Pharmacy
Pharmacist, Ms B

A Report by the
Deputy Health and Disability Commissioner

(Case 14HDC01530)

Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

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Executive summary

1. Master A, eight years old at the time of these events, suffers from epilepsy and Fanconi's syndrome, a disorder of the kidney tubules whereby the body is unable to absorb certain substances normally.[1] To treat the latter condition, he had been taking sodium bicarbonate twice daily for approximately one year.

2. On 14 May 2014, Master A's general practitioner (GP) prescribed Master A 60 x 840mg sodium bicarbonate capsules, two capsules to be taken once daily, with two repeats.

3. On 20 May 2014, Master A's mother, Ms A, presented at the pharmacy to collect Master A's medication. A trainee technician, Ms H, typed up Master A's prescription and generated a dispensing label that stated: "SODIUM BICARBONATE CA 840mg".

4. The person dispensing Master A's prescription dispensed 60 zinc capsules (50mg) in error, rather than dispensing sodium bicarbonate capsules. The zinc capsules were in the original bottle with a label stating "Zincaps", "ZINC SUPPLEMENT", and "50mg". The staff member dispensing the medication attached the dispensing label generated by Ms H to the bottle of zinc capsules; however, the original label was still visible. The staff member who dispensed the medication failed to initial Master A's prescription, so the pharmacy was unable to identify who dispensed the prescription.

5. Pharmacist Ms B checked the dispensing of Master A's prescription. As part of her checking process, Ms B opened the medication bottle to check inside. Zinc and sodium bicarbonate capsules are similar in appearance, and Ms B did not recognise the error. In addition, she did not notice the words "Zincaps", "ZINC SUPPLEMENT" or "50mg" on the outside of the bottle.

6. In September 2014, Ms A began giving Master A the zinc capsules dispensed by the pharmacy on 20 May 2014, believing that the medication was sodium bicarbonate. On 22 September 2014, Master A suffered epileptic seizures, unrelated to having taken zinc capsules, and was admitted to a public hospital via ambulance. Ms A took Master A's medications with him to the hospital, in case he needed them while he was there.

7. On 23 September 2014, the hospital paediatric pharmacist, Ms J, undertook a medications reconciliation of Master A's medication (comparing his physical medication with the medication he had been prescribed). Ms J noticed that Master A had been dispensed zinc capsules rather than sodium bicarbonate. Ms J notified Ms A, the ward doctor, and the pharmacy of the error.

[1] Glucose, amino acids, uric acid, phosphate and bicarbonate are released into the urine instead of being absorbed into the bloodstream.

Findings

8. Ms B failed to adequately check the dispensing of Master A's prescription. Accordingly, Ms B failed to provide Master A with services in accordance with professional standards and breached Right 4(2)[2] of the Code.

9. Criticism is made of the pharmacy's failure to ensure that all staff complied with its dispensing standard operating procedure and that these errors led to an unsatisfactory service being provided to Master A by its staff members.

Complaint and investigation

10. The Commissioner received a complaint from Ms A about the services provided to her son, Master A, by the pharmacy. The following issues were identified for investigation:

- *Whether the pharmacy provided an appropriate standard of care to Master A in May 2014.*
- *Whether pharmacist Ms B provided an appropriate standard of care to Master A in May 2014.*

11. An investigation was commenced on 3 February 2015. This report is the opinion of Rose Wall, Deputy Commissioner, and is made in accordance with the power delegated to her by the Commissioner.

12. The parties directly involved in the investigation were:

Master A	Consumer
Ms A	Complainant
The pharmacy	Provider
Ms B	Pharmacist/provider

Also mentioned in this report:

Ms C	Pharmacist
Ms D	Pharmacist
Ms E	Technician
Ms F	Technician
Ms G	Technician
Ms H	Trainee technician
Ms I	Shop assistant
Ms J	Paediatric pharmacist
Ms K	Pharmacy director
Dr L	Clinical director for paediatrics

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

13. Independent expert advice was obtained from pharmacist Ms Carolyn Oakley-Brown (**Appendix A**).

Information gathered during investigation

Master A

14. Master A, eight years old at the time of these events, suffers from epilepsy[3] and Fanconi's syndrome. Fanconi's syndrome is a disorder of the kidney tubules whereby the body is unable to absorb certain substances, including bicarbonate,[4] normally. The body becomes overly acidic and deficient in these substances. As part of the treatment of this condition, Master A had been taking sodium bicarbonate[5] twice daily for approximately one year.

Prescription

15. On 14 May 2014, Master A's GP[6] prescribed Master A 60 x 840mg sodium bicarbonate capsules, two capsules to be taken once daily, with two repeats. Master A's prescription also contained a prescription for three other medications, one of which was an extemporaneous mixture.[7] The GP faxed the prescription to the pharmacy, to be picked up at a later date.

The pharmacy

16. On Tuesday 20 May 2014, Ms A presented at the pharmacy to collect Master A's medication. On 20 May 2014, the following staff members were working at the pharmacy:

a) pharmacist Ms B;
b) pharmacist Ms D;
c) pharmacist Ms C;
d) technician Ms E;
e) technician Ms F;
f) technician Ms G;
g) trainee technician Ms H;[8] and
h) shop assistant Ms I.

Usual process

17. The Director of the pharmacy, Ms K, told HDC that on a normal Tuesday, Ms B and Ms H opened the pharmacy, tidied the dispensary, and started typing up faxed

[3] A pattern of repeated seizures caused by nerve cells in the brain firing electrical impulses at a rate of up to four times higher than normal.
[4] As well as glucose, amino acids, uric acid and phosphate.
[5] A salt, also known as baking soda or bicarbonate of soda.
[6] The GP is vocationally registered in general practice.
[7] A drug or combination of drugs prepared or compounded in a pharmacy according to a prescription.
[8] Ms H was supervised by Ms B in the main dispensary, and by Ms D in the second dispensary.

prescriptions "if necessary". Prescriptions for people waiting in the pharmacy are prioritised over faxed prescriptions.

18. Ms K said that the rest of the staff normally arrive later, at which time three staff members, Ms H, Ms D and Ms B, pack and check blister packs in an upstairs dispensary (second dispensary) separate from the main dispensary. Ms C, Ms E and Ms F remain in the main dispensary. The staff in the second dispensary are available to assist the staff in the main dispensary if required.

Dispensing label generated

19. Ms H advised HDC that on the morning of 20 May 2014 she typed up Master A's prescription and generated dispensing labels. The dispensing label for sodium bicarbonate stated: "SODIUM BICARBONATE CA 840mg". Ms H does not recall being involved in dispensing the medication in Master A's prescription.

Prescription dispensed in error

20. It is unclear whether Master A's medication was dispensed in the main dispensary or the second dispensary. The pharmacy told HDC that at the time Master A's prescription was dispensed, usual practice was for the person dispensing the medication to initial the prescription to indicate his or her involvement in the dispensing of the prescription. The dispensing staff member failed to initial Master A's prescription. For this reason, the pharmacy is unable to identify who dispensed Master A's prescription for sodium bicarbonate.

21. Rather than dispensing sodium bicarbonate capsules, the person dispensing Master A's prescription dispensed 60 zinc capsules (50mg) in error. The zinc capsules were dispensed in their original bottle with a label stating "Zincaps", "ZINC SUPPLEMENT", and "50mg". The staff member dispensing the medication attached the dispensing label generated by Ms H to the bottle of zinc capsules; however, the original label was still visible (see **Appendix B**).

22. Zinc capsule bottles are white with a narrow dark blue label, while sodium bicarbonate capsule bottles are white with a narrow maroon and blue label. Sodium bicarbonate capsules and zinc capsules are both white, but are different sizes.

23. At the time that Master A's prescription was dispensed, the zinc capsules were kept on a shelf directly below the sodium bicarbonate capsules.

Prescription checked

24. On 20 May 2014 at 10am, Ms B moved from the second dispensary to the main dispensary. Ms B checked the dispensing of Master A's prescription and signed the prescription. With regard to usual practice at the pharmacy, Ms K told HDC:

> "Self Checking is something pharmacists do, I do agree with that, but at the pharmacy it has always been an unwritten policy that I advise against it … it is not the safest checking process and is not necessary as we have enough staff in the dispensary. Hence I do think that it is very unlikely that [Ms B] had checked her own dispensing at the time of the incident."

25. Ms B recorded on the incident form regarding the error that, as part of her checking process, she opened the medication bottle to check the appearance of the capsules inside but, because of the similarities between the appearance of zinc and sodium bicarbonate capsules, she did not recognise the error. Furthermore, Ms B did not notice the words "Zincaps", "ZINC SUPPLEMENT" or "50mg"on the outside of the bottle.

Recollections of other staff at the pharmacy

26. Ms C told HDC that she made up the extemporaneous medication on Master A's prescription in accordance with usual process,[9] but was not involved in dispensing the rest of the prescription.

27. Ms F was not involved in any part of the dispensing process for any prescriptions on 20 May 2014, other than handing out medication. Similarly, Ms G was not in the main dispensary on 20 May 2014, and was therefore not involved in dispensing Master A's prescription.

28. Ms D and Ms E advised HDC that they have no recollection of any involvement in dispensing Master A's prescription.

Following the dispensing error

29. Ms A took home the medication dispensed by the pharmacy on the day it was dispensed. However, she already had sodium bicarbonate capsules from previous prescriptions for Master A, which she gave to him over the next few months.

30. In September 2014, Ms A began giving Master A the zinc capsules dispensed by the pharmacy, believing that the medication was sodium bicarbonate. By that time, Master A was taking only one sodium bicarbonate capsule each day, as his dose had been decreased from two capsules each day. Ms A gave Master A one zinc capsule each day for up to ten days.

Error discovered

31. On 22 September 2014, Master A suffered six epileptic seizures and was admitted to hospital via ambulance.[10] Ms A took Master A's medications with him to the hospital, in case he needed them while he was there.

32. On 23 September 2014, the hospital paediatric pharmacist, Ms J, assessed Master A. Ms J told HDC that she undertook a medications reconciliation of Master A's medication (comparing his physical medication with the medication that he had been

[9] Ms C told HDC that the usual process for prescriptions that include extemporaneous mixtures is as follows: "[The prescription is] usually put through the computer, the non-extemporaneous items are then dispensed, checked and bagged. The checked, bagged items are placed in a basket with the extemporaneous mixture label, batch sheet and the prescription. The extemporaneous mixture is then made up at a more convenient time, often the next day or so."

[10] As stated above, Master A suffered from epilepsy. The clinical director for paediatrics, Dr L, oversaw Master A's care while he was in hospital. Dr L told HDC: "From the information obtained through [Master A's] medical notes and electronic records I do not feel that the medicinal error had affected his health."

prescribed). Ms A told Ms J the type of medication Master A had been taking, and showed her the medication she had brought with her.

33. Ms J noticed that Master A had been dispensed zinc capsules rather than sodium bicarbonate.[11] Ms J told HDC that the sodium bicarbonate label had been placed on the original bottle of zinc capsules, but that the original zinc capsules label was "fully visible". Ms J told HDC:

> "I checked with [Ms A], that she had not transferred any capsules to other bottles. She confirmed that she never does this and always dispensed medication to Master A from the original bottle suppled by the retail pharmacy.
>
> I brought the Zincaps down to the inpatient's pharmacy ([at the] Hospital) and compared them to the Sodium Bicarbonate 8.4% capsules we had in stock. Although Zincaps and Sodium Bicarbonate 8.4% capsules are both white they are of a different size."

34. Ms J notified Ms A and the ward doctor of the error. The same day, Ms J took the zinc capsules to Ms C at the pharmacy and told her of the error. The pharmacy re-dispensed the correct medication for Master A. Ms J retained the zinc capsules at the public hospital.

Incident forms completed

35. On 23 September 2014, Ms B and Ms C both completed incident forms regarding the dispensing error. Ms B recorded:

> "During dispensing [I] opened bottle to check appearance which was similar but failed to peel label away to check original bottle.
>
> …
>
> Similar appearance of both capsules. Although the appearance of the capsules was checked by opening the bottle the label on the bottle was not checked correctly.
>
> The Zinc and sodium bicarb were directly placed below the other increasing chances of error …"

36. With regard to her notes on the incident form, Ms B told HDC:

> "The note I wrote in the incident report 'failed to peel label away to check original bottle' was theorised. When I was filling out the incident report I was trying to list all the possible reasons why this could have happened and to prevent future incidents of this nature. I did not have the original bottle to examine at hand at the time of filling out the report as it was kept with Pharmacist [Ms J] at the hospital."

37. Ms C recorded on an incident form:

[11] Ms J advised that at the time of this investigation there were 49 capsules remaining; however, she noted that she "might have used one or two to compare with the sodium bicarbonate capsules".

"[R]e-dispensed sodium bicarbonate to [Ms J]. Gave [Ms J] copy of script. Offered pamphlet from Health + Disability [Commissioner].

…

→ Changed position of zincaps.

→ SOP changed recently to reinforce 2 people being involved in dispensing …"

38. Master A was monitored at hospital and discharged on the afternoon of 23 September 2014.

Standard operating procedure

39. The pharmacy's "Dispensing Prescriptions" standard operating procedure (SOP) valid in May 2014[12] stated:

"7.7 Check the strength, quantity of the medicine against the prescription …

7.8 Dispense product in a suitable container, and affix the label so that directions are clear, and if using an original container, no important information on the label is obscured. Affix Cautionary & Advisory labels as appropriate. Check the labelling against the prescription.

…

7.11

…

The pharmacist responsible for dispensing the prescription must initial the prescription. Then assemble the prescription items, with the prescription form and the prescription receipt and place in alphabetical order on the shelf to await collection.

7.12 On the return of the patient (or patient's agent) check the items against the receipt label and hand them over to the patient …"

Actions taken following these events

The pharmacy

40. Since these events, the pharmacy has reviewed its dispensing SOP in order to ensure that at least two people are involved in the dispensing process for each prescription. The dispensing SOP dated 1 February 2015 now states:

"7.3 In the dispensary (pharmacy technicians, interns or pharmacists):

…

If dispensing pharmacist and checking pharmacist is the same person, attach a note [to draw the dispensing and checking pharmacists' attention to relevant points].

[12] The Dispensing Prescriptions SOP is dated 1 Jan 2011.

…

7.5 Labelling and dispensing medicines

…

The pharmacist/technician entering the prescription into the computer must initial in the box of the date stamp headed 'ENT'.

…

7.6 Dispense medicines:

…

Check the name, brand, strength and formulation against the prescription, not the label.

…

Double check labels against the original prescription, before attaching them to the container.

…

Do not obscure any important information.

…

In cases where the stock bottle/box cannot be left beside the dispensed medicine such as when labels are placed on original bottles/boxes ensure labels do not cover or obscure the medicine name and strength of original bottle or box to allow for accurate checking.

…

When all the items have been dispensed, the prescription should be annotated with the dispenser's initials in the box of the pharmacy date stamp headed 'DISP'.

…

Leave the prescription (and any attached notes), stock bottles and dispensed items in the designated checking area for an accuracy check by the pharmacist.

7.7 Accuracy Check

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

…

Formulation, strength and quantity of medicine

Open each dispensed bottle or skillet to compare contents with stock supply.

…

Do not self check. If a pharmacist has dispensed the prescription, the final check must be done by another pharmacist other than themselves. No pharmacist is to complete all process to minimise potential errors.

> If self-checking can't be avoided, separate the 'physical' and 'mental' activities by another task e.g by dispensing another prescription.
>
> Initial each item on the prescription when it has been checked and passed for accuracy.
>
> The final check requires the checking pharmacist to initial in the 'chck' [sic] box on the date stamp of the prescription …"

41. In addition to updating its dispensing SOP, the pharmacy has reminded staff that if medication is dispensed in the original bottles, original labels must not be covered by the dispensing label. Ms K told HDC that she also "stressed the importance of never obscuring important information on original bottles with our pharmacy labels". Furthermore, medicines dispensed in new bottles must have the original bottles placed next to them in order to compare appearance, name and strength.

42. Staff have also been reminded that all staff involved in dispensing must initial the prescription to ensure that someone is accountable for every action taken. The pharmacy has supplied staff members with a stamp to be used on each prescription, which indicates a space for the signature of each person who is involved in the dispensing process.

43. Owing to the zinc and sodium bicarbonate bottles and capsules having a similar appearance, zinc capsules are now stored on the lowest shelf, away from the sodium bicarbonate capsules, which are placed at eye level. In addition, warning signs have been placed on the shelves. On the sodium bicarbonate shelf, the warning sign states:

> "WARNING SODIBIC, NOT TO CONFUSE WITH ZINCAPS."

44. On the zinc shelf, the warning sign states:

> "WARNING ZINCAPS, NOT TO CONFUSE WITH SODiBIC [sic]."

45. The pharmacy advised HDC that it has now placed similar warning signs in front of other medications with similar bottles or capsules.

46. The pharmacy has employed a full-time Charge Pharmacist, whose role includes ensuring that extra dispensary staff are sought if required.

47. The pharmacy advised that the incident involving Master A, as well as all changes implemented, have been discussed at its monthly staff meeting to prevent a recurrence.

48. In order to avoid interrupting a staff member during the dispensing process, requests are now put in writing and placed in a queue with prescriptions.

Ms B

49. Ms B acknowledged that the Pharmacy can be busy at times, but stated:

> "I work with a good supportive team. I have never felt understaffed or overworked and have at least 1 technician per pharmacist at all times in the dispensary. We

also had more dispensary staff upstairs that I could have called down for assistance at my own discretion."

50. Ms B noted that the team at the Pharmacy, including Ms K, had been very supportive in ensuring that such an error does not occur again. Ms B also advised HDC that she assisted in updating the SOP and discussed the changes with other dispensary staff and technicians. Ms B said that she has also taken "corrective action" in response to this event, including review of her dispensing processes and checking techniques. She stated:

"I am currently using this opportunity to improve on my accuracy in dispensing through the Continued Professional Development Programme ENHANCE 2.0."[13]

51. In October 2014, having been made aware of the medication dispensing error, Ms B provided a letter of apology to Ms A, for her role in the incident.

Relevant professional standards

Pharmacy Council of New Zealand Competence Standards for the pharmacy Profession 2010 (PCNZ Competence Standards)

52. "Element 6.6
6.6.2 Maintains a logical, safe and disciplined dispensing procedure."

Pharmacy Council of New Zealand — Safe Effective Pharmacy Practice, Code of Ethics 2011 (PCNZ Code of Ethics):

53. "**Principles**
1.2 Take appropriate steps to prevent harm to the patient and the public.

…

5.1 Be accountable for practising safely and maintain and demonstrate professional competence relative to your sphere of activity and scope of practice."

Response to Provisional Opinion

Ms B and the pharmacy

54. In a combined response to the provisional opinion Ms B and Ms K stated that they were "overall satisfied with both the proposed recommendations and follow up actions which will allow [them] to ensure the continual improvement of [their] dispensary practices, as well as guarantee the wellbeing and trust from our patients."

[13] The recertification programme provided by the Pharmaceutical Society of NZ Incorporated, and accredited by the Pharmacy Council of NZ.

Ms A

55. In response to the 'information gathered' section of the report Ms A told HDC that she hopes that her complaint will mean that this kind of error does not happen to anyone else in the future.

Opinion: Ms B

Checking dispensing of Master A's prescription — breach

56. On 20 May 2014, Ms B checked the dispensing of Master A's prescription. The dispensing label stating "sodium bicarbonate" was placed on the original bottle of zinc capsules. However, the dispensing label did not obscure the original label, which was still clearly visible and included the words "Zincaps", "ZINC SUPPLEMENT", and "50mg".

57. Ms B wrote in the incident report form that as part of her checking process she opened the medication bottle to check the appearance of the capsules inside but, because of the similarities in appearance between zinc and sodium bicarbonate capsules, did not recognise that an error had been made. She also did not notice the words "Zincaps", ZINC SUPPLEMENT" or "50mg", which were clearly visible on the outside of the bottle.

58. As a registered pharmacist, Ms B is responsible for ensuring she adheres to professional standards. The PCNZ code of ethics, outlined above, requires registered pharmacists to "… take appropriate steps to prevent harm to the patient and the public …" and to be accountable for practising safely and for maintaining and demonstrating "professional competence". My expert advisor, pharmacist Ms Carolyn Oakley-Brown, stated that it is common practice for checking to include the "[f]ormulation strength and quantity" of the medication. She advised: "The accuracy of the checking by the Pharmacist showed a lack of care."

59. Ms B told HDC:

> "… I work with a good supportive team. I have never felt understaffed or overworked and have at least 1 technician per pharmacist at all times in the dispensary. We also had more dispensary staff upstairs that I could have called down for assistance at my own discretion."

60. Ms B failed to undertake an adequate check of the dispensing of Master A's prescription. Accordingly, I consider that Ms B failed to provide Master A with services in accordance with professional and ethical standards and breached Right 4(2) of the Code.

61. I acknowledge that, following these events, Ms B apologised to Ms A for her role in the error, and has taken steps to review and improve her dispensing processes, including undertaking a continued professional development programme through

ENHANCE 2.0. Ms B has also advised that she has been involved in implementing changes at the pharmacy.

Opinion: The pharmacy— adverse comment

Dispensing Master A's prescription

62. As outlined above, on Tuesday 20 May 2014 when Master A's prescription was dispensed, there were three pharmacists, three technicians and a trainee technician working at the pharmacy. Ms H typed up Master A's prescription and Ms B checked the dispensing of the prescription. The pharmacy told HDC that it does not know who dispensed Master A's prescription and, therefore, who selected the bottle of zinc capsules in error, rather than sodium bicarbonate capsules.

63. The relevant pharmacy dispensing SOP stated that the dispensing pharmacist was required to:

> "7.7 Check the strength, quantity of the medicine against the prescription …
>
> 7.11 … initial the prescription …"

64. The staff member dispensing the medication failed to comply with the dispensing SOP in a number of ways. The staff member dispensed zinc capsules in error, rather than sodium bicarbonate capsules. Furthermore, I note that the medication dispensed was the incorrect strength. Master A's prescription was for 840mg capsules; however, the zinc capsules were 50mg. Ms J told HDC that while zinc capsules and sodium bicarbonate capsules are both white, they are different in size. Finally, the staff member dispensing the medication failed to initial the prescription in order to identify that she was involved in the dispensing process.

65. Owing to the dispensing staff member's failure to initial the prescription, I am unable to identify that person. However, I am highly critical that these errors occurred. In my opinion this brings into question the systems in place at the pharmacy for the oversight and monitoring of staff adherence to its SOPs.

Checking dispensing of Master A's prescription

66. Ms B was also an employee of the pharmacy. 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 may be vicariously liable for any act or omission by an employee. Under section 72(5) of the Act, it is a defence for an employing authority if it can prove that it took such steps as were reasonably practicable to prevent acts or omissions leading to an employee's breach of the Code.

67. This Office has previously found providers not liable for the acts or omissions of staff, when those acts or omissions clearly relate to an individual clinical failure made by the staff member.[14]

[14] Opinion 12HDC01483 (12 July 2013) available at: www.hdc.org.nz.

68. As outlined above, Ms Oakley-Brown advised:

> "The accuracy of the checking by the Pharmacist showed a lack of care. 'Formulation strength and quantity' are all included as steps in the accuracy check as documented in the Pharmacy's SOP and this is common practice."

I accept my expert's advice, and am satisfied that Ms B's breach of the Code was an individual failure. I consider that the pharmacy's dispensing SOP, relevant at the time of these events, was ambiguous with regard to when checking was expected to occur. However, there is no evidence that staff were unclear about expected practice with regard to the checking of prescriptions, and I am satisfied that the ambiguities in the SOP did not impact on the checking of Master A's medication.

Conclusions

69. A pharmacy has an obligation to ensure that it has adequate policies in place to facilitate safe and disciplined dispensing. It is also responsible for ensuring that staff adhere to policies and procedures. I acknowledge that the pharmacy's dispensing SOP at the time appears to have been satisfactory. The errors appear to be that the dispensing staff member selected the incorrect medication and failed to initial the prescription. Furthermore, the checking pharmacist failed to detect the error. Accordingly, three aspects of the SOP were not adhered to.

70. In my view it is concerning that multiple individual errors occurred with regard to the dispensing of Master A's medication. I have found no evidence of systemic failings at the pharmacy that resulted in the errors however, I remain concerned that these errors occurred despite the systems in place, and that these errors led to an unsatisfactory service being provided to Master A by its staff members.

71. I consider that there are lessons to be learnt from this incident. I am encouraged by the changes made by the pharmacy following these events. The pharmacy has taken steps to review and improve its dispensing SOPs and processes, including introducing the use of the stamp to encourage staff to initial prescriptions to indicate their involvement in the dispensing processes.

Recommendation

72. In accordance with the recommendations of my provisional opinion, the pharmacy has agreed to:

- provide a written apology to Ms A and Master A, to be sent to this Office for forwarding to Ms A within three weeks of the date of this report.
- conduct an audit of three months' compliance with the SOPs for dispensing, which have been updated since this incident, and report the results of the audit to HDC within four months of the date of this report.

Follow-up actions

- 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 the DHB, and they will be advised of Ms B's name.

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

Appendix A — Independent pharmacy advice to the Commissioner

The following expert advice was obtained from pharmacist Ms Carolyn Oakley-Brown:

"**I, Carolyn Oakley-Brown have been asked to provide an opinion to the HDC Commissioner on Compliant: Master A ref: 14/01530.**

I have read and agree to follow the Commissioner's Guidelines for Independent Advisors.

After graduating from Otago University in 1982 with a Bachelor of Pharmacy, I completed my internship at Christchurch Hospital then worked as a Hospital Pharmacist in NZ and the UK. Since returning to NZ I have owned and managed a number of Community Pharmacies including overseeing pharmaceutical sales, marketing, merchandising, operations, and staff. I completed and gained a Post Graduate Certificate in Pharmacy from Otago University in 2012.

I have worked at governance level for Pharmacy Council of NZ from 2003 until 2011 — 6 of these years were in the role of Chair. Other Governance roles include: Chair of the Community Pharmacy Leaders Forum in 2012. Chair of Canterbury Community Pharmacy Group (CCPG) from 2008–2013. In May 2014, I was made a Fellow of the Pharmaceutical Society of NZ in recognition of significant and outstanding contribution to the advancement of the practice of Pharmacy in NZ.

Together with my husband Simon, I am Pharmacist Owner of Brighton Village, Union St, Belfast, Rolleston, Rolleston Central and Shelley St Pharmacies, all based in Christchurch. All of our Pharmacies have passed regular Medsafe audits and second on the list of our Company core values, after exceptional customer service is quality.

I have extensive experience in dispensing and other Clinical Pharmacist services e.g. Medicines Use Reviews (MUR), Emergency contraception, INR monitoring for Warfarin patients, Medicines Therapy Assessment (MTA) and medico packing.

Below I have stated my advice regarding the appropriateness of the care provided to [Master A] by [the pharmacy], and its pharmacy staff in May 2014. Specifically:

Q1.The appropriateness of the care provided by [Ms H] to [Master A] in entering [Master A's] prescription into the computer.

[Ms H] who generated the label and processed the prescription through [the pharmacy's] computer appears to have done so and been consistent with accepted standards of practice for her role. She was a trainee Technician which could be described below as a Pharmacy Technician Student.

I have listed below a summary of Supervision Requirements which are:

Pharmacy Technicians, Dispensary Assistants, pharmacy graduates, pharmacy students and pharmacy technician students **may dispense medicines** only under the direct personal supervision of a pharmacist — Medicines Act section 3 and section 18(1)(a), Medicines Regulations 42(1) and (1A) and regulation 63. This Act also states that trainee Technicians can assist the Pharmacist with computer entry for generation of prescription labels which is what [Ms H] was recorded as doing. I am assuming that this computer data entry was under direct supervision of a Pharmacist on that day.

She appears to have followed [the pharmacy's] Standard Operating Procedure (SOP) for dispensing but the only evidence that we have that the label was done correctly was from her brief description of the events. We have no copy of the label that was generated. I would assume that the Hospital Pharmacist ([Ms J]) who picked up the dispensing error would have reported a label that wasn't consistent with good practice or that didn't meet Medsafe's legal requirements. [Ms H] mentioned that 'it was a dispensing error' and not one of labelling so this is what I have assumed. Labelling requirements come from: Regulation 42 of the medicines Regulations 1984, Code of Ethics and Quality Standards for Pharmacy in NZ.

Q2. The appropriateness of the care provided to [Master A] by the pharmacist dispensing [Master A's] prescription.

There are a few factors that show a lack of care which are:

1. The person who dispensed any or all of the medications on this prescription form was not identified. It could have been either of the two Pharmacists, [Ms B] or [Ms C] or the Technician [Ms E]. Less likely but it is possible to have been [Ms F] who was filling in for a retail person who was off sick. In [the pharmacy's] SOP it states 'when all items have been dispensed, the prescription should be annotated with the dispenser's initials in the box of [the pharmacy] date stamp headed "DISP"'. Their stamp didn't have this option and so this wasn't done. The Pharmacist signed the item label but as the final checker. No one signed as the dispenser and it is not clear from the correspondence who was dispensing on that day. It is important that this current process is reviewed and changed. I mention this in more detail below. I believe the written response from the Pharmacist Owner's ([Ms K]) that the inadequate dispensary date stamp has now been replaced.

   See attachment 1 for a copy of our date stamp.

2. In addition to this it is essential that as [Ms K] states in her commentary dated 17 February 2015 that changes in the dispensing procedure to have 'at least two people involved in the dispensing process' will occur from now on. How many were in each dispensary on the day the mistake was made? This is unclear. [The pharmacy] Practice eHandbook (Pharmaceutical Society of NZ) states 'the dispenser and the checker must always be readily identifiable'.

However, if the dispenser and the checker were the same person it is the Pharmacist that is at fault for incorrectly self checking.

[The pharmacy's] dispensary SOP also states that when labels are placed on original bottles, 'ensure labels do not cover or obscure the medicine name and strength of original bottle to ensure accurate checking can take place'. If this process had been followed correctly the error may not have occurred.

Q3. The appropriateness of the care provided by [Ms B] to [Master A] in checking [Master A's] prescription.

a. Please include your comment on whether you would expect [Ms B] to have pulled back the dispensing label to check underneath it.

Yes, the Pharmacist, [Ms B] should have clearly identified that the medicine was correct by peeling back the label. Pharmacists correctly do this all the time especially if a container is sealed and you don't want the seal broken. It is quite fundamental and sometimes the only way of ensuring you have the correct medicine, especially so in a less commonly used medication such as sodium bicarbonate. This example of checking did not follow best practice.

The accuracy of the checking by the Pharmacist showed a lack of care. 'Formulation, strength and quantity' are all included as steps in the accuracy check as documented in [the pharmacy's] SOP and this is common practice. In addition to the documented Pharmacy SOP, normal steps in the checking of the dispensing procedure as stated in PSNZ's eHandbook are that:

- the pharmacist is responsible for the final check of the prescription
- check for label accuracy — name, date, medicine strength and form, instructions, C&A labels and contents accuracy — correct medicine, dose, form and quantity
- the dispenser and checker of a prescription must always be readily identifiable

A pharmacy dispensing 510 prescriptions per day is not uncommon but would be classified as a 'High volume dispensary'. This busy practice would place many demands on Pharmacists' attention especially if they are constantly interrupted by other staff requests, other Pharmacist services, 'Pharmacist Only' sales or phone calls. Ways of preventing errors in busy dispensaries highlight the importance of not 'self-checking' if at all possible. Self checking often only happens now in some Pharmacies on weekends when prescription volumes and staffing are low or in extreme cases of sickness, cross over at lunch times etc.

4. The appropriateness of [the pharmacy's] policies, both at the time of these events, and subsequently updated.

The new policies and SOP's dated 1 Feb 2015 are acceptable and of a high standard. However, **I notice that pages 3 and 4 are missing** which may just be a transmitting error. Is there are reason for this? 7.4 is not included but I assume this is just an error of omission. Nonetheless, it may signify a lack of thoroughness and haste in replying.

The proposed change to the dispensing stamp and the number of people in the dispensing process (now 2) will hopefully prevent further risks of errors occurring.

The earlier policies dated 1 Jan 2011 make it clear that:

1. if using an original container, no important information on the label is obscured and
2. the Pharmacist responsible for dispensing the prescription must initial the prescription.

However these instructions were not followed which unfortunately has led to this error. Although neither of these things were correctly carried out in this situation this earlier policy (2011) was correct and gave clear instructions.

The newer policies and SOP's (2015) cover more detail and they are more specific around patient safety. As mentioned above they are adequate, clear and up to date but not complete.

It is also worth noting that the process after the error occurred was handled professionally by the staff and in a genuine way. The incident report, dated 23 September 2014, while being very messy resulted in appropriate action being taken straight after the error was identified.

Please also comment on other aspects of the care provided to [Master A] by [the pharmacy] that you consider relevant.

Errors occur infrequently in many Pharmacies and ways to minimise these must be discussed and communicated with the whole Pharmacy team because everyone has a part to play in preventing them. I would suggest having a staff meeting to implement the new policies e.g. discussing the new stamp, no or minimal self checking and extra care especially in busy times when relabelling so as not to put new label over description and strength of a medicine. Plus the need to have dispensers and checkers with initialling of both on the prescription. Some of these things were highlighted in the comments on page 4 summary of facts report where [Ms C] stated that '[the pharmacy] have reminded staff that if a medicine is dispensed in original bottles staff must not cover the label on the original bottle'.

Well run large Pharmacies have in place regular mini weekly meetings to aid with communication and improve customer safety and service. Everyone in the team is encouraged to actively participate in these. Monthly meetings are mentioned as standard practice at the [the pharmacy] which is acceptable if this is what occurs.

Near miss logs are an important procedure to help prevent errors. Please see an example of this in attachment 2. Near miss logs, recorded in a folder are mentioned in the Feb 2015 SOP which is encouraging and they are reviewed three monthly. We are presuming this happens but could ask that it happens more frequently than it does already.

The management team at [the pharmacy] could look at their technician to pharmacist ratio and safe dispensing numbers although if 3 technicians and 3 Pharmacists were working on any given day the ratio appears good. However on the day of the error one technician was covering a retail person who was sick which may have led to the problem. Two other Technicians and one Pharmacist may have been busy packing the medico packs.

If [the pharmacy] is dispensing 510 prescriptions per day on a regular basis it would be good to have 3–4 people at least dispensing these items and to also know what this Pharmacy's technicians to Pharmacist ratio is. In this Pharmacy the numbers are confused by having two dispensaries — one for off the street customers and one for medico packing. It is difficult to say whether the ratio or numbers of staff were unsafe on the day of the dispensing error as it was unclear how many technicians and Pharmacists were working in which area and most importantly who was dispensing with [Ms B]. Either [Ms C], [Ms E] or [Ms B] herself. This is where signing the prescription is very important.

Ratio of Technicians to Pharmacists

The Pharmaceutical Society Council in July 2003 revoked the required ratio of technicians to pharmacists during the dispensing process. This change now requires pharmacists to make a judgement on what constitutes adequate staffing levels in order to maintain safe and appropriate professional standards.

In making this judgement regarding dispensing, pharmacists must remember that regulation 42(1A) of the Medicines Regulations requires technicians to work under the direct personal supervision of a pharmacist. At all times a safe working environment must be maintained and the Pharmacy Council Code of Ethics obligations 7.5 and 7.1 must be fulfilled.

Code of Ethics Obligation 7.5 Dispensing: Charge Pharmacist must ensure that all dispensing is under the supervision of a pharmacist who must be ready and available in the professional area and willing to intervene, advise or check the dispensing and issuing of any prescription.

Code of Ethics Obligation 7.1 Supervision: The pharmacist must provide appropriate direct supervision for other personnel for whom they have responsibility.

This supervision can change on a daily basis depending on volumes and rosters and is for the Pharmacist in charge to decide on. These statements above are just for noting as we presume that this process was followed in [the pharmacy].

Also for noting, if the staff at [the pharmacy] were or are under pressure there is a good resource called 'Workplace Pressures in Pharmacy — practical advice for NZ Pharmacists, Pharmacy staff, and Employers' written in 2012 on [the pharmacy] Council website — see link below:

http://www.pharmacycouncil.org.nz/cms_show_download.php?id=350

In summary:

This error from the Pharmacist, [Ms B] shows she was practising below the level of accuracy required of her in her role as checking Pharmacist on the day when the error occurred. She clearly may not have had the support of a dispensing Technician which shows not only a lack of care but a deviation from [the pharmacy's] written process and the Pharmaceutical guidelines. This can sometimes happen in a very busy dispensary. In practice, the error was a relatively easy one for a Pharmacist to make given the other circumstances surrounding her which were: high volumes, self checking, no peeling back of the label when checking, possible haste and possible distractions. However, it is hard to believe why [Ms B], the checking Pharmacist, opened the bottle of Zinc and although she couldn't distinguish between that and sod bicarb because of their similar colourings she didn't take that any further. In other words, why didn't she peel back the label which is the most common thing to do and look at the original label? Even so, I don't believe this is a significant departure from the accepted level of care. It is well below, as far as quality measures go but still a possible unfortunate result in any current busy Pharmacy. The consequences for the patient and his Mother were significant which is unfortunate. [***Deputy Commissioner Comment:*** As previously noted, the clinical director for paediatrics, [Dr L], oversaw [Master A's] care while he was [in hospital]. [Dr L] told HDC: "From the information obtained through [Master A's] medical notes and electronic records I do not feel that the medicinal error had affected his health."]

The steps and processes that are being put in place are very necessary to ensure this doesn't happen again and probably need regular review especially if or when new team members start working in this Pharmacy."

On 3 July 2015, the following further expert advice was received from Ms Oakley-Brown:

"It seems that both [Ms B] and [Ms K] have taken on board the seriousness of the error and my advice which is good.

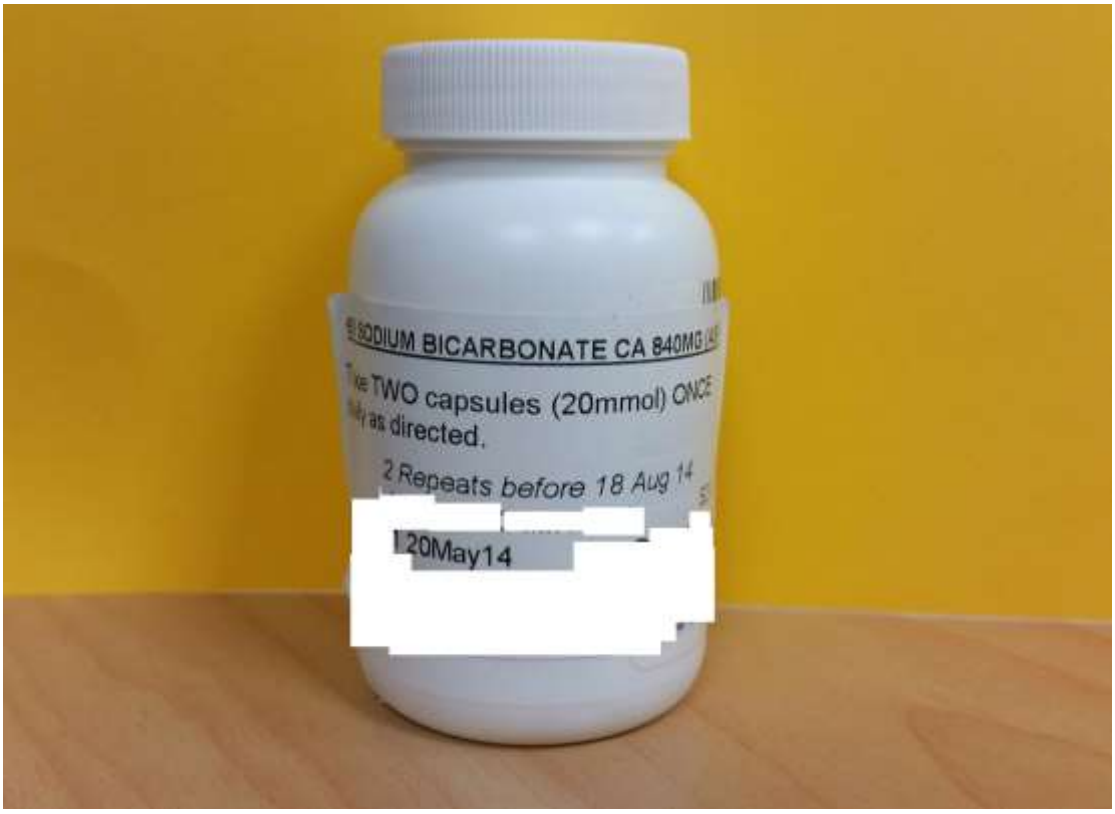
The fact that they have been open to it without making excuses shows insight. In saying that when looking at the near miss log there was some alarmingly dangerous near misses. The fact that the tablets hadn't left [the pharmacy] showed good checking by whichever Pharmacist it was on that particular day, though.

This aside, they seem to have implemented all of the improvements I mentioned in my report:

— Having an extra Pharmacist (this will help immensely)
— No self-checking
— More learning especially around dealing with stress and interruptions in the workplace
— Workshops
— Introducing weekly short team meetings again

Also, I was encouraged by the high quality of the letters from both [Ms B] and the Owner."

Appendix B — Photographs of the bottle of zinc capsules dispensed to Master A



Names have been removed (except the expert who advised on this case) to protect privacy. Identifying letters are assigned in alphabetical order and bear no relationship to the person's actual name.