Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

A Decision by the Deputy Health and Disability Commissioner

(Case 22HDC01295)

Introduction

1. This report is the opinion of Dr Vanessa Caldwell, Deputy Health and Disability Commissioner, and is made in accordance with the power delegated to her by the Commissioner.

2. The report discusses the care provided to Mrs A by Mr B at a pharmacy on 27 May 2022 when Mrs A was dispensed incorrect medication.

3. The following issues were identified for investigation:

- *Whether Mr B provided Mrs A with an appropriate standard of care on 27 May 2022.*
- *Whether the pharmacy provided Mrs A with an appropriate standard of care on 27 May 2022.*

4. The parties directly involved in the investigation were:

Mrs A	Consumer/complainant
Mr B	Pharmacist
Pharmacy	

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

5. Further information was received from Mr C, the owner and director of the pharmacy and Ms D, a pharmacy technician at the pharmacy. Ms E (a pharmacist at the pharmacy, and the previous owner of the pharmacy) is also mentioned in the report.

Background — initial complaint

6. On 27 May 2022 Mrs A visited the pharmacy to collect her prescription for Provera[1] and clomiphene[2] (as prescribed by a doctor at a fertility clinic). Clomiphene was prescribed to be taken starting on 'day 3 of [Mrs A's menstrual] cycle'.

7. Mr B was the pharmacist on duty who processed Mrs A's medication, with the help of Ms D, the pharmacy technician who dispensed the medication. Mrs A collected her medication from Mr B, but when she returned home that day, she noticed that she had received clomipramine[3] instead of clomiphene. Mrs A called the fertility clinic, who confirmed that Mrs A had received the wrong medication.

8. Mrs A returned to the pharmacy the next day (28 May 2022) and raised the error with Ms E, who acknowledged and apologised for the error, directed Mrs A to a different pharmacy to receive the correct medication (as the pharmacy had insufficient clomiphene in stock), and processed a refund. Mrs A did not consume any of the prescribed clomipramine.

Information gathered during investigation

Standard dispensing process

9. The standard process for dispensing medications at the pharmacy at the time of the events is set out in the pharmacy's Standard Operating Procedures[4] (SOPs) (see Appendix A). Of particular note:

- When the pharmacist enters prescription details into the computer, an accuracy and clinical check should be carried out before the medication label is prepared or dispensing occurs. This includes checking the dosages, quantities, and clinical appropriateness of any medication. Any changes or differences should be investigated and confirmed with the patient and/or prescriber.[5]
- When dispensing medicines, the name, brand, strength, and formulation should be checked against the prescription, as opposed to the label. Labels should then be double checked against the original prescription before attaching to the container.[6]
- At the final accuracy check stage, the pharmacist should check the label and dispensed medicine against the original prescription and the stock supply used to dispense the

[1] Typically used to treat endometriosis, lack of menstrual periods, abnormal bleeding from the uterus, and certain cancers, and as hormone replacement therapy.
[2] Typically used to treat infertility by stimulating ovulation.
[3] Class of antidepressant used in the treatment of depression, OCD, phobias, sleep disorders, and chronic pain.
[4] The SOPs provided are marked as being issued between 2013 and 2015 and reviewed on 20 October 2020.
[5] Dispensing 2 of the SOPs.
[6] Dispensing 3 of the SOPs.

medicine, noting the prescriber, instructions for use, and formulation. Self-checking is not recommended, but if self-checking cannot be avoided, the 'physical' and 'mental' activities should be separated by another task.[7]

- When handing the medication to the patient, pharmacists should use 'check-back' questions to ensure that the patient understands the purpose and reasons for use for each medicine, and any changes, such as altered formulation.[8]
- In the case of a dispensing error detected and reported after the medication has left the pharmacy, the pharmacist should seek to correct the error immediately, replace the incorrect item, and apologise to the patient. An Incident Form should be filled in and the Pharmacy Defence Association should be contacted.[9]

Dispensing error (27 May 2022)

10. Mr B and Ms D were the staff directly involved in dispensing Mrs A's prescription on 27 May 2022. Mr B qualified as a registered pharmacist in 2021 and began working as a full-time registered pharmacist at the pharmacy. Ms D had several years' experience as a pharmacy technician and qualified as a pharmacy accuracy check technician (PACT) in 2018. Ms D began working at the pharmacy in 2020 and was working in the role of pharmacy technician at the time Mrs A's prescription was dispensed. Ms E was the other pharmacist present at the pharmacy on both 27 and 28 May 2022.

11. Mrs A's prescription was sent by the fertility clinic and received by the pharmacy at 11.25am on 27 May 2022. The prescription requested 10 tablets of Provera 10mg, 1 tablet to be taken once daily, and 10 tablets of clomiphene 50mg, 1 tablet to be taken daily for 5 days, starting on day 3 of Mrs A's menstrual cycle.

12. Mr B told HDC that he processed the Provera tablets correctly, but misread clomiphene for clomipramine, and did not pick up on the error due to insufficient clinical and accuracy checking.[10] Mr B adjusted the dosage instructions and annotated a change in the quantity of the tablets to be dispensed from 10 clomiphene tablets to 20 clomipramine tablets (as clomipramine came in only 25mg tablets, and the prescription required a 50mg dose) without a thorough clinical check of the medication in context. Mr B acknowledged to HDC that it would be unlikely for the fertility clinic to prescribe clomipramine, and that on reflection, the short course of the prescription would be 'unusual instructions' for clomipramine.

13. The error was 'carried forward' at the dispensing step by Ms D. Ms D told HDC that she noticed that the pharmacy label for clomipramine was different to the prescription, but incorrectly assumed that clomipramine was a new brand name for clomiphene, as she believed there had been a brand change some time previously. Ms D said that her error was

[7] Dispensing 4 of the SOPs.
[8] Dispensing 5 of the SOPs.
[9] 'Dispensing errors' section of the pharmacy's Standard Operating Procedures at the time of events.
[10] On reflection, Mr B accepts that certain contextual signs were ignored, such as the fact that the prescription had come from a fertility clinic, so it was highly unlikely that the prescription would be for antidepressants, and that the 'short course each month' instructions were unusual instructions for clomipramine.

in part because she read from the label, as opposed to the prescription, when selecting the medication from the shelf.

14. A final accuracy check was carried out by Mr B at around 5.15pm on 27 May 2022 when Mrs A came to collect her medications. Mr B told HDC that he self-checked the medication as there were only two pharmacists present in the pharmacy at the time (Mr B and Ms E), and Ms E was 'unavailable'.

15. Mr B told HDC that although the 'mental' and 'physical' activities of the prescription were separated (by Ms D carrying out the dispensing of the medication), he accepts that there may have been an element of confirmation bias in his final check, as he had processed the prescription earlier that day, and he also felt pressured not to keep Mrs A waiting.

Subsequent events following dispensing error

16. The pharmacy held a dispensary staff meeting on 30 May 2022 (at which both Mr B and Ms D were present) to discuss the events surrounding the dispensing error and implement preventative measures. These are set out below in the 'Changes made' section of this report.

17. An Incident Notification Form was also completed and submitted to the Pharmacy Defence Association on 30 May 2022.

18. The pharmacy provided HDC with a copy of an apology letter dated 17 June 2022 that Mr B told HDC he sent to Mrs A via post. However, Mrs A told HDC that she did not receive the letter, and she had 'been at the same address for 3 nearly 4 years'.

19. Mr B told HDC that he is 'truly sorry' for the error, and both Mr B and the pharmacy were surprised and sorry that Mrs A did not receive his apology letter.

Contributing/mitigating factors

20. Of note, Mr B received his pharmacy qualification in 2021, which is when he first began working as a registered pharmacist at the pharmacy. The dispensing error occurred on 27 May 2022, five months into full-time work as a registered pharmacist.

21. Mr B told HDC that on the day of the event there were three pharmacists rostered throughout the day, and pharmacy roles are rotated halfway through the day so that the 'workload/mental load was spread, and that self-checking could be avoided'. He said that during the day, usually another pharmacist would be available to check prescriptions he had been involved with, but this could be difficult in the last half hour before closing if the pharmacy was busy.

Standard Operating Procedures (SOPs)

22. The pharmacy provided HDC with the relevant Dispensing SOPs in place at the time of the dispensing error (see Appendix A). The pharmacy stated that there was no specific reference to 'look-alike, sound-alike' (LASA) medications in the Dispensing 2 SOP, as the final checking procedure is designed to identify dispensing errors regardless of whether or not the medication is a LASA medication. However, the Dispensing 2 SOP was revised in May 2022,

for an 'additional layer of protection'.[11] The pharmacy also began a complete revision of its SOPs in October 2023, aimed to be completed by February 2024.

Other relevant standards

23. The Pharmacy Council of New Zealand's Competence Standards for the Pharmacy Profession (2015) provides that a pharmacist '[m]aintains a logical, safe and disciplined dispensing procedure', and 'monitors the dispensing process for potential errors and acts promptly to mitigate them'.[12]

Responses to provisional opinion

Pharmacy

24. The pharmacy was given the opportunity to respond to the relevant sections of the provisional opinion. The pharmacy told HDC that it wished to reiterate its apologies for what happened, and that 'significant' changes have occurred in light of this incident and resulting investigation.

25. Mr C told HDC that it is his belief that the SOPs were kept up to date by the managing director at the time, but he accepts that the dates on the versions provided to HDC do not indicate this. The owner of the pharmacy also told HDC that in 2023 the pharmacy noticed that its SOP reviews and updates may not have been saved as expected on the online platform used to store its SOPs. The pharmacy confirmed that the fault was identified, the platform was disestablished, and a new SOP storage system is in place. The pharmacy confirmed that a new system is in place, and that all the pharmacy's SOPs have been revised.

26. The pharmacy confirmed that Ms D had the opportunity to respond to the relevant sections of the provisional opinion and had no comment to make.

Mr B

27. Mr B was given the opportunity to respond to the relevant sections of the provisional opinion. He confirmed that he had no further comments to make in response.

Mrs A

28. Mrs A was provided with the opportunity to comment on the 'information gathered' section of the provisional opinion and had no comments to make.

Opinion: Mr B — breach

29. As a registered pharmacist, Mr B is responsible for ensuring that he provides services of an appropriate standard, including compliance with the professional standards set by the Pharmacy Council of New Zealand (PCNZ) and with the pharmacy's SOPs.

[11] See Appendix B.
[12] Competency 03.2 Dispense Medicines. See: https://pharmacycouncil.org.nz/wp-content/uploads/2021/03/CompStds2015Web-1.pdf.

30. In a previous dispensing error case, HDC noted:[13]

> 'It is a fundamental patient safety and quality assurance step in the dispensing process to adequately check the medication being dispensed against the prescription for accuracy. This involves checking that the correct medicine, dose, form, strength, and quantity is being dispensed …'

31. At several points throughout the processing and dispensing process Mr B did not utilise the safeguards set by the pharmacy's SOPs:

a) Mr B did not carry out a complete clinical check on the prescription in accordance with the Dispensing 2 SOP. He told HDC that he did not consider the prescription in the context of the prescriber (the fertility clinic) and the dosage instructions (which were 'unusual' instructions for clomipramine).

b) Mr B's final accuracy check as required by the Dispensing 4 SOP was carried out with an element of confirmation bias and pressure from not wanting to keep Mrs A waiting, which affected the purpose of the final accuracy check.

c) Mr B appears not to have discussed Mrs A's medication with her in accordance with the Dispensing 5 SOP. If the purpose and reasons for use of the medication had been discussed, either Mr B and/or Mrs A may have realised that the wrong medication had been dispensed, as the purpose and reason for use of clomipramine and clomiphene are distinctly different.

32. The pharmacy's SOPs outline processes to minimise the risk of processing and dispensing errors occurring, and to identify and correct errors before the patient leaves the pharmacy with the medication. By not following the SOPs in his dispensing process, Mr B missed numerous opportunities to identify the error at an earlier stage, and to prevent the error in the final checking stage.

Conclusion

33. Mr B's lack of thorough checking meant that he did not identify the dispensing error at several stages of the dispensing process, despite the various checkpoints set out in the SOPs. Ultimately this led to the wrong medication being dispensed to Mrs A.

34. I acknowledge that Mr B had been practising as a full-time pharmacist for less than a year when this error occurred. However, having completed all the requirements to be a registered pharmacist, Mr B had an obligation to meet and to be measured against the required standards of all other registered pharmacists. The assessment and checking steps are basic competencies required of a registered pharmacist, as set out by the Pharmacy Council.[14] I find that by not providing services that complied with professional standards, Mr

[13] 20HDC00383.
[14] As set out in paragraph 23.

B breached Right 4(2) of the Code of Health and Disability Services Consumers' Rights (the Code).[15]

35. I commend Mr B for taking full responsibility for his mistake, and for taking proactive steps to learn from this event and make appropriate changes to his practice (as set out in the 'Changes made' section below).

Opinion: Ms D — adverse comment

36. Ms D was the pharmacy technician who dispensed Mrs A's medication. Ms D told HDC that she did not follow Dispensing 3 of the SOPs, as she selected the medication from the shelf against the label, not against the prescription itself. She also accepts that she did not check her (incorrect) assumption regarding clomipramine being a new brand name for clomiphene with a pharmacist.

37. Although ultimately under the supervision and care of the supervising pharmacist, Ms D played a key role and had a key responsibility in the dispensing of medication to Mrs A. All dispensary staff are responsible for adhering to the pharmacy's SOPs, so it is equally Ms D's responsibility to reduce error in areas that have already been identified by these SOPs (such as reading from the original prescription, not the pharmacy-generated label).

38. Considering that Ms D is an experienced pharmacy technician with several years' experience and holds an additional PACT qualification (although not working in this capacity at the time), I am critical that she did not complete a more thorough check, and that despite being aware of the importance of reading from the prescription (not the label), this did not occur in practice.

Opinion: Pharmacy — adverse comment

39. First, I commend the pharmacy for taking prompt corrective action in line with PDA requirements and the SOPs as soon as it was alerted to the error.

40. The pharmacy has an overall duty to ensure that its staff and processes support the provision of services to customers with a reasonable level of care and skill, and to an appropriate standard. This includes ensuring that pharmacy staff work in an environment conducive to safe, effective dispensing practice, and that the pharmacy's policies facilitate safe dispensing and checking of medication.

41. Although there were clear shortfalls by Mr B and Ms D, I consider that there may be areas for improvement in the pharmacy's processes and policies.

42. I question whether the pharmacy could improve its staffing arrangements to reduce instances in which self-checking occurs, and/or create more robust processes that reduce the element of confirmation bias that exists as a result of self-checking. Noting that the

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

pharmacist in charge is responsible for Dispensing 4 of the SOPs, I am critical that a junior pharmacist such as Mr B was placed in an environment where self-checking had to occur, and question whether there can be improvements to the management of staffing and more support for, and oversight of, junior staff.

43. The pharmacy told HDC that specific reference to LASA medication was not required in the SOP in May 2022, as the final checking procedure is designed to identify dispensing errors regardless of the nature of the error. However, considering that LASA medication is a well-recognised cause of medication errors,[16] I believe that specific guidance around look-alike sound-alike medication is prudent to have included. I am pleased that the pharmacy has since amended its SOPs and added warning labels to medications so that this potential source of error can be identified more readily.

44. Guidelines set out by the PCNZ state that SOPs should be kept 'up to date' and reviewed at least once every two years.[17] I am critical that the pharmacy's first review of its SOPs appears to have occurred five years after the date of issue, and in the case of Dispensing 5, seven years after the date of issue. The pharmacy told HDC that the SOPs were being updated at the time, but that the online platform used at the time may not have saved and stored updates and reviews to SOPs as expected. Without further evidence of such SOP reviews at the time, I consider it is difficult to make a finding on whether SOPs were reviewed within PCNZ timeframes. However, I consider that checking that updated SOPs are correctly loaded onto a system should form a part of the pharmacy's review process. I remind the pharmacy of the importance of reviewing its SOPs regularly and ensuring that reviews are documented clearly. I am pleased that the pharmacy has a new SOP storage system and has revised its SOPs.

Changes made since events

Mr B

45. Mr B told HDC that he has since reviewed his checking procedures and identified areas for improvement in the following ways:

a) He has reviewed the importance of accuracy checks and clinical checks in his process, which includes checking the medication, strength, and instructions in the context of the prescription.

b) He has adjusted his work practice by taking mental breaks, not carrying information from the processing stage into the checking stage, and slowing his checking procedure when under pressure.

[16] https://cdn.who.int/media/docs/default-source/patient-safety/patient-safety-solutions/ps-solution1-look-alike-sound-alike-medication-names.pdf?sfvrsn=d4fb860b_8; Medication safety for look-alike, sound-alike medicines (who.int)

[17] https://pharmacycouncil.org.nz/wp-content/uploads/2021/03/Writing-SOPs-updated-Dec2017-1.pdf

c) He has taken suggestions from pharmacist peers for a more robust checking procedure, such as underlining the medication name in syllables, reading the medication name out loud, and blocking off noise and creating an environment in which to focus.

d) He has completed the Clinical Checking Workbook provided by the Pharmaceutical Society of New Zealand (PSNZ), applying the learnings of the Five Rights (right patient, right medication, right dose, right route of administration, right time to administer) to his practice.

e) Currently he is working through another PSNZ course (Improving Accuracy in Your Dispensary) and has learned about including a four-way checking procedure: product→prescription→label→ product.

Ms D

46. Ms D told HDC that she has reviewed and identified the following areas of improvement in her practice:

a) To check both the generic and brand names on the Toniq system[18] when in doubt about unfamiliar medicine names.

b) To raise any changes, uncertainties, and assumptions with a pharmacist.

c) To work from the prescription (not the label) in all future cases.

Pharmacy

47. The following changes were identified at the dispensary staff meeting on 30 May 2022:

> 'Clomiphene and Clomipramine tablets were previously stored next to each other … We have since separated both medicines and Clomiphene tablets are now stored in a designated shelf alongside with fertility/hormonal replacement therapy/contraceptive treatment.
>
> Warning labels are affixed to the dispensary shelf … to prompt the dispensary staff to take extra care …
>
> A warning note is now attached to both clomipramine and clomiphene in our computer, where a reminder note will appear … to double check the medication is correct against the prescription.
>
> All dispensary staff have been reminded to take extra care when processing and dispensing medicines with similar sounding name.
>
> If uncertain about brand changes, all pharmacy technicians are to discuss this with the pharmacist at the time of dispensing.

[18] Software used by the pharmacy to dispense medications.

> The Dispensing SOP has been further reviewed and amended to identify potential similar sounding medicines to be identified and tagged in the computer as an ongoing process.[19]'

48. The pharmacy has also installed two robotic dispensary systems (Alpaca[20] and EV-54[21]) with the intention of improving accuracy and reducing error in medicine selection, and it has housed the top 54 dispensing prescription items to create more space on stock shelves, reducing the risk of picking closely stocked medications.

49. As mentioned, the pharmacy also commenced a further revision of its SOPs in October 2023, with the aim of completing this by February 2024.

Recommendations

50. I acknowledge that both Mr B and the pharmacy have already taken proactive steps to improve their processes and practice, such as reviewing and updating the SOPs, reflecting on and updating processes, and undergoing further education and training.

51. I recommend that Mr B:

a) Provide a formal written apology to Mrs A for the failures identified in this report. The apology is to be provided to HDC, for forwarding to Mrs A, within one month of the date of this report.

b) Complete the PSNZ 'Improving Accuracy in Your Dispensary' course and provide evidence of completion (or an update) to HDC within three months of the date of this report.

52. I recommend that Ms D:

a) Reflect on the learnings from this report and report back to HDC on the changes made, within three months of the date of this report.

b) Provide evidence of recent self-review of the SOPs, in particular the SOPs relating to dispensing processes, and provide HDC with evidence of that review within three months of the date of this report.

53. I recommend that the pharmacy:

a) Consider whether the SOPs should include guidance on how new/junior staff will be supported, and report back to HDC on this matter within three months of the date of this report.

[19] Updated to include the following: 'Medications with similar sounding names should be flagged in the dispensing software and a sundry label set to print on dispensing of either medication to remind the checking Pharmacist to be extra vigilant with such medications.'
[20] Semi-automated blister packing machine.
[21] Nano vial dispensing machine.

b) Provide HDC with a copy of the revised SOPs within three months of the date of this report, including information about the process for SOP implementation and how compliance and effectiveness of the SOP will be monitored.

c) Conduct a random audit of dispensing and checking of medication of 20 prescriptions over a one-month period to assess compliance with the revised SOPs and provide HDC with a report on the findings within three months of the date of this report.

Follow-up actions

54. A copy of this report with details identifying the parties removed will be sent to the Pharmacy Council of New Zealand, and it will be advised of Mr B's name.

55. A copy of this report with details identifying the parties removed will be sent to the Pharmacy Defence Association and placed on the Health and Disability Commissioner website, www.hdc.org.nz, for educational purposes.

Appendix A: Standard Operating Procedures at the time of events

STANDARD OPERATING PROCEDURE		
Pharmacy Name		
Subject	Dispensing 1 — Receive prioritise and validate prescription	
Page	Document N˚ C 34	**Issue Date** 27/09/15

Purpose: To ensure all required details on new prescriptions are checked and confirmed

Responsible Person(s): Pharmacist—in-Charge

Procedure:

At the prescription receipt counter (dispensary staff and shop assistants) :

- Any staff member receiving prescriptions should check that all required patient, prescriber and funding eligibility details are included eg
  - Patient name and street address (not PO Box number)
  - age or date of birth - highlight the date of birth for children under 5 years, to prompt dose review by a pharmacist during the clinical check
  - NHI number
  - Community services, high user, or pharmaceutical subsidy card.
  - Prescriber full name, street address, and telephone number
  - Prescriber signature
- Dispensing should be completed in order of receipt. Prioritise dispensings by asking the patient/caregiver if they will wait or return later.
- Inform patient of approximate wait time eg standard prescriptions generally 5 to 10 minutes, or 15 to 30 minutes for a compounded prescription.
- If returning later, record time on prescription and make sure it is dispensed by this time.

In the dispensary (pharmacy technicians, interns or pharmacists):

- **Where queried,** check patient eligibility for funded prescriptions on the Ministry of Health website (2011 Guide to Eligibility) : http://www.moh.govt.nz/moh.nsf/indexmh/2011-eligibility-guide
- If required, explain non-eligibility and medicine(s) costs to patient or family / carer; if not prepared to pay, refer back to the prescriber.
- Where anomalies need noting eg expired antibiotic prescription, medicine missing from usual regime, early, late or infrequent dispensing, or duplicated therapy, ensure a note is attached to draw the dispensing and checking pharmacists' attention to relevant points.
- If dispensing pharmacist and checking pharmacist is the same person, attach a note as above.
- Check that it is within the prescribers SCOPE OF PRACTICE

- Regulation 39 was changed with effect 1/12/12 so that the only restriction on what may be prescribed by medical practitioners, dentists and midwives is that the medicine is within the prescribers scope of practice.

- Note that Designated Prescribers (optometrists, nurse practitioners and diabetes nurses) can only prescribe those prescription medicines listed in their relevant prescriber regulations. See:
  http://wvvw.legislation.govt.nz/regulation/public/2005/0256/latest/DLM348602.html
  http://www.legislation.govt.nz/reoulation/public/2005/0266/latest/DLM350325.html
  http://www.legislation.govt.nz/regulation/public/2011/0054/latest/DLM3589235.html

STANDARD OPERATING PROCEDURE			
Pharmacy Name			
Subject	Dispensing 1 – Receive prioritise and validate prescription		
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Created by	Date 27/09/15
Approved by	Date
Review date	

Reviewed 20/10/2022

STANDARD OPERATING PROCEDURE			
Pharmacy Name			
Subject	Dispensing 2 - Prescription assessment and clinical check		
Page	Document N° C 35	Issue Date	27/09/15

Purpose: To ensure all prescriptions are assessed for validity, safety and clinical appropriateness

Responsible Person(s): Pharmacist in Charge/Pharmacist

Procedure:

- When entering prescription details into computer, check new prescription against available patient history for changes such as:
  - newly prescribed medicines or
  - different strengths or frequency, or
  - duplicated medicines eg different brands of the same medicine or
  - regular medicines not ordered

Note: Dispensary staff should ensure the dispensing programme is kept up to date each month with Pharmaceutical Schedule changes, by applying the update files supplied by the software vendors.

- Note relevant discrepancies, changes or amended prescription details on attached notes or in prescription margins to alert dispensing and checking pharmacists. Examples could include:
  - expired prescription for antibiotics
  - medicine missing from usual regime
  - early, late or infrequent dispensing
  - duplicated therapy,
- Leave notes with prescription through the clinical check, labeling and dispensing and accuracy check processes until the counseling step.
- Any change in quantity or presentation dispensed must be annotated on the prescription.
  - If there is a change in the quantity prescribed, regardless of whether it results in a financial implication to the DHB or not, the pharmacist cannot increase the quantity of the prescription without the change being endorsed by the prescriber. It must be sent back to the prescriber even if it results in an increased cost to the DHB (not patient).
  - A pharmacist can change the presentation of a medication, as long as the change is clearly annotated by the pharmacist. In this instance it does not need to be sent back to the prescriber.
- Check the PERIOD OF SUPPLY

Dentists:
- From 1/12/11 dentists may prescribe 3 months supply of medication. These prescriptions will be funded under the Pharmaceutical Schedule.
- the maximum period of supply for controlled drugs (both Class B and Class C) is seven days.
- Only five days supply of Class B controlled drugs will be funded under the Pharmaceutical Schedule.
- From 1/12/11 Seven days supply of Class C controlled drugs will now funded on the Pharmaceutical Schedule

Midwives:

- From 1/12/11 midwives may prescribe six months supply of an oral contraceptive.

Before any label preparation and dispensing occurs, a pharmacist should complete a clinical check on the prescription.

Health & Disability Services Pharmacy Services Standard NZS 8134.7: 2010, (page 54) clinical

STANDARD OPERATING PROCEDURE			
Pharmacy Name			
Subject	Dispensing 2 - Prescription assessment and clinical check		
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check includes assessment for safety and clinical appropriateness in the following areas, if known:

- Appropriate dosage form and route of administration
- Dosage is within therapeutic range
- Appropriateness for patient's parameters (ie age, weight, renal function) and for previous medications. This is particularly important for treatments with narrow therapeutic index, oncology preparations, or for babies and young children.
- Compatibility with other medication or known conditions (including known OTC therapy) eg.
  - drug / drug interactions (eg. erythromycin and simvastatin)
  - drug / disease interactions (eg. new NSAID for an asthmatic)
- Possible side effects
- Duration of treatment
- Potential for non-concordance, inappropriate use or misuse by patient

- Investigate and confirm any changes or differences with the patient and/or the prescriber as appropriate.
- Document any prescribing changes on the prescription

Pharmacy changes written on a prescription must be distinguishable from what the prescriber has written ie use different pen colour.

Created by		**Date**	27/09/15
Approved by		**Date**	
Review date			

Reviewed 20/10/2022

STANDARD OPERATING PROCEDURE		
Pharmacy Name		
Subject	Dispensing 3 Labelling and dispensing medicines	
Page	Document N° C 36	Issue Date 27/09/15

Purpose: To ensure label generation and medicine dispensing follows a safe and logical process.

Responsible Person(s): Pharmacist in Charge/Pharmacist

Procedure:

Label generation:

- Language and lettering on the label should be simple, clear and easily read.
- Where possible, adapt labeling instructions to address communication barriers such as literacy level and cultural background.
- Labels should have the pharmacy name and address pre-printed on them.
- Generate enough labels for each container dispensed. Place a "more than one container of the same medicine" note on multiple containers of same medicine to alert the patient.
- Label font size should not be compromised by adding too many cautionary instructions. Where required, use additional coloured Cautionary Advisory labels instead.
- Don't overwrite corrections on label - edit label on screen and reprint label.
- If a generated label is not needed or is wrong, cross through with pen and discard so it is not inadvertently used.

Dispense medicines:

- When dispensing more than one item, take items from shelf one at a time. Count or pour and label first item before selecting the next.
- Check the name, brand, strength and formulation against the prescription, not the label.
- Check expiry date of the stock medicine.
- Substituting a prescribed brand of medicine with another brand must follow this pharmacy's SOP for Medicine Substitution.
- Use appropriate containers (bottle, skillet etc) and use safety caps (child resistant) where required (See SOP Child resistant Caps).
- Double check labels against the original prescription, before attaching them to the container.
- Where possible, label the medicine, rather than an outer box, eg label inhalers or ointment tubes as opposed to their containers.
  - Ensure label is straight and at an appropriate height on the bottles.
  - Do not obscure any important information.

- Attach any Cautionary and Advisory (C&A) labels if required.
- Where interpreter help is used to adapt or deliver instructions from English to another language, document that an interpreter has been used.
- Leave all stock bottles used beside the dispensed medicine for the accuracy check.
- Note on prescription if there are any owed medicines.
- Attach a note to the prescription to highlight any counselling points eg how to use an eye drop, inhaler or suppository.
- When all items have been dispensed, the prescription should be annotated with the

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dispenser's initials.

- Leave the prescription (and any attached notes), stock bottles and dispensed items in the designated checking area for an Accuracy check by a pharmacist. (See SOP Accuracy Check).

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Approved by			Date
Review date			

Reviewed 20/10/2020

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Pharmacy Name		
Subject	Dispensing 4 Accuracy check	
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Purpose: To ensure that all dispensed items have undergone a documented accuracy check by a checking pharmacist.

Responsible Person(s): Pharmacist in Charge

Procedure:

- Check the label and dispensed medicine against the original prescription and the stock supply used to dispense the medicine. This includes
  - Correct patient name
  - Prescriber
  - Instructions for use
  - Formulation, strength and quantity of medicine
  - Open each dispensed bottle or skillet to compare contents with stock supply
  - If more than one stock bottle or skillet has been used, check dispensed medicine against all sources of supply.
- Self-checking is not recommended – wherever possible the check should be done by a second person
- If self-checking can't be avoided, separate the 'physical' and 'mental' activities by another task eg by dispensing another prescription
- Initial each item on the prescription when it has been checked and passed for accuracy.
- Ensure any documentation accompanying the dispensed items (such as prescription records, counselling notes and receipts) belongs to the right patient.
- Set aside completed, checked prescriptions in a basket or clear plastic holding bag, (with the prescription attached) in a designated collection area. Store in patient alphabetical order.
- If fridge or safe items are included in the prescription, put a note with other items as a reminder to retrieve before handing prescription out.
- Where dispensing errors have been detected during the checking process (up to and including the point at which the medicine is handed over to the patient or representative), complete the process for documenting and reviewing the error (see SOP Dispensing Near Misses).

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Approved by		**Date**	
Review date			

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STANDARD OPERATING PROCEDURE		
Pharmacy Name		
Subject	Dispensing 5 Counselling for dispensed medicines	
Page 1 of 1	**Document N°** C 38	**Issue Date** 11/07/13

Purpose: To ensure that patients or their carers are offered appropriate counselling about their medicines when they come to collect them.

Responsible Person(s): Pharmacist in Charge

Procedure:

- It is the sole responsibility of the pharmacist to counsel patients. However there may be circumstances where it is not always necessary to discuss the medicine or product with the person collecting the prescription (eg. where the person collecting the prescription is not the patient).
- Check the customer is the right person by asking them their name and address. It is extremely important that the customer should ALWAYS be asked their name and address, rather than being asked if the address is correct (to avoid yes/no answers).
- Ensure counselling is done in an area which offers privacy for the patient
- Use 'check-back' questions to ensure patient understands the purpose of each medicine, especially newly prescribed ones.
- Even if the patient has been taking the medicine for a number of years, counselling may not be required but still provide an opportunity for them to ask questions.
- Inform and advise about the medicines being collected, including:
  - Reason for use and health benefits
  - Medicine doses, storage, altered formulation or packing, different brands supplied on generic-request prescriptions
  - Dose frequency and when to take in relation to food or other factors affecting correct administration
  - Duration of therapy; encourage compliance/concordance
  - Precautions and adverse effects, as appropriate without causing alarm
- Where appropriate, demonstrate and discuss purpose of any new devices (eg spacers) and encourage the customer to demonstrate their use to you before they leave the pharmacy.
- Provide written information if required, to help promote better understanding of the condition and treatment.

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Approved by	27/07/13	**Date**
Review date		

Renewed 20/10/2020

STANDARD OPERATING PROCEDURE		
Pharmacy Name		
Subject	Dispensing errors	
Page 1 of 3	**Document Nº** K 06	**Issue Date** 24/08/15

Purpose: To ensure correct procedures are followed if a dispensing error is identified to ensure it is dealt with quickly, safely and responsibly; and to enable appropriate steps to be taken to reduce the likelihood of the error being repeated.

Responsible Person(s): Pharmacist manager

Procedure

Please note – this SOP is to be read in conjunction with SOP K 12 (Incident Reporting) SOP K 16 (Dispensing Near Misses) and SOP K 05 (Customer Complaints)

A dispensing error is defined as an error that has been detected and reported after the medication has been consumed by the patient or has left the pharmacy.

A Near Miss is defined as a dispensing incident that has been picked up in the dispensing checking process, up to and including the point which the medication is handed over to the patient or the patient's representative.

- When presented with a complaint, ensure that the pharmacist in charge handles the matter.
- Show concern and willingness to correct any error immediately.
- Listen to the complaint, check out the alleged error, and if established, replace the incorrect item as soon as possible.
- If the item was dispensed at another pharmacy, contact that pharmacist and replace if possible - take care not to compound the problem and retain the evidence (quarantined) if possible.
- Apologise and show concern. Give a sensible explanation if possible. If the error is obvious it is no use being evasive – admit the mistake.
- If the wrong drug/dose or strength has been dispensed, ask:
  - **Has any of the wrong medicine been ingested?** If so the prescriber should be contacted
  - **Has any harm been suffered?** If so ask for details of symptoms.
  - **Has any expense been incurred?** If so it may be sensible at this stage to say that you will, cover any reasonable expenses i.e. taxi to hospital or doctor's visit. If unsure contact the PDA.
- Do not offer compensation, this may look like an attempt to bribe your way out of trouble.
- Do not mention that you have insurance cover or the society disciplinary committee, as it may sow seeds of opportunity.
- Show empathy with the patient. This gives them the opportunity to vent their feelings, and opens the opportunity for dialogue

- At all times remain calm, sympathetic and cooperative. Advise that you will investigate how the incident occurred and revise any procedures to help prevent any reoccurrence. Ensure you let the customer know what measures have been taken, and follow up promptly. If there is a delay (e.g. relevant staff member away), inform the customer.
- Fill out the Incident Form - complete all sections and alternative contact numbers when applicable. These can be printed and filled out by hand OR saved to your

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desktop and completed electronically. .
(Ref: SOP K 12 for full details of completing an incident report.)

- **Contact the Pharmacy Defence Association**: Phone 0800 PDA HELP (0800 732 4357), Fax 04 802 8208, email pda@pharmacy-house.org.nz and notify them of the incident. You will be advised of any further action that is needed. **It is important to report any incident as a claim could be lodged at some future date.**
- Record the incident in your Incident Log Book, and on patient notes in the computer as appropriate. Ensure you record any dialogue or action taken in relation to the incident, at any stage, as it may be needed if a Health and Disability Commission complaint results.
- If the patient has left the pharmacy and you suspect an error may have occurred act speedily to confirm/eliminate any possibility without causing unnecessary alarm.
- When a complaint is initiated by correspondence it is important that you do not reply without first asking advice from PDA.

Do not send anything in writing without asking advice.

- If confronted by any investigating officer (police, Medsafe etc) seeking information relating to drugs dispensed for any patient – ask for identification and check the legality of the request with PDA.
- When any medicine-related incident occurs, contact the prescriber as a matter of courtesy.
- If the incident cannot be resolved in a timely manner to the patient's satisfaction, you are obliged to inform the person that they can make a complaint the Health & Disability Commission.

REVIEW PROCESS

- All dispensing errors will result in a review of the processes involved.
- The Charge Pharmacist and Dispensary manager are responsible for completing this review.
- Near miss logs and incidents should be reviewed regularly at least every 3 months or more often if necessary.

All review documents are to be attached to a copy of the Incident Form and filed in the relevant section of the Incident folder:

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Appendix B: Revised Dispensing 2 SOP

STANDARD OPERATING PROCEDURE		
Pharmacy Name		
Subject	Dispensing 2 – Prescription Assessment and Clinical Check	
Page 1 of [redacted]	**Document N°** C35A	**Issue Date** 31/05/2022

Purpose:

Check includes assessment for safety and clinical appropriateness in the following areas, if known:

- Appropriate dosage form and route of administration
- Dosage is within therapeutic range
- Appropriateness for patient's parameters (ie age, weight, renal function) and for previous medications. This is particularly important for treatments with narrow therapeutic index, oncology preparations, or for babies and young children.
- Medications with similar sounding names should be flagged in the dispensing software and a sundry label set to print on dispensing of either medication to remind the checking Pharmacist to be extra vigilant with such medications.
- Possible side effects
- Duration of treatment
- Potential for non-cordance, inappropriate use or misuse by patient
- Compatibility with other medication or known conditions (including known OTC therapy) eg
  - Drug/drug interactions (eg erythromycin and simvastatin)
  - Drug disease interactions (eg new NSAID for asthmatic)

Investigate and confirm any changes or differences with the patient and/or prescriber as appropriate.

Document any prescribing changes on the prescription
Pharmacy changes written on a prescription must be distinguishable from what the prescriber has written ie use different pen colour.

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