HEALTH & DISABILITY COMMISSIONER
TE TOIHAU HAUORA, HAUĀTANGA

Medication error due to deficiencies in dispensing and checking processes

Introduction

1. On 15 June 2022, the Health and Disability Commissioner (HDC) received a complaint from Mr A regarding the standard of care provided to his mother, Mrs B, at their local pharmacy (the pharmacy) in 2022.[1]

2. On Friday 27 May or Saturday 28 May 2022,[2] a dispensing error occurred at the pharmacy in which losartan 50mg (commonly used to treat high blood pressure) was incorrectly dispensed instead of paroxetine 20mg (used to treat various mental health conditions) tablets in a pre-packed sachet roll. The error was not detected or corrected by the pharmacist at the final checking stage, despite the VIZEN checking system[3] identifying several discrepancies in the sachet roll. Mrs B took one dose of the incorrect medication and subsequently reported a loss of consciousness for approximately four hours. The error was reported to the pharmacy on 8 June 2022.

3. Mr A raised concerns that the dispensing error may have caused serious harm to his mother and that the pharmacy failed to provide a timely explanation or follow-up after the incident.

4. This report focuses on the standard of care provided to Mrs B by the pharmacy, and by pharmacists Ms C[4] and Ms D.

Findings

5. Given the presence of several systemic issues, I find the pharmacy in breach of Right 4(1) of the Code of Health and Disability Services Consumers' Rights (the Code) for failing to provide services to Mrs B with reasonable care and skill. I also make educational comments in relation to the care provided by Ms C and Ms D.

Recommendations

6. The pharmacy told HDC it acknowledged the error and stated that it was 'sincerely apologetic' for the distress caused, apologising to Mrs B and her family for the incident and its impact.

7. The pharmacy advised that it made following changes to its practice since the events:

[1] At the time of events, the pharmacy was owned by a different company. In 2024, the pharmacy was sold to another company.
[2] The pharmacy was unable to determine the exact day, time, or staff member responsible for the error, advising only that it occurred between 27 May 2022 and 2 June 2022. However, VIZEN photographs show that the sachet roll was processed on 28 May 2022, indicating that the error most likely occurred on 27 or 28 May 2022.
[3] An automated dispensing and packaging system that captures photographs during the sachet preparation process, enabling verification of the timing and sequence of production.
[4] Ms C ceased employment with the pharmacy on 25 June 2022. She currently resides in Australia and is a non-practising pharmacist of New Zealand.

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

a. Undertook a review of its compliance packaging processes, including the operation of the sachet-packing robot and VIZEN checking system, to identify and reduce the risks of dispensing errors.

b. Introduced improved documentation requirements, including ensuring that pharmacists and dispensary staff sign and document each step of the dispensing and checking process to provide a clear audit trail.

c. Reinforced expectations that pharmacists must carefully review VIZEN checking reports, including flagged discrepancies, and take appropriate steps to resolve errors before sign-off.

d. Implemented additional checks and safeguards in the preparation and loading of medicines into the robot, including increased oversight and double-checking of high-risk steps.

e. Provided staff training and refresher training on dispensing processes, compliance packaging systems, and incident management procedures.

f. Reinforced requirements for timely incident documentation and reporting, including adherence to procedures for recording dispensing errors and notifying relevant parties.

g. Emphasised the importance of notifying prescribers when dispensing errors are identified, particularly where incorrect medication has been ingested.

8. I am satisfied that the pharmacy has undertaken sufficient remedial actions following its internal review (discussed further at paragraph 23). In light of this, and noting the change of ownership in 2024, I recommend that the pharmacy:

a. Provide a written apology to Mrs B and her family for its breach of Right 4(1) of the Code as identified in this investigation. The written apology is to be sent to HDC within three weeks of the date of this report, for forwarding to Mrs B.

Information gathered

Dispensing processes at the pharmacy

9. At the time of events, the pharmacy dispensed medications using a combination of manual processes and automated technology. In 2018, the pharmacy introduced a sachet-packing robot (the robot), which packaged medicines into individual sachets assembled into rolls. Each sachet was intended to contain the prescribed medicines for a particular time of day ('breakfast' and 'bedtime') and was labelled accordingly. The pharmacy also utilised a VIZEN checking system, which photographed the contents of each sachet and generated a report highlighting sachets that may contain errors, for pharmacist review.

10. In early 2022, the pharmacy underwent a change in ownership and management. Following this transition, the owner/manager/pharmacist, Mr E, reviewed the dispensary processes and identified that aspects of the sachet-packing system were 'sub-optimal'. These included practices relating to how medicines were handled prior to packing and inconsistent annotation of scripts during the dispensing steps.

11. On 24 May 2022, Mrs B was prescribed several medications by her general practitioner, including paroxetine 20mg, with the prescription noting that generic substitution was permitted (meaning that the pharmacy could supply an equivalent funded brand instead of the specified brand). The prescription was subsequently provided to the pharmacy and entered into the dispensing system on 27 May 2022.

12. The dispensing process involved several stages: prescriptions were to be entered into the computer (Toniq) system, clinically checked by a pharmacist, dispensed via the robot (with pharmacist technician involvement), checked using the VIZEN system, and then subject to a final pharmacist accuracy check before being supplied to the consumer.

Dispensing error

13. On either Friday 27 May or Saturday 28 May 2022, one losartan 50mg tablet was incorrectly included in place of the paroxetine 20mg in five out of seven 'morning' sachets in Mrs B's weekly sachet roll for 2–8 June 2022.

14. The pharmacy provided HDC with a copy of Mrs B's prescription, which had a pharmacy stamp dated 27 May 2022. The 'enter[ed]' and 'disp[ensed] by' boxes were not completed, although the 'ch[e]ck by' box was signed. Ms C acknowledged that the signature was hers and said this indicated that she had completed the clinical check and confirmed that the prescription matched the information entered in the Toniq dispensary software for the sachet-packing machine.

15. In early June 2022, Mrs B took one incorrect dose and reportedly lost consciousness for four hours. She later noticed differences in the colour and shape of the tablets and returned to the pharmacy to report the issue. Mr A stated that the pharmacist advised the matter would be investigated and an update provided.

16. On 8 June 2022, pharmacist Ms D received a telephone call from Mrs B. Based on the information given by Mrs B, Ms D suspected a losartan dispensing error and advised Mrs B to stop taking the medication and return it. Upon inspection, Ms D confirmed the error, corrected the sachet roll, removed the incorrect tablets, apologised, and advised Mrs B to seek medical attention if unwell. An alert note was added to Mrs B's file. Ms D told HDC that she was not involved in the dispensing or checking of the sachet roll and had limited training in the robot and VIZEN system at the time.

17. Mr A expressed concern about the lack of follow-up communication from the pharmacy following the dispensing error. The pharmacy stated that it was unaware that further investigation was expected. Mr E reported that, when he later saw Mrs B, she indicated she was 'fine now',[5] and he therefore did not consider further action necessary.[6]

<u>Cause of the error</u>

18. The pharmacy was unable to determine how the dispensing error occurred. The pharmacy stated that it used an open bottle system for the sachet-packing robot in which medicines

[5] In response to the provisional decision, Mr A disputed that his mother was fine at the time. He submitted that this is her usual response, even when experiencing difficulties, and considered that the staff member had failed to appreciate her actual circumstances.

[6] Mr E stated that, as of August 2022, the pharmacy had dispensed 'a further [ten] lots of medication to [Mrs B] without any errors'.

were deblistered or stored in canisters/cassettes and selected by the machine during dispensing, with technician supervision and pharmacist checking. It said that incorrect tablets may have entered the dispensing process either through contamination of a cassette or during manual addition via a Special Tray System (STS).[7] However, it noted that contamination of the cassette was unlikely given the differing size and shape of losartan and paroxetine tablets.

19. The pharmacy stated that, when the error was first reported, the team checked and emptied the paroxetine cassette, confirming that it only contained paroxetine tablets and no losartan tablets. It stated that no other patients received losartan instead of paroxetine and therefore submitted that it was not a case of the cassette being filled with the wrong medicine. However, Ms C stated that a possible cause of the error was if paroxetine did not have a 'designated cassette' at the time (which can happen when a medicine is not commonly used in sachet packs or has recently undergone a brand change). She stated that, in such cases, the medication may have been added manually via an STS tray, requiring preparation by a technician and checking by a pharmacist.

Failure of pharmacist to detect the error during final check

20. On 28 May 2022, the VIZEN checking system generated a report that clearly identified discrepancies in several sachets, including the presence of incorrect tablets and missing medicines in Mrs B's prescription. However, the pharmacist responsible for the final accuracy stage failed to detect the error or correct the sachet roll prior to it being supplied to Mrs B.

21. There is uncertainty regarding both the timing of the final accuracy check and the extent of individual staff responsibility. The pharmacy attributed the final sign-off of the prescription to Ms C and considered that this indicated she had completed the final accuracy check. However, Ms C stated that her signature on the prescription related to the clinical check prior to the sachet roll being processed and that it did not indicate that she conducted the final check on the completed sachet roll. She did not recall whether she conducted the final check. The pharmacy was also unable to determine the exact date on which the final check occurred and could not identify which staff members completed the earlier stages of the dispensing process, due to incomplete annotation by staff. The available evidence does indicate that Ms C was working on 28 and 31 May 2022, being the two days on which the final check may have occurred.

Incident Notification Form – 12 August 2022

22. The dispensing error was not formally documented or reported at the time it was identified on 8 June 2022. On 12 August 2022, approximately two months later, the pharmacy completed a pharmacy Defence Association Incident Notification Form. It acknowledged that it 'did not document the incident near the time of occurrence and consequently, this was not reported to [the] pharmacy professional body in a timely manner'.

[7] A manually prepared tray used to add medicines to a sachet-packing robot when they cannot be dispensed from standard cassettes.

Internal review – 23 August 2022

23. On 23 August 2022, the pharmacy conducted an internal review of its sachet-packing processes and compliance with standard operating procedures (SOPs). The review identified several systemic issues, including:

a. The absence of SOPs specific to the sachet-packing robot.

b. Deficiencies in documentation and accountability, including the need to clearly annotate the person responsible at each stage of the process, which resulted in an inadequate audit trail and an inability to determine which staff members had entered, processed, or dispensed Mrs B's prescription.

c. The need for additional double checking at key stages of the process, including verifying medicines added to canisters and trays and checking entries into the system, with pharmacist involvement identified as necessary for these higher-risk steps.

d. The use of processes involving medicines removed from original packaging (such as deblistered stock and open containers), which increased the need for additional checking controls to reduce the risk of error.

e. Weaknesses in process and workflow, including the need for clear separation of dispensing stages, appropriate handling and tracking of sachet packs, and for critical tasks (such as clinical checking and review of VIZEN reports) to be undertaken with minimal interruption.

f. Deficiencies in staff training and capability, including the limited number of staff familiar with the sachet-packing system and the need for all dispensary staff to be fully trained to ensure consistent and safe practice.

24. Ms C advised that the change in ownership, high staff turnover, and implementation of new processes contributed to reduced consistency in procedures and an increased risk of dispensing errors. Ms D similarly advised that she had commenced employment in late April 2022 and had not yet been trained in the robot and VIZEN systems at the time she responded to Mrs B's complaint.

Responses to provisional opinion

Mr A

25. Mr A was given an opportunity to respond to the 'information gathered' section of the provisional opinion. He stated that better procedures and training were needed to prevent staff from operating dispensing machinery without appropriate training, as even a minor dispensing error could cause significant distress and potentially fatal consequences for vulnerable patients.

The pharmacy

26. The pharmacy was given an opportunity to respond to relevant sections of the provisional opinion.

27. The owner and manager of the pharmacy at the time of events, Mr E, stated that he was genuinely sorry that Mrs B had experienced adverse health outcomes as a result of the

medication error and agreed to the recommendation that he provide a written apology to Mrs B and her family.

28. However, Mr E disagreed that the dispensing error was caused by inadequate pharmacy processes, systems, and oversight. He noted that no similar errors had occurred before or after this incident and submitted that the error was a one-off failure to follow established procedures rather than evidence of a systemic deficiency. Further comments made by Mr E have been incorporated into this report where relevant.

29. The current owners of the pharmacy noted that there was a change of ownership in September 2024, more than two years after the events at issue, and that the dispensing error occurred under the previous ownership and management. They acknowledged the seriousness of the incident and emphasised that patient safety is their highest priority. They advised that they have since conducted a comprehensive review of dispensing and checking procedures and implemented a range of measures to strengthen safety and reduce the risk of similar errors occurring, including enhanced documentation and accountability processes, additional checking stages, strengthened pharmacist oversight, improved staff training, technology-assisted checking systems, and added safeguards for compliance packaging and robotic dispensing.

Ms C

30. Ms C was given an opportunity to respond to relevant sections of the provisional opinion and had no further comment to make.

Ms D

31. Ms D was given an opportunity to respond to relevant sections of the provisional opinion and did not provide a response.

Analysis

Opinion: The pharmacy – breach

32. Under Right 4(1) of the Code, providers are required to ensure that health services are provided with reasonable care and skill. This includes ensuring that dispensing and checking processes (including those involving automated compliance packing) are safe and reliable, adhered to, and supported by appropriate SOPs, training, and oversight. In my view, this case demonstrates systemic failings that, when considered cumulatively, amount to a departure from the expected standard of care.

33. First, Mrs B was dispensed an incorrect medication, with losartan 50mg supplied in place of paroxetine 20mg in five sachets. In response to the provisional decision, Mr E stated that losartan had its own cassette and therefore would not have been added manually. Consequently, he submitted that a manual handling error was not a possible cause.

34. However, Ms C stated that the absence of a designated cassette for paroxetine at the time may have introduced a point of error, as the medicine would have required manual addition via an STS tray. I note that, in 2019, the funded (generic) brand of paroxetine changed from Apo-Paroxetine to Loxamine, and that Mrs B's prescription permitted generic substitution. It is therefore possible that the similarity in the names *Loxamine* and *losartan* may have contributed to a selection error during manual handling.

35. In addition, I note the pharmacy's previous statements to HDC, which noted several points in the dispensing process that involved manual handling (and, therefore, opportunities for error).

36. In my view, these factors suggest that the dispensing error most likely arose during a manual stage of the dispensing process on approximately 27 May 2022, where medicines were added or handled outside of the standard cassette system.

37. The dispensing process requires accurate medicine selection and effective checking controls. I note that this error occurred within a compliance packaging system designed specifically to improve safety and reduce the risk of such errors. However, the pharmacy was unable to determine how or exactly when the error occurred, which in my view indicates deficiencies in its systems and processes at the time.

38. Second, I consider that the final checking process did not operate effectively. The pharmacy advised that the VIZEN system flagged discrepancies in several sachets. Despite this, the incorrect sachets were not detected and corrected prior to being provided to Mrs B. The purpose of the final accuracy check is to act as a critical safeguard against dispensing errors, particularly where automated systems are used. However, the pharmacy was again unable to confirm who performed the final check or when it occurred because of a lack of documentation and annotation.

39. Third, I am concerned about the broader systems within which this error occurred. At the time of events, the pharmacy had recently undergone a change in management and had identified that its processes for sachet packing were 'sub-optimal' prior to this dispensing error occurring. The subsequent internal review confirmed several deficiencies (as outlined at paragraph 23).

40. In addition, there was a lack of clarity regarding staff roles and responsibilities, with multiple staff, including new and casual employees, involved in the dispensing and sachet-packing process. This was compounded by gaps in staff familiarity and training in the relevant systems. For example, Ms D had not yet received training in the sachet-packing and VIZEN systems at the time she became involved in this matter. Although her involvement arose after the error had occurred, this context reflects deficiencies in the pharmacy's processes, training, and oversight at the time.

41. Finally, as acknowledged by the pharmacy, it failed to document and report the incident in a timely manner, with the incident not formally recorded until approximately two months after it was brought to its attention. In my view, timely documentation and internal review of dispensing errors are essential components of a safe dispensing system, as they enable prompt identification of risks and implementation of corrective actions. It would also have been reasonable, in keeping with the pharmacy's SOPs and a consumer-centred approach under the Code, to inform Mrs B of the outcome of its internal review to ensure appropriate follow-up.

42. I acknowledge Mr E's submission that the pharmacy had not experienced any similar incidents before or after this incident, and his view that the error arose from a one-off failure to follow established procedures rather than from a systems failure. However, having considered the

circumstances of this case as a whole, I do not consider that the error can be attributed solely to individual human error.

43. As outlined above, the pharmacy was unable to identify how the incorrect medication came to be dispensed and that its final checking processes failed to detect the error before the medication was supplied to Mrs B. In addition, the incident occurred in the context of identified deficiencies in the pharmacy's sachet-packing processes, staff training, role clarity, documentation, and oversight. Although the absence of similar reported incidents before or after this event is relevant, it does not in itself establish that the systems in place were adequate.

44. Accordingly, I find that the pharmacy failed to provide services to Mrs B with reasonable care and skill and, as such, breached Right 4(1) of the Code.

Opinion: Ms C – educational comment

45. As a registered pharmacist, Ms C was required to provide services in accordance with professional standards and to exercise reasonable care and skill, including ensuring that appropriate checks were undertaken prior to medicines being supplied to a consumer.

46. The evidence establishes that Ms C signed the prescription in the 'checked by' section on 27 May 2022. She advised that this signature reflects that she undertook the clinical check and confirmed that the prescription was accurately entered into the Toniq dispensing system before being sent to the robot for dispensing.

47. There is conflicting evidence as to whether Ms C also completed the final accuracy check of the sachet roll. The pharmacy attributed the final check to her based on the signed prescription; however, Ms C explained that the final check would ordinarily be recorded separately (for example, by signing the sachet roll), and her signature on the prescription did not indicate that she undertook this step. She further advised that she has no recollection of conducting the final check of Mrs B's sachet roll.

48. In the absence of clear documentation or a reliable audit trail, I am unable to make a finding of fact as to whether Ms C completed the final accuracy check and am therefore unable to attribute responsibility to her for the failure to identify the error at that stage.

49. However, I remind Ms C of the importance of clear documentation, adherence to checking processes, and ensuring that professional standards are maintained, particularly during periods of organisational change.

Opinion: Ms D – educational comment

50. I am satisfied that Ms D's actions on becoming aware of the dispensing error on 8 June 2022 were appropriate. As noted above, she took reasonable steps to prevent further harm, rectify the dispensing error, and ensure Mrs B's wellbeing.

51. I am mindful that, at the time of events, Ms D was relatively new to the pharmacy and had not yet been trained in the relevant processes and the VIZEN system. Her involvement occurred after the dispensing error had already taken place, and her actions were directed toward identifying and correcting the error and supporting Mrs B.

52. However, I note that there is no evidence that Ms D contacted the prescriber following confirmation that Mrs B had ingested an incorrect medication. I take the opportunity to highlight that relevant professional standards and the pharmacy's own SOPs indicate that prescribers should be notified in such circumstances. Although Ms D advised the patient to seek medical attention, direct notification to the prescriber would have been the more appropriate course of action.

53. I also note that, although Ms D recorded details of the incident in the patient's file and escalated the matter within the pharmacy, no formal incident report was completed at the time. I highlight that, although responsibility for incident reporting did not rest solely with Ms D, timely documentation is an important part of managing dispensing errors.

Conclusion

54. In summary, Mrs B was provided with incorrectly dispensed medication due to failures in the pharmacy's dispensing and checking processes. Although the exact cause and responsibility could not be determined, the error was not identified despite discrepancies being flagged by the VIZEN system. These failures occurred in the context of inadequate documentation, training, and oversight, for which the pharmacy is ultimately responsible and I therefore find it breached Right 4(1) of the Code. I also make educational comments about pharmacists Ms C and Ms D.

Distribution

55. A copy of the sections of this report that relate to Ms C and Ms D will be sent to the Pharmacy Council of New Zealand.

56. A copy of this report with details identifying the parties removed will be sent to the Ministry of Health (Medicines Control) and placed on the HDC website, www.hdc.org.nz, for educational purposes.

Dr Vanessa Caldwell
Deputy Health and Disability Commissioner