Pharmacy

Pharmacist, Mr B

A Report by the

Deputy Health and Disability Commissioner

(Case 14HDC01653)

Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

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Executive summary

1. Ms A was taking a regular medication called fluoxetine (a selective serotonin reuptake inhibitor (SSRI)) to manage depression. She was travelling in New Zealand and needed further fluoxetine. On 25 June 2014, Ms A saw a general practitioner (GP) to obtain a repeat prescription of fluoxetine, along with the contraceptive pill.

2. On 25 June 2014, Ms A had the prescription filled at a pharmacy. Mr B was a pharmacist on duty that day. Mr B mistakenly dispensed Duride[1] 60mg in place of fluoxetine 20mg. The pharmacy label on the box stated that the contents were fluoxetine; however, the box and pill packets were marked "Duride". Ms A did not question the name "Duride" on the box or pill packets.

3. Ms A then started taking the Duride dispensed by Mr B. During the time she was not taking fluoxetine, Ms A experienced an exacerbation in her depression. She started seeing a counsellor again and struggled to find a job owing to her feelings of inadequacy. Her relationship broke down and she suffered severe migraines, felt nauseous, experienced random heart palpitations, and was always fatigued.

4. Ms A went to another GP for a further prescription. The GP immediately told Ms A that the pills she had been taking for depression were not anti-depressants. On 10 September 2014, the GP contacted the pharmacy on Ms A's behalf. Ms A received letters of apology from Mr B and the pharmacy.

Findings

5. Mr B failed to ensure that he dispensed the correct medication and the correct dose to Ms A on 25 June 2014. Accordingly, Mr B failed to provide Ms 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).[2]

6. The pharmacy was found not to have breached the Code or to be vicariously liable for Mr B's breach of the Code.

Complaint and investigation

7. On 19 November 2014, the Commissioner received a complaint from Ms A about the services provided to her by Mr B and the pharmacy.

8. On 13 March 2015, an investigation was commenced. The following issues were identified for investigation:

- *Whether the pharmacy provided Ms A with an appropriate standard of care in 2014.*

[1] Cardiac medication used to prevent angina. Duride contains the active ingredient isosorbide mononitrate.
[2] Right 4(2) states: "Every consumer has the right to have services provided that comply with legal, professional, ethical, and other relevant standards."

- *Whether pharmacist Mr B provided Ms A with an appropriate standard of care in 2014.*

9. This report is the opinion of Rose Wall, Deputy Commissioner, and is made in accordance with the power delegated to her by the Commissioner.

10. The parties directly involved in the investigation were:

Ms A	Consumer/Complainant
Mr B	Provider/Pharmacist
The pharmacy	Provider

11. Further information was received from:

Ms C	Manager of the pharmacy/Pharmacist
Pharmacy Council of New Zealand	

Information gathered during investigation

Background

12. Ms A, aged 26 years at the time of these events, was taking a regular medication called fluoxetine[3] to manage depression. In 2014, she needed further fluoxetine. Because she was travelling, Ms A kept the box of her current medication to show the doctor.

13. On 25 June 2014, Ms A saw a general practitioner (GP) for a repeat prescription of fluoxetine, along with the contraceptive pill. The GP prescribed her further fluoxetine and the contraceptive pill. The prescription for fluoxetine read:

> "**Rx:** Fluoxetine 20 mg Capsules
> **Dose:** 1 capsule 1 times per day
> **Qty:** 3 packs of [28]"

14. Consequently, Ms A was prescribed a three-month supply of fluoxetine.

15. Ms A had the prescription filled at the pharmacy, which employs pharmacists, as well as dispensary and retail staff.

16. At the time of these events, Mr B was employed by the pharmacy part-time as a locum/consultant pharmacist. He had worked in that role for over five years, and was a registered pharmacist with many decades of dispensing experience.

[3] Fluoxetine is a commonly prescribed antidepressant in the SSRI (selective serotonin reuptake inhibitors) group. It is sold under different brand names, including Mylan and Prozac. The dosage range is between 15mg and 90mg.

25 June 2014 — visit to the pharmacy

17. On 25 June 2014, Mr B was the sole pharmacist on duty. A pharmacy technician and retail assistants were also working at the pharmacy that day.

18. Mr B took Ms A's prescription from the prescription collection box and entered the details of the prescription into the computer. He selected the medication and, after checking the labels generated by the computer against the prescription, attached the labels to the respective boxes of medication without realising that he had selected the wrong medication (i.e. box) in relation to the fluoxetine.

19. Instead of dispensing fluoxetine, Mr B mistakenly dispensed Duride.[4] Ms A provided HDC with a photograph of the box given to her, which shows a label affixed stating "90 Fluoxetine Arrow Capsules 20mg", but the box is marked "Duride 60 mg CR".

20. In mid-2014, Ms A moved to another region. In September 2014, she consulted a GP there for a new prescription of fluoxetine. She took her current medication with her. On viewing the box, the GP immediately told Ms A that the medication she had been taking for depression was not an antidepressant medication. The GP took copies of the prescription receipt and, on 10 September 2014, contacted the pharmacy to bring its attention to the matter.

21. On 11 September 2014, Mr B completed an incident report form and emailed this to the Pharmacy Defence Association, along with a detailed description of events. He also telephoned Ms A to apologise for the error.

22. Ms A said that on discovering that she had been taking the wrong medication she felt shocked, experienced a drop in her quality of life, and was left feeling vulnerable. She said:

> "Looking back, it made a lot of sense. My depression had taken a steep turn for the worse, and my quality of life was severely compromised for months. I started seeing a counsellor again. I struggled to find a job due to my intensified feelings of inadequacy and hatred that comes with depression. My relationship was lost also. I had (albeit accidentally) been taken off anti-depressants immediately, without my knowledge, after being on them for more than a year, for the second period of depression in my life."

23. When a person stops taking antidepressant medication, he or she can be at risk of "sudden cessation". The person may experience flu-like or stomach upset symptoms, difficulty in thinking, and/or disturbing thoughts.

24. Mr B said that his usual procedure is to sign against the third part of the standard three-part prescription label issued for prescribed medicines,[5] as opposed to signing

[4] Cardiac medication used to prevent angina. Duride contains the active ingredient isosorbide mononitrate.

[5] The label for a prescription is computer-generated and comprises three parts. One part contains directions for use and is placed on the medication container or box; one part is an address label placed on the bag for delivery; the third part summarises the dispensing and is placed on the prescription form. Each part of the label contains the unique identifier number for that prescription.

the prescription container or box. The pharmacy provided HDC with a copy of the original prescription form with the third part label affixed, initialled by Mr B. The third part label states "FLUO, 2" and the unique identifier number for "90 Fluoxetine Arrow". This matches the larger, first part label that was affixed to the box marked "Duride".

25. Mr B says that he has "no explanation" for the fact that his dispensing process resulted in "the correct wording on the labels but in the case of the fluoxetine, the wrong medication". Mr B told HDC:

> "I have been over and over this in my mind and have discussed it with a member of PDA (Pharmacy Defence Association) and [Ms C], manager of the pharmacy. It is an issue which defies logic in that I simply cannot understand the error."

26. Mr B noted that, at the time, fluoxetine and Duride shared similar packaging, and were relatively close together on the shelves. He observed:

> "The brands currently subsidised have changed since June 2014 and so have the packets … There are significant physical differences between Duride and fluoxetine tablets but that would not be noticed by the dispenser as they would most often be dispensed in the original packs. The difference could have been noticed by the patient however, especially since [Ms A] told me on the phone that she had taken fluoxetine several times previously."

27. As to similarity of packaging, Ms C said:

> "The only explanation I can offer for the error is that the packaging of Duride and the old subsidised brand of Fluoxetine (Mylan) are very similar; however, I wouldn't want this to be seen as an excuse."

28. Mr B said that he is unable to recall the incident, but accepted that in the past his checking procedures "have been more robust". Mr B is not able to recall whether he left a distinct gap between the dispensing and checking. He does recall that at the time of dispensing, the pharmacy technician on duty was engaged in other duties, and had no involvement in dispensing Ms A's prescription. Mr B says that he was the only pharmacist on duty that day.

29. Ms A told HDC that she did not question the name "Duride" on the box or pill packs. She stated: "I have been given different drugs by different names for the 3 years that I have been away from [my home country]." Ms A does not recall Mr B discussing the medication with her, and advised that someone else may have handed her the medication.

30. The pharmacy accepts that Mr B made a dispensing error on this occasion. Mr B stated:

> "My checking procedure did not pick up an error in the dispensing of one of the medications on the prescription. My checking procedure did not meet the pharmacy's expectations in standards of patient care and this incident did not meet my own standards of patient care."

Subsequent events

31. Ms A stated that during the time she was not taking fluoxetine, she suffered severe migraines, felt nauseous, experienced random heart palpitations, and was always fatigued.

32. On 12 September 2014, the pharmacy sent Ms A a written apology and, on 16 September 2014, Mr B sent Ms A a written apology.

33. The pharmacy provided HDC with a copy of its Standard Operating Procedure (SOP) dated 15 May 2012 and headed "Dispensary Procedures". This contains five separate SOPs covering the dispensing process.[6] The pharmacy explained that Mr B assisted Ms C in developing the SOP when it was being introduced. Mr B told HDC:

> "[The pharmacy] has the relevant policies in place, as I had my own pharmacy before I closed it. Those policies were very similar and reflect what is standard dispensing and checking practices by pharmacists."

34. According to the SOP entitled "Dispensing 4 — Accuracy check", the pharmacist is required, during the dispensing process, to check (among other things) the label and dispensed medicine against the original prescription and the stock supply used to dispense the medicine. This includes the formulation, strength and quality of the medicine. Each item is to be initialled when it has been checked and passed for accuracy.

35. The same SOP further states under "Purpose" that all dispensed items should undergo a documented accuracy check by a checking pharmacist. It indicates that the same individual should not dispense and check where this can be avoided. It states that if self-checking cannot be avoided (ie, when there is no checking pharmacist available), the "physical" and "mental" activities should be separated by another task.

36. Items checked by a dispenser should be left in the designated checking area for an accuracy check by a pharmacist (see SOP Dispensing 3 — Label generation and dispensing medicines).

37. The "Dispensing 5 — Counselling for dispensed medicines" SOP is designed to ensure that all customers are offered appropriate counselling about their medicines when they collect them. It states that prior to handing the medication to the customer, the pharmacist is to inform and advise the customer about the medicines being collected. The SOP further states: "[E]ven if the patient has been taking the medicine for a number of years, counselling may not be required but still provide an opportunity for them to ask questions."

Changes made since the incident

38. Because of the similarity in packaging with the earlier, subsidised brand of fluoxetine, and as a result of the incident, the pharmacy decided to move the fluoxetine and Duride boxes further apart on the pharmacy shelves. Ms C said that she has not made

[6] The pharmacy also provided HDC with a Locum Pharmacist Guide dated February 2015 and a Dispensing Checklist and Incident Form.

any changes to the SOP since becoming aware of the error. She told HDC that the SOP "Dispensing 4 — Accuracy Check" appears fairly robust, and she can only assume that "the SOP was not followed in this situation".

39. After the incident, Ms C began training another technician to assist during weekends and evenings. A prompt has been entered into the computer system to make sure that for fluoxetine and Duride, the pharmacist is reminded to be extra careful. Ms C also advised that she has asked pharmacists to be more careful, and has provided them with a checklist to "clarify what is important to look out for". Relevant checks include, "Have you checked selected medicine against prescription to ensure correct med[icine], form and strength?" and, "Has the dispenser and checker signed the prescription?". There is a laminated copy of the checklist in the dispensary, and also a copy in the Locum Pharmacist Guide.

40. Ms C has made it compulsory (as of April 2015) for all pharmacists at the pharmacy to read the Locum Pharmacist Guide (updated February 2015), and to initial relevant pages. A copy is available in the pharmacy's dispensary and in the Locum Pharmacist Guide Folder.

41. Mr B has had several discussions with Ms C, and together they have reviewed what happened. Despite this, Mr B said that he could find no logical explanation of "why the checking procedure had failed to pick up the error".

42. Mr B said that he has always had a technician check his controlled drug[7] dispensing but, since the incident, he has undertaken less work and has had his dispensing checked by a technician in all cases.

Further information received from the pharmacy

43. The pharmacy advised HDC that, on 22 May 2012, it had participated in a Pharmacy Quality Audit undertaken by the Ministry of Health. This revealed some minor discrepancies relating to reference resources, and resulted in modifying SOPs for compounding and repackaging medicines, and ensuring that the dispensing of methadone is accurately described in the SOP. The pharmacy attained a 10/10 score for C.2 Dispensing Practice. On 26 September 2012, the pharmacy attained all audit criteria.

Relevant professional standards

44. The Pharmacy Council of New Zealand (PCNZ) publication *Safe Effective Pharmacy Practice* (2011) provides in its *Code of Ethics* that the pharmacist:

> "1.2 Take appropriate steps to prevent harm to the patient and the public.
>
> …

[7] Fluoxetine is not a controlled drug.

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

45. Furthermore, the PCNZ *Competency Standards for the Pharmacy Profession* (2011) states:

"1.1.5 Works accurately

Examples of Evidence: Minimises mistakes. Acts immediately to rectify harm arising from mistakes. Documents errors and steps taken to prevent their recurrence.

…

6.2.2 Follows workplace dispensing criteria when dispensing a prescription item.

…

6.5.1 Confirms that each selected medicine is suitable for the patient.

Examples of Evidence: Confirms that dosage, route of administration & duration of therapy are suitable.

…

6.6.2 Maintains a logical, safe and disciplined dispensing procedure.

Examples of Evidence: Selects correct product, dose form & quantity for each prescribed medicine. Dispenses off prescription, not label.

…

6.9.2 Acts to minimise the effects of his/her dispensing errors.

Examples of Evidence: Identifies potential/actual errors in own dispensing. Acts to minimise effect on patient, e.g. contacts patient, contacts prescriber, supplies correct medicine. Documents own dispensing errors & actions undertaken to minimise their effects. Complies with workplace procedures for documenting dispensing errors.

6.10.3 Informs and advises about medicines

Examples of Evidence: Explains indications for use & benefits of medicines. Advises on dosage, storage, alterations in formulation/packaging, different brands supplied on generic-request medicines. Advises about precautions & adverse effects without alarming patients. Advises on frequency; relationship to food & duration of therapy. Provides written information, e.g. pamphlets, self care cards."

Responses to provisional opinion

46. Having reviewed the provisional opinion, Mr B advised that he was comfortable with the proposed recommendations.

47. The pharmacy noted that the pharmacy and Mr B have done everything possible to remedy the situation, and followed correct procedure when the error came to light. It said that, in Ms C's experience, a dispensing error was a "rare and regrettable incident" for the pharmacy. It said that this error was an isolated incident and noted that no blame is attributed to the pharmacy.

Opinion: Mr B — Breach

48. Mr B accepts that he dispensed Ms A's medications on 25 June 2014 and that, in doing so, he mistakenly dispensed Duride in place of fluoxetine. Although he is unable to recall the incident, Mr B accepted that in the past his checking procedures "have been more robust". Mr B states that his "checking procedure failed on this occasion" and "did not meet the pharmacy's expectations in standards of patient care and … my own standards of patient care".

49. As a registered pharmacist, Mr B is responsible for ensuring his adherence to professional standards. The Pharmacy Council of New Zealand's *Competence Standards for the Pharmacy Profession (2011)*, outlined above, require registered pharmacists to ensure that they:

- follow workplace dispensing criteria when dispensing a prescription item;
- confirm that each selected medicine is suitable for the patient;
- maintain a logical, safe and disciplined dispensing procedure including selecting the correct product for each prescribed medicine; and
- inform and advise about medicines.

50. The PCNZ Code of Ethics requires registered pharmacists to be accountable for practising safely and to "maintain and demonstrate professional competence".

51. The pharmacy had a number of SOPs in place to ensure safe dispensing. The "Dispensing 4 — Accuracy Check" SOP requires the pharmacist to check the label and dispensed medicine against the original prescription and the stock supply used to dispense the medicine. Mr B said that his usual procedure is to sign against the third part label and against each individual item dispensed and listed on the prescription, as opposed to signing the prescription container or box.

52. On Ms A's prescription, the third part of the fluoxetine label is attached with a signature next to it. In my view, this indicates that Mr B checked the label against the

prescription. However, given that the Duride medication was dispensed instead of fluoxetine, I consider that Mr B failed to check the dispensed medicine adequately against the prescription or the label, as required by the SOP. Failing to check the medicine against the prescription label also meant that the wrong dose was administered — Duride 60mg was dispensed instead of fluoxetine 20mg. This is unacceptable. Checking that the correct medication, including the correct dose, is being dispensed is a fundamental aspect of pharmacy practice, and is a requirement of both the pharmacy's SOPs and the PCNZ professional standards.

53. Mr B failed to ensure that he dispensed the correct medication and the correct dose to Ms A on 25 June 2014. He did not comply with the checking procedure required by the pharmacy's SOP, and he did not comply with the PCNZ competence standards requiring a pharmacist to maintain a safe and disciplined dispensing procedure including selecting the correct product for each prescribed medicine. Accordingly, I consider that Mr B failed to provide Ms A with services in accordance with professional standards, and, accordingly, breached Right 4(2) of the Code.

54. It is not clear whether, as the only available pharmacist on duty, Mr B ensured that there was a gap between the dispensing and checking procedures, so that he could "self-check" the medication before it was given to Ms A. It is also unclear whether any counselling was offered, as required by SOP 5 — Dispensing and Competency Standard 6.10.3 (noted above). I note that Ms A was a new customer to the pharmacy.

55. I would therefore remind Mr B of the importance of ensuring that the "physical" and "mental" dispensing tasks are separated and that, when giving customers their medication, he offers counselling to them, where appropriate. Counselling also serves as a final check for accuracy.

56. I note that Mr B accepts his error and has adopted a professional approach in ensuring that such a mistake does not happen again.

Opinion: The Pharmacy — No breach

57. 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 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".[8] In addition, under section 72(2) of the Health and Disability Commissioner Act 1994, 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.

[8] Opinion 13HDC00819, 23 June 2014.

58. At the time of these events, the pharmacy had a number of relevant SOPs in place relating to the dispensing of medications. The pharmacy explained that Mr B assisted Ms C in developing the SOPs when they were being introduced. Mr B said that previously he had his own pharmacy, and the current pharmacy's policies "were very similar and reflect what is standard dispensing and checking practices by pharmacists". At the time of these events, Mr B was a registered pharmacist with a current practising certificate and many decades' experience in the industry.

59. I note that in May 2012 the pharmacy participated in a Pharmacy Quality Audit undertaken by the Ministry of Health. This revealed some minor discrepancies, but the pharmacy attained a 10/10 score for C.2 Dispensing Practice. On 26 September 2012, the pharmacy attained all audit criteria.

60. As noted above, Mr B accepts that his checking procedure failed on this occasion. By his own admission, there was "no explanation for the fact that [his] checking resulted in the correct wording on the labels but in the case of the fluoxetine the wrong medication". In these circumstances, and having examined the SOPs, I am satisfied that the pharmacy's SOPs are robust, and that the error occurred as a result of Mr B's individual error 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.

Recommendation

61. Mr B and the pharmacy have each apologised to Ms A.

62. I recommend that Mr B reflect on his dispensing practice and provide HDC with a written summary of his reflection within three weeks of the date of the final decision.

Follow-up actions

- 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 Mr B's name.
- A copy of this report with details identifying the parties removed, will be sent to the New Zealand College of Pharmacists.
- A copy of this report with details identifying the parties removed, will be sent to the Centre for Adverse Reactions Monitoring.
- A copy of this report with details identifying the parties removed, will be sent to the Health Quality & Safety Commission.
- A copy of this report with details identifying the parties removed, will be placed on the Office of the Health and Disability Commissioner website, www.hdc.org.nz, for educational purposes.