A Pharmacy

Pharmacist, Mr B

A Report by the

Deputy Health and Disability Commissioner

(Case 13HDC01413)

Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

Table of Contents

Executive summary

1. Mrs A takes a number of regular medications, including mesalazine for ulcerative colitis and levothyroxine for hypothyroidism, which are dispensed by her local pharmacy.

2. On 7 September 2013, Mrs A visited the pharmacy to collect a prescription for mesalazine (Pentasa) and atorvastatin (Lipitor). Mr B was the sole pharmacist on duty at the pharmacy that day. He dispensed Mrs A's medications, replacing Lipitor with another brand of atorvastatin, Zarator, and noted this change on the prescription.

3. Mr B mistakenly dispensed Salazopyrin in place of Pentasa. Like Pentasa, Salazopyrin is also used to treat ulcerative colitis. Unlike Pentasa, Salazopyrin contains a sulpha group that is a common cause of liver abnormalities. Mr B accepts that he made a dispensing error on this occasion and that he did not follow the pharmacy's checking procedures.

4. A shop assistant provided Mrs A with her medications. Mrs A queried the Pentasa medication, noting that the packaging differed from what she had received previously. Mrs A's query was relayed to Mr B by the shop assistant. Mr B mistakenly believed that Mrs A was querying the change from Lipitor to Zarator, and advised the shop assistant that it was a generic version of the same medication. The shop assistant then relayed this advice to Mrs A. Mr B did not speak directly with Mrs A.

5. Mrs A then started taking the medications dispensed by Mr B. She began to feel extremely fatigued and took time off work to rest. On 24 September 2013, she attended a consultation with her general practitioner, Dr C, who took some blood tests and issued a prescription for a number of regular medications, including levothyroxine.

6. Later that day, Mrs A visited the pharmacy to collect her prescription. Pharmacist Mr D dispensed her medications, using a combination of two different levothyroxine brands (one of which Mrs A had not taken previously) to make up the new dosage. Mrs A was concerned that further changes were being made to her medication regimen. Mr D advised Mrs A that generic substitutions would not make her feel unwell, and declined to contact Dr C as he had dispensed the correct medications.

7. Mrs A continued to take the medications that had been dispensed by Mr B. Her blood test results were markedly deranged, and Dr C discovered that she had been taking Salazopyrin in place of Pentasa for approximately three weeks.

8. On 6 October 2013, Mrs A was admitted to hospital with a primary diagnosis of deranged liver function. The overall opinion was that her condition was caused by a reaction to Salazopyrin. Mrs A was discharged from hospital on 11 October, and returned to full-time work in December 2013.

Findings

9. Mr B failed to ensure that he dispensed the correct medication to Mrs A on 7 September 2013. He also failed to counsel Mrs A effectively about her medications, resulting in a missed opportunity to identify the error. Accordingly, Mr B failed to provide Mrs A with services in accordance with professional standards, in breach of Right 4(2) of the Code of Health and Disability Services Consumers' Rights (the Code).[1]

10. The pharmacy had relevant Standard Operating Procedures (SOPs) in place at the time. Mr B accepts that he did not follow the checking procedure required by the SOP. I am satisfied that the error occurred as a result of Mr B's individual conduct as opposed to systemic issues at the pharmacy. I do not consider that the pharmacy has breached the Code in this regard or is vicariously liable for Mr B's breach of the Code.

11. Adverse comment is made about Mr D.

Complaint and investigation

12. HDC received a complaint regarding services provided to Mrs A by pharmacist Mr B at a pharmacy.

13. On 27 March 2014, an investigation was commenced. The following issues were identified for investigation:

- *Whether the pharmacy provided appropriate services to Mrs A.*
- *Whether pharmacist Mr B provided appropriate services to Mrs A.*

14. This report is the opinion of Ms Theo Baker, Deputy Commissioner, and is made in accordance with the power delegated to her by the Commissioner.

15. The parties directly involved in the investigation were:

Mrs A	Consumer/Complainant
The pharmacy	Provider
Mr B	Provider

16. Information was also reviewed from:

The district health board
The medical centre
ACC
Pharmacy Council of New Zealand

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

17. The following are also mentioned in this report:

The public hospital
Dr C (the medical centre)
Mr D, Pharmacist (pharmacy)
Dr E (the medical centre)
Dr F (public hospital)

18. Independent expert advice was obtained from pharmacist Mr Ross Carrick.

Information gathered during investigation

Background

19. Mrs A takes a number of regular medications, which include mesalazine[2] for ulcerative colitis[3] and levothyroxine[4] for hypothyroidism.[5] Mrs A has been taking mesalazine for approximately 11 years, and levothyroxine for approximately 20 years.

20. Mrs A's local pharmacy employs pharmacists, as well as dispensary and retail staff.

21. At the time of these events, Mr B was employed by the pharmacy as the Pharmacist Manager.[6] He was a registered pharmacist with many years of pharmacy experience.

22. The pharmacy told HDC that it was unable to locate a copy of Mr B's employee induction checklist, but said that "there is an assumption that a Pharmacist who holds an Annual Practising Certificate has met all the requirements of the Pharmacy Council to be registered and is deemed competent to dispense medicines".

23. This report is concerned with the standard of services provided to Mrs A on two successive visits to the pharmacy, on 7 and 24 September 2013.

Standard Operating Procedures

24. The pharmacy provided HDC with copies of its relevant Standard Operating Procedures (SOPs) in place as at September 2013. The pharmacy explained that its SOPs are reviewed annually (or more frequently if required) and are signed by staff (including Mr B) to indicate that they have read and understood the requirements of each SOP.

Dispensing prescriptions

25. The pharmacy's Dispensing Prescriptions SOP dated 10 October 2012 (signed by Mr B) sets out a dispensing process designed to ensure that prescriptions are dispensed

[2] Brand names include Pentasa.
[3] An inflammatory bowel disease that causes long-lasting inflammation and ulcers in the digestive tract.
[4] Brand names include Eltroxin and Synthroid.
[5] Abnormally low activity of the thyroid gland.
[6] Mr B subsequently retired from this position.

accurately. According to this SOP, the pharmacist is required to check during the dispensing process that (among other things) the medicine and brand being dispensed are correct. This is to be checked again prior to handing the medication to the customer.

26. The Dispensing Prescriptions SOP further states that the same individual should never dispense and check where this is an option, and that every effort is made to have a dispensary technician and pharmacist working together. However, the Dispensing Prescriptions SOP states that when working alone in the dispensary, pharmacists are to ensure that the dispensing and final checking procedures are "mentally" and "physically" separated.[7]

27. According to the Dispensing Prescriptions SOP, the pharmacist is to discuss dispensed medicines with the customer in accordance with the pharmacy's Counselling for Dispensed Medicines SOP (the details of which are set out below).

Counselling for dispensed medicines

28. The Counselling for Dispensed Medicines SOP dated 2 April 2012[8] is designed to ensure that all customers leave the pharmacy with full counselling on how to use their medicine, how much to use, and how often to use it. It states that the pharmacist should hand out medicines to customers, along with appropriate information.

Medicine substitution

29. The Medicine Substitution SOP dated 3 August 2013 (which was created by Mr B) is designed to ensure that prescription medicine substitution follows legislative and professional requirements. According to this SOP, the pharmacist is to dispense the brand of medicine prescribed unless a change has been authorised, with the statement, "Generic substitution permitted". In such cases, the pharmacist is to advise the patient that an approved substitution has been made.

First visit to the pharmacy — 7 September 2013

30. On 6 September 2013, Dr E of the medical centre issued a prescription to Mrs A for Pentasa (mesalazine) 500mg, two tablets twice daily, and Lipitor (atorvastatin)[9] 40mg, one tablet daily, which was sent by facsimile to the pharmacy. The prescription did not state that generic substitution was permitted.

31. On 7 September 2013, Mrs A visited the pharmacy to pick up her prescription. Mr B was the sole pharmacist on duty. Three retail assistants were also working in the pharmacy that day.

Dispensing error

32. Mr B signed Mrs A's prescription indicating that he had dispensed Pentasa and another brand of atorvastatin, Zarator. Mr B wrote "Zarator" on the prescription,

[7] This is discussed later at paragraph 74.
[8] The pharmacy advised that a signed copy of its Counselling for Dispensed Medicines SOP in place as at September 2013 was unavailable, as it had been superseded and replaced. An unsigned electronic version of that SOP was provided to HDC.
[9] Atorvastatin is typically used to lower cholesterol levels in the bloodstream.

indicating that the atorvastatin (which had been ordered as Lipitor) had been replaced with Zarator. The prescription was not countersigned to indicate that the dispensing had been checked.

33. The pharmacy's records indicate that Mr B dispensed Pentasa and atorvastatin (without specifying the brand). Mrs A provided HDC with a photograph of the bottle given to her, which was labelled "Pentasa".

34. However, instead of dispensing Pentasa, Mr B mistakenly dispensed Salazopyrin in place of Pentasa. Like Pentasa, Salazopyrin is also used to treat ulcerative colitis. Unlike Pentasa, Salazopyrin contains a sulpha group that is a common cause of liver abnormalities. Mr B stated that he cannot specifically recall the dispensing and checking of Mrs A's medication on this occasion, but he "accept[s] that [he] made an error and that [his] check was inadequate as it did not identify this".

35. Mr B noted that Salazopyrin and Pentasa have similar sounding generic names (sulfasalazine and mesalazine respectively). He stated:

> "I can not explain why I should have picked Salazopyrin EN rather than Pentasa, other than the fact we have medicines on our shelves listed by their generic drug name Salazopyrin (sulfasalazine) and Pentasa (mesalazine), in my mind I must have erroneously transposed the generic names […] although there was no real pressure in the dispensary I could not have been fully focused on the job at hand. We have a procedure of checking prescriptions which either involves 2 people or if only a pharmacist on duty a re-check after a short period to avoid this sort of error, I obviously did not follow the approved procedures."

36. The pharmacy told HDC that it accepts that Mr B made a dispensing error on this occasion.

Response to query raised by Mrs A

37. Mrs A was served at the counter by a sales assistant who told HDC that she has no recollection of the sale. Mrs A recalls that the sales assistant picked up a bottle and said, "Pentasa". Mrs A told HDC:

> "I immediately noticed it was not the blue box that I have received for many years. I therefore questioned her and informed her that the bottle was different and that normally I receive pills in a blue box. She went and checked with the pharmacist and came back and told me that this was a generic version of the same. No other information was given to me about the pill at the time."

38. Mr B stated that he had thought that Mrs A was querying the change from Lipitor to Zarator. The pharmacy explained that Mrs A's query had been conveyed to Mr B by the sales assistant, and noted that Mr B's response "highlighted that [Mr B] was not clear on which medicine she was referring to as he was not speaking directly with [Mrs A], but via a shop assistant".

39. Mrs A told HDC: "As the pharmacist was the specialist I just, regrettably, accepted this situation. I am aware of generics being used and have before faced different medication that has been changed through Pharmac."

8 to 23 September 2013

40. Over the following days, Mrs A started taking the medication dispensed by Mr B. On 16 September she began to feel extremely fatigued and took time off work to rest.

Second visit to the pharmacy — 24 September 2013

Consultation with Dr C

41. On 24 September 2013, Mrs A attended a consultation with Dr C at the medical centre. Dr C recorded in his notes that Mrs A had been "feeling tired last few weeks" and issued a prescription to Mrs A for a number of her regular medications, including levothyroxine.

42. In her complaint to HDC, Mrs A stated:

> "I went to the doctor thinking I had flu or sinus infection. I had a bad headache and body aches and seemed a bit blocked up. I felt absolutely exhausted and extreme fatigue. At this time I did not make mention or think of the tablets. The doctor said it wasn't sinus infection but he would take some blood tests."

Levothyroxine prescription

43. On 4 July 2013, the dosage of Mrs A's regular levothyroxine had been reduced from 100mcg to 75mcg. In order to make up the reduced dosage of 75mcg daily, she had been instructed to alternate between 50mcg and 100mcg of Eltroxin each day. A prescription for 50mcg levothyroxine tablets to be taken on alternate days was filled at the pharmacy that day.

44. Dr C and the pharmacy have each provided HDC with copies of the prescription issued on 24 September 2013, both of which state, "Levothyroxine sodium 50mcg Tab", with an instruction for 75mcg daily.[10] The brand is not specified, and the prescription further records: "Generic Substitution Allowed."

45. MedSafe (March 2013) states: "Some medicines, although they may have shown bioequivalence, cannot freely be changed due to the nature of the active ingredient (eg levothyroxine due to its incomplete and variable absorption)."

Medication dispensed

46. Mrs A attended the pharmacy to pick up her prescription. Pharmacist Mr D dispensed Mrs A's medications, noting alongside the levothyroxine prescription that he had dispensed 90 tablets of 50mcg Eltroxin and 90 tablets of 25mcg Synthroid. The pharmacy stated that Mrs A had previously been taking Eltroxin 100mcg, and that in order to dispense the prescribed strength of 75mcg, two different brands had to be dispensed.

[10] The prescription provided by Dr C contains a typed instruction for "75mcg daily". The prescription provided by the pharmacy contains a typed instruction for "1 on [alternate] days 75mcg daily", with the instruction "1 on [alternate] days" crossed out by hand.

47. The pharmacy stated: "[Mr D] decided to continue [Mrs A] on the Eltroxin brand she had been on previously at the 50mcg strength and add in Synthroid 25mcg. Synthroid is the only brand that markets the 25mcg strength."

48. Mrs A told HDC:

> "I … was given my thyroxine medication (which was also a new one). I again mentioned to the pharmacist [Mr D] about the Pentasa being different and not feeling well. He argued with me when I complained that he was giving me Synthroid instead of levothyroxine. I didn't like changing two medications within such a short period of time. He was extremely rude and very dismissive of my comments. He said generic pills wouldn't make me feel not well."

49. Mr D told HDC that this was the first time he had met Mrs A, and that he "dispensed what the doctor prescribed and fully informed [Mrs A] of the brand change due to new dosing levothyroxine". Mr D stated that he "cannot fathom" what he could have done "in terms of tone of voice, body and verbal language" to make Mrs A feel that he was being rude and dismissive. Mr D recalls that Mrs A mentioned her fatigue problems "a couple of times", and that he assumed that this was associated with her hypothyroidism.

Request to contact doctor

50. In her complaint, Mrs A noted that Mr D had asked her whether she would like him to contact her doctor. Mr D also recalls that Mrs A asked him to call her doctor regarding the levothyroxine dosage.

51. Mrs A told HDC that Mr D then "went away for about five minutes. He came back and was rude again, and told me he decided he would not phone my doctor and that this was the medication he was dispensing". Mr D told HDC that he "did not consider it was significant to phone the GP as [he] dispensed exactly the correct regime as the doctor ordered".

52. Mrs A stated in her complaint that although the medication dispensed by Mr D on 24 September appeared to be acceptable, this was another point at which Mr B's earlier medication error could have been identified because she had queried it. Mrs A said that the manner in which she was dealt with was "despicable".

Subsequent events

Further consultations with Dr C

53. Mrs A continued to take the medication that had been dispensed by Mr B. On 25 September, Dr C recorded in his notes that Mrs A's blood test results were "markedly deranged". In particular, her blood test results indicated elevated LFTs.[11] The following day, Mrs A attended a consultation with Dr C. He noted that Mrs A was "tired and some nausea today, achey all over" with deranged liver function. Dr C suspected a viral infection and ordered some further tests.

[11] Alkaline phosphatase 306U/L (normal range 40–100U/L), AST 323U/L (normal range 0–45U/L), ALT 520U/L (normal range 0–45U/L) and GGTP 185U/L (normal range 0–50U/L).

54. Mrs A told HDC that she informed Dr C that Mr B had given her a "new generic Pentasa pill" and queried whether this might be the cause of her developing symptoms. Mrs A recalls that Dr C did not think so, as generic medications are "normally okay", but asked Mrs A to bring the medication in with her to her next appointment.

55. On 4 October 2013, Mrs A attended a further consultation with Dr C to discuss her test results. She recalls that Dr C examined the medication she had brought in, and told her that it was not the generic version of Pentasa. Dr C recorded in his notes that Mrs A had been "given Salazopyrin instead of Pentasa (mezalazine) for the past 3 weeks".

56. Mrs A told HDC that she had already taken her medication that day. However, on Dr C's instruction, she then stopped taking the medication that had been dispensed by Mr B.

Admission to hospital

57. Mrs A told HDC that she then became "very ill" over the next two days. In her complaint, Mrs A states: "My whole body ached, my head was causing extreme pain, I was sensitive to light, I was nauseous, I had no power or strength, I had extreme exhaustion."

58. On 6 October, Mrs A was taken by ambulance to hospital, where she was admitted with deranged liver function noted to be "likely drug induced". The district health board advised that there was also evidence of haemolysis,[12] and noted that the sulpha groups in Salazopyrin are a common cause of liver abnormalities and can also cause haemolysis.

59. Mrs A was discharged from hospital on 11 October. Consultant physician Dr F noted that the overall opinion was that Mrs A's condition was caused by a reaction to Salazopyrin. The district health board told HDC that although there are other potential causes for the overall scenario (such as a viral infection or autoimmune disease), it was thought that "the timing of the incorrect medication would fit for this to be a reaction against the Salazopyrin". Mrs A returned to full-time work in December 2013.

Changes made since this incident

Changes made by the pharmacy

60. The pharmacy conducted an internal investigation into the incident, which concluded that its "systems and procedures were robust but were not followed as [Mr B] failed in his final check".

61. The pharmacy told HDC that it has made a minor amendment to its Dispensing Medications SOP, which now states: "It is the sole responsibility of the pharmacist to counsel patients. Any medicine related enquiries will be referred to the pharmacist on duty to discuss." The pharmacy advised that this change has been communicated to all staff.

[12] The rupture or disintegration of red blood cells.

62. The pharmacy has apologised in writing to Mrs A, and made an ex gratia payment to her in recognition of the harm suffered by her.

Changes made by Mr B

63. Mr B subsequently resigned from his position at the pharmacy and told HDC:

> "The incident caused me considerable personal distress and anguish. I am dismayed that I made such a fundamental error and that it has caused [Mrs A] to suffer. After a [long] career in pharmacy I did not want a situation such as this to occur ever again and on terminating my employment at [the pharmacy] I decided to relinquish my practice certificates and retire from the industry. I also removed my name from any locum list."

64. Mr B told HDC that he attempted to contact Mrs A to discuss the incident, but was unable to reach her. He provided HDC with a letter of apology for forwarding to Mrs A.

Responses to provisional opinion

The pharmacy

65. The pharmacy advised that it had no further comments, other than that it is happy to provide HDC with the results of an audit of staff compliance with its checking procedures.

Mr D

66. Mr D agreed with the conclusions regarding his encounter with Mrs A, and acknowledged that there is always room to expand the capacity to assist the public.

Mr B

67. Mr B reiterated that it disturbed him to know that his oversight and error had caused so much distress.

68. With regard to the Medicine Substitution SOP, Mr B noted that under regulation 42(4) of the Medicines Regulations 1984, a pharmacist is entitled to dispense a generic substitution without the prescriber's permission unless the prescription states, "No brand substitution permitted", or words to that effect, provided that certain steps are followed, including the pharmacist informing the patient of the brand substitution.

Relevant professional standards

Pharmacy Council of New Zealand — Safe Effective Pharmacy Practice, Code of Ethics 2011

69. "*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."

Pharmacy Council of New Zealand — Safe and Effective Pharmacy Practice, Competence Standards for the Pharmacy Profession

70. "**Element 6.6 Fill prescriptions**

…

6.6.2 Maintains a logical, safe and disciplined dispensing procedure

Examples of Evidence:
Selects correct product, dose form & quantity for each prescribed medicine …"

71. "**Element 6.10 Counsel patients about their medicines**

…

6.10.3 Informs and advises about medicines

Examples of Evidence:
Advises on dosage, storage, alterations in formulation/packaging, different brands supplied on generic-request medicines …"

Opinion: Mr B — Breach

72. As a registered pharmacist, Mr B was responsible for ensuring his adherence to professional standards. The Pharmacy Council of New Zealand (PCNZ) competence standards, outlined above, require registered pharmacists to ensure that they "maintain … a logical, safe and disciplined dispensing procedure" including selecting the correct product for each prescribed medicine. These standards further require that pharmacists counsel patients about their medicines, including advising patients on different brands supplied in generic-request medications. The PCNZ Code of Ethics requires registered pharmacists to be accountable for practising safely, and for "maintaining and demonstrating professional competence".

73. Mr B accepts that he dispensed Mrs A's medications on 7 September 2013, and that, in doing so, he mistakenly dispensed Salazopyrin in place of Pentasa. He is unable to recall the incident but suggested that he may have erroneously transposed the generic names (sulfasalazine and mesalazine respectively).

74. It is not necessary for me to make a specific finding as to why Mr B picked up Salazopyrin in place of Pentasa. In any event, Mr B accepts that he failed to perform the necessary checks required by the Dispensing Medications SOP in place at the time. In particular, that SOP states that when working alone in the dispensary, pharmacists are to ensure that the dispensing and final checking procedures are "mentally" and "physically" separated. As noted by Mr B, this system involves "a re-

check after a short period". In practical terms, such self-checking can be achieved by introducing a temporal separation (ie, a delay, even for a few seconds) and a physical separation (ie, checking in a slightly different place to where the original dispensing was done — even if only the other side of the bench). This helps the pharmacist to "psychologically reset".

75. Mr B did not countersign the prescription to indicate that the dispensed medications had been checked. He advised that there was "no real pressure" in the dispensary that day, but that he could not have been fully focussed "on the job at hand". This is suboptimal.

76. I am particularly concerned by the error given that Mrs A queried the dispensed medication at the time. Mrs A recognised that the Pentasa medication was in different packaging from what she usually received, and questioned the shop assistant. Her query was conveyed to Mr B by the shop assistant. Mr B did not speak directly with Mrs A, and did not appreciate that Mrs A's query related to the Pentasa medication. Instead, he mistakenly believed that Mrs A had queried the replacement of Lipitor with Zarator, and advised the shop assistant that this was a generic substitution. The shop assistant then conveyed that advice to Mrs A, who told HDC that she accepted the situation because "the pharmacist was the specialist".

77. It is concerning that Mr B chose to communicate with Mrs A in this manner. As the Counselling for Dispensed Medicines SOP makes clear, Mr B was required to counsel patients in relation to dispensed medications (including handing out medicines to customers along with appropriate information). In addition, PCNZ competence standard 6.10.3 required Mr B to inform and advise patients about their medicines and alterations in formulation/packaging. Mr B therefore ought to have addressed Mrs A's query with her directly. Had he done so, the confusion as to which medication Mrs A was querying may well have been avoided. In my view, this was an important missed opportunity to identify the error that had occurred. Mrs A was entitled to rely on Mr B to dispense the correct medication and to provide her with accurate advice in response to any queries or concerns she had in relation to that medication.

78. I also have some concern regarding the dispensing of Zarator in place of Lipitor. Contrary to the Medicines Substitution SOP, this change appears to have been made without proper authorisation, in that the prescription does not carry the statement: "Generic substitution permitted." In addition, Mr B did not advise Mrs A that an approved substitution had been made, as required by PCNZ competence standard 6.10.3 and the Medicine Substitutions SOP. As set out above, it was not until Mrs A queried the change herself that Mr B informed her, via a shop assistant, that a change had been made. While I acknowledge that the Medicines Substitution SOP was more onerous than regulation 42(4) of the Medicines Regulations 1984, I remain concerned that Mr B did not discuss the substitution with Mrs A.

79. Mr B failed to ensure that he dispensed the correct medication to Mrs A on 7 September 2013. He also failed to counsel Mrs A effectively about her medications, resulting in a missed opportunity to identify the error at the outset. Accordingly, I consider that Mr B failed to provide Mrs A with services in accordance with professional standards, in breach of Right 4(2) of the Code.

Opinion: The pharmacy — No breach

80. In the course of this investigation, I have carefully considered the extent to which the dispensing error that occurred is attributable to individual action or inaction by Mr B, as opposed to systems or organisational issues at the pharmacy. As this Office has previously stated, "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".[13] In addition, under section 72(2) of the Health and Disability Commissioner Act 1994 (the Act), an employing authority may be vicariously liable for acts or omissions by an 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 acts or omissions leading to an employee's breach of the Code.

81. At the time of these events, the pharmacy had a number of relevant SOPs in place relating to the dispensing of medications and the counselling of patients. As is set out above, these SOPs were reviewed regularly and set out detailed checks to be completed during and following the dispensing of medications, and the circumstances in which pharmacists were expected to communicate with patients directly. The pharmacy explained that the SOPs were signed by Mr B to indicate that he had read and understood their terms. At the time of these events, he was a registered pharmacist with a current practising certificate and many years' experience in the industry.

82. As noted above, Mr B accepts that he did not follow the checking procedure required by the SOP in place at the time. By his own account, there was "no real pressure" in the dispensary that day but he was not fully focussed on the job at hand. In these circumstances, I am satisfied that the error occurred as a result of Mr B's individual conduct as opposed to systemic issues at the pharmacy, and that the pharmacy took steps that were reasonably practicable to prevent acts or omissions such as Mr B's in this case. Therefore, I do not consider that the pharmacy has breached the Code or is vicariously liable for Mr B's breach of the Code.

[13] Opinion 13HDC00819, 23 June 2014.

Opinion: Mr D — Adverse comment

83. I have some concern in relation to Mrs A's interaction with Mr D on 24 September. It appears from the evidence that Mrs A raised some concern regarding her fatigue and the changes being made to her dispensed medications. There was also some discussion as to whether Mr D ought to contact Mrs A's doctor, Dr C, in relation to her levothyroxine prescription.

84. I note Mr D's explanation for his decision not to contact Dr C, and I accept that he dispensed the medication that had been prescribed. That said, I also note the advice received from my independent pharmacy expert, Mr Ross Carrick, that "the most logical outcome that would have been clinically correct and least confusing for Mrs [A], would have been for the pharmacist to ask for or generate a prescription for approval for Eltroxin 50mcg take one tablet on one day and two the next".

85. I also note Mrs A's comment that this was another missed opportunity to identify Mr B's error. While I am unable to speculate as to whether a discussion between Mr D and Dr C may have uncovered the error at this stage, in my view such a discussion would have at least assisted in allaying Mrs A's concerns at the time.

86. Mrs A recalls that Mr D's manner was rude and dismissive. Mr D "cannot fathom" what he could have done to make Mrs A feel this way. I am unable to make a factual finding as to the specific communications that took place between Mrs A and Mr D in this regard. However, it is disappointing that Mrs A did not feel that her concerns were addressed appropriately, and I suggest that Mr D reflect on how, in the future, he can assist consumers who have concerns about their medication.

Recommendations

87. The pharmacy and Mr B have each provided written apologies to Mrs A. the pharmacy has also made an ex gratia payment to Mrs A, and made a minor amendment to its Counselling for Dispensed Medicines SOP to make clear that it is the "sole responsibility" of the pharmacist to counsel patients in relation to dispensed medications.

88. I recommend that the pharmacy:

a) Audit staff compliance with its checking procedures including all relevant SOPs (particularly when the pharmacist is working alone in the pharmacy), and provide HDC with the outcome of that audit within three months of this decision.

b) Provide HDC with evidence that all relevant staff have been trained in the above procedures (including the amended Dispensing Medications SOP) within three months of this decision.

89. I note that Mr B has retired and is no longer working as a pharmacist. It is therefore unnecessary for me to make any further recommendations in relation to his

professional training and/or education. I recognise that this error has caused him to reflect on his practice and has had a great impact on him.

Follow-up actions

90.
- A copy of this report with details identifying the parties removed, except the name of the expert who advised on this case, will be sent to the Pharmacy Council of New Zealand, and it will be advised of Mr B's name.
- A copy of this report with details identifying the parties removed, except the name of the expert who advised on this case, will be sent to the New Zealand College of Pharmacists.
- I will recommend to the Pharmacy Council of New Zealand that, in the event that Mr B reapplies for a practising certificate, the Council assess the appropriateness of him returning to practice. In the event that Mr B does return to practice, I recommend that the Council determine any necessary conditions on his practice, supervision and monitoring, and training needs, and advise HDC accordingly.
- A copy of this report with details identifying the parties removed, except the name of the expert who advised on this case, will be sent to the district health board and it will be advised of Mr B's name.
- A copy of this report with details identifying the parties removed, except the name of the expert who advised on this case, will be placed on the Health and Disability Commissioner website, www.hdc.org.nz, for educational purposes.