Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

A Decision by the Deputy Health and Disability Commissioner

(Case 22HDC01773)

Executive summary

1. This report concerns a pharmacist's failure to dispense the correct medication and appropriately check the dispensed medication against the prescription before providing it to the consumer. The report also emphasises the importance of pharmacies having updated standard operating procedures (SOPs) with clear processes for dispensing and checking medication, including when there is only one pharmacist on site.

Findings

2. The pharmacist, Ms B, accepted full responsibility for failing to check that the correct medication had been dispensed. The Deputy Commissioner considered this to be a breach of the pharmacist's professional standards, as set out by the Pharmacy Council of New Zealand|Te Pou Whakamana Kaimatū o Aotearoa (the Pharmacy Council). Accordingly, the Deputy Commissioner found the pharmacist in breach of Right 4(2) of the Code.

3. The Deputy Commissioner did not find a second pharmacist, Mr C, in breach of the Code.

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

4. The Deputy Commissioner criticised the pharmacy for failing to ensure that relevant SOPs were kept up to date and for the adequacy of the Dispensing and Checking SOPs.

Recommendations

5. The Deputy Commissioner recommended that the pharmacist, Ms B, and the pharmacy each provide an apology to the consumer.

6. The Deputy Commissioner recommended that in addition, the pharmacy review and rewrite all relevant SOPs and conduct an audit of compliance.

Complaint and investigation

7. This report discusses the care provided to Mrs A by Ms B and Mr C at the pharmacy. The complaint concerns a dispensing error in which Salazopyrin[1] was dispensed incorrectly instead of Pentasa.[2]

8. The following issues were identified for investigation:

- *Whether Ms B provided Mrs A with an appropriate standard of care between May 2022 and June 2022 (inclusive).*
- *Whether Mr C provided Mrs A with an appropriate standard of care between May 2022 and June 2022 (inclusive).*

9. This is the opinion of Deputy Commissioner Dr Vanessa Caldwell and is made in accordance with the power delegated to her by the Commissioner.

10. The parties directly involved in the investigation were:

Mrs A	Consumer/complainant
Ms B	Pharmacist/pharmacy owner
Mr C	Pharmacist/pharmacy owner/manager

11. Further information was received from the medical centre of Mrs A's general practitioner (GP).

12. I thank Mrs A for taking the time to bring her concerns to the Health and Disability Commissioner. I also thank Ms B and Mr C for their timely responses, which have helped with the investigation process.

[1] Salazopyrin is the brand name for sulfazalazine (the active ingredient is sulfasalazine). It is an anti-inflammatory agent and suppresses the immune system. See: https://www.medsafe.govt.nz/consumers/cmi/s/salazopyrin.pdf

[2] Pentasa is the brand name for mesalazine (the active ingredient in Pentasa is mesalazine). It is an anti-inflammatory agent (used to help to reduce inflammation in the bowel). See: https://www.medsafe.govt.nz/consumers/cmi/p/pentasa-tab.pdf

Background

13. Mrs A was receiving care from her GP for gastrointestinal issues. Mrs A told HDC that in March 2022, her GP sent the pharmacy a prescription for Pentasa.[3] On 25 May 2022, a dispensing error occurred at the pharmacy, where Salazopyrin tablets were dispensed incorrectly instead of Pentasa tablets (both medications are used to treat and manage inflammatory bowel conditions but are different in appearance).

14. Mrs A told HDC that between late May and early June 2022, she opened her prescription package at home and found Salazopyrin tablets. She immediately started to take the tablets as prescribed ('two tablets, three times a day' — totalling six tablets daily), as she believed that they were a substitute for her usual medication.[4] Mrs A took the incorrect medication for approximately seven weeks. She stated that after four weeks of taking the Salazopyrin tablets, she began to feel 'very unwell' and experienced very bad headaches, nausea, and a loss of appetite. Mrs A recalled her son telling her that she looked very unwell during this time.

15. On 11 July 2022, Mrs A received another repeat prescription from the pharmacy (this time containing the correct medication). Mrs A immediately started to take the Pentasa tablets and felt well within a week.

16. On 20 July 2022, Mrs A took the incorrect medication to the pharmacy for an explanation. Pharmacist Mr C confirmed to Mrs A that a dispensing error had occurred (she should not have received Salazopyrin). Mr C verbally apologised and corrected the prescription. Ms B then rang Mrs A and apologised, enquired about Mrs A's wellbeing (including whether she had experienced any side effects) and stated that she would follow up with Mrs A's GP.

Subsequent events

17. On 20 July 2022, a Pharmacy Defence Association Incident Notification Form was completed, noting that pharmacist Ms B had incorrectly dispensed Salazopyrin (500mg) instead of Pentasa (500mg) on 25 May 2022. The 'completed form' provided limited information about the dispensing error:[5]

a) In the section 'Reflect on the potential cause(s) of the incident', Ms B wrote: '[D]ouble check the brand name even though it is quite busy. 2 people were down, as staff were sick and with sick kid.'

b) In the section 'What action(s) have been taken to reduce the likelihood of similar incident occurring?', Ms B wrote: 'Taking time and coming back to check if dispensing by a pharmacist.'

c) The section 'Reflect on the potential cause(s) of the incident' was later updated to state:

[3] Pentasa 500mg Prolonged Release Tab, 3 months' supply.
[4] Both medications (Pentasa and Salazopyrin) are used to treat and manage inflammatory bowel conditions. However, the tablets are a different shape and colour.
[5] The form states to '[f]ill out ALL boxes in as much detail as possible'. However, it also notes: 'This report is a living document. It should be edited as new information becomes available.'

> '[F]inal check carried out by the same pharmacist, who did the dispensing. [M]issed on picking up my own mistake.
>
> [S]hould do double-check the brand name even though it is quite busy. [S]hould have taken it slow and checked it thoroughly. 2 people were down, as staff were sick and with sick kid. [W]e did 421 rxs on the day the mistake happened.'

18. On 21 July 2022, this Office received a complaint from Mrs A about the dispensing error. Mrs A stated that she was 'appalled' that this happened and believed she could have ended up in the hospital. Mrs A stated that in making this complaint, she wants something to be done to prevent this from happening to others in the future.

19. On 25 July 2022, Ms B telephoned Mrs A's medical centre to inform it of the dispensing error. Ms B telephoned the medical centre again on 4 August 2022 to report that Mrs A had experienced gum bleeding, nausea, and a headache, and to request a follow-up blood test. Ms B told HDC that during this conversation, the medical centre said that it would follow up with Mrs A 'in the coming week'. Mrs A had a blood test on 8 August 2022, which indicated a 'stable' (not abnormal) result.

20. On 12 August 2022, Ms B telephoned the medical centre to enquire about Mrs A's blood test results. She was advised that Mrs A's results were normal. In her responses to this Office, Ms B said that subsequently she telephoned Mrs A to apologise again, explained changes the pharmacy intended to make to prevent this from occurring again, and offered to cover any costs associated with the blood test. Mrs A told HDC that she did not receive the results of her blood test,[6] but she noted that the pharmacy did call her to 'see if [she] was OK'.

Provider responses

21. In their responses to this Office, Mr C and Ms B cited busyness, staffing issues,[7] and the COVID-19 pandemic as factors that contributed to the dispensing error. Mr C and Ms B stated that on the day of the dispensing error, they had a high volume of walk-in clients and completed 421 scripts.

Pharmacy's Standard Operating Procedures

22. As new owners of the pharmacy, Mr C and Ms B 'inherited' various SOPs created by the previous owner. In particular, the incident reporting procedure was originally written in 2009, and the complaints procedure in 1999. Despite being reviewed throughout the years (as evidenced by handwritten annotations), the SOPs had not been updated by Mr C as the pharmacy manager. As a result, updated practices (such as the double-checking process) were not explicitly referenced in the SOPs.

[6] At the time, the medical centre's policy was to communicate results to a patient only if they were abnormal.
[7] The pharmacy stated that staff were 'constantly away' on sick leave during this period. On the day of the dispensing error, the pharmacy had four staff working (two pharmacists, a trainee technician, and an intern pharmacist), and two staff on leave (the dispensing technician and shop assistant).

Double-checking process

23. Mr C and Ms B told HDC that a key part of their process for dispensing and checking prescriptions involved different staff working on an individual step at a time. This process was in place to ensure that a prescription was checked by two (different) staff members. They stated:

> 'The process we take to dispense and check is by having different staff working on an individual step at a time. For example, if a [pharmacy] tech[nician] processes a script and dispenses, pharmacists just tend to check the medication(s) and get bagged up for collection.'

24. However, when the pharmacy became busy and/or there were staff shortages, staff were unable to follow this double-checking process. Mr C and Ms B accepted that the double-checking process was not followed in this case, as Mrs A's prescription was both dispensed and checked by the same staff member (Ms B). They told HDC:

> 'We have been struggling since we took ownership of this rural pharmacy [during the COVID-19 pandemic]. We struggled with staff retention and just general pressure with prescriptions and pharmacy services. It hit us emotionally and physically then …
>
> However, we take full responsibility for making this mistake and not documenting every step of the incident after. We will take this as a lesson and improve on this further.'

25. In their responses to this Office, Mr C and Ms B did not provide any evidence of formal training or documentation of this double-checking process. The process was not set out in a policy or SOP at the time of the events. There was also no evidence of guidance to staff on what to do in situations where a second pharmacist was not available to check medication.

Proposal for an agreed breach

26. On 2 April 2024, I contacted Mr C and Ms B and proposed the option of agreeing to a breach of Right 4(2) of the Code of Health and Disability Services Consumers' Rights (the Code).[8] This option was proposed on the basis of their responses during the preliminary assessment process (including their willingness to achieve resolution and make changes), the passage of time since the incident (speedy resolution) and the potential to be more restorative (the pharmacy is Mrs A's long-term and current pharmacist).

27. On 5 April 2024, Mr C and Ms B jointly responded to HDC's proposal, stating that they wished to proceed with an agreed breach finding and that they did not have any further questions. They commented:

> 'We serve the community with the same mindset everyday as the right states, and unfortunately this incident happened unintentionally. We understand the nature of this

[8] Right 4(2) of the Code states that 'every consumer has the right to have services provided that comply with legal, professional, ethical, and other relevant standards'.

> complaint. We are responding rather promptly as this has been a stressful event for us. We wish to resolve this with you as effectively and swift[ly] as possible.'

28. On 17 April 2024, Mr C and Ms B jointly responded to HDC's request for further information, which further detailed changes made since the dispensing error (outlined below). Regarding the double-checking process, Mr C and Ms B stated:

> '[The double-checking process] policy now exists. We apologise for adding this late, however, we guarantee this practice was in place after the incident and is being considered much more than before. I am attaching our updated SOP to reflect this.'

29. Given the acceptance of HDC's proposal, this report has focused on reviewing the adequacy of the remedial work carried out since the dispensing error.

Further information provided by Mrs A

30. Mrs A was given the opportunity to comment on the pharmacy's initial response provided to this Office in 2022. Mrs A said that she was not satisfied with the pharmacy's suggestion that it was 'too busy' on the day of the dispensing error. She stated:

> 'My health was at risk and they should have been more careful regardless of how many were working that day and how busy they were. No excuse is good enough as far as I am concerned.'

31. I also note that Mrs A continues to receive her prescription from the pharmacy and has not experienced any further issues since the events of May 2022.

Responses to provisional opinion

32. Mrs A was provided with the opportunity to comment on the 'information gathered' section of the provisional opinion. Mrs A told HDC that it appears that the pharmacy has taken action to eliminate further mistakes. In addition, Mrs A stated that she can appreciate that the pharmacy gets very busy at times, but she hopes that an incident such as this will not occur again.

33. Ms B and Mr C told HDC that they accept the provisional opinion 'fully' and have no further comments on the matter. They stated that the pharmacy will now turn to working on the recommendations outlined, namely improving its SOPs and policies.

Relevant standards

34. The Pharmacy Council of New Zealand Competence Standards for the Pharmacy Profession (2015) (the Pharmacy Competence Standards) state:

> 'O3: Supply and administration of medicines
>
> Competency O3.2 Dispensing Medicines
>
> O3.2.1 Maintains a logical, safe and disciplined dispensing procedure.

> O3.2.2. Monitors the dispensing process for potential errors and acts promptly to mitigate them.
>
> …
>
> O3.2.5. Accurately records details of medications incidents and actions taken, including clinical and professional interventions, to minimise their impact and prevent recurrence.'

35. The Pharmacy Council issued a Workplace Pressures in Pharmacy guideline in August 2012, which includes the following points under the heading of 'Workplace Pressure':

> 'Ensure sole charge pharmacist take a step away from the prescription at the final check stage so that they come back with fresh eyes.
>
> …
>
> Re-deploy staff, for example have technicians do technical aspects of the dispensing while pharmacists attend to clinical aspects (clinical check, final check, counselling)
>
> …
>
> Accept that unexpected absentee staff will result in busy periods — some services may not be completed on time for example deliveries/blister packing may need to be completed out of hours of business.'

Opinion: Ms B — breach

36. I acknowledge the effect of this event on Mrs A, and her desire to prevent this from happening to others in the future.

37. As a registered pharmacist, Ms B had a professional responsibility to ensure that the health services she provided complied with legal, professional, ethical, and other relevant standards.[9] I acknowledge that Ms B has accepted full responsibility for making the dispensing error and not checking the prescription adequately. I commend Ms B's willingness to accept responsibility, and the changes she has made to her practice since the event (including reducing her hours of work).

38. The Pharmacy Competence Standards state that a pharmacist must maintain a logical, safe, and disciplined dispensing procedure. In this case, Ms B did not comply with this Standard, as she dispensed Salazopyrin instead of Pentasa, and failed to double check that the correct medication had been dispensed.

39. The Pharmacy Competence Standards also state that a pharmacist should monitor the dispensing process for potential errors and act promptly to mitigate them. In this case, Ms B did not comply with this Standard, as she was not aware of her mistake for approximately

[9] Right 4(2) of the Code.

seven weeks, when she was alerted to the error by Mrs A. As a result, Mrs A experienced adverse side effects from taking the incorrect medication for approximately four weeks.

40. I also note that the pharmacy's Dispensing and Checking SOPs did not clearly set out the 'double checking process' or provide guidance to staff on what to do in situations where a second pharmacist was not available to check medication. I have made further comments about this in my opinion about the pharmacy.

41. Accordingly, I find Ms B in breach of Right 4(2) of the Code for failing to provide services that complied with legal, professional, ethical, and other relevant standards.

Opinion: Mr C — no breach

42. Alongside being the manager and co-owner of the pharmacy, Mr C is also a registered pharmacist. Based on the information provided to HDC during this investigation, Mr C was not involved in the dispensing or checking of Mrs A's prescription. Therefore, Mr C's involvement with this incident began on 20 July 2022, when Mrs A returned to the pharmacy for an explanation. In my view, Mr C's subsequent actions after becoming aware of the dispensing error (including confirming to Mrs A that a dispensing error had occurred, verbally apologising, and correcting the prescription) were adequate.

43. In addition, Ms B acknowledged that she both dispensed and checked Mrs A's prescription, and she has accepted full responsibility for the dispensing error.

44. Accordingly, I find that Mr C did not breach the Code.

Opinion: Pharmacy — adverse comment

45. I commend Mr C's readiness (as manager and co-owner) to make changes to the pharmacy's practice to prevent such an error from occurring again. Nevertheless, the pharmacy had an obligation to ensure that it had adequate policies and SOPs in place to facilitate safe dispensing and checking. While Ms B has accepted full responsibility for the dispensing error, the pharmacy did not keep relevant SOPs up to date.

46. In my view, having up-to-date SOPs ensures that pharmacists have strategies in place for risk management and harm minimisation. It also eliminates the need for interpretation by employees and ensures that procedures are being followed as intended. I note that the Pharmacy Council of New Zealand has provided guidance on writing SOPs.[10] Key points include:

a) The dispensing process should be clearly defined in the SOP, and it should specify which activities must be carried out personally by a pharmacist (including the clinical check),

[10] Pharmacy Council of New Zealand (2017). Writing Standard Operating Procedures (SOPs). See: https://pharmacycouncil.org.nz/wp-content/uploads/2021/03/Writing-SOPs-updated-Dec2017-1.pdf (last accessed 7 May 2024).

which activities can be delegated to identified competent support staff, and how checks for accuracy are to be carried out.

b) It is good practice for SOPs to incorporate an audit trail so that the pharmacist can determine who is responsible for each aspect of the process (ie, for each item on the prescription, and the dispenser and checking pharmacist to be identified clearly).

c) All SOPs should be kept up to date, be relevant at all times, and be reviewed regularly (to allow for changes in practice or circumstances, such as legislative changes or changes of staff). In the absence of any obvious changes, reviews should be undertaken at least once every two years.

d) When SOPs are first drafted, or when new members of staff are appointed, it is good practice to ask staff to sign and say that they have read and understood them. As well as clarifying staff roles, this can offer an opportunity for staff training and development. Pharmacists should ensure that any changes to SOPs are brought to the attention of relevant staff.

47. Having considered the events that occurred, it is my opinion that the lack of clear guidance in the pharmacy's SOP around the double-checking process and workforce pressures contributed to the dispensing error. As discussed above, clear guidance is essential for situations (such as this case) where a pharmacist may be required to both dispense and check prescriptions, due to factors such as workload or staffing shortages.

48. Accordingly, I am critical of the adequacy of the pharmacy's Dispensing and Checking SOPs, and of the pharmacy for not ensuring that relevant SOPs were kept updated. I have made recommendations to address my concerns.

Changes made since events

49. Ms B and Mr C have made the following changes since the dispensing error.

Pharmacists to stay in one role where possible

50. Mr C updated the pharmacy's checking policy on 17 April 2024. Pharmacists are now encouraged to work solely on the checking stage, where possible (unless the pharmacy becomes very busy). The updated SOP includes the following statement:

> 'Checking Procedures & Policies:
>
> To minimize chances of making dispensing/checking errors, pharmacist(s) are to check the repeats and prescriptions only, unless under exceptional circumstances. If a pharmacist is involved in either processing/dispensing a script/repeat at any busy times, he/she is to come back to it and then check it with a fresh mind.
>
> Different roles are to be assigned to different individuals in the dispensary at a time to have a safe and effective outcome for the patients.'

51. However, Mr C noted that because it is a small pharmacy, pharmacists are being forced to check, process, and dispense the same prescription (around 10% of the time). In such cases, pharmacists are now required to come back to check the prescription at a later time (not immediately after dispensing).

Training

52. Mr C told HDC that all staff were informed of the dispensing error at the time of the incident. Given staff turnover (since 2022) and the ongoing HDC investigation, subsequent staff training occurred on 17 April 2024, where the following was highlighted:

a) What occurred during the dispensing error on 25 May 2022.

b) The difference between Salazopyrin, Pentasa, and Asacol.[11]

c) The importance of checking the brand name and separating medications, particularly when medications have similar names.

Staffing and workflow

53. Mr C told HDC that since the incident, staffing and workflow have improved, resulting in the pharmacy being able to manage pressure better. The pharmacy has also increased the wait time for processing prescriptions (from 5–10 minutes to 10–15 minutes) and implemented the regular use of the near-miss book (where every mistake is noted and reviewed each month).

54. Mr C told HDC that since the incident, the pharmacy has purchased two automation robots (worth $130,000 +) to reduce pressure.[12] Mr C commented that this has 'helped to save a tremendous amount of time [and] effort'. He stated: '[T]he automation does about 0.5+ of a person's workload at very least. It has been a great investment considering the flow of operations and our mental health.' However, Mr C said that 'it is a busy Pharmacy', and they intend to hire an extra pharmacist in the future (when they are in a better financial position). At present, the pharmacy employs 1.25 pharmacists (a reduction from two pharmacists previously), three trainee technicians, one shop assistant, and one casual shop assistant. Since the incident, Ms B has reduced her work hours 'significantly'. Mr C stated:

> '[Ms B] was working full time until the end of 2022, then she started to reduce her hours to about 20 hours a week. From [2024], she is now working minimally behind the scenes and is working only if she is needed.'

Follow-up with consumers

55. Mr C and Ms B stated that when mistakes occur, it is their 'top priority' to follow up and apologise to the consumer. They stated that since the incident, the pharmacy's practice is to leave a note on the computer to prompt staff processing the prescription, and to print a

[11] Another similar medication used to treat and prevent inflammatory intestinal diseases.

[12] Mr C told HDC that the robot stores approximately 30 of the most commonly dispensed medications and counts the medications as soon as they are processed. It also makes blister packs by storing, counting, and dispensing over 100 medications into a sachet roll.

sundry label to warn the dispenser and the checker to double check (noting that the consumer had a previous incident).

Recommendations

56. I acknowledge Ms B and Mr C's willingness to improve their practice, as well as the offer to cover any costs associated with the dispensing error and the organisation of Mrs A's blood test. I note that Mr C has made some changes to the pharmacy's SOPs, and the adequacy of the development and implementation of the above recommendations will be reviewed in due course. At present, I am satisfied that changes (both current and ongoing) will respond to and mitigate such an event occurring again.

57. In accordance with the proposed recommendation in my provisional opinion, Ms B has provided a written apology to Mrs A for the failures identified in this report.

58. In accordance with the proposed recommendation in my provisional opinion, Mr C (as the manager of the pharmacy) has provided a written apology to Mrs A for the deficiencies found in this report.

59. I recommend that Mr C (as the manager of the pharmacy):

a) Review all relevant SOPs to ensure that they are up to date and follow best practice (as outlined by the Pharmacy Council of New Zealand). This includes (but is not limited to) dispensing and checking prescriptions, dispensing errors, incident reporting, and the complaints process. A summary of the SOPs that have been reviewed (including which SOPs are to be updated) is to be sent to HDC within three months of the date of this report.

b) Rewrite (into one clear document, incorporating any handwritten annotations), update, and implement new policies/documented processes for all relevant SOPs. A copy of the updated policies/processes is to be sent to HDC within three months of the date of this report.

c) Conduct an evaluation of the effectiveness of these new policies/documented processes three months following their introduction via an audit of compliance and provide HDC with a report, including any corrective actions to be implemented.

Follow-up actions

60. A copy of this report with details identifying the parties removed will be sent to the Pharmacy Council of New Zealand|Te Pou Whakamana Kaimatū o Aotearoa, and it will be advised of Ms B's name in the covering correspondence.

61. A copy of this report with details identifying the parties removed will be sent to Medsafe, Medicines Control, and the New Zealand Pharmacovigilance Centre and placed on the Health and Disability Commissioner website, www.hdc.org.nz, for educational purposes.