Pharmacist, Mr C

A Report by the

Deputy Health and Disability Commissioner

(Case 14HDC00439)

Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

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Executive summary

1. On 15 October 2013, Mr A presented at a pharmacy (the Pharmacy) to have a new prescription filled and to pick up a repeat of his regular medication. One of the medications for repeat was cyclosporine 50mg. Cyclosporine is an immunosuppressant used to prevent rejection following transplants. Mr A had previously had an organ transplant. Cyclosporine capsules are white, sealed with foil, and dispensed in a cardboard box.

2. The prescriptions were processed by pharmacy technician Mr E. Cyclophosphamide 50mg tablets were selected from the shelf instead of cyclosporine 50mg capsules. Cyclophosphamide is a chemotherapy drug used to treat certain types of cancer, and is dispensed as small pink tablets in a bottle.

3. Pharmacist Mr C checked the medications and initialled the dispensing record for each repeat medication dispensed.

4. On 4 December 2013, Mr A presented at the Pharmacy for a regular test. After the test, Mr A showed the cyclophosphamide tablets to Mr C. Mr A enquired as to why the tablets were different from his regular cyclosporine capsules. Mr C told Mr A that the tablets were a "discontinued product", and that he should stop taking them. Mr A left the cyclophosphamide tablets with Mr C.

5. Following the consultation, Mr C immediately looked up who had dispensed the cyclophosphamide tablets and noted that the prescription had been processed by Mr E and the dispensing record signed off by himself. Mr C also checked to see whether the cyclophosphamide and cyclosporine medications were in their correct places on the shelf, in case the error had been caused by them being in the wrong place. Mr C noted that there was no cyclophosphamide stock left, and so changed the Pharmacy's electronic stock records to show that cyclophosphamide was out of stock, and that there was an additional unit of cyclosporine available. Mr C did not complete an incident form or notify the Pharmacy owner, Mr D, of the error. Mr D was away from the Pharmacy at the time Mr C became aware of the error, but returned approximately 20 minutes later.

6. Later that same day, Mr D processed an order for medications, and noted that there was no remaining stock of cyclophosphamide tablets. Mr D questioned his staff about this, but Mr C did not disclose the error. Mr C told Mr D that he had noticed there was no stock remaining and so had changed the records.

7. On 6 December 2013, Mr A returned to the Pharmacy and asked to speak to Mr D in private. Mr A showed Mr D the remaining cyclophosphamide tablets in his possession, and outlined Mr C's explanation for the tablets. Mr D told Mr A that he would look into the matter further.

8. Following Mr D's conversation with Mr A, the dispensing error was discovered, and the Pharmacy contacted Mr A and Mr A's GP to alert them to the incident. The Pharmacy also undertook an internal investigation.

Decision

9. By making a serious dispensing error, Mr C did not comply with professional standards and was in breach of Right 4(2)[1] of the Code of Health and Disability Services Consumers' Rights (the Code). Mr C also breached Right 6(1)[2] of the Code by failing to disclose the dispensing error to Mr A as soon as he became aware of it. Mr C's failure to report the error was in breach of the Pharmacy's policy, and professional standards, and a breach of Right 4(2) of the Code. For failing to take appropriate actions to mitigate the risk of serious harm to Mr A, Mr C breached Right 4(4)[3] of the Code.

10. Adverse comment is made about Mr E's error in selecting cyclophosphamide 50mg tablets instead of cyclosporine 50mg capsules.

Complaint and investigation

11. The Commissioner received a complaint from Mr B about the services provided to his father, Mr A, by pharmacist Mr C. Mr A supports his son's complaint. The following issue was identified for investigation:

Whether pharmacist Mr C provided an appropriate standard of care to Mr A.

12. An investigation was commenced on 23 July 2014. This report is the opinion of Theo Baker, Deputy Commissioner, and is made in accordance with the power delegated to her by the Commissioner.

13. The parties directly involved in the investigation were:

Mr A	Consumer
Mr B	Complainant
Mr C	Pharmacist/provider
The Pharmacy	Provider
Mr D	Pharmacist owner

Also mentioned in this report:

Mr E	Pharmacy technician

[1] Right 4(2) of the Code states: "Every consumer has the right to have services provided that comply with legal, professional, ethical, and other relevant standards."
[2] Right 6(1) of the Code states: "Every consumer has the right to the information that a reasonable consumer, in that consumer's circumstances, would expect to receive."
[3] Right 4(4) of the Code states: "Every consumer has the right to have services provided in a manner that minimises the potential harm to, and optimises the quality of life of, that consumer."

Information gathered during investigation

Summary

14. On 15 October 2013, Mr A was dispensed the wrong medication — cyclophosphamide (a chemotherapy drug) instead of cyclosporine (an immunosuppressant used to prevent transplant rejection). Mr A took approximately three weeks of the cyclophosphamide instead of his usual cyclosporine. While it does not appear that he suffered any long-term adverse effects from taking the incorrect medication or from going without his immunosuppressant, this was an error with the potential to cause harm, particularly because of Mr A's complex medical history.

15. This report investigates the initial dispensing error, as well as the way it was subsequently managed by the responsible pharmacist, Mr C.

Background

16. Mr A (aged 79 years at the time of events) had had an organ transplant and was on a number of medications, including cyclosporine 50mg. Cyclosporine is an immunosuppressant medication used for prevention of rejection following transplants.

Mr C

17. Mr C holds a Diploma in Pharmacy and is registered as a pharmacist in New Zealand. Mr C was employed as a dispensary manager at the Pharmacy,[4] and had held this position for more than five years at the time of the events in question.

15 October 2013 — Dispensing error

18. On 15 October 2013 at approximately 9.20am, Mr A presented at the Pharmacy with a new prescription for flucloxacillin (an antibiotic). At the same time, he requested repeats of his regular medications.

19. For repeat medications the Pharmacy holds the original prescription. When the prescription is first presented to the Pharmacy it is checked for accuracy and the information is entered into the computer to allow the generation of a label. When the consumer presents for the repeat medications, a three-part label is generated. One part of the label goes onto the medication, and one part goes into a hard copy dispensing record and is initialled by the dispenser and the checking pharmacist. The final part of the label is used as a bag label identifying the patient's name, address and the cost of the medication.

20. On 15 October 2013, a total of 12 medications were to be dispensed for Mr A. Included in the repeats was a three-month prescription for cyclosporine.

21. At 9.26am, Mr A's flucloxacillin and repeat medications were processed through the Pharmacy software system, Toniq, by pharmacy technician Mr E. Mr E then selected the medication.

[4] The Pharmacy is owned by Mr D, the sole director.

22. During the dispensing process, cyclophosphamide 50mg tablets were selected instead of the prescribed cyclosporine 50mg capsules. Cyclophosphamide is a chemotherapy drug used to treat certain types of cancer.

23. Cyclophosphamide tablets are small pink tablets dispensed in a bottle. Cyclosporine capsules are white, sealed in foil and dispensed in a cardboard box.

24. In accordance with the Pharmacy's Standard Operating Procedure (SOP) in place at the time, "Dispensing a prescription (30 July 2012)", all prescriptions processed by a pharmacy technician or intern must be checked by a pharmacist before being given to the patient. The Pharmacy advised that the pharmacist accuracy check on repeat medicines needs to ensure that the correct medicine and strength match the printed label details.

25. Mr C told HDC that he checked each of the medications that were dispensed. The medications were then placed in a bag and given to Mr A. Mr A was given a one-month supply of cyclophosphamide 50mg (two tablets per day for a total of 60 tablets dispensed) instead of a one-month supply of cyclosporine.

26. In response to the provisional opinion, Mr C additionally advised:

> "I read every label and checked the contents of each of the bottles that [Mr A's] medication had been repacked into from the dispensary bulk stock into [the Pharmacy's] bottles. But I did not check the contents of the bottle labelled cyclosporine as it was an original manufacturer's bottle with the pharmacy's printed label placed over the label of that original container and content."

27. Mr A manages his own medications and sorts them himself into a weekly organiser. He maintains a buffer of approximately one month of his regular medications and, as such, did not start taking the dispensed cyclophosphamide tablets until approximately 12 November 2013.

28. During November, Mr A again presented to the Pharmacy and obtained repeats of his regular medication, including cyclosporine.

4 December 2013 — Identification of error

29. On 4 December 2013, Mr A presented to the Pharmacy for a regular INR[5] test carried out as part of the Community Pharmacy Anti-Coagulation Management Service.[6]

30. Mr C conducted the test at 10.16am. Mr C said that during the test he talked to Mr A about Mr A's general health and well-being, and that Mr A had told him that everything was "normal". Mr C told HDC that, after the test was completed, Mr A showed him the bottle of tablets dispensed on 15 October 2013 and labelled "cyclosporine 50mg". Mr A told Mr C that he had noticed that the medication in this

[5] The international normalisation ratio (INR) is a measure of how long it takes for blood to clot.
[6] A service provided by pharmacies where a community pharmacist performs INR tests and adjusts a patient's anticoagulant dose.

bottle was a pink tablet, but that his subsequent repeat prescription of cyclosporine (dispensed in November) had gone back to the usual capsule.

31. Mr C said that when Mr A showed him the bottle of tablets he noted that the label showed the correct medication (cyclosporine 50mg).

32. Mr C advised HDC that when he looked in the bottle he noted that there were some tablets left. Mr C questioned Mr A as to why there were still so many tablets left given that they had been dispensed some time ago, on 15 October 2013. Mr A told him that he had a surplus supply, and that he had only just noticed the change in the medication shape and colour when he received his next month's supply of cyclosporine, which was again white capsules.

33. Mr C stated that he realised immediately that a dispensing error had occurred, but did not want to alarm Mr A. Mr C stated:

> "I explained [to Mr A] that he had been given a discontinued product and that he should immediately start back on his cyclosporine capsules which he had new stocks of from his November repeat dispensing at home and to discontinue these [cyclophosphamide] tablets."

34. Mr C said that Mr A then gave him the cyclophosphamide tablets and left the Pharmacy. Mr C said that it was his "sincere intention" to disclose the error and to follow it up, "when I had the opportunity to gather clearly all the information".

Mr C's actions following identification of dispensing error

35. Mr C said that after Mr A left the Pharmacy he immediately looked up who had dispensed the cyclophosphamide and noted that Mr E dispensed the medication and the dispensing record was signed off by himself. Mr C said that he "highlighted" the error by circling it in the pharmacy log. The pharmacy log from 15 October 2013 shows that the label for cyclosporine was circled.

36. Mr C told HDC that he also checked to see whether the error had occurred because the medications were incorrectly placed on the shelf. Mr C told HDC that at that time he noted that there was no cyclophosphamide on the shelf, and so "took steps to ensure it was replaced". Mr C said that he went into Toniq and noted that the stocks were showing that the Pharmacy had one unit of cyclophosphamide in stock. Mr C changed this to zero to trigger the stock ordering process on Toniq. At the same time, Mr C also changed the cyclosporine stocks from zero to one unit. Toniq shows that these changes were made at 10.24am. In response to the provisional opinion, Mr C stated that "it is a common practice when performing daily stock checks to correct the stock card quantity on the computer", and that his doing so was not a "sinister act".

37. Mr C said that he then placed the returned medications in the yellow "returned medicines bag", as is standard procedure at the Pharmacy for the management of all returned medicines.

38. Mr C said that he did not complete an incident form or notify anyone of the error at that time, because he was busy. Mr C stated:

> "Instead of completing an Incident Report Form at this time, I was distracted due to dispensing staff requesting that I continue checking the current completed prescriptions to be given out to waiting customers, as I was the only qualified pharmacist in store. I did not inform the owner at this time because he was away from the pharmacy."

39. Mr C stated in a summary of the incident recorded on 7 December 2013 that by the time Mr D arrived back at the pharmacy, "the dispensing error was at the back of my mind". Mr D advised that he arrived at the Pharmacy approximately 20 minutes after Mr A left the Pharmacy.

Stock re-order

40. On 4 December 2013, between 2pm and 2.30pm, Mr D generated an electronic stock re-order using the Toniq system. Cyclophosphamide was included on the stock re-order list, as the electronic records showed that there was no stock remaining.

41. Mr D advised HDC that because cyclophosphamide is an "unapproved" medicine under section 29 of the Medicines Act 1981 (the Act)[7] he needed to identify the name of the patient and doctor who prescribed the medicine as part of the Pharmacy's obligations under the Act. Accordingly, he said that he asked the dispensary team if this medicine had been dispensed, so that he could supply the relevant details if more stock was required. Mr D said that at that time Mr C told him that he had noted that there was no cyclophosphamide stock on the shelf, and so had zeroed the stock levels on Toniq. Mr C did not mention the error. Mr C said that he chose not to disclose the error to Mr D when he was asked about the stock levels, because he considered Mr D was "not very good with his staff" and he, himself, is not very good at conflict.

42. In response to Mr C's comment above, Mr D provided evidence to HDC from dispensary staff past and present about his relationships with the staff members of the dispensary. The evidence indicated that staff members found Mr D to be a good manager and good with dispensary errors that arose. Independently, Mr E also provided comments about his relationship with Mr D. These comments supported evidence provided by Mr D that his relationship with dispensary staff was good.

6 December 2013 — Mr A notifies Mr D

43. On 6 December 2013, Mr A returned to the Pharmacy and asked to speak to Mr D in private. Mr D said that Mr A showed him a small bag of six pink tablets and asked him if he knew what they were. Mr D told Mr A that he could not be sure just by looking at them. Mr D said that Mr A told him that he had previously asked Mr C about these tablets, and that Mr C had told him that they were the "generic version" of Mr A's normal cyclosporine tablets, and that Mr C had told him to stop taking them and to start taking the normal cyclosporine tablets he already had.

[7] Section 29 of the Act permits the sale or supply to medical practitioners of medicines that have not been approved, and requires the "person" who sells or supplies the medicine to notify the Director-General of Health of that sale or supply in writing, naming the medical practitioner and the patient, describing the medicine and the date and place of sale or supply, and stating the number of packs supplied.

44. Mr D said that he told Mr A that there was no generic form of cyclosporine, and that he would look into the matter further.

Pharmacy's actions following identification of dispensing error

45. Mr D advised HDC that, after his conversation with Mr A, he showed Mr C the pink tablets that Mr A had brought in and asked Mr C what they were. Mr D said that Mr C disclosed that an error had occurred, and that Mr A had inadvertently been given cyclophosphamide rather than cyclosporine. Mr C told Mr D that he had meant to tell him (Mr D) about the error. Mr D said that he asked Mr C how many tablets Mr A had taken, but that Mr C did not know.

46. Mr D said that they then located the returned cyclophosphamide bottle in the returned medicines bag and calculated that Mr A may have taken up to 45 (22 and a half days' supply) of the cyclophosphamide tablets.

47. Mr C said that at that stage he offered to contact Mr A's GP, but at this point it was determined that Mr D would manage the situation.

48. Mr D then contacted Mr A's GP to advise him of the error. Mr A's GP said that he would contact Mr A's renal physician and arrange for blood tests.

49. Mr D said that he then contacted Mr A by telephone and informed him of the incident, and explained what cyclophosphamide is and its side effects. Mr D told Mr A that he had spoken to his GP, and that either the GP surgery or the hospital would contact him shortly to arrange some tests.

50. Mr D apologised to Mr A for the error and the way it was handled.

51. Mr D said that Mr A contacted him later that afternoon and informed him that his tests were normal.

52. Mr D requested that Mr C and Mr E complete incident reports about the medication error. On 6 December 2013, Mr E completed an incident form on which he recorded that he "had no prior knowledge of the incident and do not recall it in great detail". Mr E then completed an additional incident form on 9 December 2013. On the 9 December 2013 form, Mr E stated:

> "I do not have a very clear memory of the incident but what could be a possible explanation is, I checked the [incident] reports once they got made up by [Mr C], cyclophosphamide 50mg tabs [tablets] were dispensed in place [of] cyclosporine 50mg capsules. Since both medicines have a 'cyclo' component in the name and both the strengths were '50mg' I possibly overlooked the names. I was rushed to give them out as [Mr A] was waiting. Again this is a possible explanation of the incident as I do not remember the incident very distinctively."

53. According to Mr C, on 6 December 2013 he completed a handwritten incident form. On 7 December, Mr C completed the electronic incident form, including a full summary of his recollections of the events. Mr C also wrote a letter of apology to Mr A, in which he apologised for the error and the way he handled it. Mr C advised HDC:

"My letter to [Mr A] convey[ed] my sincere apology and remorse for the error coupled with my understanding not to make my own judgement calls and the need to strictly follow reporting protocol …"

54. Additionally, on 7 December 2013 an incident report was completed by Mr D and emailed to the Pharmacy Defense Association. In regard to his discussion with Mr C, Mr D recorded the following:

> "I approached [Mr C] with the pink tablets and explained that [Mr A] had given these to me & asked [Mr C] what they were.
>
> [Mr C's] response was to say 'oh yes, I meant to tell you … we inadvertently gave [Mr A] cyclophosphamide instead of cyclosporine'.
>
> I said '[…] [Mr C] how many has he had' [Mr C] said he didn't know.
>
> …
>
> I asked [Mr E] & [Mr C] to complete an incident form. I told the staff that as nerves were high I would have a meeting next week to discuss the incident."

55. On 9 December 2013 Mr C tendered his resignation from his position at the Pharmacy. On 27 January 2014, Mr D notified the Pharmacy Council of New Zealand of the events. The Council considered the matter and concluded that there were no concerns identified in relation to Mr C's competence. The Council considered that the error was a one-off dispensing error, but that the way Mr C handled the error was "well below the accepted standard".

Standard Operating Procedures (SOPs)

56. At the time of events, the Pharmacy's SOP, "Dispensing a prescription (30 July 2012)" stated in regard to checking repeat prescriptions:

> "Any prescription with repeats available has had the computer entry details re-checked against the Toniq log for accuracy as part of the sorting & filing process (*SOP 15 — sorting & filing scripts).*
>
> With repeats a number of clinical & accuracy checks have been undertaken on the original prescription. If a pharmacist has concerns or queries on a repeat dispensing, they should refer to the original prescription.
>
> The pharmacist accuracy check on repeat medicines needs to ensure that the correct medicine & strength match the label details."

57. At the time of events, the Pharmacy's SOP, "Procedure for Dispensing Incidents — handling the error (January 2012, reviewed in June 2013)", set out the steps to be taken when a dispensing error is identified, as follows:

> "When informed of a potential dispensing error ensure the pharmacist in charge handles the complaint.
>
> …

> If pharmacy staff suspected/detected an error once a patient has left the pharmacy, prioritise identifying, eliminating or correcting the error without causing undue concern.
>
> Staff should be debriefed to know what happened, so that repeat errors of the same type are minimised and so staff are aware of how future errors should be handled.
> …
>
> Details of conversations and actions taken about any dispensing incidents should be recorded on the incident form or in the Toniq notes field for future reference especially if a HDC complaint arises."

58. Furthermore, at the time of the events in question, the Pharmacy's SOP "Procedure for Dispensing Incidents (January 2012)" outlined the following procedures for serious incidents:

> "A serious incident is one whereby a dispensing error that occurs (or a near miss which if not spotted) would have the potential to cause serious harm. Examples include incorrect medication dispensed, incorrect instructions provided or medication handed to the wrong patient. These incidents should be recorded on the Incident Reporting form (F8.10a) located in the 'incident folder' consulting room filing cabinet.
>
> Reporting of serious incidents (including near misses) should record
>
> - Date & time
> - What happened
> - Who was responsible or involved
> - Analysis of cause of error
> - What corrective action has been taken
> - Any preventative action/s put in place to minimize risk of repeat incidents.
>
> The pharmacist manager should be notified of all serious incidents."

59. Mr D subsequently reviewed the Pharmacy's SOPs and policies, with particular focus on the SOPs "Procedure for Dispensing Incidents — handling the error (January 2012, reviewed in June 2013)" and "Procedure for Dispensing Incidents (January 2012)". As a result, minor changes were made and the two SOPs were merged into one document.

Further comment by Mr C

60. Mr C advised HDC:

> "My responsibilities on 15th October 2013 were no different than on any other day. However, circumstances were more pressured than usual with the resignation and subsequent leaving shortly before of … the other pharmacist who worked 2.5 days a week alongside me and had not been replaced. … This left me as sole pharmacist in the dispensary under resourced. To cap it off, on October 15th, … the pharmacist intern was away on a training course. I myself had just completed two weeks back to back shifts working six days a week covering, as [Mr D] went [on

holiday]. I was taking medico packs home in the evening to check them in order to keep up with the workload …"

61. Mr C told HDC that he considers that the Pharmacy's SOPs for managing dispensing errors were "perfectly adequate". He said that he was first made aware of the Pharmacy's SOPs at the time of his employment, and that he is aware that he did not follow correct procedure in this case.

62. In his account of the incident, set out in his incident report dated 7 December 2013, Mr C acknowledged that he, as the responsible pharmacist, missed the error during his final check. By way of explanation, Mr C stated:

"To add to the hectic workload I am expected to work away from the dispensary focusing on the important task of performing INR tests which average 3 per day which is an interruption to the flow of the dispensary and checking. Immediately prior to the dispensing error, I had worked two weeks back to back six days a week while [Mr D] was on leave. It was a very busy two weeks including me having to take medico packs home in the evening to check in order to complete the workload on time."

63. Furthermore, in a statement to HDC, Mr C said:

"[T]he failure on my part to note the dispensing error is deeply regrettable. This was truly out of character for me as I am always fastidious with my dispensing and checking procedures. My explanation to [Mr A] was not meant in any way to be a deception. I always maintain a high level of professionalism and always show great care and concern to all my customers. I certainly had every intention to report as soon as possible the error. However circumstances dictated that I was under resourced and was doing the work of two pharmacists under a difficult employer–employee relationship. I should have handled the incident so much better as per the SOPs and have certainly learnt from this experience.

…

Nothing by way of my actions would indicate any intent on my part not to report the incident or bring it to [Mr D's] notice. … I should have come straight out and told [Mr A] that a dispensing error had been made. But my immediate reaction was to ensure [Mr A] was not alarmed or upset."

64. Mr C advised HDC that he was aware of the different uses of the two medications (cyclophosphamide and cyclosporine) and their side effects, and that he was confident that Mr A was not suffering any side effects. Mr C stated:

"Knowing cyclophosphamide is used in cancers and autoimmune conditions and that his cyclosporine is used as an immunosuppressant, both have similar common side effect[s] of occasional G.I. upset and/or diarrhoea. When taking [Mr A's] INR reading only moments before, standard questions are asked relating to any recent hospital admissions and unusual bleeding or bruising. [Mr A] stated that 'All was normal'. It was at this point, I believed from chatting with [Mr A] and observing his demeanour that he was not to be in any imminent poor health. I had, in good

> faith assessed [Mr A's] condition to the best of my professional ability when performing his INR test."

65. Mr C told HDC that since this incident he is now much more cautious with all his dispensary checking, including checking the labelling as well as the medication itself.

Response to provisional opinion

66. Mr A, Mr C, Mr E and the Pharmacy were given an opportunity to provide comment on the relevant portions of the provisional opinion.

Mr A

67. Mr A did not provide additional comment on the "information gathered" section of the provisional opinion.

Mr C

68. In response to the provisional opinion, Mr C advised: "My total remorse and sincere apology for not following protocol in a timely manner showed a serious lack of judgement on my part and was totally out of character."

69. Mr C told HDC that during the INR consultation on 4 December 2013 he made best endeavours to ensure that Mr A did not continue taking cyclophosphamide. Mr C advised HDC that he was "clearly able to establish that [Mr A] was now able to take his correct immunosuppressant medication which he had stocks of at home and he was now ceasing taking the wrongly dispensed medication". Mr C submitted: "By directing [Mr A] back on his correct immunosuppressant medication I was minimising a potential risk of harm."

70. In addition, Mr C provided HDC with details of his assessment of Mr A on 4 December 2013, reiterating:

> "I believed [Mr A] was feeling fine and that I would follow up with his GP and report the incident. There is nothing to suggest that I would not. I admit my professional judgement was clouded in not reporting immediately the error. In my mind I wanted to handle the reporting and follow up process clearly giving myself time to gather all the facts to present to [Mr D] without a conflict situation occurring. However with the day's workload and being the only pharmacist on duty checking a) the technician's work b) the intern's work c) Medico trays made up by another technician, this resulted in me not following SOPs in an appropriate timely manner."

Mr E

71. Mr E accepted the findings and provided brief comments in response to the provisional opinion, which have been considered in the finalising of this opinion.

The Pharmacy

72. Mr D (for the Pharmacy) provided comment on the provisional opinion, and his comments have been considered and incorporated where relevant into the opinion.

73. Mr D further advised HDC:

"• [Mr C] was **not** the sole pharmacist on 15th October 2013, I was present in the dispensary from opening at 8.30am [emphasis in original].

- [Mr C] was **not** the sole pharmacist while I was on leave. [Another pharmacist] was also working full time over this period [emphasis in original].
- [Mr C] says that another pharmacist '… worked 2.5 days alongside me and had not been replaced …' Although [the other pharmacist] assisted with dispensary duties a large part of her role involved clinical/administrative activities around Medicine Use Reviews, warfarin testing, etc.
- [Mr C] states 'I myself had just completed two weeks back to back … covering … as [Mr D] went on holiday'. My holiday was 23 September 2013 to 5 October 2013 and I had been back full time at work from 7 October 2013. The dispensing error occurred on the 15 October 2013.
- Dispensary prescriptions volumes appear to have been quieter the week prior to 15 October 2013. Certainly no overtime hours were paid to [Mr C] the week commencing 14 October 2013, suggesting things were up to date.
- [He is] concerned that [Mr C] states that he was taking blister packs home to check. This activity is not legal as it is still part of the dispensing process and all dispensing must be carried out at a registered pharmacy. This was done without my knowledge or approval and I would not have permitted this to occur. [Mr C] would not have the stock containers to check against if he had an issue and would have had to also take home scripts and drug charts to check the pack against. Sometimes we do have to stay at the pharmacy after hours or come in early before the pharmacy is open to complete this checking process, but the packs must never be taken home to check."

74. Furthermore, Mr D told HDC that, in regard to Mr C's comments about INR testing:

> "On the day in question (15 October 2013) only 1 INR test was undertaken and it was performed by me at 2.54pm. This was a fairly new service and averaged 10 tests per **week**. There were TWO pharmacists on duty with any tests performed in a gap in dispensing. INR testing did **not** contribute to 'interruption in dispensary flow' on the morning of 15 October 2013 [emphasis in original]."

75. In regard to staffing levels on 15 October 2013, Mr D advised HDC that while an intern was away, a third technician provided five hours of cover. Mr D stated:

> "On 15 October 2013 there were two pharmacists and three technicians on duty. During the one hour period when this error occurred there were 28 prescriptions dispensed for patients in the pharmacy, 12 of these being [Mr A's]. (If rest-home prescriptions are included 49 scripts were processed in total.)"

Relevant standards

76. The Pharmacy Council of New Zealand *Code of Ethics (2011)* provides that the 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."

77. The Pharmacy Council of New Zealand *Competence Standards for the Pharmacy Profession (2011)* provides:[8]

> "Element 4.2 Work effectively within the workplace organisation
>
> 4.2.1 Works with the documented procedures and systems
>
> …
>
> Element 6.6 Fill prescriptions
>
> …
>
> 6.2.2 Follows workplace dispensing criteria when dispensing a prescription item
>
> …
>
> 6.6.2 Maintains a logical, safe and disciplined dispensing procedure.
>
> *Examples of Evidence:*
> Selects correct product, dose form & quantity for each prescribed medicine …
>
> …
>
> 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."

Opinion: Mr C — Breach

Dispensing error

78. At the time of the incident, the Pharmacy's SOP "Dispensing a prescription (30 July 2012)" required that any prescription dispensed by a pharmacy technician be checked

[8] The Competence Standards were updated in January 2015. This opinion refers to the 2011 standards, which were in place in 2013.

by a pharmacist before being issued to the patient. With regard to the checking of repeat prescriptions, the SOP outlined that the pharmacist must check repeat medicines accurately to ensure that the correct medicine and strength match the label details.

79. Accordingly, while the pharmacy technician, Mr E, processed the repeat, Mr C was the pharmacist responsible for checking the correct medication was dispensed.

80. The Pharmacy Council of New Zealand *Safe Effective Pharmacy Practice (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 your sphere of activity and scope of practice". Furthermore, when filling prescriptions, a pharmacist must maintain "a logical, safe and disciplined dispensing procedure".

81. There is no dispute that Mr E selected the incorrect medication, and that Mr C did not identify that the medication being dispensed did not match the label when dispensing Mr A's medications on 15 October 2013. As I have noted previously, "Checking that the patient is being dispensed the correct medication is a fundamental aspect of pharmacy practice …"[9] Dispensing the wrong medication can have significant health implications for the patient.

82. It is clear that Mr C did not check the medication being dispensed to Mr A adequately on 15 October 2013 in accordance with the professional standards set by the Pharmacy Council of New Zealand, or in accordance with the Pharmacy's policies and procedures. Accordingly, I conclude that Mr C breached Right 4(2) of the Code.

Disclosure of error

Failure to inform Mr A

83. Mr C first became aware of the dispensing error on 4 December 2013 when Mr A questioned the appearance of the tablets he had been dispensed on 15 October.

84. When Mr C realised that an error had occurred, he did not advise Mr A, instead telling him that he had been given a "discontinued product". Mr C said that he told Mr A this because he did not want to alarm him. Mr C stated that having questioned Mr A he was confident that Mr A was not suffering any side effects, and advised him to start taking the normal cyclosporine capsules he had at home.

85. Right 6(1) of the Code gives all consumers the right to receive the information that a reasonable consumer in his or her circumstances would expect to receive. As noted in HDC's *Guidance on Open Disclosure Policies*,[10] consumers have the right to know what has happened to them when an error has occurred. In my view, Mr C's failure to disclose the error to Mr A demonstrated a serious lapse in judgement. Accordingly, for failing to disclose the error to Mr A as soon as he was aware that it had occurred, Mr C breached Right 6(1) of the Code.

[9] See Opinion 13HDC01618.
[10] Available at http://www.hdc.org.nz/decisions--case-notes/open-disclosure.

Failure to report the incident

86. Mr C advised HDC that he intended to disclose the error and to follow it up. However, in addition to failing to disclose the error to Mr A, Mr C also did not complete an incident report or notify any other Pharmacy staff of the error.

87. Mr C told HDC that, after Mr A left the Pharmacy, he checked Toniq to see who had been involved in dispensing the medication. Mr C identified that Mr E dispensed the medication, and that he (Mr C) had been the pharmacist responsible for checking the dispensing.

88. Mr C then checked whether the error had occurred because cyclophosphamide had been incorrectly placed on the shelf. Mr C noted that there was no cyclophosphamide on the shelf, and so "took steps to ensure it was replaced". At 10.24am Mr C changed the electronic stock records of cyclophosphamide to zero. At the same time, Mr C also changed the cyclosporine stocks from zero to one unit.

89. Mr C said that he then placed the returned medications in the yellow "returned medicines bag", as is standard procedure at the Pharmacy for the management of all returned medicines.

90. Mr C stated that it was always his intention to inform Mr D of the error, but that he then became distracted, and "the dispensing error went to the back of my mind".

91. Mr D advised that he arrived back at the Pharmacy at around 10.40am, approximately 20 minutes after Mr C would have become aware of the error.

92. Between 2pm and 2.30pm, Mr D created a medication re-order list on Toniq. He noted that cyclophosphamide was on the list and questioned staff about whether this had been dispensed. Mr C told him that he had zeroed the stock levels as he had noticed there was no stock remaining, but did not disclose that an error had been made that involved incorrect dispensing of cyclophosphamide.

93. Mr C told HDC that he chose not to disclose the error to Mr D as he wanted to avoid any conflict.

94. It was not until 6 December 2013, after Mr D questioned Mr C directly about Mr A's concerns, that Mr C disclosed the error.

95. At the time of these events, the Pharmacy's SOP "Procedure for Dispensing Incidents (January 2012)" required that, following the identification of a serious error, the pharmacist involved complete an Incident Reporting Form. In addition, the Pharmacy's SOP "Procedure for Dispensing Incidents — handling the error (January 2012)" outlined that other Pharmacy staff should be debriefed about the incident so that repeat errors of the same type are minimised and staff are aware of how future errors should be handled.

96. Mr C had a duty to comply with the SOPs in place at the Pharmacy. Mr C told HDC that he considered that the Pharmacy's SOPs for reporting dispensing errors were

"perfectly adequate", and confirmed that he was aware of them at the time of the incident.

97. I have significant concerns about the way that Mr C managed this error and, again, consider Mr C's actions demonstrate a serious lapse of judgement. I do not accept that Mr C simply became busy and that the error "went to the back of [his] mind". There were a number of opportunities where Mr C could have advised someone of the error or documented it on an incident form: immediately after he identified the error, when Mr D returned to the Pharmacy approximately 20 minutes later, when Mr D questioned the cyclophosphamide stock levels at approximately 2.30pm, or when he had had time to reflect on the incident over the next few days. Mr C eventually completed an incident report on 7 December 2013 — after Mr A informed Mr D of his concerns, and Mr D discovered what had occurred.

98. Mr C told HDC that he never intended not to report the incident or not to bring it to Mr D's attention. I do not accept Mr C's reluctance to enter into any conflict with Mr D as a valid excuse for not reporting the serious medication error. According to the Pharmacy Council of New Zealand *Competence Standards for the Pharmacy Profession (2011)*, Mr C had a professional duty to minimise the effects of his dispensing error, and to work within documented procedures and systems, and he failed in both respects. The Pharmacy's SOPs clearly outline requirements for reporting incidents and debriefing others in the Pharmacy to ensure that the incident is handled appropriately, and that similar errors do not occur in the future.

99. I find that Mr C withheld information on the error from Mr D and other staff in the dispensary, including Mr E, who was involved in the error. By failing to report the incident at the time he identified the error on 4 December 2013, Mr C failed to comply with the Pharmacy SOPs and professional standards and, as such, Mr C breached Right 4(2) of the Code.

Risk of harm

100. The dispensing error in this case placed Mr A at significant risk of harm, not only because of the risk of medication toxicity from the cyclophosphamide, but also because of the risk of not taking his prescribed immunosuppressant medication. Mr C's actions after he became aware of the dispensing error failed to mitigate this risk. I do not consider that it was appropriate for Mr C to conclude that Mr A was not suffering any side effects from the medications on the basis of his interactions with him during his INR test. Mr C needed to notify all relevant parties, including Mr A's GP, in order for any relevant tests and monitoring to be carried out. By failing to do so, Mr C failed to minimise the potential harm to Mr A, and breached Right 4(4) of the Code.

Opinion: Mr E — Adverse comment

101. On 15 October 2013, Mr E processed Mr A's request for his repeat prescriptions through the Pharmacy's software system. These included a repeat prescription for

cyclosporine 50mg capsules. Mr E then selected the medication to be dispensed. According to an incident report completed by Mr E on 6 December 2013, he had very little recollection of the error.

102. Instead of selecting cyclosporine 50mg capsules, Mr E selected cyclophosphamide 50mg tablets. Cyclophosphamide tablets are small pink tablets dispensed in a bottle. Cyclosporine capsules are white, sealed in foil and dispensed in a box. This mistake was the first step in this serious dispensing error, and I consider that Mr E should have been more cautious in medication selection. I do, however, note that, as recognised by the Pharmacy's SOPs and the relevant professional standards, it is the pharmacist in charge of the dispensing (in this case, Mr C) who is ultimately responsible for the safe dispensing of medication. Mr C checked the medication after it was dispensed, and signed that the medication was selected correctly, which was an error.

Recommendation

103. I recommend that Mr C provide a written apology to Mr A, apologising for his breaches of the Code. The apology should be provided to this Office for forwarding to Mr A within three weeks of the date of this report.

Follow-up actions

104.
- Mr C will be referred to the Director of Proceedings in accordance with section 45(2)(f) of the Health and Disability Commissioner Act 1994 for the purpose of deciding whether any proceedings should be taken.
- A copy of this report with details identifying the parties removed will be sent to the Pharmacy Council of New Zealand and the relevant district health board, and they will be advised of Mr C's name.
- 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 Ministry of Health, and placed on the Health and Disability Commissioner website, www.hdc.org.nz, for educational purposes.

Addendum

105. The Director of Proceedings filed a charge before the Health Practitioners Disciplinary Tribunal. Professional Misconduct was made out and Mr C was fined and had two conditions placed on his practice.