# Pharmacist, Ms B

# Pharmacist, Ms C

# Pharmacy

## A Report by the

## Deputy Health and Disability Commissioner

## (Case 16HDC00441)

Health and Disability Commissioner
*Te Toihau Hauora, Hauātanga*

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## Executive summary

1. In December 2015, a general practitioner (GP) prescribed the consumer, Master A, among other medications, three Epilim 100mg tablets twice daily (600mg per day), with a total quantity of 180 tablets.

2. On 19 January 2016, pharmacist Ms B carried out the dispensing and checking of a repeat prescription of Epilim for Master A. The prescription label stated: "180 Epilim Tablets 100mg. Take THREE tablets TWICE daily with food." Master A's mother, Ms A, told HDC that instead of receiving 180 Epilim 100mg tablets, she was dispensed 200 Epilim EC 500mg tablets.

3. Ms A said that when she discovered the dispensing error, she returned to the pharmacy. Ms B recalled that this was approximately one week later. Master A had not taken any of the Epilim EC 500mg. Ms A spoke to Ms B about the error and stated that the explanation she received for the error was that the pharmacy was busy and lacked staff.

4. On 22 February 2016, another repeat prescription of Epilim for Master A was dispensed from the pharmacy. Ms A received two boxes of Epilim. The first was a full box containing 100 Epilim 100mg tablets (10 trays of tablets). The second box contained 50 Epilim 100mg tablets (five trays) and 30 Epilim EC 200mg tablets (three trays). On 26 March 2016, Ms A discovered the dispensing error and returned to the pharmacy. The pharmacy has been unable to identify who carried out this dispensing, but pharmacist Ms C carried out the checking of the dispensing

### Findings summary

5. Ms B failed to dispense the correct medication and check her dispensing adequately. She also failed to complete an incident report form once her dispensing and checking error was identified. By doing so, Ms B failed to provide Master A with services in accordance with the professional standards set by the Pharmacy Council of New Zealand, and with the pharmacy's SOPs and, as such, breached Right 4(2) of the Code.[1]

6. While the pharmacy had in place appropriate SOPs, it had not ensured that there was a sufficient number of qualified staff supporting Ms B in the dispensary on that day. It therefore did not take all reasonably practicable steps to prevent the acts or omissions of Ms B's breach of the Code and, as such, the pharmacy is vicariously liable for Ms B's breach of Right 4(2) of the Code.

7. By failing to perform the final check for the dispensing adequately on 22 February 2016, in accordance with the professional standards set by the Pharmacy Council of New Zealand and with the pharmacy's SOPs, and replacing the 80 tablets returned by Ms A with 100 tablets, Ms C failed to provide Master A with services in accordance with professional and other relevant standards, in breach of Right 4(2) of the Code.

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

8. The pharmacy had in place appropriate SOPs, and had ensured that there was a sufficient number of trained staff working on that day. In these circumstances, it is considered that this dispensing error was Ms C's alone and, therefore, the pharmacy did not breach the Code and is not vicariously liable for Ms C's breach of the Code.

**Recommendations**

9. It is recommended that the pharmacy randomly audit, over a period of three months, its staff compliance with its SOPs for dispensing and checking medication.

10. In response to the provisional opinion, the pharmacy provided a written apology to HDC, for forwarding to Ms A and Master A.

11. It is recommended that Ms B provide a written apology to Ms A and Master A.

12. In response to the provisional opinion, Ms C provided a written apology to HDC, for forwarding to Ms A and Master A. No further recommendations have been made in relation to Ms C.

## Complaint and investigation

13. 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 Master A with an appropriate standard of care in 2016.*
- *Whether pharmacist Ms B provided Master A with an appropriate standard of care in 2016.*
- *Whether pharmacist Ms C provided Master A with an appropriate standard of care in 2016.*

14. This report is the opinion of Meenal Duggal, Deputy Health and Disability Commissioner, and is made in accordance with the power delegated to her by the Commissioner.

15. The parties directly involved in the investigation were:

| | |
|---|---|
| Master A | Consumer |
| Ms A | Complainant |
| Pharmacy | Provider |
| Ms B | Pharmacist |
| Ms C | Pharmacist |

16. Information was reviewed from two pharmacists.

17. Independent expert advice was obtained from a pharmacist, Mr Paul Vester.

## Information gathered during investigation

### Background

18. Master A, aged 11 years at the time of these events, is prescribed, among other medications, sodium valproate (brand name Epilim[2]). In early 2016, Master A's mother, Ms A, visited a pharmacy to have two repeat prescriptions of Epilim filled. On both occasions, the Epilim was dispensed incorrectly.

*Epilim*

19. In December 2015, a GP[3] prescribed Master A, among other medications, three Epilim 100mg tablets twice daily (600mg per day), with a total quantity of 180 tablets. The first dispensing of Master A's Epilim occurred on 16 December 2015.

20. Epilim comes in doses of 100mg, 200mg, and 500mg. All three strengths of Epilim come in trays of 10 tablets. The foil on the tablet tray of Epilim 100mg is silver with purple text. The foil on the tablet tray of Epilim EC[4] 200mg is light purple with silver text. The foil on the tablet tray of Epilim EC 500mg is dark purple with silver text. Epilim 100mg tablets are white, whereas Epilim EC 200mg and 500mg tablets are lilac. The three boxes of Epilim trays come in different sizes and are varying shades of purple for each different strength.

21. Epilim overdose of up to five to six times the maximum therapeutic level may cause symptoms such as nausea, vomiting, and dizziness. Epilim overdose of 10 to 20 times the maximum therapeutic level may cause central nervous system depression or coma, and in some cases death.

### Dispensing error on 19 January 2016

22. On 19 January 2016, pharmacist Ms B[5] carried out the dispensing and checking of a repeat prescription of Epilim for Master A. The prescription label stated: "180 Epilim Tablets 100mg. Take THREE tablets TWICE daily with food." Ms A told HDC that, instead of receiving 180 Epilim 100mg tablets she was dispensed 200 Epilim EC 500mg tablets.

23. The pharmacy told HDC that when dispensing 180 Epilim 100mg tablets, a normal approach would involve providing the customer with two boxes, one with 100 tablets (a full box) and one with 80 tablets (a partly full "broken" box).

[2] An anticonvulsant medication used for the treatment of epilepsy.
[3] The GP has been vocationally registered since 2009.
[4] Enteric-coated.
[5] Ms B received her Bachelor of Pharmacy in 2004, and is a member of the Pharmaceutical Society of New Zealand.

*Dispensing and checking*

24. Master A's repeat prescription was processed at 1.25pm and collected at 1.39pm. Ms B was the only pharmacist rostered to work between 8.00am and 4.00pm on this day. Ms B told HDC that she was in the dispensary by herself, and that the pharmacy was busier than usual.

25. The pharmacy told HDC that between 1.25pm and 1.39pm, Ms B dispensed six prescriptions and/or repeats, four of which were Master A's. The pharmacy confirmed that Ms B was the only pharmacist working on 19 January 2016, and advised that she was supported by a sales assistant.

26. Ms B told HDC that she recalls Ms A ordering Master A's repeat prescription but she cannot remember the dispensing exactly. Ms B stated that her normal practice would be:

> "— Print the labels out from the computer and print out a CRC.[6]
> — Count each medicine out/pack each medicine one at a time checking each item against CRC.
> — Place label onto packed medicine.
> — Annotate 3rd part label on the CRC.
> — I then put on a 'different hat' and do a final check of each medicine before signing the CRC.
> — If I am completely on my own in the shop, I would normally try to minimise disruption by greeting a new customer coming in, thanking them for being patient and telling them I will be with them as soon as I finish this prescription. If the phone rings, I try not to answer it unless it keeps ringing."

27. One signature can be found at the bottom right-hand corner of the prescription next to the words "Checked by".

*Discovery of error*

28. Ms A told HDC that when she discovered the dispensing error, she returned to the pharmacy. Ms B recalled that this was approximately one week later. Master A had not taken any of the Epilim EC 500mg.

29. Ms A spoke to Ms B about the error and stated that the explanation she received for the error was that the pharmacy was busy and lacked staff. Ms A said that despite being advised that the incident would be recorded and investigated, she received no further contact or follow-up about the incident. Ms B recalled taking the incident very seriously and apologising immediately.

*Incident reporting*

30. Ms B stated that she informed the pharmacy's retail manager of the error. She recalled beginning to type out an incident reporting form but cannot remember whether this was completed. Ms B explained that she may not have saved the incident report when she finished typing.

[6] Certified Repeat Copy.

31. The pharmacy stated that it was not aware that Master A had been dispensed 200 Epilim 500mg tablets on 19 January 2016 until 20 April 2016, after it received Ms A's complaint from HDC. It cannot find any record of an incident report form being completed.

32. The pharmacy told HDC that had its standard operating procedures (SOPs) been followed, it would have had the opportunity to put in place steps to reduce the likelihood of the error being repeated.[7]

**Dispensing error on 22 February 2016**

33. On 22 February 2016, another repeat prescription of Epilim for Master A was dispensed from the pharmacy. The pharmacy has been unable to identify who carried out this dispensing. Ms A received two boxes of Epilim. The first was a full box containing 100 Epilim 100mg tablets (10 trays of tablets). The second box contained 50 Epilim 100mg tablets (five trays) and 30 Epilim EC 200mg tablets (three trays).

*Dispensing and checking*

34. The repeat prescription was processed at 9.53am and collected at 10.46am. The pharmacy understands that the prescription was telephoned in. At this time, two pharmacists were rostered on: Ms B, and the Dispensary Manager and Director of the pharmacy, Ms C.[8]

35. Ms B told HDC: "I am adamant that I was not involved in the dispensing on the 22nd of February as I usually sign the prescription or third part label if I have dispensed it." Ms C told HDC: "[I]t was my signature on the dispensing from 22 February. I would have taken a full box of 100 Epilim 100mg and a part box of 80 to make up the 180 and taped them together." However, she later stated: "I do not recall dispensing the medication, but I certainly did the final check. If we have more than one pharmacist present, we try to check the other pharmacist's work."

36. The pharmacy explained that the Epilim 100mg and Epilim EC 200mg are kept on different shelves in the dispensary because their boxes are so similar. This is done to ensure that the incorrect strength is not dispensed to anyone. The pharmacy believes that the incorrect Epilim EC 200mg must have come from another dispensing where some of the tablet trays were taken out of a full box and mixed with a broken box that contained Epilim 100mg. The pharmacy reported that there are a number of patients on Epilim EC 200mg, and any of their dispensing could have mixed loose Epilim EC 200mg trays with Epilim 100mg trays.

*Final check*

37. Ms C believed that when she checked the dispensing, she followed all the SOPs in place at the time. She stated:

> "For each item I checked:
>
> …

[7] See "Dispensing Incidents" SOP below.

[8] Ms C received her Bachelor of Pharmacy in 1983 and is a member of the Pharmaceutical Society of New Zealand. Ms B ceased work at the pharmacy in March 2016.

- … [the] medicine strength and quantity on the label and CRC.

…

- … the label [was] correct, medicine name, dose …
- … that the content of each container [was] correct against the CRC. I would have expected to find a box of 80 Epilim 100mg attached, with tape, to a full, unopened box of 100 Epilim 100mg tablets, and one label reading 180 Epilim 100mg. Sheets of Epilim tablets are silver on one side and have purple printing on the other side. If, when I was checking the quantity, the sheets were all lined up on the silver side, I could have completed the final check without realising there were mixed strengths in the 80 box."

38. Ms C also stated that despite the tablets and manufacturer's boxes being different in size, the Epilim 100mg and Epilim EC 200mg tablet trays are identical in size.

*Discovery of error*

39. On 26 March 2016, Ms A discovered the dispensing error and returned to the pharmacy. She spoke to Ms C, who reassured her that there would be a full investigation. Ms C told HDC that Ms A presented her with a box of Epilim containing five trays of Epilim 100mg and three trays of Epilim EC 200mg (80 tablets in total).

40. Ms C stated that she quarantined this box for further investigation, and replaced it with a box of 100 Epilim 100mg. She reasoned that she had no way of knowing whether the returned box originally contained 100 or 80 tablets and, therefore, erred on the side of generosity. She also considered that it would be safer to dispense a full, unopened box.

41. Ms C told HDC that she cannot be certain that this box was dispensed on 22 February 2016, and queried whether it could have been dispensed in January or prior. She could not, however, determine this because Ms A had un-taped the box and returned it without a dispensing label.

*Incident reporting*

42. Ms C completed a Community Pharmacy Dispensing Incident Reporting Form on 26 March 2016. She documented:

"**Details of the incident:**

[Ms A] presented unlabelled box of Epilim 100mg, untaped from another box containing 5 sheets of Epilim 100mg and 3 sheets Epilim 200mg.

**Immediate action taken:**

Replaced with 100 Epilim 100mg tablets, with reprinted label.

...

**Action taken by pharmacy:**

Retrieved Certified Repeat Copy, reviewed time of dispensing, reviewed staff levels. Reviewed quality of staff. 26/3/16

**Review/change in policy?**

Remind all pharmacists to check any contents of broken OP[9] dispensing by removing each sheet from box."

**Further information — Ms B**

43. Ms B agrees that the error made on 19 January 2016 was serious and could have been prevented by following the pharmacy's SOPs. She told HDC that the error has had a very sobering effect on her.

44. Ms B told HDC that for the remainder of her time as a retail pharmacist, she slowed down her dispensing and checked everything very carefully before signing it off.

45. Ms B reported that she asked for additional support in the dispensary as there was a large amount of work to be done by a single person in a busy pharmacy. She believes that the busy nature of the dispensary led to mistakes and near misses being made by not only herself but all pharmacists working at other times. Ms B stated that her requests for additional staff were not listened to.

46. Ms B stated that she was not the dispensary manager (as stated in the pharmacy's response dated 12 February 2017), and her contract stipulated that she was employed as a pharmacist. Ms B told HDC that she worked at the pharmacy for 37.5 hours a week without lunch or tea breaks, and felt under extreme time pressure in these working conditions.

**Further information — Ms C**

47. Ms C told HDC that she is always trying to think of new ways to improve the standard of care provided to her patients. She stated that she keeps herself updated on pharmacy practice via weekly emails from the Pharmacy Guild of New Zealand and *Pharmacy Today* E-Learning. Ms C belongs to two informal networking groups attended by pharmacists on a monthly basis to share and review their practices. She is a member of a group that met last year to compare ideas and improve practice.

**Further information — the pharmacy**

48. The pharmacy recognised that its prescription numbers were increasing in 2015. It stated that it used a number of tools to ensure that its staff were operating in a safe environment that was appropriate for the busy nature of the pharmacy. During the second half of 2015, in anticipation of regular staff being on leave, and in response to the growing prescription numbers, the pharmacy advertised and interviewed for additional staff, but was unable to find a suitable candidate. Instead, it hired a pharmacy student over the summer to allow more time to find a pharmacy technician.

[9] Original pack.

49. The pharmacy told HDC that it prepared its rosters six weeks in advance. It stated that this allowed Ms B adequate time to voice any concerns about staffing levels. Ms C does not recall Ms B's request for additional staff, and stated that, had there been one, she would have increased her own hours.

50. The pharmacy told HDC that the dispensing error on 22 February 2016 was discussed at a meeting with dispensary staff. The pharmacy reported that it has since reviewed its staffing levels and has employed a pharmacy technician for 30 hours a week and a pharmacist for 40 hours a week. The pharmacy stated that it now has two dispensary staff rostered on for nine of the 12 hours it is open each day.

51. The pharmacy has updated its "Dispensing Medication" SOP to include that when dispensing trays of tablets or capsules from a "broken" box, each tray must be removed completely from the box and checked.

52. The pharmacy has updated its "Final Prescription Checking" SOP to include:

> "Self-checking is not recommended — wherever possible the check should be done by a second person.
>
> …If self-checking can't be avoided, separate the 'physical' and 'mental' activities by another task e.g. by dispensing another prescription."

53. The pharmacy has updated its "Dispensary Incident" SOP, which now specifically requires reporting an incident to the dispensary manager and owner. Further to this, the incident is reported on a Google Sheet document so that the manager and owner can review the incident promptly.

54. The pharmacy has created a new "Broken Packs" SOP, which details the storage and dispensing process when a manufacturer's pack is partly dispensed.

55. Staff training — particularly aimed at SOPs associated with dispensing procedures — has occurred, and rosters have been improved. The pharmacy stated that it discourages a pharmacist working longer than eight hours a day or more than 40 hours a week.

**Responses to the provisional opinion**

*Ms A*

56. 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.

*Ms B*

57. Ms B was provided with an opportunity to comment on the provisional decision. She advised that she accepted the findings in the report and had no further comment.

*Ms C and the pharmacy*

58. Ms C provided a response to the provisional opinion personally and as the director of the pharmacy. She provided a formal letter of apology to HDC for forwarding to Ms A.

**Relevant pharmacy SOPs**

59. The following are excerpts from relevant SOPs in place at the time of the dispensing errors in early 2016.

*"Dispensing Medication" SOP*[10]

60. The pharmacy's "Dispensing Medication" SOP included the following:

"**1.0 PURPOSE**

This procedure describes how to dispense a medication.

…

**6.0 RESPONSIBILITY**

6.1 It is the responsibility of all dispensary staff members to ensure that medications are dispensed according to this operating procedure.

…

**8.0 PROCEDURE**

8.1 Select the correct medication from the shelves. Ensure that you check the following against the prescription and not the labels.

- Check you're using the right medicine and brand.
- Check the expiry date.
- Check that the medicine is in the right form.
- Check that the medicine is in the right strength.

8.2 Count or pour the medicine

- If dealing with more than one item, take items from the shelf one at a time, counting and labelling the first item before selecting the next item.

…

8.4 Check what you have dispensed:

- Label accuracy — name, date, medicine dose and form, instructions, C&A labels[11]
- Contents accuracy — correct medicine, dose, form, quantity

…

8.5 Sign your initials on the prescription as having dispensed and checked the prescription.

8.6 Allow a qualified pharmacist to check the prescription according to MPSOP/21 before placing the prescription in a bag, attaching receipt and notes

[10] Issued on 15 May 2012. Additional dates of 25 April 2015 and 22 September 2015 are handwritten with signatures.
[11] Cautionary and Advisory labels.

and filing it away according to surname. Ensure that the number of items dispensed matches the number of items on the script and on the receipt."

*"Final Prescription Check" SOP*[12]

61. The pharmacy's "Final Prescription Check" SOP outlined the following:

**"1.0 PURPOSE**

This procedure describes checks on a prescription.

…

**6.0 RESPONSIBILITY**

6.1 It is the responsibility of all qualified pharmacists in the dispensary to ensure that each completed prescription is checked before it is handed out to the patient (or put away for delivery/postage).

6.2 It is the responsibility of the pharmacist checking the prescription to initial the prescription as having been checked.

…

**8.0 PROCEDURE**

8.1 Check prescription details are correct …

…

8.4 Check medicine strength and quantity against prescription and label.

8.5 Check medicine expiry date.

8.6 Check label is correct, medicine name, dose, form, C&A labels, patient name, date, prescription number, directions are correct, clear and concise — check these against prescription.

8.7 Check C&A labels are all on and are appropriate.

8.8 Check that all containers belong with the prescription.

8.9 Check that the content of each container is correct against the prescription."

*"Dispensing Incidents" SOP*[13]

62. The pharmacy's "Dispensing Incidents" SOP included the following:

"**1.0 PURPOSE**

This procedure gives guidelines for how a dispensary incident should be handled.

…

[12] Issued on 15 May 2012. Additional dates of 25 April 2015 and 22 September 2015 are handwritten with signatures.
[13] Issued on 15 May 2012. No review date.

**5.0 DEFINITIONS**

5.1 Dispensing Error — This is any dispensing error that leaves the dispensary.

**6.0 RESPONSIBILITY**

6.1 It is the responsibility of the dispensary manager and manager to ensure that the correct procedures are followed and required forms filled and filed.

**7.0 PROCEDURE**

Dispensary errors must be dealt with immediately and with the utmost seriousness.

All dispensary incidents must be accurately documented and retained by the pharmacy for future reference. The report must include the date, prescription number, a description of what happened, what action was taken and the outcome.

All steps must be taken by all dispensing staff to minimise the risk of dispensary incidents. These include thorough checking at all stages of dispensing and where possible having more than one dispensary member involved in the dispensing and checking process … All checks and changes must be annotated and signed by that person.

…

The dispensary incident must be fully discussed with all dispensary staff and the dispensing procedures reviewed to see if changes are required in order to avoid a recurrence.

A separate Dispensary incident form should be filled out for each incident and are to be kept separate to general incident reports."

## Other relevant standards

63. The Pharmacy Council of New Zealand's *Code of Ethics (2011)* requires that a pharmacist:

> "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."

64. The Pharmacy Council of New Zealand *Competence Standards for the Pharmacy Profession (2015)* provides that the pharmacist:

> "Domain O1: Health and medicine management

…

O1.4.3 Acts to optimise health outcomes by identifying and mitigating potential sources of error in service delivery.

…

O1.4.5 Participates in ongoing incident analysis (including 'near misses') and adopts recommendations for resolution or change that come from that analysis.

Domain O3: Supply and administration of medicines

…

O3.2.1 Maintains a logical, safe and disciplined dispensing procedure

O3.2.2 Monitors the dispensing process for potential errors and acts promptly to mitigate them."

## Opinion: Ms B — breach

### Dispensing error

65. As a registered pharmacist, Ms B was responsible for complying with professional standards. The Pharmacy Council of New Zealand's *Code of Ethics (2011)* provides that a pharmacist must "take appropriate steps to prevent harm to the patient and the public" and "be accountable for practising safely and maintain and demonstrate professional competence relative to [the pharmacist's] sphere of activity and scope of practice". Further, the Pharmacy Council of New Zealand *Competence Standards for the Pharmacy Profession (2015)* require that a registered pharmacist "maintains a logical, safe and disciplined dispensing procedure" and "monitors the dispensing process for potential errors and acts promptly to mitigate them".

66. The pharmacy's "Dispensing Medication" SOP requires those dispensing medication to check that the item is correct in dose, form, and quantity. The pharmacy's "Final Prescription Check" SOP requires the pharmacist to check the medication's strength and quantity against the prescription and label, and check that the content of each container is correct against the prescription.

67. On 19 January 2016, Ms B dispensed 200 Epilim EC 500mg tablets instead of 180 Epilim 100mg tablets. Although Ms B does not recall dispensing or checking the prescription, it is not disputed that she was the only pharmacist rostered to work between 8.00am and 4.00pm on this day. On the prescription itself, one signature can be found next to the words "Checked by".

68. Ms B reported that the pharmacy was busier than usual. She told HDC that she had asked for additional support in the dispensary but her requests were not listened to. She believes that the busy nature of the dispensary led to mistakes and near misses being made.

69. My expert advisor, pharmacist Mr Paul Vester, advised that the steps taken to dispense the medication on 19 January 2016 were inadequate, as a clear error of dose and strength occurred. His view is that this would be considered a severe departure from accepted practice. He noted that Epilim is a medication of considerable risk to a vulnerable person, especially if the person is also taking other medications. Mr Vester noted that the quantity given was 200 tablets rather than the prescribed quantity of 180 tablets, further contributing to the departure from accepted practice.

70. Ms B dispensed the wrong quantity and strength of Epilim to Master A. This indicates to me that Ms B's dispensing and checking practice was inadequate, and she did not follow the pharmacy's SOPs carefully. I agree that Ms B's failure to dispense the correct strength and quantity of tablets, to check the medication she was dispensing adequately, and to follow the SOPs carefully represents a significant departure from accepted practice.

**Incident reporting**

71. The Pharmacy Council of New Zealand *Competence Standards for the Pharmacy Profession (2015)* require that a registered pharmacist "acts to optimise health outcomes by identifying and mitigating potential sources of error in service delivery" and "participates in ongoing incident analysis".

72. The pharmacy's "Dispensing Incident" SOP requires dispensing incidents to be documented and fully discussed with all dispensary staff. Dispensary procedures are to be reviewed to see whether changes are required to avoid a recurrence of the error.

73. Whilst Ms B recollected that she informed the retail manager of the error and began typing out an incident reporting form, it is clear that she did not finalise it because the pharmacy cannot find any record of an incident form being completed.

74. Mr Vester advised that Ms B's management of the dispensing error was "not only a serious departure from expected pharmacy practice, but also a serious departure from the *Dispensing Incidents* standard operating procedures".

75. As HDC has noted previously, "once a pharmacist had been put on notice of an error having occurred, it is the pharmacist's duty to minimise the ongoing harm and take steps to prevent the error from occurring again … An essential component of a pharmacist's duty in this regard is to complete an incident report form."[14] I am critical that Ms B did not complete an incident reporting form for her dispensing error. Mr Vester has advised that this failure was a serious departure from expected practice, and I agree. It was Ms B's responsibility to document the dispensing error in order for the appropriate processes to be put in place to prevent future errors.

**Conclusion**

76. Ms B failed to dispense the correct medication and check her dispensing adequately. She also failed to complete an incident report form once her dispensing and checking error was identified. By doing so, Ms B failed to provide Master A with services in accordance with the professional standards set by the Pharmacy Council of New

[14] See opinion 14HDC00551.

Zealand, and with the pharmacy's SOPs and, as such, breached Right 4(2) of the Code.

## Opinion: Ms C — breach

### Dispensing error

77. As a registered pharmacist, Ms C was responsible for complying with professional standards. The Pharmacy Council of New Zealand's *Code of Ethics (2011)* provides that a pharmacist must "take appropriate steps to prevent harm to the patient and the public" and "be accountable for practising safely and maintain and demonstrate professional competence relative to [the pharmacist's] sphere of activity and scope of practice". Further, the Pharmacy Council of New Zealand *Competence Standards for the Pharmacy Profession (2015)* require that a registered pharmacist "maintains a logical, safe and disciplined dispensing procedure" and "monitors the dispensing process for potential errors and acts promptly to mitigate them".

78. The pharmacy's "Final Prescription Check" SOP requires the pharmacist to check the medication's strength and quantity against the prescription and label, and check that the content of each container is correct against the prescription.

79. I accept that Ms C does not recall dispensing the medication on 22 February 2016, and I am not able to make a finding on this. However, it is not disputed that Ms C checked the dispensing.

80. I note that Ms C has queried whether the box with three erroneous tablet trays may have been dispensed in January 2016 or prior; however, this query is not supported by the information available. On 19 January 2016, no tablets of 200mg strength were dispensed. Therefore, it is not possible that the erroneous 200mg tablets were a part of that dispensing. Furthermore, there is nothing to suggest that Ms A still had tablets from any dispensing prior to January 2016. I therefore find that it was more likely than not that the erroneous 200mg tablets were dispensed on 22 February 2016.

81. Mr Vester advised that both the dispensing and checking errors on 22 February 2016 would be regarded as a moderate departure from accepted practice.

82. While Ms C has told HDC that she completed checks and followed the SOP in place at the time, the SOP requires pharmacists to check medicine strength against both the prescription and label, and to check that the content of each container is correct against the prescription. Even if Ms C carried out some checks, they were clearly inadequate, as the incorrect medicine strength was dispensed. I note Mr Vester's advice that, regardless of what went before the final check, the pharmacist checking the medication takes professional responsibility for the correctness of the dispensing. I agree.

### Management of dispensing error

83. On 26 March 2016, Ms A discovered the dispensing error and returned to the pharmacy. Ms C told HDC that Ms A presented her with a box of Epilim containing five trays of Epilim 100mg and three trays of Epilim EC 200mg (80 tablets in total). Ms C said that she quarantined this box for further investigation, and replaced it with a box of 100 Epilim 100mg. She reasoned that she had no way of knowing whether the returned box originally contained 100 or 80 tablets and, therefore, erred on the side of generosity. She also considered that it would be safer to dispense a full, unopened box.

84. Mr Vester considered that Ms C's course of action (replacing the box of 80 Epilim tablets with 100 Epilim tablets) represented "a minor departure from standard practice". He was concerned that Ms C did not engage Ms A to bring back all the dispensed tablets so that she could check the whole dispensing and give back the correct amount of tablets.

### Conclusions

85. By failing to perform the final check for the dispensing adequately on 22 February 2016, in accordance with the professional standards set by the Pharmacy Council of New Zealand and with the pharmacy's SOPs, and replacing the 80 tablets returned by Ms A with 100 tablets, Ms C failed to provide Master A with services in accordance with professional and other relevant standards, in breach of Right 4(2) of the Code.

## Opinion: Pharmacy — breach

86. In the course of this investigation, I have carefully considered the extent to which the dispensing errors that occurred indicate broader systems or organisational issues at the pharmacy. As this Office has stated previously, "a pharmacy has a responsibility to ensure that all pharmacists working in the pharmacy are appropriately trained and experienced, and aware of the pharmacy's expectations, including the SOPs".[15]

87. I further note that under section 72(2) of the Health and Disability Commissioner Act 1994, an employing authority may be vicariously liable for acts or omissions by any employee. Under section 72(5), it is a defence for an employing authority to prove that it took such steps as were reasonably practicable to prevent the acts or omissions. In addition, the pharmacy may also be directly liable for the services it provides.

### Standard operating procedures

88. Written SOPs provide set procedures to assist staff to comply with their legal and professional obligations, and are central to ensuring safe and effective dispensing. Mr Vester advised that the "Dispensing Medication" and "Final Prescription Check" SOPs that the pharmacy had in place at the time of the dispensing errors were appropriate and, had they been followed, the errors should not have occurred.

[15] Opinion 13HDC00819, 23 June 2014.

89. However, Mr Vester also advised that the pharmacy did not have a process for dealing with broken packs, nor did it require staff to report dispensing incidents to management. Additionally, Mr Vester identified that the SOPs did not appear to have been reviewed since 15 May 2012. I note that there are handwritten dates with accompanying signatures on some of the SOPs; however, it is unclear what purpose they serve. I am critical of these aspects of the pharmacy's SOPs.

**Staffing levels**

90. Ms B told HDC that she was the only pharmacist rostered to work between 8.00am and 4.00pm on 19 January 2016. The pharmacy does not dispute this, and advised that she was supported in the pharmacy by a retail assistant. Ms B expressed that there was a large amount of work to be done by one person in the pharmacy, which she described as busy. She stated that she had requested additional support in the dispensary but her request had not been listened to.

91. The pharmacy disputes that Ms B ever raised concerns about staffing levels, and stated that Ms C would have increased her hours if concerns had been voiced. While I am unable to make a finding regarding whether this request was made expressly, the pharmacy has acknowledged that prescription numbers had been increasing in 2015, and described the pharmacy as busy in nature. It reported that it had attempted to employ a pharmacy technician but was unable to find a suitable candidate. A pharmacy student was hired instead.

92. My expert advisor, Mr Vester, noted that there was no other qualified assistance such as a pharmacy technician to support Ms B in the dispensary on 19 January 2016, including during breaks. Mr Vester considered that, whilst it may not be unusual in some pharmacies, it was inadequate that Ms B was the only pharmacist working on 19 January 2016. While it did not excuse the dispensing error, Mr Vester's view is that it may have contributed to it. He stated that it would be difficult not to become distracted from dispensing; the processes from accepting prescriptions, entering the script into the computer to produce labels and create records, dispensing each item, checking the prescription, and giving out could all be easily interrupted, which increases the risks of errors.

93. Despite the adequacy of the SOPs, I am critical that, for a busy pharmacy, there was only one staff member qualified to work in the dispensary on 19 January 2016. I consider that it was the pharmacy's responsibility to ensure that its staff were supported adequately, and the onus should not be on staff to raise concerns in order for appropriate changes in staffing levels to be implemented.

**Conclusions**

94. Ms B did not follow the processes required by her professional standards and the pharmacy's SOPs carefully when dispensing and checking Master A's prescriptions on 19 January 2016. While the pharmacy had in place appropriate SOPs, it had not ensured that there was a sufficient number of qualified staff supporting Ms B in the dispensary on that day. It therefore did not take all reasonably practicable steps to prevent the acts or omissions of Ms B's breach of the Code and, as such, I find the pharmacy vicariously liable for Ms B's breach of Right 4(2) of the Code.

95. Ms C also did not follow the processes required by her professional standards and the pharmacy's SOPs carefully when checking Master A's prescriptions on 22 February 2016. Further, the pharmacy had in place appropriate SOPs and had ensured that there was a sufficient number of trained staff working on that day. In these circumstances, I am satisfied that this dispensing error was Ms C's alone and, therefore, I do not consider that the pharmacy breached the Code or is vicariously liable for Ms C's breach of the Code.

## Recommendations

96. I recommend that the pharmacy randomly audit, over a period of three months, its staff compliance with its SOPs for dispensing and checking medication, and provide HDC with the outcome of that audit within six months of the date of this report.

97. In response to the recommendations made in the provisional decision, the pharmacy provided a written apology to HDC for forwarding to Ms A and Master A.

98. I recommend that Ms B provide a written apology to Ms A and Master A. The apology should be sent to HDC within three weeks of the date of this report, for forwarding to Ms A and Master A.

99. In response to the recommendations made in the provisional opinion, Ms C provided a written apology to HDC for forwarding to Ms A and Master A.

## Follow-up actions

100. A copy of this report, with details identifying the parties removed, will be sent to the Pharmacy Council of New Zealand and the district health board, and they will be advised of Ms B's and Ms C's names.

101. A copy of this report, with details identifying the parties removed, will be sent to the Pharmaceutical Society of New Zealand, the Health Quality and Safety Commission, and the New Zealand Pharmacovigilance Centre, and will be 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 Mr Paul Vester:

"I have been asked to provide an independent opinion on case number C16HDC00441 Complaint: [Master A]/[the pharmacy].

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

I am a current practising pharmacist and co-owner of Morrinsville Pharmaceutical Services Ltd in Morrinsville which has the only two pharmacies in Morrinsville. I qualified as a pharmacist with a Diploma in Pharmacy from CIT Heretaunga becoming registered as a pharmacist in 1981. I have worked as a pharmacist since qualifying, first as pharmacist for 2 other Pharmacies before buying my own business in 1989, then forming a partnership in 1999 for our current business. I have qualified as a preceptor trainer and had 6 interns over the last 10 years. We currently employ 21 staff (including 6 fulltime pharmacists). I was a founding member, and one time chairman of the Midland Community Pharmacy group, which developed many new pharmacy services for not only The Midland area but also New Zealand. This included helping set standards, developing reporting templates, and developing Standard operating procedures and policies. I am currently also engaged by the New Zealand Pharmacy Council as one of the pharmacists developing and critiquing the scenarios for the final assessment day for Pharmacy Interns, and as an assessor on those days.

1) *Whether the dispensing pharmacist took the appropriate steps to check and dispense [Master A's] medication on 19 January 2016 and 22 February 2016.*

Firstly I must say that all Pharmacists, including myself, do make errors even though we do our very best not to, despite often robust and sound processes.

These errors are usually rare events and often a cause can be arrived at. I start my opinion with this statement, as I ask that any comments I make after this are read being aware that I am cognisant of these facts.

The two errors involve the same medication but have different risk and processes components.

The 19th January 2016 event poses more physical risk to [Master A] as the dose is fivefold increased. The steps taken to dispense the medication were inadequate as this blatant error of dose strength occurred (no reason given), and would be considered a severe departure from accepted practice as Epilim is a medication of considerable risk to a vulnerable person, especially if they are taking other medications as well. I can only say 'considerable risk' as the toxicity in regards to risk to life rather than some unpleasant side effects depends on many factors, with data sheets having considerable variation in doses needed to cause harm (manufacturer's data sheet vs Medscape articles on toxicity).

Another fact I note that causes me to consider the departure from accepted practice to be serious, is that the quantity given (according to the information I received) was 200 tablets not the 180 prescribed. I can think of no reason this should happen.

As to the adequacy of the managing of the error, it is not only a serious departure from expected pharmacy practice, but also a serious departure from the 'Dispensing Incidents' Standard operating procedures of that time as there is no record at all of the error except the records kept by [Ms A].

The error on the 22nd February 2016 is an error where the risk may not be as great to [Master A], as the dose that could be given in error is much lower and the quantity of the wrong strength tablets given is a smaller number, so may be regarded as a moderate departure from accepted practice.

*Did the pharmacist take the appropriate steps to check and dispense [Master A's] medication*? In both cases, in accordance with the Standard Operating Procedures at the time, there was a failure to complete correctly MSOP/16: 8.1, 8.4, 8.5 (if a technician was involved), MSOP/21: 8.1, 8.4 and 8.9.

2) *The adequacy of the [pharmacy's] standard operating procedures at the time of the dispensing error?*

Some general comments: The SOPs did not appear to have been reviewed since 15/05/12 and they should be reviewed annually (maybe the review dates are electronic and not on the printed forms?). There is no mention of a 'Near-Miss Event' register, which is an excellent way to see common situations that may lead to errors.

For the 19th January dispensing, had the SOPs in place at the time been followed, then an error should not have occurred, as they were adequate.

For the 26th March incident (relating to the 22nd February 2016 dispensing) had adequate dispensing process been followed as expected of all Pharmacists then the error should not have occurred (but all errors fail this). As to the SOPs having adequate information on dealing with 'broken packs' then this was not in place.

MPSOP/30 Dispensing Incidents for dealing with dispensing errors clearly indicates 'All dispensary incidents must be accurately documented and retained by the Pharmacy for future reference' and this clearly was not completed for the 19th January 2016 dispensing error, which is a serious departure from expected protocols. At this time the SOP does not have a specific requirement to report all incidents to the Manager/owner, although it does say 'The dispensary incident must be fully discussed with all dispensary staff …' which is inadequate.

3) *Whether the standard operating procedures have been adequately amended in light of the dispensing errors.*

Yes I think they have been adequately amended. Addressing not only the dispensing procedure of broken packs and the reporting of Dispensary Incidents but also the annotation of prescriptions, inclusion and use of 'Near-Miss register',

the inclusion of using the Toniq PDA Incident form, and the formal pathway to including any errors for discussion at staff meetings.

4) *Please comment on [the pharmacy's] response, and in particular whether it provides clinically sound and adequate explanations for the dispensing errors that occurred.*

The error of 19th January 2016 was inadequately dealt with in relation to the Pharmacy's SOPs, New Zealand Pharmacy Standards and expected behaviour of a Pharmacist by their peers. I see in [Ms A's] complaint submission that she returned to the Pharmacy regarding that error (having sought advice from the 'Pharmacy Association' which I presume is the NZ Pharmaceutical Society?). Presumably close to the date of the dispensing? She records that the Pharmacist said they would record the incident in the computer, a course of action not undertaken as far as can be determined in the Pharmacy's submission. Also there is no recorded follow up to the patient as to the outcome of their investigation.

As for the [the pharmacy's] response to the 22 February 2016 incident which is covered in the Letter to [Ms A] on 4th May: The letter seems adequate in explanation of trying to address the situation, however it is sent some 40 days after the Dispensary Manager was advised of the error which I would think is maybe double what may be a reasonable period. [Ms A] mentions in her submission that 'She (Ms C) wishes to work with me', which I think most of my peers would identify as being a situation that would 'encourage frequent contact'.

[The pharmacy's] response to the complaint to HDC adequately gives explanation, in as much as they are able, to the cause of the incidents. I note the Pharmacy states there were 5 strips of 10 Epilim 100mg, while all the other information states there were 4 strips of 10 Epilim 100mg. This may or may not be significant, in as much as I noted it as a concern in my answer to Issue 1.

5) *Any other comments you wish to make about the Pharmaceutical care [Master A] received at [the pharmacy]*.

Regardless of Policies and Standard operating procedures that each Pharmacy has in place, it is still the Professional responsibility of every practising pharmacist to the best of their abilities, to give adequate Pharmaceutical care to the public, which includes as well as utilising their knowledge and training as a registered Pharmacist, to dispense accurately. It also entails a commitment to constant review and improvement of their practice. As I said at the start, I believe all Pharmacists will make some errors in their career, and as yet, I have not seen any SOPs that can absolutely prevent that. My point is, that although the SOPs in place at the time of the 19th January error, could be improved on, they did not allow for the incidents to go unrecorded which was the responsibility of the dispensing Pharmacist at the time (Ms B), which has meant any changes to prevent a future similar error or need to address issues such as staffing, skills etc., were also not addressed.

It would seem that [Ms A] had been happy with the pharmaceutical care that [Master A] had received for some years as it took a third error for her to feel the need to seek the problems to be reviewed more carefully. I wonder had the

previous errors/incidents been actively managed, that this HDC complaint may not have eventuated?

Paul Vester
26/8/16"

On 20 April 2017, Mr Vester provided the following further expert advice:

"I have been asked to provide an independent opinion on case number C16HDC00441 Complaint: [Master A]/[the pharmacy].

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

This is the further expert advice I have been asked to give. I am not altering the advice already given and will attempt to highlight where this new information would change my previous advice.

**[Ms B]:**

The error in the dispensing of the prescription on the 19th of January, I see no reason to change the previous advice I gave, 'The steps taken to dispense the medication were inadequate as this blatant error of dose strength occurred (no reason given), and would be considered a severe departure from accepted practice as Epilim is a medication of considerable risk to a vulnerable person, especially if they are taking other medications as well.'

The lack of signature on both the dispensing and checking areas of the prescription on the 19th of January falls short of the required standards of the SOP MPSOP/16 8.5 and MPSOP/23 6.2, both of which provided to me for this review I note are 'issued' on 31/3/16 and 4/5/16 which is AFTER the incidents. I would also like to comment that as [Ms B] was the only pharmacist dispensing on site that day, then this is not such a problem as she was the only one who could dispense and check, so would not consider this a significant departure from accepted practice.

That an incident form was not completed in relation to this incident my comment 'it is not only a serious departure from expected pharmacy practice, but also a serious departure from the "Dispensing Incidents" Standard operating procedures of that time' still stands.

[Ms B's] letter to HDC received 22Feb2017 highlights her concern at the lack of staffing on 19/1/16 and I feel my peers would consider this a reasonable concern, as there was no other 'qualified assistance' such as a technician, and no support for 'breaks'. This of course does not excuse the error, but I feel it may have contributed, as the details of dispensing numbers given by [Ms C] show it was a slightly higher number of dispensing per hour than the current dispensing levels where there are 2 Pharmacists and a technician most of the time.

**[Ms C]:**

The final check on the 22nd February 2016, is just that a final check, and regardless of what went before it the signing Pharmacist is taking professional responsibility for the correctness of the dispensing. I understand as a dispensing Pharmacist myself that an error in the process before us can 'set us up for an error', but it still doesn't remove the final checking responsibility.

As for the standard of care I stand by my previous comment that this is 'an error where the risk may not be as great to [Master A] so may be regarded as a moderate departure from accepted practice.'

**[The pharmacy]:**

As I explained above for [Ms B], if one pharmacist only is on site and doing both the dispensing and checking then I feel it would be common practice for there only to be the one signature, although I know myself and other pharmacists I work with, would have initialled each '3rd part label' on each item as we checked before signing the prescription off. This also brings up the point again that the Pharmacist signing off the final prescription takes the responsibility for the whole prescription. It would be considered standard practice in our pharmacy (and I feel by my peers as a whole) that if the final checking pharmacist was to notice that items they had not dispensed, were not signed, they would get the Pharmacist/Technician having dispensed it, to sign the item/s before the final check.

[The pharmacy] does appear to have made attempts before any of the errors to keep the 3 strengths of Epilim separated, and that a failure to adhere to the SOPs (which were made much more robust after these errors) may have led to incorrect strengths of loose tablets being put in the wrong box. It is also possible as well, of course, that the wrong strength tablets were selected when constructing the 80 tablets for the prescriptions broken pack. I feel the attempts to reduce the risks of such an error were of an acceptable standard.

On the 19th January 2016, the staffing was only [Ms B] and a retail staff member, which although it may not be unusual in some pharmacies, I feel is inadequate as it would be difficult to not become distracted from dispensing. All the processes from accepting prescriptions, entering the script into the computer to produce labels and create records, dispensing each item, checking the prescription and giving out could all be easily interrupted, which increases the risks of errors.

The staffing on the 22nd February 2016 does mean there is for most of the day more support to prevent interruptions, and allow for breaks, which I feel is adequate.

My comments on the adequacy of the standard operating procedures that I gave in my original advice under the heading *'The adequacy of [the pharmacy's] standard operating procedures at the time of the dispensing error?'* remains unchanged.

Comments on other matters:

The blister pack error: I must say that the explanation given by [Ms C] I find very difficult to follow. It contains many comments such as 'could be due to', 'it is plausible', 'would it be possible' and 'may have had enough of', which I think highlights a lack of clarity around this dispensing. I will comment that I realise that blister pack dispensing is hugely complicated and often being done for patients who are struggling with organising their medications and health care (often not getting Doctors appointments on time, having many medication changes etc). My one suggestion in this area is that keeping patient notes about interactions (with Doctors, patient, caregiver, medication changes, late pick ups etc) is a high priority to be done, and may have clarified some of the issues encountered here.

I mentioned in my original response 'There is no mention of a "Near-Miss Event" register …' to which some evidence of there being one has been supplied. My comments here is:

(a) the evidence given is from Jan 2017

(b) An actual copy of the registered near misses is not given.

(c) '[First name]' gives a summary of the error types which is fine but my suggestion is that this would then be discussed at a staff meeting, and ways to prevent these 'near misses' becoming errors be discussed and actions to address the risk areas be recorded.

Paul Vester

20/04/17"

On 9 May 2017, the following further expert advice was received from Mr Vester:

"1. Please could you advise further on the following issue: On 26 March 2016, the complainant returned to [the pharmacy] with the broken box of 80 tablets (three trays being of the incorrect dose of 200mg). In response to this dispensing error, the pharmacist, [Ms C] replaced the 80 tablets with a full unbroken box of 100 tablets. [Ms C] reasoned that she did this because she did not know whether the box originally contained 100 tablets or 80, so she erred on the generous side of 100 tablets. *Did [Ms C] take the appropriate course of action? If not, what do you consider the appropriate steps would have been? If there are any departures, please advise how significant.*

I consider [Ms C's] course of action to be a minor departure from standard practice. My area of concern is [Ms C] is relying on the complainant's responsibility to be sure the tablets not brought in are also the correct strength. I think most of my peers and myself would try and engage the complainant to bring back all the dispensed tablets so that we may check the whole dispensing and give back the correct amount of tablets.

2. In your additional advice, at the second paragraph on page 1, starting 'The lack of signature …', you refer to SOPs dated after the incidents. Please find **attached** the CRC and SOPs in place at the time of the incidents. *Please advise whether the*

*lack of signatures still falls short of the SOPs and make any amendments to your additional advice you consider appropriate.*

On checking the SOPs present at the time I find in MPSOP 13/8.5 and MPSOP 21/6.2 directions that the dispenser, and the checking pharmacist, must both initial the prescription when dispensing, so my comments '*For the 19th January dispensing, had the SOPs in place at the time been followed, then an error should not have occurred, as they were adequate.*

*For the 26th March incident (relating to the 22nd February 2016 dispensing) had adequate dispensing process been followed as expected of all Pharmacists then the error should not have occurred (but all errors fail this).'* Still stand.

Paul Vester

09/05/17"