Pharmacy

Pharmacist, Mr B

A Report by the

Deputy Health and Disability Commissioner

(Case 16HDC01764)

Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

Table of contents

Executive summary

1. On 8 August 2016 Mr A was prescribed 67 tablets of Sinemet 100mg (25/100) to be taken once daily for one week, and then one tablet to be taken twice daily for one month. This was the first time Mr A had been prescribed Sinemet.

2. On the same day, Mr A took the prescription to a pharmacy to have the Sinemet dispensed.

3. Mr B, employed as a pharmacist and OTC Manager (Over the Counter Manager), processed Mr A's prescription incorrectly in the pharmacy's Toniq dispensary computer system, and generated a label for Sinemet 200mg. He did not check the medication against the prescription. He then dispensed 200mg Sinemet to Mr A instead of the 100mg prescribed.

Findings

4. Mr B created an incorrect label, selected the medication from the pharmacy shelf in accordance with the incorrect label, and did not check the selected medication against the prescription. He also failed to perform a self check of the medication against the prescription before giving it to Mr A. Mr B also failed to think critically about the significance of Sinemet being a new medication for Mr A. Accordingly, Mr B failed to act in accordance with professional standards and breached Right 4(2) of the Code of Health and Disability Services Consumers' Rights (the Code).

5. The pharmacy took all such steps as were reasonably practicable to prevent the acts and omissions that led to Mr B's breach of the Code. Accordingly, the pharmacy is not vicariously liable for Mr B's breach of the Code.

Recommendations

6. In response to my recommendations in the provisional opinion, Mr B informed HDC that he has familiarised himself with the pharmacy's standard operating procedures (SOPs), and has contacted the New Zealand College of Pharmacists at the Pharmaceutical Society of New Zealand for the purpose of enrolling in the "Practical Dispensing Assessment" course. He has also provided a letter of apology for Mr A.

7. In the provisional opinion I recommended that the pharmacy conduct a review of its dispensary processes, in particular the arrangement of medications on dispensary shelves, to consider whether improvements could be made in labelling and placement to reduce errors in dispensing. The pharmacy has informed HDC that it has now reviewed its dispensary shelves as recommended.

8. Also in response to my recommendations in the provisional opinion, the pharmacy stated that staff members are now inducted with its SOPs as part of the induction process for new staff members.

9. I recommend that the pharmacy randomly audit, over a period of one month, its staff compliance with its SOPs for dispensing and checking medications, handling customer complaints, and dispensing errors, and provide HDC with the outcome of that audit within three months of the date of this report.

Complaint and investigation

10. The Commissioner received a complaint from Mr A about the services provided by the pharmacy. The following issues were identified for investigation:

- *Whether the pharmacy provided an appropriate standard of care to Mr A between 8 August and 29 August 2016.*
- *Whether Mr B provided an appropriate standard of care to Mr A between 8 August and 29 August 2016.*

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

12. The parties directly involved in the investigation were:

Mr A	Consumer/complainant
Pharmacy	Provider
Mr B	Provider

13. Information from Dr C, a specialist physician and geriatrician, was also reviewed.

Information gathered during investigation

Prescription for Sinemet

14. On 8 August 2016, Dr C prescribed Sinemet[1] to Mr A (aged 77 years at the time of these events). Dr C prescribed 67 tablets of Sinemet 25/100.[2] The prescription stated that one tablet of Sinemet was to be taken once daily for one week, and then one tablet was to be taken twice daily for one month. This was the first time Mr A had been prescribed Sinemet.[3]

Dispensing of Sinemet

15. In August 2016, Mr B was employed as a pharmacist and OTC Manager[4] at the pharmacy.

[1] Sinemet is used to treat some of the symptoms of Parkinson's disease. This is a disease of the nervous system that mainly affects body movement. Sinemet contains two active ingredients, levodopa (a chemical that allows the body to make its own dopamine) and carbidopa (which ensures that enough levodopa gets to the brain where it is needed).
[2] Sinemet is available in three formulations — 100mg levodopa with 25mg carbidopa (25/100), 200mg levodopa (long acting) with 50mg carbidopa (50/200), and 250mg levodopa with 25mg carbidopa (25/250).
[3] The New Zealand Consumer Medicine Information for Sinemet, published by Medsafe, states that the usual starting dosage of Sinemet is 25/100.
[4] As Pharmacist/OTC Manager, Mr B's responsibilities included operating or contributing to the pharmacy and dispensary operations in-store, complying with legal safety and business requirements through consistent application of professional and technical competencies, and providing customers and staff in-store with accurate and appropriate technical information and advice on the use of OTC and prescription pharmaceuticals.

16. On 8 August 2016, Mr B was the Charge Pharmacist and Pharmacy Manager. He was the only pharmacist on duty in the pharmacy at the time, and was also responsible for the services provided in the pharmacy outside of the dispensary. As well as dispensing prescriptions, Mr B's responsibilities included the sale of pharmacist-only medicines, oversight for the sale of, and advice given for, pharmacy-only medicines, and providing health advice to customers.

17. On 8 August 2016, Mr A visited the pharmacy to have the Sinemet dispensed.

18. Mr B processed Mr A's prescription on the pharm acy's Toniq[5] dispensary computer system. Mr B entered Mr A's details into the system and entered the word "Sinemet" into the medicine field. Mr B states that he saw the "25" written on the prescription and interpreted it incorrectly as Sinemet 200/50 CR (controlled release) tablets, and selected Sinemet 200/50 CR tablets from the Toniq dispensary computer system.

19. Mr B then generated a label, which stated "67 SINEMET TABLETS 200+50MG CR (LEV[6])". The label stated that one tablet was to be taken once daily in the morning for one week, then one tablet was to be taken twice daily.

20. The pharmacy had several SOPs relating to dispensing in place at the time of the error. Mr B informed HDC that when he was first employed by the pharmacy, it was under different management, and he did not receive training on the SOPs at that time. However, Mr B stated that he was aware of the SOPs.

21. The pharmacy's dispensing SOP 3, "Labelling and dispensing medicines", states that, to ensure label generation and medicine dispensing follows a safe and logical process, the pharmacist is required to:

> "• Check the name, brand, strength and formulation against the prescription, not the label.
> …
> • Double check labels against original prescription, before attaching them to the container.
> …
> • Leave the prescription (and any attached notes), stock bottles and dispensed items in the designated checking area for an Accuracy check by a pharmacist."

22. Mr B told HDC that he dispensed off the label, rather than the prescription, and selected Sinemet 200/50 tablets from the pharmacy shelf.

23. Mr B stated:

> "I was working sole charge on Monday 8th August in the dispensary and I mis-read the specialist writing of 25/100mg Sinemet as 200/50mg. I dispensed off the

[5] Computer software used by pharmacies to manage dispensary operations, including the generation of labels for prescribed medication.
[6] Levodopa.

label and by interpreting the handwriting incorrectly resulted in the incorrect dosage being dispensed."

24. The pharmacy's dispensing SOP 4, "Accuracy check", requires the pharmacist involved to ensure that all dispensed items have undergone a documented accuracy check by a checking pharmacist. The pharmacist in charge should:

> "Check the label and dispense medicine against the original prescription and the stock supply used to dispense the medicine. This includes:
>
> - Correct patient name
> - Instructions for use
> - Formulation, strength and quantity of medicine
> - Open each dispensed bottle or skillet to compare contents with stock supply
> - Self checking is not recommended — wherever possible the check should be done by a second person
> - If self-checking can't be avoided, separate the physical and 'mental' activities by another task e.g. by dispensing another prescription"

25. Mr B informed HDC:

> "After producing a label for Sinemet 200/50 CR, I selected stock from the shelf based off the label before counting 67 Sinemet 200/50 CR tablets. I signed the prescription after completing my final check and did not look at the original bottle again before bagging the medicine. I did not have a second pharmacist, intern pharmacist or technician available to double check the prescription at the time. In hindsight, I should have performed a second check of the prescription against the label and dispensed medicine, particularly as it was new medicine for [Mr A]. I believe this would have prevented the error reaching [Mr A].
>
> [Mr A] was waiting in the pharmacy to collect his medicine. When I served him I mentioned that this was a new medicine, and I gave him instructions about how to take it."

Side effects

26. Mr A followed the instructions on the prescription and took one tablet per day of the dispensed Sinemet 200/50 during the first week, and increased his intake to one tablet of the dispensed Sinemet 200/50 twice a day during the second week.

27. From 9 August 2016, the day after he started taking the Sinemet, Mr A started experiencing side effects, which he described as dull headaches, light-headedness when driving, mild leg cramps, bumping shoulders and elbows when opening doors, tummy aches, tremors, gut pain and cramp, and giddiness. On 19 August 2016, after experiencing gut pain, cramp in his calf, and giddiness, Mr A made the decision to reduce his intake of Sinemet to one tablet a day.

Discovery of the error

28. On 29 August 2016, Mr A returned to Dr C and informed him of the side effects he was experiencing. Dr C telephoned the pharmacy and checked the original prescription, and discovered that the pharmacist had made an error and dispensed 200mg Sinemet instead of the 100mg Sinemet prescribed.

Actions taken following discovery of the error

29. On the same day, Mr B completed an incident form. He recorded: "[Mr A] experienced Dyskinesia[7] and had trouble moving and falling down." Mr B also recorded that on 8 August 2016 it was busy and he was solely in charge of dispensing medication and was doing other tasks, including taking passport photos, and providing vaccinations.

30. On 29 August 2016, Mr B contacted Mr A by telephone, and recorded in the incident form that Mr A had requested a letter of apology. On 30 August 2016, Mr B wrote a letter of apology to Mr A.

31. In his response to HDC, Mr B stated:

> "I am deeply sorry that this dispensing error has happened and I have taken very seriously what happened to [Mr A] and the experienced side effects or associated distress that has occurred."

32. Mr B stated that because he thought an apology would resolve the situation, he informed the intern pharmacist and the retail staff but did not inform management about his dispensing error.

33. The Pharmacy told HDC:

> "Sinemet was a new medicine for [Mr A], so this should also have been a warning flag as when someone commences on Sinemet they do not usually start on a higher dose. This prescription was for an increasing dose of the lowest strength."

Changes to the pharmacy's practice

34. The following actions were taken as a result of the dispensing error:

- The incident was investigated to find out how it occurred and to reduce the occurrence of similar errors in the future. The pharmacy also informed HDC that Mr B's dispensing error was an isolated incident. Possible causes identified were Mr B's failure to follow the pharmacy's dispensing SOPs, and the placement in the dispensary of different strengths of Sinemet.

- Sinemet of different strengths had been placed together on a shelf at the time of this event. After learning of this investigation, the different strengths of Sinemet tablets were spaced out on the dispensary shelf.

[7] Abnormality or impairment of voluntary movement.

- Black and white stickers were attached to the dispensary shelf where the different strengths of Sinemet are placed, to alert the dispensary staff to stop and check that they have selected the correct strength of Sinemet tablets.

- Staff dispensing medication were reminded that during the final check, the dispensed containers must be opened to ensure that the contents being dispensed match the medication name on the script.

- Pharmacy management spoke to Mr B about the dispensing error, and he is having weekly training on how to handle customer complaints.

- All dispensary staff at the pharmacy were informed of the dispensing error to alert them to the serious consequences of this incident and similar incidents.

- Staff were asked to read the SOPs about dispensing, dispensing errors, and customer complaints.

Relevant professional standards

35. The Pharmacy Council of New Zealand *Competence Standards for the pharmacy Profession* (2015) requires that a pharmacist:

> "Domain 03: Supply and administration of medicines
>
> 03.1.1 Validates prescriptions ensuring they are authentic, meet all legal and professional requirements and are correctly interpreted
>
> 03.1.2 Uses a systematic approach to assess and review available patient medical history and medication record or notes
>
> …
>
> 03.2.1 Maintains a logical, safe and disciplined dispensing procedure
>
> 03.2.2 Monitors the dispensing process for potential errors and acts promptly to mitigate them"

36. The Pharmacy Council of New Zealand 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.
>
> …
>
> 5.1 Be Accountable for practising safely and maintain and demonstrate professional competence relative to your sphere of activity and scope of practice."

Response to provisional opinion

37. Mr A was provided with a copy of the "information gathered" section of the provisional opinion. He advised that he had no further information to add.

38. Mr B was provided with a copy of the relevant sections of my provisional opinion. In response, Mr B informed HDC that he has:

- Familiarised himself with the pharmacy's SOPs.
- Contacted the New Zealand College of Pharmacists at the Pharmaceutical Society of New Zealand for the purpose of enrolling in the "Practical Dispensing Assessment" course.
- Provided a written apology to Mr A for his breach of the Code.

39. The pharmacy was provided with a copy of the relevant sections of my provisional opinion, and has advised that it had no further information to add.

Opinion: Mr B — breach

Dispensing error

40. Mr A was prescribed 67 tablets of Sinemet 25/100. Sinemet was a new medication for Mr A, and his prescription was for an increasing dose of the lowest strength.

41. Mr B misread the strength of Sinemet prescribed as Sinemet 200/50 and generated an incorrect label. He then used the label to dispense Sinemet 200/50 to Mr A instead of using the prescription as required by the pharmacy's SOPs. Mr B then failed to check that he had dispensed the correct medication strength against the prescription.

42. According to Mr B, there was no other pharmacist, pharmacy intern, or technician available that day to perform the final check. Therefore, instead of performing a second and final check against the prescription, Mr B handed the Sinemet 200/50 CR to Mr A.

43. The Pharmacy told HDC that when a person is prescribed Sinemet for the first time, the usual practice is to start the person on a lower dose and gradually increase the dosage, and therefore, as Sinemet was a new medicine for Mr A, "this should have been a warning flag" to Mr B. It appears that Mr B did not think critically about the significance of Sinemet being a new medication for Mr A.

44. As a registered pharmacist, Mr B is responsible for complying with the professional standards set by the Pharmacy Council of New Zealand. Mr B created an incorrect label, selected the medication from the pharmacy shelf in accordance with the incorrect label, and did not check the selected medication against the prescription. He then failed to perform a self check of the medication against the prescription before giving it to Mr A. Mr B also failed to think critically about the significance of Sinemet

being a new medication for Mr A. Accordingly, I consider that Mr B failed to act in accordance with professional standards and breached Right 4(2) of the Code of Health and Disability Services Consumers' Rights (the Code).[8]

Opinion: Pharmacy — no breach

45. Pharmacist and Over the Counter Manager Mr B is an employee of the pharmacy. When Mr A's prescription was presented to the pharmacy, Mr B created an incorrect label, selected the medication from the pharmacy shelf in accordance with the incorrect label, and did not check the selected medication against the prescription. He then failed to perform a self check of the medication against the prescription before giving it to Mr A. Due to these errors, Mr B failed to identify that he had dispensed the incorrect strength of Sinemet to Mr A. I have found that Mr B breached Right 4(2) of the Code.

46. Section 72(2) of the Health and Disability Commissioner Act 1994 provides that an employing authority is vicariously liable for any act or omission by an employee. However, a defence is available under section 72(5) if the employing authority can prove that it took such steps as were reasonably practicable to prevent the act or omission. As a provider itself, the pharmacy can also be held directly liable for breaching the Code.

47. There is no doubt that Mr B was aware of the dispensing requirements contained in the pharmacy's SOPs in place at the time of this dispensing error. Although Mr B did not receive training on the SOPs — and this is concerning — I am satisfied that he was aware of the SOPs.

48. The SOPs clearly require the pharmacist to create a label in accordance with the prescription, select the medication in accordance with the prescription, and check the selected medication against the prescription. In my view, the error in dispensing occurred as a result of an individual's mistake, and cannot be attributed to any deficiency in the pharmacy's SOPs.

49. Overall, I consider that the pharmacy took all such steps as were reasonably practicable to prevent the acts and omissions that led to Mr B's breach of the Code. Accordingly, I do not consider that the pharmacy is vicariously liable for Mr B's breach of Right 4(2) of the Code. I also do not consider that the pharmacy breached the Code directly.

[8] 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."

Recommendations

50. In the provisional opinion, I recommended that Mr B review and familiarise himself with the pharmacy's SOPs, and arrange for training and an assessment, through the New Zealand College of Pharmacists, regarding the processing of prescriptions and accurate dispensing and checking processes. In response to the provisional opinion, Mr B informed HDC that he has familiarised himself with the pharmacy's SOPs, and has contacted the New Zealand College of Pharmacists at the Pharmaceutical Society of New Zealand for the purpose of enrolling in the "Practical Dispensing Assessment" course. He has also provided a letter of apology for Mr A.

51. In the provisional opinion, I recommended that the pharmacy:

a) Conduct a review of its dispensary processes, in particular the arrangement of medications on dispensary shelves, to consider whether improvements could be made in labelling and placement to reduce errors in dispensing.

b) Put in place processes to ensure that new staff receive training on SOPs and other relevant matters.

52. In response to the provisional opinion, the pharmacy stated that it has now conducted a review of its dispensary shelves as recommended, and that staff members are now inducted with the SOPs as part of the induction process for new staff members.

53. I recommend that the pharmacy randomly audit, over a period of one month, its staff compliance with its SOPs for dispensing and checking medications, handling customer complaints, and dispensing errors, and provide HDC with the outcome of that audit within three months of the date of this report

Follow-up actions

54. 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 B's name.

55. A copy of this report, with details identifying the parties removed, will be sent to the Pharmaceutical Society of New Zealand, the Health Quality & Safety Commission, and the New Zealand Pharmacovigilance Centre, and will be placed on the Health and Disability Commissioner website, www.hdc.org.nz, for educational purposes.