Pharmacist, Mr A Pharmacy

A Report by the Deputy Health and Disability Commissioner

(Case 20HDC02229)

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Executive summary

- 1. This report concerns a pharmacist's failure to check a medication adequately before it was given to a consumer, which resulted in the wrong medication being dispensed. The report highlights the importance of pharmacists undertaking adequate checks.
- 2. The Deputy Commissioner considered that by selecting the wrong medication, not checking the dispensed prescription adequately, and allowing an incorrect medicine to be dispensed, the pharmacist failed to adhere to the professional standards set by the Pharmacy Council of New Zealand, and breached Right 4(2) of the Code.
- 3. The Deputy Commissioner did not find the pharmacy in breach of the Code, but reminded the pharmacy of the importance of maintaining and complying with up-to-date Standard Operating Procedures.
- 4. The Deputy Commissioner noted that the pharmacist and the pharmacy made changes to their processes following these events. She recommended that the pharmacy provide training for staff in relation to dispensing and checking medications, and undertake an audit of medication dispensing and checking. The Deputy Commissioner recommended that the pharmacist provide a written apology and show evidence of his completed training in Improving Accuracy and Self Checking.

Complaint and investigation

- 5. The Health and Disability Commissioner (HDC) received a complaint from Ms B about the services provided to her by Mr A at a pharmacy. The following issues were identified for investigation:
 - Whether Mr A provided Ms B with an appropriate standard of care between 3 September 2020 and 12 November 2020 (inclusive).
 - Whether the pharmacy provided Ms B with an appropriate standard of care between 3 September 2020 and 12 November 2020 (inclusive).
- 6. This report is the opinion of Deputy Health and Disability Commissioner Deborah James, and is made in accordance with the power delegated to her by the Commissioner.
- 7. The parties directly involved in the investigation were:

| Mr A | Pharmacist |
|----------|------------|
| Ms B | Consumer |
| Pharmacy | Provider |



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Information gathered during investigation

Introduction

8. This report concerns a dispensing error in which an anti-cholesterol medication (ezetimibe) was dispensed in place of a cancer medication (exemestane).

Background

9. Ms B had been diagnosed with breast cancer, and in September 2020 had completed two years of treatment with tamoxifen.¹ Her oncologist then prescribed a different antioestrogen medication, exemestane.

Dispensing on 3 September 2020

- 10. On 3 September 2020, Ms B took her prescription to the pharmacy for dispensing. The pharmacist was Mr A.²
- 11. Mr A entered the information from the prescription into the computer and printed the label. Exemestane was on the shelf next to ezetimibe. Mr A told HDC that he "picked the wrong medicine from the shelf (ezetimibe) and put on the label [he had] produced that said exemestane". Mr A did not notice the error when checking the prescription. The dispensing technician completed a second check, and did not notice the error either. Mr A stated:

"Very unfortunately we have both concentrated on ensuring the label is correct against the prescription, while missing that the dispensed medicine is wrong."

12. The medication was given to Ms B, and she took it over the next two months.

Discovery of dispensing error and subsequent events

- ^{13.} In November 2020, Ms B obtained another prescription for exemestane, and this was dispensed from another pharmacy on 10 November 2020. She noticed that the pills looked different to those she had been taking. The next day, she discussed this with the pharmacist from the second pharmacy who informed her that the first pharmacy had dispensed ezetimibe instead of the prescribed exemestane.
- 14. On 11 November 2020, Ms B contacted the first pharmacy and queried whether the error was on the part of the doctor or the pharmacy. Mr A confirmed that it was his error, and apologised. Mr A called Ms B's oncologist, and later her GP, to advise them that she had taken incorrect medication and to ask for advice on the next treatment steps. Mr A called Ms B and apologised again. He also filled out a Customer Complaint Record, which detailed the actions taken.

¹ Tamoxifen is an anti-oestrogen medication used to treat some types of breast cancer.

 $^{^{2}}$ Mr A registered as a pharmacist, and graduated with a Diploma in Pharmacy. He is the owner of the pharmacy.

²

Contributing factors

- 15. Ms B's prescription was processed between 12–1pm on 3 September 2020. The pharmacy told HDC that 34 prescriptions were processed during this time, and for two other time periods that morning, the number of prescriptions processed exceeded 30. This was an "uncommonly high" rate. The pharmacy said that overall prescription numbers were 20% higher than the previous September, and attributed this to the flow-on effects of the COVID-19 pandemic, in particular stock shortages.
- 16. Mr A stated:

"It would be my normal procedure to counsel patients on new medications and provide written information as required. In this case this did not happen. The prescription was collected the day following processing and this may have been a contributing factor in that the dispensed medicine was put on the shelf when I would normally take it straight out and talk to the patient about their new medicine."

Standard Operating Procedures

- 17. Standard Operating Procedures (SOPs) are documents that describe standard procedures and actions to be taken by staff when performing their duties.
- 18. The SOPs in place at the time of events required three separate checks, each confirming that the drug, strength, and quantity matched the prescription. The third check required the checker to compare "stock bottle against prescription, label against prescription and contents of dispensed medicine against prescription and label". Relevant sections of the SOPs are included in Appendix B.
- ^{19.} Mr A told HDC: "We believe the SOP in use at the time was appropriate, but I missed several steps in my usual process and that is what has led to this error."
- 20. Mr A said that the pharmacy's SOPs were due for review in October 2020 (the month after Ms B was provided with the incorrect medication), but "[u]nder the additional stress of COVID lockdown and subsequent ongoing additional workload, [he] did not review [the] SOPs on time". Subsequently, in January 2021, he reviewed and updated the SOPs for dispensing and checking, and for incident reporting.
- 21. The SOP for incident reporting required that the pharmacy report the incident to the Pharmacy Defence Association (PDA). The pharmacy told HDC that it "failed to do this at the time". After realising the oversight, the pharmacy reported the incident to the PDA in December 2020.

Further information

22. Ms B stated:

"I will never know whether a recurrence of cancer is the result of the error in receiving cholesterol treatment, rather than anti-oestrogen treatment. Almost as important to



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me, is the shock and feeling of being completely let down, knowing no one can reassure me all is ok because this situation is unprecedented."

23. Mr A told HDC:

"[E]very time we dispense either of the medicines involved, the incident comes to mind.

...

Both myself and [the dispensing technician] are deeply upset by the grief and angst we must have caused [Ms B]. I hope by immediately responding to the error as soon as we heard about it, determining what had happened, and being up front with the details of the incident has helped [Ms B] through this process."

Responses to provisional opinion

- 24. Ms B received the "Information gathered" section of the provisional opinion for the opportunity to comment. She had nothing further to add.
- ^{25.} Mr A and the pharmacy accepted the findings of the provisional opinion.

Opinion: Mr A — breach

- 26. As a registered pharmacist, Mr A was responsible for ensuring that he provided services of an appropriate standard to Ms B, including complying with the professional standards set by the Pharmacy Council Code of Ethics.
- 27. The Pharmacy Council of New Zealand's *Competence Standards for the Pharmacy Profession* (2015) provides that a pharmacist "[m]aintains a logical, safe and disciplined dispensing procedure", and "[f]ollows relevant policies, procedures and documentation requirements for the administration of medicines" (see Appendix A).
- ^{28.} In a similar case that involved a dispensing error,³ this Office stated:

"It is a fundamental patient safety and quality assurance step in the dispensing process to adequately check the medication being dispensed against the prescription for accuracy. This involves checking that the correct medicine, dose, form, strength, and quantity is being dispensed, and checking for any interactions."

29. At three stages, the pharmacy's SOPs require a check that the medication matches the prescription. More specifically, the drug, strength, and quantity of medication must be checked against the prescription at the following three stages: when selecting the medicine from the shelf, when placing the dispensing label on the container, and when the completed prescription is being checked. The third check requires the checker to compare "stock bottle

³ 20HDC00383, available on <u>www.hdc.org.nz</u>.



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against prescription, label against prescription and contents of dispensed medicine against prescription and label".

- 30. Mr A stated that when completing the checks for Ms B's medication, he concentrated on ensuring that the label was correct against the prescription, while missing that the dispensed medication was wrong. That is, he failed to check the contents of the dispensed medication adequately against the prescription and the label. Had he done so, he would have identified that he had mistakenly filled the script with ezetimibe instead of exemestane.
- ^{31.} In selecting the wrong medication and not checking the dispensed prescription adequately, and thus allowing an incorrect medicine to be dispensed, Mr A failed to adhere to the professional standards set by the Pharmacy Council of New Zealand. He also failed to adhere to the pharmacy's SOPs. Accordingly, I find that Mr A breached Right 4(2)⁴ of the Code of Health and Disability Services Consumers' Rights (the Code). Notwithstanding this finding, I commend Mr A for his swift action when he became aware of the error, his acceptance of full responsibility for the mistake, and the changes he made after becoming aware of the error (see below).

Opinion: Pharmacy — other comment

- 32. The pharmacy had a duty to ensure that it provided services to Ms B with reasonable care and skill. This included ensuring that its staff provided safe, accurate, and efficient dispensing services.
- As detailed above, I have found that Mr A breached Right 4(2) of the Code. I consider that the medication error was the result of an individual's actions, and does not indicate organisational issues at the pharmacy. Further, the pharmacy was entitled to rely on Mr A, as an experienced pharmacist, to dispense accurately and in accordance with its SOPs. Accordingly, I do not find the pharmacy in breach of the Code, either directly or vicariously.

SOPs

^{34.} The pharmacy's SOPs were due to be updated in October 2020, but the update did not occur until January 2021. Further, the pharmacy delayed reporting the error to the PDA, and so did not follow its SOP. I remind the pharmacy of the importance of maintaining and complying with up-to-date SOPs, to ensure that they reflect best practice and the contemporary environment.



Names have been removed to protect privacy. Identifying letters are assigned in alphabetical order and bear no relationship to the person's actual name.

⁴ Every consumer has the right to have services provided that comply with legal, professional, ethical, and other relevant standards.

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Changes made

- 35. The pharmacy has since made the following changes:
 - Increased staffing, including a weekend pharmacist and other part-time pharmacy technicians. Mr A told HDC: "With this extra staffing, I try to get the technicians to do as much dispensing as possible, so I am limiting the amount I am checking my own work."
 - Introduced a tray system to hold the script, dispensed medication, and labels. This makes the workflow more efficient and the checking easier.
 - Added labels that indicate that a new item has been dispensed. This enables staff to discuss the new medication with the patient, and provides an opportunity for the patient to ask questions.
 - Separated the two medications (ezetimibe and exemestane) on the shelf.
 - Selected the "label per pack" setting for both medications, so that each box will be labelled and checked individually.
 - Registered with Guild Link, an online SOP management system.
- ^{36.} Mr A has completed the Improving Accuracy and Self-Checking Workbook provided by the Pharmaceutical Society of New Zealand.

Recommendations

- ^{37.} I recommend that Mr A provide a formal written apology to Ms B for the breach of the Code identified in this report. The apology is to be sent to HDC, for forwarding to Ms B, within three weeks of the date of this report.
- ^{38.} I note with approval that Mr A has already completed the Improving Accuracy and Self-Checking Workbook provided by the Pharmaceutical Society of New Zealand. I recommend that he provide evidence of this, and outline any further changes or improvements he has made to his practice as a result of this training, within three months of the date of this report.
- ^{39.} I recommend that the pharmacy undertake a random audit of the dispensing and checking of medication of 20 prescriptions over a one-month period to assess the compliance with dispensing and checking SOPs. The pharmacy should report back to HDC regarding the result of the audit and any action plan to address the findings, within three months of the date of this report.
- 40. I recommend that the pharmacy arrange refresher training for its staff in relation to dispensing and checking medications and dispensing errors, and provide HDC with evidence of the training and any learning, within three months of the date of this report.

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Follow-up actions

- 41. A copy of this report with details identifying the parties removed will be sent to the Pharmacy Council of New Zealand, and it will be advised of Mr A's name.
- 42. A copy of this report with details identifying the parties removed will be sent to the Pharmaceutical Society of New Zealand (College Education and Training Branch), the Health Quality & Safety Commission, and the New Zealand Pharmacovigilance Centre, and placed on the Health and Disability Commissioner website, <u>www.hdc.org.nz</u>, for educational purposes.



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HX

Appendix A: Relevant standards

The Pharmacy Council of New Zealand's *Competence Standards for the Pharmacy Profession* (2015) provides that a pharmacist "[m]aintains a logical, safe and disciplined dispensing procedure", and "[f]ollows relevant policies, procedures and documentation requirements for the administration of medicines".



Appendix B: Standard Operating Procedures

The pharmacy's SOP for Dispensing in place at the time of events includes the following:

"<u>When selecting the medicine</u> from the shelf, <u>CHECK</u>

3.1 The drug, strength and quantity against the prescription for the first time

•••

4. When placing the dispensing label on the container CHECK

4.1 The drug, strength and quantity against the prescription for the **second** time."

"6. When completed prescription being checked

Where there is more than one dispensing staff on duty a second person (different to the dispensing person) should check the script.

Note: Either the dispensing person or the checking person must be a pharmacist. Each person, the dispenser and the checker must initial the prescription.

<u>CHECK</u>

6.1 The drug, strength and quantity against the prescription for the THIRD time (stock bottle against prescription, label against prescription and contents of dispensed medicine against prescription and label)."

