Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

# A Decision by the Deputy Health and Disability Commissioner

# (Case 21HDC03090)

## 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 by a pharmacy in 2020.

3. On 7 December 2021, this Office received a complaint from Mr A, which raised concerns about the care provided to his then four-year-old son by the pharmacy. The complaint concerned a dispensing error of an antipsychotic medication (haloperidol) mixed in with hay fever medicine.

4. The following issue was identified for investigation:

- *Whether the pharmacy provided Master A an appropriate standard of care on 20 January 2020.*

## How the matter arose

5. Master A had been prescribed liquid loratadine for hayfever by his general practitioner (GP). This prescribed medication was dispensed on 20 January 2020, approximately two years before it was opened and administered to Master A by his parents twice, on 25 and 26 November 2021. Approximately 30 minutes after the second administration Master A experienced an apparent allergic reaction and was admitted to hospital. Toxicology screening of the liquid medication identified the presence of haloperidol.

6. This report discusses the event and the subsequent investigation undertaken by Medsafe and reviews the changes the pharmacy implemented as a result.

### Incident Notification completed by the pharmacy on 3 December 2021

7. The pharmacy was made aware of the dispensing error on 1 December 2021. The pharmacy completed an Incident Notification form on 3 December 2021. The form included a summary of the event and the key staff members involved and outlined the actions taken as a result.

8. The pharmacy told HDC that when dispensing medication, the Pharmacy stamp on the medication has three signature boxes — one for entering the script, one for dispensing, and one for checking. In its response to the provisional opinion, the pharmacy confirmed that

Mr B signed the checking box, indicating that he checked the medication. However, the entering and dispensing boxes were left empty. The pharmacy stated that at the time of these events, the pharmacy did not strictly require the dispenser to sign the script, especially when the pharmacy was very busy. Further, it told HDC that this practice has now changed (as seen below in 'changes made since events'). The pharmacy noted that a pharmacy technician and an intern were also working, and it is more likely that one of them dispensed the medication. However, the pharmacy accepted that responsibility rests with the checking and supervising pharmacist.

9. The pharmacy explained that loratadine was supplied to the pharmacy in 120ml bottles, so to fill Master A's prescription (which was for 200ml), the pharmacy had to dispense the medicine into a new bottle. The pharmacy's records show that the last time it had dispensed liquid haloperidol was on 15 January 2020, which was five days prior to the loratadine dispensing. The pharmacy said that a cylindrical flask is used to dispense this type of liquid medication, and the standard practice is to wash the flask immediately after use. The pharmacy stated: '[I]t is unlikely that the flask would not have been washed for 5 days.' After reviewing its stock levels against dispensing records from the Ministry of Health, the pharmacy could not find any discrepancies to indicate that a dispensing error had occurred.

10. The pharmacy told HDC: '[W]e regret that we are not able to locate a definite reason for this occurrence and are at a loss as to how this event could have happened.'

11. The pharmacy sent an apology letter to Master A's parents on 23 December 2021. The letter openly disclosed that the pharmacy was investigating the matter and outlined the steps being taken to understand how the event had occurred, to prevent recurrence.

**Medsafe investigation**

12. In response to a referral from the New Zealand Pharmacovigilance Centre on 2 December 2021, Medsafe conducted an initial unannounced inspection audit at the pharmacy on 3 December 2021. Following the initial audit, Medsafe commenced an investigation into the alleged dispensing error that had occurred.

13. Medsafe's investigation focused on the following aspects:

1. To investigate the alleged dispensing error made by the pharmacy;
2. To identify the contents of the dispensed medicine; and
3. To obtain assurance that the pharmacy practice activities relating to dispensing conducted at the pharmacy are appropriate and do not present an ongoing risk to public safety.

14. The investigation found the following:

a) The contents of the dispensed medication (as at the date of testing) included loratadine and haloperidol.

b) It is probable that a dispensing error occurred at the pharmacy on 20 January 2020, with the dispensed medication incorrectly containing haloperidol solution in addition to the prescribed loratadine solution.

c) The pharmacy practice activities conducted at the pharmacy, as reviewed by Medsafe at the time of an unannounced inspection audit on 3 December 2021, are not considered to present an ongoing risk to public safety.

15. Medsafe's report stated:

> '[Medsafe] has been provided with comprehensive information to demonstrate the Pharmacy has undertaken a thorough and critical reflection of their systems surrounding the potential incident. This has included a review of relevant SOPs with amendments made where deemed necessary, staff training in updated procedures, consideration of possible causes and an acknowledgement has been made of potential shortfalls in the system at the time. The pharmacy has advised Medsafe that a number of preventative strategies have been implemented as a result, including, but not limited to, increased staffing levels, strengthening of dispensing processes and attempts to minimise distractions.'[1]

16. Following its investigation, Medsafe completed a full Pharmacy Quality Audit on 24 May 2022. Medsafe told HDC: '[Medsafe has] received and assessed the corrective actions[2] submitted by the Pharmacy in response to the Audit report, and the Audit process has been completed.'

**Notification of HDC investigation**

17. On 1 September 2023, following the complaint made by Mr A, I notified the pharmacy of HDC's investigation and proposed that HDC accept the findings of Medsafe's investigation and find the pharmacy in breach of Right 4(1) of the Code of Health and Disability Services Consumers' Rights (the Code).[3]

18. I proposed this option given the high probability that the medication in question was dispensed incorrectly by the pharmacy on 20 January 2020 and had an adverse effect on Master A. I considered this option to be appropriate given the significant passage of time since the dispensing, which would affect HDC's ability to identify possible causes not already identified by Medsafe's extensive investigation, and given the areas of improvement identified and changed in the pharmacy's standard operating procedures.

19. On 12 October 2023, the pharmacy responded to HDC's proposal of an agreed breach by noting the findings of the Medsafe report and stating:

> 'The time which has now passed since the dispensing of the medication means that the HDC will likely be faced with similar difficulties in investigating. The Pharmacy considers

[1] Medsafe provided a copy of its investigation report to Mr A on 16 March 2022.
[2] The corrective actions related to several areas of non-compliance identified by Medsafe's audit, including with respect to risk management and stock management.
[3] Right 4(1) states: 'Every consumer has the right to have services provided with reasonable care and skill.'

that it is in the interest of everyone involved in this complaint to move towards a conclusion. In light of this, the Pharmacy agrees to your proposal to adopt the findings of the Medsafe report and to find a breach of Right 4(1) of the Code as a result.'

**Responses to provisional opinion**

*Mr A*

20. Mr A was given an opportunity to comment on the 'how the matter arose' section of the provisional opinion, but he had no further comment to make.

*Pharmacy*

21. The pharmacy was given an opportunity to comment on the provisional opinion and provided a response, which has been incorporated in this report where relevant.

## Opinion: Pharmacy — breach

22. I acknowledge the effect of this event on Master A and his parents, and the desire for timely closure.

23. I commend the pharmacy on the actions taken once it became aware of the incident, including openly disclosing to Master A's parents that the incident had occurred and that the pharmacy was investigating it, extending an apology, and undertaking an incident notification.

24. Nevertheless, as outlined above, a serious incident occurred that resulted in hospitalisation of Master A after he had ingested the medication. The pharmacy has an organisational responsibility to provide a reasonable standard of care to its consumers. Having considered the events that occurred, I am, with the agreement of the pharmacy, adopting the findings of the Medsafe report. I therefore consider it more likely than not that the inadvertent addition of haloperidol to the loratadine dispensing bottle was a result of a dispensing error at the pharmacy. In my opinion, the error represents a failure by the pharmacy to provide services with reasonable care and skill.

25. As such, I find the pharmacy in breach of Right 4(1) of the Code for failing to dispense liquid loratadine correctly on 20 January 2020.

## Changes made since events

26. I consider that the pharmacy took Medsafe's investigation and audit of this event very seriously, and I am encouraged by the pharmacy's prompt response and thorough review of events.

27. Medsafe's investigation concluded that the most likely scenario was the inadvertent addition of haloperidol into the loratadine dispensing bottle (to make up a total of 200ml). In response to this investigation, the pharmacy acknowledged that after checking records of dispensing this medication, Mr B was the sole person who checked and dispensed the medication in question. Therefore, I consider it adequate that the key change made by the

pharmacy was to implement a requirement for two people to check the medication during preparation and dispensing.

28. I also note that since this event several changes have been made to the pharmacy's standard operating procedures to reduce the possibility of such an incident occurring again. The changes include the following:

a) The pharmacy reaffirmed the standard practice of washing measuring flasks immediately after use, and of selecting flasks only from above the sink.

b) In January 2021, the pharmacy acquired a Kirby tablet counting machine. This frees up technicians and pharmacists and enables them to focus on patient interactions and medical interventions, rather than dedicating significant time to manual tablet counting. The visible number shown on the tablet counter also assists in reducing the likelihood of errors.

c) In June 2023, the pharmacy acquired an Alpaca blister packaging machine. This uses the information from the pharmacy's Tonique software to pack medication. It also generates a list of items that need to be packed manually. Any manually packed items must be scanned using the medication barcodes for each item. If the medication does not match, a red alert will be issued. A final check of the dispensed medication is then undertaken by a pharmacist. The machine helps to ensure more accurate dispensing and reduce error rates. It also significantly reduces the technician and pharmacist hours spent on packaging tasks. This allows them more time to focus on other tasks, such as dispensing and checking.

d) The pharmacy has continued to increase staffing levels. Currently, the team consists of:

   i. Three full-time pharmacists, each working 40 hours a week.

   ii. One intern pharmacist working 40 hours a week.

   iii. One full-time technician with over five years of experience and one part-time technician who works three days a week and has three years of experience.

e) The pharmacy has implemented new processes to ensure that staff members are aware of any brand changes and changes to medication positioning. The pharmacist responsible prints a list of medications undergoing changes from Pharmac and discusses these changes with staff. This approach ensures that staff members are well informed about upcoming changes, which reduces the likelihood of confusion during transitions. Previously, changes were communicated to staff only verbally. In hindsight, it is considered that potentially more formal documentation of this process could have prevented the dispensing error had it been in place at the time. Prior to the dispensing to Master A, loratadine had recently changed from a 100ml bottle to a 120ml bottle. The look of the label had changed at the same time. This may have contributed to the error.

f) Where medications have similar appearances or names, the pharmacy proactively relocates stock to prevent similar-looking medications from overlapping. Usually, this is identified in the monthly list of Pharmac changes.

g) The introduction of e-scripts has significantly improved the dispensing process. With e-scripts, the pharmacist scans the script, rather than having to type in the script manually. This reduces the potential for typographical errors related to medication strength and quantity. This streamlining of the process has allowed pharmacists more time to focus on tasks such as checking, ensuring the language is appropriate for the patient's understanding, considering potential interactions, and reviewing past medical history, ultimately enhancing patient safety.

h) The pharmacy continues to monitor error rates and engage in discussions with staff. The emphasis on a more proactive approach has increased awareness, and staff are more open to discussions about strategies for minimising errors.

29. The pharmacy told HDC that these changes have had a positive effect with a noticeable improvement in dispensing accuracy, and the implementation of the pair checking system (two people checking during dispensing) has made a significant contribution.

## Recommendations

30. I acknowledge the pharmacy's efforts throughout this investigation and its willingness to continue to improve its practice. I note that it has written an apology to Master A's parents for these events, made significant changes to its standard operating procedures, and has been subject to two unannounced Medsafe audits and those processes have been concluded. I am satisfied that the changes made to the pharmacy's standard operating procedures are an appropriate response and will mitigate such an event occurring again.

31. I recommend that the pharmacy undertake an audit of a random sample of 20 dispensed liquid medications that required reconstitution/compounding or transfer to a dispensing bottle, to determine whether these were checked by two people. The pharmacy is to report back to HDC with an audit summary and any corrective actions should aberrant findings be identified, within three months of the date of this report.

## Follow-up actions

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