.01%, 1 drop both eyes at night, 3 months supply'.

On 26 March 2017 (a Sunday), [Ms A] presented to [a pharmacy] to have her daughter's prescription for atropine 0.01% dispensed. Pharmacist, [Mr B] was the only pharmacist working on this day. He completed the processing and dispensing of atropine. [Mr B] told HDC that he 'noticed the prescriber had written 0.01% atropine eye drops' and considered 'this was an unusual strength [as he] had only seen 1% drops prescribed'.

[Mr B] said that he used '[the dispensary software], MIMS (a medicine information resource) and [the pharmacy's] medicine supplier's website to search for formulations of atropine which were commercially available. Apart from 1%, there were no other eye drop strengths available'. [Mr B] added that 'there were no other dispensary staff members working at the time to check with if they had any knowledge of the strength

[1] Please note, the Commissioner does not require comment on the care provided to Miss A during this consultation.
[2] Short-sightedness.

being prescribed'. [Mr B] concluded that 'based on the information I had available, I made a judgement call in good faith that the prescriber had inadvertently written the strength as 0.01% so I processed the prescription as 1% eye drops'.

[Mr B] told HDC that 'there were no further avenues available to me for investigation, so before completing processing of the prescription, I raised the issue with [Ms A] and offered to return the prescription to her if she was not comfortable proceeding with the dispensing. Specifically I remember showing her the prescription noting that where the prescription read 0.01%, it perhaps should have read 1%, and that I believed there may have been a "computer typo" made by the prescribing doctor'. [Ms A] told HDC that she is 'very confident' that [Mr B] did not convey this information to her prior to dispensing the atropine.

On the evening of 26 March 2017, [Ms A] followed the prescription instructions and gave her daughter one drop of atropine per eye. She told HDC that immediately following this, she noticed that the bottle said 'atropine 1%' and recalled seeing 'atropine 0.01%' on the prescription. She said she became confused and concerned.

On 27 March 2017, [Ms A] rang [the pharmacy] and spoke to [Mr B]. She told HDC that she asked him to enquire about the correct strength of atropine however [Mr B] recalled that [Ms A] told him that 'the atropine was not working'. He stated that he contacted the [optometry clinic] who confirmed that 0.01% was the intended strength and that only [(Pharmacy 2)] could dispense this dose of atropine. [Mr B] phoned [Ms A] back to convey the above information and apologised.

[Mr B] told HDC that he did ask [Ms A] whether the atropine had been used and requested that [Ms A] monitor her daughter closely and to contact him if she required any further assistance or advice. [Mr B] said that he did not specifically ask whether there had been any ill-effects from the atropine and in hindsight, he accepts that he ought to have done so.

[Mr B] faxed the prescription to [Pharmacy 2] and deleted the dispensing recorded. He explained that he did this 'as it would have claimed a payment from the government if left in the system'. He told HDC that he filled out an incident report form as soon as the error was dealt with.

1. Adequacy of knowledge.
Atropine 0.01% eye drops have been favoured for use in myopia over atropine 1% eye drops due to a comparative reduction in side effects, but no reduction in efficacy. This information is readily available on the internet. A warning regarding the differing strengths of atropine eye drops, and their relative availability, was published in the Pharmacy Defence Association (PDA) practice points August 2016 Vol.26 (as mentioned by [Mr B]).

The standard of care required is outlined in the Competence Standards 2015, M1.1.5 which commits to life-long learning and professional development, with the onus on the individual professional.

[Mr B's] lack of knowledge regarding these drops would be considered moderate.

Not possessing this knowledge would not be regarded too severely by his peers, who are sympathetic to the time demands of the profession, and the ever changing nature of medicines. However not searching the internet more thoroughly to obtain more definitive information would be regarded as not very thorough.

Recommendations for improvement would include obtaining a list of reliable websites that can be used for such information when prescribers are unavailable.

2. Adequacy and appropriateness of steps taken prior to dispensing.
a) Accepted practice when in doubt about a prescription is to contact the prescriber in the first instance. As this was not possible, one would then check patient history, on the computer, and verbally, to see if the patient has had the product before. This step is not recorded, but we are assuming that [Ms A] had not had these drops before. Research to check the appropriateness of the strength should have revealed that 0.01% was an acceptable strength. However as the strength could not be verified, dispensing should have been deferred until the prescriber could be contacted. As [Ms A] was presenting the prescription 6 days after it was written, waiting one more day for confirmation would not have compromised treatment. 'A judgement call in good faith' is no substitute for professional responsibility, and is not accepted practice. Neither is giving the customer the option of either taking a different strength to the one prescribed or delaying the dispensing. This is asking [Ms A] to be complicit in a decision that is not hers to make. Reference to a 'computer typo' implies a slur on the practice of fellow professional[s], and is unprofessional and unethical.

b) This is a severe departure from accepted practice.

c) While being sympathetic to the position that [Mr B] was in of a sole pharmacist, operating on a Sunday, these actions would not be viewed as being as thorough and professional as required by [Mr B's] peers.

d) As mentioned by [Mr B], a decision has already been made to not dispense any prescriptions with queries, until the prescriber can be contacted.

3 a) To not have discussed with [Ms A] the dispensing of a different product from the one prescribed would be a severe departure from the accepted practice of keeping the customer fully informed about their medication.

As mentioned above in 2(a), the decision about dispensing a prescription ultimately rests with the pharmacist. It is not one for the customer to make. The dispute about this discussion taking place may also be as a result of [Ms A] not fully understanding the options [Mr B] was presenting to her, and would further emphasise the inappropriateness of this conversation, and indicates a severe departure from accepted practice. The only discussion with the customer should have stated doubt over the strength required, the need to contact the prescriber to confirm, and whether [Ms A] wanted to leave the prescription at the pharmacy to await confirmation of the dose on Monday morning, or take the prescription, undispensed, away with her.

4. Dispensing appropriateness
[Mr B's] decision to dispense the atropine 1% drops was inappropriate due to his lack of certain knowledge regarding varying strengths of the drops, and the lack of confirmation with the prescriber. As previously mentioned, the disputed conversation

with [Ms A] does not exonerate his action. This is a moderate/severe departure from accepted standard of care, especially as the difference in strength of the eye drops is very significant. Acknowledging the pressure exerted on pharmacists on a Sunday, when few prescribers are contactable does not mitigate the decision. As mentioned by his employer, [Mr B] was an experienced pharmacist. As earlier stated, the prescription was six days old and a day waiting for confirmation would not compromise treatment.

5. Actions taken after error detected.
a) After detecting the error it would be accepted practice for [Mr B] to have offered to immediately uplift the drops from [Ms A], if not himself, then at least a staff member. This would have removed the danger of [Ms A], or [Miss A] inadvertently administering the incorrect strength again, or mixing the two bottles, when the new drops arrived from [Pharmacy 2]. It would also have reassured [Ms A] that [Mr B] was concerned about the error and her daughter.

b) By his own admission [Mr B] regrets not asking if [Miss A] was suffering any ill effects from the eye drops. Again there is dispute over what was said, which may have allayed his fears. It would have been more appropriate for [Mr B] to have contacted the prescriber first thing on Monday morning to confirm the strength of the eye drops and his actions. Waiting until [Ms A] phoned did not present a concerned image. At this stage, in between phone calls to the prescriber and [Ms A], [Mr B] could have researched the eye drops, and the likelihood of any side effects from the increased strength used. This information could have been given to [Ms A], and to reassure her that there would be no long lasting ill effects. Therefore [Mr B's] level of advice and counselling would be seen as a moderate departure from accepted practice.

c) Deleting the dispensing record, and not keeping a copy of the prescription (particularly as it was still on hand when the error was detected) [is] a severe departure from accepted practice, and would be deemed very unwise by his peers. It also means [Mr B] was unable to fully complete the Incident Form. He also would not be able to make any notes against the dispensing on the computer as to the nature of the issue for future reference. [Mr B] does acknowledge that he should have kept a copy.

6. Adequacy of reporting.
[Mr B's] incident reporting was comprehensive, except for a copy of the prescription, and timely. It would be viewed as well within accepted practice.

7. Relevant Standard Operating Procedures.
The relevant Standard Operating Procedures (SOPs) in place at [the pharmacy] are generic SOPs produced by Green Cross Health, individualised for all their members and are adequate.

8. With the disputes that occurred over what was said during this incident, it may be appropriate to remember the importance of effective communication, and ensuring accurate meanings are fully understood."

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

"I, Sharynne Fordyce, have been asked to provide an opinion to the Commissioner on Case number 17HDC00538 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 locum for the Wairarapa DHB.

In particular, I have been asked to reply to [Mr B's] response to my original report. Please review this response and advise whether any of the concerns raised by [Mr B] cause you to change your advice in any way. Please provide an explanation for why your views remain the same or have changed, including whether the level of departure has been altered.

1. Adequacy of knowledge

In response to [Mr B], I was not disputing the reputable sources he used for reference. I was acknowledging that medical information is now available from many sources, including the internet. Upon typing 'Atropine drops 0.01% in NZ' into a popular search engine request, the first page of results revealed two references from the Pharmacy Defence Association (PDA) and one from a Pharmac subcommittee on Opthalmology, all of which dealt with this strength of drops in New Zealand, including indications for their use, and availability.

a) By citing the Competence Standard M1.1.5 I meant to give an emphasis on the onus of the individual to remain as up to date as possible with knowledge about new products. This is not to imply that this is an easy process, but to acknowledge that any professional could be judged by the same standard if unaware of a product's availability.

b) My recommendations for improvement would be better altered to read that a general search of the internet is applicable if regular sources have not produced the information required. Professional judgment can be used to distinguish reputable sources of information, eg Pharmac, from those produced by more commercial sites, in this case various ophthalmic retail sites.

2. Adequacy and appropriateness of steps taken prior to dispensing.

a) My apology. My notes should read "we are assuming that *[Miss A]* had not had these drops before".

3. I believe I covered the important aspects of the decision making when I commented 'The only discussion with the customer should have stated doubt over the strength required, the need to contact the prescriber to confirm, and whether [Ms A] wanted to leave the prescription at the pharmacy to await confirmation of the dose on Monday morning, or take the prescription, undispensed, away with her.' The customer had been informed of [Mr B's] concerns and offered suitable alternatives, that did not include having to make a clinical decision about the strength of eye drops she should or could accept. As previously stated, a decision about whether to accept the 1% drops was not [Ms A's] to make.

I fully concur with [Mr B's] statement that prescribers are not infallible, and that pharmacists are often called upon to check the strength, and agree it is part of our job. The remainder of my original report remains unaltered and my views remain the same."