Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

A Decision by the Deputy Health and Disability Commissioner

(Case 21HDC01408)

Introduction

1. This report is the opinion of Deborah James, Deputy Health and Disability Commissioner, and is made in accordance with the power delegated to her by the Commissioner. HDC received a complaint from Mr B about the care provided to his father, Mr A, by Ms C at a pharmacy.[1] The pharmacy is one of a group of pharmacies.

2. Mr B's concerns relate to dispensing errors in his father's regular medications. Mr B said that changes were made to his father's regular medication regimen, but when his prescription was dispensed, Mr A received both the old and new dose of one of his medications, resulting in overmedication.

3. The following issues were identified for investigation:

- *Whether Ms C provided Mr A with an appropriate standard of care between May 2021 and June 2021 inclusive.*

[1] The pharmacy company is the management group empowered with supporting the provider pharmacies and their staff under the umbrella.

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- *Whether the pharmacy provided Mr A with an appropriate standard of care between May 2021 and June 2021 inclusive.*

4. The parties directly involved in the investigation were:

Mr A	Consumer
Mr B	Complainant/son
Ms C	Pharmacist
The pharmacy	
The pharmacy company	Pharmacy management support

5. Further information was received from:

Dr D	General practitioner (GP)
Dr E	Endocrinologist

6. Independent advice was obtained from a pharmacist, Ms Sharynne Fordyce (Appendix A).

Background

7. Mr A, aged in his fifties at the time of the events, has multiple comorbidities, including diabetes, and has a complex medical history and polypharmacy[2] involving input from several healthcare providers.

8. On 26 March 2021, Mr A was reviewed by Dr E, an endocrinologist. Following the review, Dr E suggested that Mr A discontinue spironolactone[3] and reduce his candesartan[4] dose from 8mg daily to 4mg daily due to a low blood pressure reading of 106/70mmHg. Dr E provided Mr A with a handwritten prescription for the candesartan 4mg and for empagliflozin,[5] which had been introduced by Dr E in February 2021, noting the reduction in the dose of candesartan on the prescription.

First dispensing event

9. On 13 May 2021, Mr A presented Dr E's handwritten prescription at the pharmacy, where Ms C was the sole pharmacist. Ms C told HDC that she supplied a month's supply of loose 4mg tablets of candesartan (a lowered dose, as noted on the prescription). Ms C said that she had prepared Mr A's usual blister pack[6] on 10 May 2021, and the pre-prepared blister pack contained candesartan tablets at the old 8mg dose, and spironolactone. Ms C stated that she was 'rushed', so she removed the 8mg candesartan from the pre-prepared blister pack, supplied the loose tablets to Mr A instead, and advised him to take one 4mg candesartan tablet with the blister pack in the morning as the dose had been reduced. Ms

[2] The simultaneous use of multiple medications.
[3] Medication to treat high blood pressure and heart failure.
[4] Medication to treat high blood pressure and heart failure whilst protecting the kidneys.
[5] Medication to lower blood sugar levels.
[6] Reliable medication storage that is organised into a labelled pack with the right time and day to take each medication.

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C said that Mr A 'appeared to understand these instructions' and she annotated the candesartan dose change on the pharmacy's internal medicine dose chart for Mr A.

10. Regarding the discontinuation of spironolactone, Ms C said that she was unaware that it had been stopped as there was no patient discharge summary or letter from Dr E available to her, and Mr A did not mention the change. Therefore, spironolactone was included as part of Mr A's regular blister pack prescription.

11. Ms C did not update the pharmacy's Toniq dispensary software[7] to reflect the reduction in the candesartan dose, and she did not document the dose reduction in Mr A's pharmacy file. Ms C told HDC that during May 2021, COVID-19 was still predominant and there was a large strain on healthcare services, including pharmacies, which led to her 'rushing to complete tasks' while being 'constantly interrupted' with customer queries and phone calls. The pharmacy emphasised that due to the COVID-19 pandemic there was increased stress and workload for pharmacy teams across New Zealand, and these factors were 'environmental and systemic issues' that were 'largely unavoidable'.

Second dispensing event

12. On 27 May 2021, Mr A presented a prescription to the pharmacy from his GP, Dr D, dated 25 May 2021. The prescription included spironolactone 25mg and candesartan 8mg, instead of the updated dose of 4mg candesartan, and did not include empagliflozin. Dr D told HDC that at the 25 May appointment, she discussed with Mr A changing his medications as per the advice from Dr E, but Mr A insisted that no changes be made and that he would discuss the changes with Dr E. On this basis, Dr D issued a repeat for Mr A's previous medication regimen (including spironolactone and candesartan 8mg), unaware that Mr A had already been given a prescription for the new regimen by Dr E. Mr A told HDC that he does not remember any discussion around the implementation of the medication changes and there are no clinic notes documenting any conversation. I will be addressing Dr D's prescription separately to this opinion.

13. Ms C told HDC that she put most of the items on hold in the Toniq system to be dispensed in the next monthly blister pack cycle. She said that unfortunately she did not recognise that the old dose of 8mg candesartan was included on the prescription rather than the new lower dose. She did not complete a medicines reconciliation, and the discrepancies in the medications were not discovered before the prescription was put on hold.

14. On 31 May 2021, Ms C processed[8] Mr A's next monthly blister pack that had been placed on hold on 27 May. Ms C told HDC that due to the pressure from completing a high workload and other distractions, she rushed through processing and packing of the blister pack and

[7] The Toniq dispensary software is used to process prescriptions and maintain patient information. This is done through a comprehensive patient history grid that includes information on a patient's repeat prescriptions and prescriptions on hold. The software also contains patient notes and patient alerts where important patient information (such as allergies or medication changes) can be entered. The software has close integration with several other healthcare systems to improve the communication of prescribing/dispensing information between providers. See: https://toniq.nz/products/toniq-dispensary/.

[8] Taking the necessary steps to evaluate the medications and dosages prescribed.

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did not perform a thorough medicines reconciliation of Mr A's dispensing history, missing the candesartan dose annotation she had made on his dose chart on 13 May 2021. Subsequently, Ms C processed a repeat of 4mg candesartan from Dr E's prescription dated 26 March, and she took off hold and processed the prescription from Dr D, dated 25 May, which included 8mg candesartan and 25mg spironolactone. Ms C told HDC that on 31 May it was 'extra busy', which would likely have been a contributing factor to the error.

15. On 8 June 2021, Ms C prepared[9] and checked Mr A's blister pack, containing both the 4mg and 8mg strength of candesartan and 25mg of spironolactone. Ms C told HDC that if the dose chart had been updated on 13 May or 27 May, this would have prompted her to clarify the candesartan dose. Ms C said that as she was never advised that spironolactone had been stopped, this would likely still have been dispensed.

16. Mr A picked up his blister pack from the pharmacy on 11 June 2021. He began taking the medications from the blister pack, including both the 4mg and 8mg candesartan, and the spironolactone.

Subsequent events

17. Mr B told HDC that his father began experiencing dizzy spells from 31 May 2021. On 18 June 2021, Mr A was admitted to the emergency department at the public hospital having experienced four episodes of fainting or passing out. Each time, Mr A reported getting out of the car, standing up, and around 30 seconds later collapsing to the ground with brief loss of consciousness, with the last episode resulting in a fall in his driveway. Mr A was diagnosed with postural hypotension[10] and remained in hospital until 22 June 2021, when he was discharged. Whilst in hospital, a medication reconciliation was completed, identifying the medication discrepancies, and a new script was sent to the pharmacy for the correct medications and doses (candesartan 4mg only, and no spironolactone).

Standard Operating Procedures

18. Standard Operating Procedures (SOPs) are documents that describe standard procedures and actions to be taken by staff when performing their duties. The pharmacy told HDC that the SOPs relevant to this incident accurately reflect requirements detailed in the Medicines Regulations 1984, the Pharmacy Council Competence Standards for the Pharmacy Profession 2015, and the Code of Ethics 2018.

19. The pharmacy told HDC that the pharmacy company (the company) has centralised SOP templates for the group of pharmacies, which are reviewed at a group management level at least every two years to keep them current and up to date. These templates are then adapted at a store level across the sites, with oversight by the clinical support team and individual store managers and staff. The pharmacy told HDC that the company has centralised internal reminders set to ensure that all sites review SOPs at a store level as required and that the Full Pharmacy Quality Audit (PQAIV) framework and Standard

[9] Packing the prescribed medications into the blister pack.
[10] A form of low blood pressure that happens when standing up from sitting or lying down.

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Inspection Audit tool are utilised to conduct 'internal mock audits' and 'ensure compliance with all legislative, ethical and regularity requirements'.

20. The pharmacy acknowledged that as a result of the ongoing work pressures and demands of COVID-19, management support in updating and personalising the SOP templates was delayed. As such, no SOP reviews were completed between December 2019 and July 2022. The PQAIV audits were also 'paused' during this period in recognition of the pressure the sector was under 'to just keep the doors open'.

21. The pharmacy told HDC:

> 'Despite the complexity of the patient's medication regime and the multiple prescribers not [necessarily] being aligned in their prescribing for the patient, if due process had been followed as detailed in the aforementioned SOPs there were multiple opportunities to provide the appropriate level of care.'

22. The pharmacy said that Ms C was inducted by the Senior Pharmacy Technician and Operations Manager at the time, on 3 December 2019, which included The Dispensing Process and compliance packaging processes. Ms C was the sole pharmacist responsible for processing and dispensing at the pharmacy at the time of the events and dispensed all of Mr A's medications between May and June 2021.

Dispensing New Prescriptions SOP

23. The pharmacy has a Dispensing New Prescriptions SOP (relevant sections outlined in Appendix B) that describes the process of dispensing prescriptions to ensure that prescriptions are received, dispensed, and handed out correctly and accurately, in accordance with legislative and ethical requirements.

Prescription Interventions SOP

24. The pharmacy has a Prescription Interventions SOP (relevant sections outlined in Appendix B) that describes the intervention process when a prescription query occurs. The SOP outlines when prescription intervention[11] may be required, and the procedural steps to be taken to reconcile any queries or inconsistencies.

Dispensing Compliance Packs SOP

25. The pharmacy has a Dispensing Compliance Packs SOP (relevant sections outlined in Appendix B) that outlines the appropriate procedures for dispensing patient medications, from both new and repeat prescriptions, into unit dose packing (blister packs). The SOP also sets out the procedural steps for when medication changes have occurred.

Relevant professional standards

26. The relevant professional standards for processing, dispensing, and checking prescriptions are set out in the Medicines Regulations 1984,[12] the Pharmacy Council Competence Standards for the Pharmacy Profession 2015, and the Pharmacy Council Code of Ethics 2018.

[11] Querying concerns about medication errors in a prescription.
[12] https://www.legislation.govt.nz/regulation/public/1984/0143/latest/DLM95668.html

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In summary, these standards ensure that the correct medication, strength, and dosage intended for the patient is supplied.

27. The Competency M1.2 of the Pharmacy Council 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'.[13]

28. Principle 3.F of the Pharmacy Council Code of Ethics 2018 states:

> 'Promotes professional and environmental responsibility and accountability for the control, procurement, preparation, handling, supply, storage and disposal of medicines and other healthcare products.'

Further information

Ms C

29. Ms C told HDC that she is sincerely apologetic to Mr A and his family for the error involved in the blister pack and the resulting experience. Ms C reiterated that she has learnt significantly from the issues experienced and that since the events she has changed the way she operates to ensure that no similar incident arises in the future.

Pharmacy

30. The pharmacy advised HDC that since these events, the SOPs have been reviewed and updated to reflect the learnings from the events.

Pharmacy company

31. The pharmacy company told HDC that it was not aware of the HDC complaint until receiving notification of the investigation from HDC, as Ms C did not notify the directors of the initial complaint or her response. However, Ms C had contacted the company's clinical support pharmacist to advise of the HDC complaint, but she was advised that there was no capacity to support her due to COVID-19-related workload, and instead she was advised to contact the Pharmacy Defence Association (PDA) for support and guidance. The pharmacy company acknowledged that this was a 'gap in support' offered to Ms C.

Response to provisional opinion

Ms C

32. Ms C was given an opportunity to comment on the provisional opinion and told HDC that she had reviewed the opinion and had no further comments. Ms C told HDC that she agrees with everything written in the opinion and is happy with it.

33. Ms C also provided HDC with correspondence from the Pharmacy Council of New Zealand (PCNZ). PCNZ acknowledged the actions taken by Ms C to prevent a similar error from recurring but made recommendations to assist Ms C in ensuring that good practices are being followed.

[13] See: https://pharmacycouncil.org.nz/wp-content/uploads/2021/03/CompStds2015Web-1.pdf.

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34. PCNZ recommended that Ms C enrol in the Pharmaceutical Society's 'Improving Accuracy in your Dispensing' course. Ms C was also encouraged by PCNZ to review the 'Workplace Pressures in Pharmacy' guidelines on the PCNZ website to help her to manage workplace pressures in the future. Following completion of these recommendations, Ms C is to provide PCNZ with a critical self-reflection of the incident by 13 January 2025.

35. Ms C advised HDC that currently she is on leave, but she intends to comply with the PCNZ recommendations. Ms C said that she intends to return to work after the submission of the recommendations and at the conclusion of her leave.

Pharmacy and pharmacy company

36. The pharmacy and the company were given an opportunity to comment on the provisional opinion and this information has been incorporated into the report where relevant. The response received came from the company on behalf of both itself and the pharmacy.

37. The response stated that the pharmacy has carefully reflected on this incident and has made a series of changes to ensure that there is no repeat of these events. The company said that the directors and management team will continue to take all the steps they can to ensure that nothing of this nature occurs again and that they do not seek to minimise or avoid the consequences of the incident.

Mr A and Mr B

38. A copy of the 'Background' section of the provisional opinion was sent to Mr A and Mr B and they were invited to comment. Mr B confirmed that they had no comments.

Opinion: Ms C — breach

Introduction

39. Under Right 4(2) of the Code of Health and Disability Services Consumers' Rights (the Code), Mr A had the right to pharmacy services of an appropriate standard that complied with legal, professional, ethical, and other relevant standards.

40. The standards that apply in this instance are those set out in the Medicines Regulations 1984, the Pharmacy Council Competence Standards for the Pharmacy Profession 2015, and the Pharmacy Council Code of Ethics 2016. Of particular significance is Principle 3.F of the Pharmacy Council Code of Ethics 2016 and Competency M1.2 of the Pharmacy Council Competence Standards for the Pharmacy Profession 2015. Also applicable are the pharmacy's SOPs for Dispensing New Prescriptions, Repeat Prescriptions, Dispensing Compliance Packs, and Prescription Interventions, which aim to reflect the industry standards above.

41. As part of my assessment of the care that Ms C provided to Mr A, I obtained independent advice from pharmacist Ms Sharynne Fordyce.

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First dispensing event

42. On 13 May 2021, when Mr A presented the handwritten prescription from Dr E, it specifically noted the reduced dose of candesartan (from 8mg to 4mg). Ms C told HDC that due to the strain on the pharmacy as a result of COVID-19, she was in a rush to remove the 8mg candesartan from Mr A's pre-prepared blister pack and therefore rushed through her usual process. Ms C said that she was unaware that spironolactone had been stopped, and therefore this was dispensed as part of Mr A's usual blister pack.

43. The Dispensing Compliance Packs SOP requires that 'any changes of existing Medico Pack patients must be verified and their drug chart updated with the change immediately'. Whilst Ms C annotated the candesartan dose change on the pharmacy's internal medicine dose chart for Mr A, she did not update the Toniq dispensary software to reflect the candesartan dose change, and the change was not documented in Mr A's pharmacy file, as was required by the pharmacy's SOP.

44. I am critical that Ms C did not complete these steps of the Dispensing Compliance Pack SOP, as updating Mr A's patient file to reflect the reduced dose of candesartan on the Toniq dispensary software and pharmacy file may have prevented future medication errors. However, I accept that Ms C was unaware that spironolactone had been stopped, and I am not critical in this regard. Whilst I acknowledge the impacts that COVID-19 had on all healthcare services, I do not consider that this materially mitigates Ms C's responsibility for the error.

Second dispensing event

45. The Dispensing Compliance Packs SOP requires that the pharmacist 'review patient medication history to ensure consistency of medications. Compare new prescription with history on computer and compliance medication chart (if they are an existing compliant pack patient)'. It also sets out that 'whenever checking, it is preferred that the person who checks the packs is NOT the person who filled them'.

46. When Mr A presented the prescription from Dr D (dated 25 May 2021) on 27 May 2021, most of the items were placed on hold by Ms C for later collection. Ms C accepts that medicines reconciliation should have been completed at the time of holding the prescription in order to clarify any differences or discrepancies and to avoid confusion when processing in the future.

47. HDC's independent advisor, Sharynne Fordyce, advised that Ms C should have noticed, as the prescription was being put on hold, that it contained 8mg candesartan, which had been reduced to 4mg by Dr E in the previous prescription. I agree and am therefore critical that the prescription was placed on hold without discrepancies being identified or reconciled.

48. Ms C acknowledged that on 31 May 2021, when she was 'unholding' and processing the prescription prior to packing Mr A's next monthly blister pack, she again rushed through the processing and packing of the medications. Therefore, a full medicines reconciliation was not completed, as required under the 'Dispensing Compliance packs' SOP, and the

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annotated note on the dose chart was missed, resulting in the processing of the 4mg repeat and processing of the 8mg prescription. Spironolactone was also processed.

49. Ms Fordyce advised that as Ms C had been involved in adjusting Mr A's last pack to reflect the new, lower dose of candesartan, she should have been aware of the anomaly and taken steps to clarify the dosage required. Ms Fordyce considered that as Ms C was the pharmacist responsible for processing and dispensing both the prescriptions (each containing candesartan of different strengths), she was responsible for checking the inconsistency between the two prescriptions and taking steps to ascertain which was the correct dosage. Ms Fordyce considers this to be a serious departure from accepted practice. I accept this advice and, whilst I appreciate the large workload and competing responsibilities, it is vital that the checks and procedures that are required under both the SOPs and the industry standards are carried out, even if this means increasing prescription wait-times, to reduce the risk of such errors occurring.

50. Ms C accepts that when the blister packs were prepared on 8 June 2021, she did not perform a thorough medicines reconciliation of Mr A's dispensing history. This resulted in her missing the candesartan dose annotation made on 13 May, and therefore she dispensed a repeat for the 4mg candesartan (from Dr E's prescription on 13 May), as well as 'unholding' and dispensing the prescription containing 8mg candesartan and spironolactone (from Dr D's prescription dated 25 May).

51. Ms Fordyce advised that Ms C did not follow the pharmacy's SOPs, as she failed to check the medication history and deal with any queries appropriately. Ms Fordyce also advised that as Ms C did not involve the dispensary technician in any of the checks, this is also inconsistent with the SOPs and, as such, would be viewed as a moderate to severe departure from accepted practice. I accept this advice and agree that Ms C had several opportunities to identify and reconcile the inconsistencies in the two prescriptions, had she followed the SOPs appropriately.

Conclusion

52. Ms C had a responsibility to ensure that Mr A received care of an appropriate standard that complied with the Code. I acknowledge the complexity of Mr A's medication regimen given the number of medications and prescribers involved, and I appreciate the added pressure and uncertainty occurring at this time due to the impacts of COVID-19.

53. However, in my view, Ms C did not follow the professional standards or the pharmacy's SOPs adequately when processing Mr A's prescriptions dated 13 May 2021 or 31 May 2021. As such, several opportunities to identify and rectify the discrepancies in Mr A's prescriptions were missed. It is noted that these were individual errors by Ms C, and as such I have not attributed them to the pharmacy. Accordingly, I find that Ms C breached Right 4(2) of the Code in failing to provide Mr A with services of an appropriate standard that complied with professional standards and the pharmacy's SOPs.

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Opinion: Pharmacy — no breach

54. The pharmacy is the legal entity that employed Ms C at the time of the events. As such, the pharmacy was the entity providing care to Mr A.

55. Having investigated the issues raised in this complaint, I consider that the dispensing errors were individual errors by Ms C, as discussed above, and cannot be attributed to the pharmacy as the employing entity. Ms C acknowledged that she was aware of the SOPs and processes that were in place at the pharmacy for dispensing blister packs, and she accepts that in this instance she did not follow these adequately. As such, I am satisfied that the dispensing errors reflect an individual error.

56. Based on the information provided by the company and the pharmacy, I understand that the company was the management group responsible for providing centralised management support to the provider pharmacies and pharmacists. Included within this role is providing support to staff through the complaint management process and the oversight of SOPs at the pharmacy. As such, the concerns I have identified in this respect and the comments I have made in terms of the management support services provided to Ms C and the SOPs have been directed to the company.

Opinion: Pharmacy company

Introduction

57. The pharmacy is one of a group of pharmacies. The company is the management group empowered with supporting the provider pharmacies and their staff and comprises a clinical support team that assists with co-designing personalised SOPs relevant to each pharmacy. Based on the information obtained from the company, I understand that the company has centralised SOP templates for the pharmacies, which are adapted at a store level with oversite from the company's clinical support team and individual store managers and staff. The SOPs are then reviewed at least every two years.

58. The pharmacy company also told HDC that it has a management team that works across all pharmacy sites supporting staff, systems, and processes in ensuring that best practice procedures are followed and ensuring patient safety.

59. As such, whilst the pharmacy was the entity providing care to Mr A, the investigation into the events and the information gathered indicates that some of the issues identified fall into the services provided by the company in its role of providing management support to the pharmacy.

Support provided to staff — adverse comment

60. The company told HDC that there was unprecedented strain and uncertainty at the time of the events due to COVID-19 and, as a result, some management staff had been shifted from normal work to prioritise the ongoing pressures and demands. Because of this, when Ms C contacted the clinical support pharmacist regarding this HDC complaint, she was advised to contact PDA for support, as 'the clinical support team did not have the capacity to fully support [Ms C] through her HDC response'. In addition, the clinical support pharmacist did

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not advise the company Directors of the HDC complaint. The company acknowledged this 'process and capacity gap' in the support offered to Ms C.

61. Ms Fordyce advised that the company's management structure is there to provide support to staff, and this seems to have been lacking in this instance. She also advised that the lack of help for Ms C from the company's management team when preparing her initial response to HDC is 'a matter for concern'.

62. I accept Ms Fordyce's advice. Ms C was also experiencing the unprecedented pressure at this time and was unsupported by the company in her initial response to HDC and the management of the complaint, although I do acknowledge that the Directors had no knowledge of the complaint at this time. Whilst I acknowledge that since these events the company has reflected on its staff support and has been providing Ms C with support and guidance, I am critical that this did not happen in the first instance, and that instead Ms C was advised to seek assistance from PDA. I encourage the company to reflect on my comments and those of my advisor.

Standard Operating Procedures — educational comment

63. As noted above, the company is the management group empowered with supporting the pharmacy and its staff. Included within this role is the co-designing of personalised SOPs for the pharmacy.

64. The pharmacy's SOPs in place at the time of the events provided an overview of the general standard of care and accepted practice for Dispensing New Prescriptions, Repeat Prescriptions, Prescription Interventions, and Dispensing Compliance Packs. In accordance with the Pharmacy Council of New Zealand guidance, all SOPs should be written specifically for the Pharmacy to which they apply, and they should be reviewed every two years.

65. The pharmacy's SOPs in place at the time of Mr A's care, between May and June 2021, were within the recommended two-year review period set out in the Pharmacy Council of New Zealand guidelines.[14] However, in the information provided to HDC, the company identified that the SOPs were then not updated within the necessary two-year time frame post Mr A's care. As such, there was an eight-month period from December 2021 to July 2022 where these policies had not been updated, outside of the expected two-year time frame. I note that this did not affect the care provided to Mr A but is an incidental finding on which I am commenting for the educational benefit of the company.

66. The company told HDC that COVID-19 resulted in increased pressure and strain on the pharmacy industry and, as such, there was a delay in the company's SOPs being updated and personalised to the pharmacy. As such, the SOPs were not updated between December 2019 and July 2022.

[14] The Pharmacy Council of New Zealand guidelines set out the standards that all pharmacies should strive to achieve when writing SOPs.

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67. Ms Fordyce advised that it is accepted practice for SOPs to be updated every two years to ensure they remain relevant to current practice and to conform with any changes in the professional and legal requirements.

68. I accept this advice on the basis that, whilst the policies in place at the time were within the recommended review period, there was a period from December 2021 to July 2022 where these SOPs had not been updated. I acknowledge the significant impact and unprecedented strain on pharmacies throughout the COVID-19 pandemic, and the level of uncertainty this brought. However, I remind the company of its responsibility to ensure that detailed and up-to-date policies are in place in order to meet the PCNZ guidelines that all pharmacies should aim to follow. A failure to do so can lead to uncertainty for staff, highlighting the importance of having clear, robust, and up-to-date policies in place. I acknowledge that since these events, the company has reviewed the SOPs for the pharmacy and made several amendments in light of these events.

Changes made since events

Ms C

69. Ms C told HDC that following the events, she undertook a thorough review of her processes associated with compliance (blister) packaging and made the following changes to her practice:

a) Strictly adhering to the pharmacy's SOPs, even if that means increased prescription wait-times. In particular:

- Performing a full medicines reconciliation every time a blister pack is processed for a returning patient, contacting the prescriber where necessary;
- Clearly annotating when medicines are placed on hold and performing a full medicines reconciliation;
- Updating any changes in medicine regimen in a blister pack in the dose chart, which is printed and stored in the patient's physical file. Changes are also noted and highlighted on the dose chart;
- For blister pack patients, reflecting and updating all changes on the actual contents of the pack;
- Clearly identifying any changes in medication regimen in the 'patient diary' and/or 'warning note' function in Toniq dispensary software; and
- Routinely reviewing 'patient diary' notes as part of the patient history check when subsequent prescriptions are processed.

b) Involving the dispensary technician in more dispensary work to reduce workload.

c) Counselling changes in medicine regimen with the patient/family/caregiver to help identify potential prescribing or dispensing errors.

d) Reducing working hours, adhering to scheduled break times, and taking regular annual leave.

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Pharmacy

70. The pharmacy told HDC that since the events it has employed a part-time pharmacist to accommodate Ms C reducing her hours.

Pharmacy company

71. The company told HDC that since the events it has made the following changes:

a) The SharePoint platform was introduced to support the clinical team to follow up on the review of SOPs at site level and check that the reviews have occurred.

b) A weekly newsletter is sent to each site and printed and placed in the lunchroom for each staff member to record the date and time they have reviewed the newsletter.

c) A forensic review of support offered to staff and the pharmacy was carried out as part of business as usual over the period before and after the incident in 2021.

d) A proposed review into these events and the issues it raised was established across the the group of pharmacies. The focus points of this review were provided to HDC.

Recommendations

Ms C

72. I recommend that Ms C:

a) Provide a formal written apology to Mr A for the deficiencies of care identified in this report. The apology should be sent to HDC within three weeks of the date of this report, for forwarding to Mr A.

b) Provide HDC with proof of having completed the PCNZ recommendations of completing the 'Improving Accuracy in your Dispensary' course and reviewing the 'Workplace Pressures in Pharmacy' guidelines. Proof of completion should be sent to HDC within three weeks of the due date indicated by PCNZ for completing these recommendations.

Pharmacy company

73. I recommend that the company:

a) Provide a formal written apology to Mr A for the lack of support provided to the pharmacy staff. The apology should be sent to HDC within three weeks of the date of this report, for forwarding to Mr A.

b) Provide HDC with a copy of the findings of the proposed review into this incident and any changes made as a result, within six months of the date of this report.

c) Use an anonymised copy of this report for education across all the company's pharmacies and report back to HDC with evidence that this has occurred, within six months of the date of this report.

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74. The pharmacy owner will be advised of these recommendations given the direct impact it will have on the running of the pharmacy and the likely cooperation it will require from the pharmacy.

Follow-up actions

75. A copy of this report with details identifying the parties removed, except the advisor on this case, will be sent to the Pharmacy Council of New Zealand, and it will be advised of Ms C's name.

76. A copy of this report with details identifying the parties removed, except the advisor on this case, will be sent to the Pharmaceutical Society of New Zealand and to Medicines Control and placed on the Health and Disability Commissioner website, www.hdc.org.nz, for educational purposes.

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Appendix A: Independent clinical advice to Commissioner

The following independent advice was obtained from a pharmacist, Ms Sharynne Fordyce:

'I, Sharynne Fordyce, have been asked to provide an opinion to the Commissioner on Case number 21HDC01408, after reading responses from [Ms C], and [the pharmacy company]. I have read and agreed to follow the Commissioner's Guidelines for Independent Advisors.

My qualifications include a Diploma of Pharmacy, and a Masters of Clinical Pharmacy. I have worked in Retail Pharmacy for over 30 years, both in New Zealand and in England, and also work for Te Whatu Ora Wairarapa.

Background.
The Commissioner is seeking your opinion on the care provided by [Ms C] at [the pharmacy] to [Mr A] in May and June 2021.

[Mr A] has several medical conditions including diabetes. He was on multiple medications which were blister packed by [the pharmacy]. On 27 March 2021 his diabetologist noted low blood pressure and in a letter to [Mr A's] GP he recommended cessation of spironolactone and reduction in dose of candesartan from 8mg to 4mg. The diabetologist provided a prescription for 4mg candesartan tabs which was dispensed by [the pharmacy].

On 25 May 2021 [Mr A] had his medications reissued by the GP. The GP continued to prescribe spironolactone and the 8mg candesartan tabs despite the diabetologist's advice. [The pharmacy] dispensed the medication in blister packs as usual. In addition to spironolactone, the packs contained the 8mg candesartan tabs prescribed by the GP as well as the 4mg candesartan tabs prescribed by the diabetologist.

From about 31 May 2021 [Mr A] began to experience dizziness when standing. This worsened after the GP prescribed him celecoxib on 16 June 2021. About two days after this [Mr A] collapsed and was admitted to [hospital] where he was diagnosed with low blood pressure secondary to over-medication.

Expert advice requested
Please review the enclosed documentation and advise whether you consider the care provided to [Mr A] by [Ms C] at [the pharmacy] was reasonable in the circumstances, and why.

In particular, please comment on: In respect of [Ms C]:

1. Whether [Ms C] should have queried the prescription of both the 4mg and 8mg candesartan on 25 May 2021;
2. Whether [Ms C] adequately followed the [pharmacy] policies and procedures when dispensing medication to [Mr A]; and

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3. Whether the documents provided raise any other issues that you consider warrant comment.

In respect of [the pharmacy]:

1. Whether their policies and procedures were adequate in the circumstances;
2. Anything else that you consider warrants comment.

For each question, please advise:

a. What is the standard of care/accepted practice?
b. If there has been a departure from the standard of care or accepted practice, how significant a departure (mild, moderate, or severe) do you consider this to be?
c. How would it be viewed by your peers?
d. Recommendations for improvement that may help to prevent a similar occurrence in future.

If you note that there are different versions of events in the information provided, please provide your advice in the alternative. For example, whether the care was appropriate based on scenario (a), and whether it was appropriate based on scenario (b).

Advice provided.

In respect of [Ms C]
1.a) The accepted practice/standard of care when processing, dispensing, and checking a prescription are laid down in the Medicines Regulations 1984, the Pharmacy Council Competence Standards for the Pharmacy Profession 2015 and the Code of Ethics 2018. Summarised they ensure the correct drug, strength and dosage intended for the patient is supplied. In this case, where multiple medications, prescriptions and doctors are involved, the process may require a number of phone calls to ascertain the correct regime, that all the doctors agree with. This also involves checking each new prescription with the patient's medication history, particularly with patients with complex medication regimes such as [Mr A], looking for new or changed medications. If a prescription is handed into [the pharmacy] but is not immediately needed by the patient, it is put "on hold" and stored at [the pharmacy] until needed. Any changes, however, should be noted and actioned at this stage.

b) When [Mr A] brought in his script from his GP on 27/05/2021, [Ms C] should have noticed, as the script was put on hold, that the script contained candesartan 8mg, which had been stopped by the diabetologist in a previous script. When [Ms C] was "unholding" and processing the prescription prior to packing the new blister pack medications, which included the incorrect dose of candesartan 8mg, she also included a repeat of the new lower dose candesartan 4mg. [Ms C] had been involved in adjusting [Mr A's] last pack to reflect the new lower dose so should have been aware of the anomaly and taken steps to clarify the dosage required. This is a serious departure from accepted practice.

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c) This would be viewed as a serious departure from accepted practice by my peers. This would be, however, with empathy, as the conflicting prescriptions and various prescribers involved in this situation would not make it easy for a sole pharmacist to deal with.

d) Recommendations for improvements would include, before putting any prescription on hold, checking against patient's current medication regime. Clarify any differences or discrepancies before putting the prescription on hold, thus eliminating the possibility of errors or confusion.

Trying to synchronise a patient's prescriptions ensures they get all their medications together and regularly. This particular patient, however, has a challenging regime which could make this process very difficult. Increased staffing would allow more time for dispensing and checking, and would also involve more than one person in the process, ensuring a fresh set of eyes for the final check.

2.a) The Standard Operating Procedures (SOPs) for [another pharmacy], which were used at [the pharmacy], generically covered the standard of care and accepted practice for Dispensing New prescriptions, Repeat Prescriptions and Prescription Interventions. It is, however, accepted practice to have SOPs that are written specifically for [the pharmacy] in which they will be used, and to review these every two years.

Addendum 7 May 2024

It has subsequently become apparent that [the other pharmacy's] SOPs were submitted in error by [Ms C], and that there were [pharmacy] Policies available. That [Ms C] had no help from the management team of [the company] in preparing her HDC response is a matter for concern.

b) [Ms C] did not adequately follow the [pharmacy] policies and procedures when dispensing medication to [Mr A]. She did not "Check medication history and appropriately deal with any adverse reactions, interactions or other queries associated with the prescribed medicines" (Dispensing New Prescriptions SOP) when unholding the GP's prescription and processing the repeat from the diabetologist for the reduced dose of candesartan. [Ms C] also did not follow the dispensing policy that recommended the dispensary technician did the initial check on a prescription, but it is unclear whether there was a technician present at the time of dispensing. This would be viewed as a moderate to severe departure from accepted practice.

c) My peers would also view this as a moderate to severe departure from accepted practice.

d) Recommendations for improvement would include having up to date policies that pertain to [the pharmacy] in which they are being used. It would also be appropriate for each staff member to sign and date the policies that applied to their job descriptions, after they had read the policies concerned.

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3. The documents provided, including prescriptions from the diabetologist, GP and the hospital, and prescriber notes from the GP and the hospital, display an alarming number of discrepancies and errors. [Mr A] has a complex medical history and regime, which does not seem to have been well served by his many interactions with the health system.

In respect of [the pharmacy].

1.a) The standard of care/accepted practice for SOPs for pharmacies is for them to be written or adapted specifically for [the pharmacy] in which they will be used. It is accepted practice for the SOPs to be updated every two years, in order for them to remain relevant to current practice and to conform with any changes in legislation. It is common practice for new staff to read the appropriate policies for their jobs, and to sign and date these policies.

Addendum 7 May 2024

It has subsequently become apparent that policies for [the pharmacy] were available, but [Ms C] was unable to locate them, and chose [another pharmacy's] SOPs in error.

b) ~~There has been a severe departure from accepted practice in regards to the policies and procedures supplied for [the pharmacy].~~

Addendum 7 May 2024

b) There has been a moderate departure from accepted practice in regards to the policies and procedures supplied for [the pharmacy].

c) ~~My peers would also regard the policies and procedures supplied for [the pharmacy] to be a severe departure from accepted practice, indicating a lack of attention to legal and professional requirements~~.

Addendum 7 May 2024

c) My peers would also regard the policies and procedures supplied for [the pharmacy] to be a moderate departure from accepted practice.

d) Recommended improvements would include a comprehensive range of policies and procedures written specifically for [the pharmacy], addressing any particular challenges this pharmacy may face. These policies need to be written by people closely involved in the day to day running of [the pharmacy], and revised every two years to include any legal and professional changes in requirements.

3. Despite a mention in one of the dispensing policies, there seems to have been no involvement of the owners of [the pharmacy] in this process.

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Addendum 7 May 2024

Mention is also made of [Ms C] not notifying the directors of [the company] about the HDC incident. It appears, however, that she did approach someone in management, and was advised to contact PDA for any help she needed.

While acknowledging that working through the pandemic produced unprecedented strain upon pharmacies and the staff, as stated in [the company's] response, their management structure is there to provide support to their staff, which seems to have been lacking in this instant.

Sharynne Fordyce'

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Appendix B: SOPs

'*Dispensing New Prescription SOP*

Dispensing the Prescription

Procedure

- Check the recorded medication history (perform medicines reconciliation) for newly prescribed medicines, consistency of treatment, different strengths or frequency, duplication of medicines, eg. Different brands of the same medicine, regular medicines not prescribed, interactions with other prescribed medicine(s), evidence of misuse, allergies, eg. Calling for repeats too early or too late.

…

- Note any relevant discrepancies, changes or amended prescription details on attached notes or in the prescription margins to alert other dispensary staff members involved in the process.

During Dispensing Process

- Where possible use another staff member to check prescriptions, labels and calculations. Where possible involve another dispensary staff member to be involved in the dispensing process and refrain from the pharmacist being involved in the whole process alone.

Checking Procedures

Final pharmacist check

- Check the appropriateness of each prescribed medicine with respect to its therapeutic use, appropriateness for the customers parameters, eg. Age, weight, renal function, possible adverse effects, contraindications dosage, route of administration, duration of treatment, and possible interactions with other medication(s) or food.
- Check that the medical history has been reviewed and that there is consistency of treatment and compliance (ie. Medicines reconciliation).
- Check for any other recent patient diary notes in relation to medicines history.

  …
- Annotations should also be made if:
  - Any changes in medicines have been made
  - Any communication/confirmation with another health professional (ie. Prescriber, nurse etc).'

'*Prescription Interventions SOP*

Procedure

- When dispensing and checking a prescription the Pharmacist must always look for any problems existing with the prescription with respect to the following:

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— That the patients medication history is reviewed (ie. Medicines Reconciliation) for consistency of treatment by reviewing patient history and compliance and evidence of misuse or calling for repeats too early or late.
— That there are no interaction with other medicines and food.
…
— The appropriateness of each prescribed medicine with respect to its therapeutic use, adverse effects, contraindications, and dosage.
...

- The Prescriber is contacted and made aware of the problem is necessary. It may be that the patient or patient's caregiver can provide the relevant information.
- The prescription is clarified and changes, if necessary, and the Pharmacist annotates all correspondence and changes on the prescription and signs and dates the annotations.'

'*Dispensing Compliance Packs SOP*

Procedure

Processing (new and repeat prescriptions):

- Review patient medication history to ensure consistency of medications. Compare new prescription with history on computer and compliance medication chart (if they are an existing compliant pack patient). This patient medication chart is filed in the dedicated Blister Pack folder, stored in the corner of the main dispensary. Any changes or anomalies that need to be confirmed with the patient, discharge summary, written confirmation and/or followed up with the prescriber.
  — NOTE: Any changes to medication of *existing* Medico Pack patients must be verified and their drug chart updated with the change IMMEDIATELY. A new drug chart is printed. This ensures the drug chart is always up to date.
  …
  — NOTE: Whenever a new prescription is presented to the pharmacy, the new prescription must be checked for any changes etc against medication chart. Every time a new prescription is presented, the pharmacist must record down the fact that it has been reviewed (even if no changes) on the bottom of the medication chart.

Checking of Medico Packs:

- Whenever checking, it is preferred that the person who checks the packs is NOT the person who filled them.

…

- A complete and independent check (of each pack, prescription and dose chart) must be carried out by a pharmacist before dispatch …

Compliance Pack Changes

- Any changes to medication of *existing* Medico Pack patients must be verified and their drug chart updated with the change IMMEDIATELY. A new drug chart is printed. This ensured the drug chart is always up to date. The pharmacist must also record down the fact that it has been reviewed on the bottom right-hand box of the medication chart …'

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