Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

A Decision by the Deputy Health and Disability Commissioner

(Case 21HDC03101)

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 Ms A by a pharmacy during the period 30 November 2021 to 8 December 2021.

3. On 8 December 2021, this Office received a complaint from Ms A that raised concerns about the care she received from the pharmacy. The complaint concerned a dispensing error of a fast-release insulin pen, NovoMix30, rather than Ms A's usual prescription — a slow-release insulin pen, Lantus Solostar.

4. The following issue was identified for investigation:

   - *Whether the pharmacy provided Ms A with an appropriate standard of care during 30 November 2021 to 8 December 2021.*

How matter arose

5. Ms A had been prescribed the insulin pen Lantus Solostar by her general practitioner (GP) and had been using the medication for 15 months prior to this event. On 30 November 2021, Ms A telephoned the pharmacy early in the day to request a repeat prescription of this medication, to be ready for collection at the end of the day. That afternoon, Ms A picked up the medication and used the insulin pen provided for the next seven days, during which time she experienced sweating, shaking, dizziness, blurred vision, and fainting. Ms A believes that on 7 December 2021, she lost consciousness while driving, as her car veered off the road.

6. Ms A told HDC that she checked her medication on 8 December 2021 and realised that although the insulin pen box was labelled as Lantus Solostar, the medication inside was in fact NovoMix 30. She saw her GP later that day. The GP confirmed that Ms A had become hypoglycaemic and gave her another script for Lantus Solostar. Ms A returned to the pharmacy that day to fill the script and informed the pharmacist of the previous dispensing error.

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Incident review completed by pharmacy

7. The pharmacy owner was on leave at the time of dispensing and was advised of the error by the GP after Ms A reported it to her. An incident notification form dated 8 December 2021 was written by the working pharmacist and provided to the Pharmacy Defence Association. Subsequently the form was provided to HDC on 25 February 2022 with further notes added post receipt of the HDC complaint. The incident form outlines the events that occurred in relation to Ms A discovering that she had been dispensed insulin incorrectly.[1] However, the form does not analyse the issues or attempt to identify how the dispensing error occurred. Furthermore, in the box that queries which individual completed the final check of the prescription, the answer inserted reads: 'Not sure — [either of two pharmacists].' In addition, under the names of the individuals involved in the incident, there are question marks next to two names, demonstrating a lack of understanding of how the events occurred, and a lack of investigation undertaken to uncover who was present and how the incident occurred.

8. The standard operating procedure (SOP) in place at the time relating to dispensing and checking of medication outlined that script labels needed to be initialled as medication was dispensed, meaning that all medications dispensed needed to be checked by a second person who was not the dispenser, and the dispenser and checker could be identified by the date worked and their signatures on the sheet. The incident report suggested that this did not occur for Ms A's medication. The repeat prescriptions record for 30 November 2021, which was provided to HDC, shows that the majority of script labels were not initialled, despite the SOP requiring that this must be completed.

9. The pharmacy owner noted that when Ms A's medication was processed, it was a 'slightly busier patch on a slightly quieter day'[2] and that one full-day pharmacist, one part-day pharmacist, and one full-day technician were working. The pharmacy owner told HDC that he suspects that there may have been a rush to dispense the medication, and, as such, protocol was not followed, or the mistake was overlooked in the pressure of the moment.

10. The pharmacy owner said that because of his 'high personal load at the time', he did not contact Ms A once he heard of the dispensing error. He stated:[3]

> 'On reflection, at the very least I should have done that to personally apologise and assure that a full investigation and any systems change would and had occurred (as this was both my intention and obligation). Failing to follow through was discourteous, unprofessional and solely my error.'

[1] How Ms A had used the dispensed insulin and had become unwell and swerved her car whilst driving, and that her blood sugars were measuring low at 5.6.
[2] The pharmacy owner told HDC that on 30 November 2021, 238 scripts were processed (147 new and 91 repeats) and during the hour Ms A's script was processed, 32 script items had been processed.
[3] This statement was included in the additional wording that was added to the incident report by the pharmacy owner.

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11. The pharmacy owner explained that he had attempted to contact Ms A belatedly to apologise, but Ms A had become upset and hung up. He acknowledged that the 'follow up … was woefully delayed and inadequate'.

12. The pharmacy owner provided a copy of the apology letter dated 24 February 2022 sent to Ms A in which he apologised that the 'onsite response to [Ms A] was inadequate' and acknowledged that the ultimate responsibility for the error rests with him as the pharmacy owner. The pharmacy owner also offered compensation for Ms A's doctor's consultation, script fee, and any days of sick leave she was required to take as a result of the incorrect medication.

Notification of HDC investigation

13. On 12 October 2023, following the complaint made by Ms A, I notified the pharmacy of HDC's investigation and proposed that HDC find the pharmacy in breach of Right 4(1) of the Code of Health and Disability Services Consumers' Rights (the Code).[4]

14. I proposed this option given the clear and accepted position that medication was dispensed incorrectly by the pharmacy on 30 November 2021 and had an adverse effect when administered by Ms A. The pharmacy also accepted that both the onsite response and follow-up with Ms A was inadequate.

15. On 24 November 2023, the pharmacy responded to HDC's proposal of an agreed breach, stating:

> '[The pharmacy] agrees with the view you have reached, that it has breached Right 4(1) of the Code due to the dispensing error that occurred, as it considers the error came about as a result of systemic issues at the pharmacy. It therefore also agrees that the scope of your investigation should now focus on independently reviewing the adequacy of remedial work carried out by [the pharmacy] following notification of the dispensing error.'

Responses to provisional opinion

Ms A

16. Ms A was given an opportunity to comment on the 'How the matter arose' section of the provisional opinion and did not wish to add any comments.

Pharmacy

17. The pharmacy was given the opportunity to comment on the provisional opinion, and its comments have been incorporated in the report where necessary.

[4] Right 4(1) states: 'Every consumer has the right to have services provided with reasonable care and skill.'

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Opinion: Pharmacy — breach

18. I acknowledge the effect of this event on Ms A, and her desire for timely closure.

19. I commend the pharmacy owner's willingness to accept responsibility for the errors, and his readiness to make changes to policies and processes at the pharmacy to prevent such an error occurring again.

20. Nevertheless, a serious incident occurred that resulted in significant adverse side effects for Ms A after she administered the medication. Ultimately, the pharmacy has an organisational responsibility to provide a reasonable standard of care to its consumers. Having considered the events that occurred, it is my opinion that the pharmacy failed to provide services with reasonable care and skill.

21. I note that the working pharmacist's statement indicates that at the time of events, staff were not initialling the 'dispensing third part label that was placed on the A5 sheet with the date stamped on it'. This is further supported by two pharmacists, whose statements to HDC indicate that this practice was widespread as opposed to being an isolated incident. As outlined above in paragraph 8, this was a required step under the SOPs for the pharmacy at the time.

22. Furthermore, although it is not clear how the dispensing error occurred, or whether the medication was checked before being dispensed, I consider it more likely than not that staff practice did not match the required SOPs at the time this event took place and failed to pick up that the incorrect medication was being dispensed.

23. In addition to the issues included by HDC in the agreed breach proposal, the pharmacy has acknowledged and claimed responsibility for the inadequate follow-up with Ms A, and I am also critical that this fell below expected standards.

24. As such, with the pharmacy in agreement, I find the pharmacy in breach of Right 4(1) of the Code for failing to dispense the insulin pen Lantus Solostar correctly on 30 November 2021.

Changes made since events

25. The pharmacy has confirmed that it considers that the error came about as a result of systemic issues at the pharmacy. Therefore, I consider it adequate that the key changes made by the pharmacy relate to processes, including increasing the staffing levels at the pharmacy.

26. I note that following this event, several changes were made to the SOPs promptly to reduce the possibility of such an incident occurring again. The changes include the following:

    a) A revised SOP on New and Repeats Dispensing and a new SOP on Insulin Dispensing have been implemented.

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b) Certified Repeat Copies of original scripts (CRCs) are now printed as an additional visual check, and the dispenser/checker is recorded on the individual script as a repeat script workflow record.

c) An A4 bold note was added to the pharmacy fridge door, prompting staff to check the insulin.

d) An additional cautionary check label is now generated with all insulins.

e) A note was added to Ms A's patient record, advising of this incident.

f) Re-training was initiated on the new phone system to prevent delay in actioning requests for scripts.

g) Re-training was initiated on the complaints procedure and incident analysis and reporting.

h) The dispensary staffing pattern was amended, increasing the roster to one pharmacist and two pharmacy technicians on full time, each weekday.

i) Investment was made in automation and reorganisation of dispensary set-up to smooth dispensing workflows.

27. Following HDC's notification of investigation, the pharmacy informed HDC of further changes it had made since the event. These changes include the following:

a) To keep up with the growth in dispensing, physical changes have been made to the dispensary itself, with the dispensing bench and medicine storage area being made larger with better lighting. The dispensary fridge has also been upgraded to a larger vaccine fridge.

b) Pharmacists and technicians are no longer involved in the retail operation of the pharmacy, with the dispensary counter and shelving being placed higher than the front retail counter to remove patient/pharmacist interaction.

c) Dispensing automation has been introduced for patient compliance rolls and for dispensing high volume 'count and pour' medicines, which has resulted in greater accuracy.

d) Subscription has been made to ReCare Services,[5] a 'push' technology that sends repeat reminders to customers via text message. The customer's response then generates an e-prompt in the dispensary, allowing a 48-hour window for fulfilment. This is intended to decrease the interruptions created by phone calls, and the need for staff to check phone messages.

28. The pharmacy told HDC that these changes have allowed for smoother workflow, easier dispensing and stock selection, and less distraction or interruption of dispensary staff.

29. Regarding the implementation of, and compliance with, updated SOPs, the pharmacy acknowledged that historically, measurement of these has been driven by error events and

[5] ReCare is digital prescribing software.

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externally organised audits, rather than being formally scheduled by the pharmacy itself. As such, the pharmacy told HDC:

> '[The pharmacy] will now complete a review of all of its SOPs by February 2024 and, following this, 6 monthly audits will be undertaken to tie in with the internal 6 monthly Controlled Drug audits, which occur on 31 December and 30 June each year. In addition, a review of any incidents that have occurred in the preceding 6 months and a review to ensure that the SOPs are being complied with will also be undertaken at this time.'

30. I note that the pharmacy owner advised that documentation to formalise these reviews will be completed in the form of another SOP by February 2024.

Recommendations

31. I acknowledge the pharmacy's willingness to improve its practice, and the thorough apology and the offers of compensation provided to Ms A for these events. I note that the pharmacy has made significant changes to its SOPs, as well as to the physical layout and processes of the pharmacy. I am satisfied that the changes made are an appropriate response and will mitigate such an event occurring again.

32. Notwithstanding this, I recommend that the pharmacy undertake an audit of a random sample of 20 dispensed insulin pens to determine whether these were checked in line with the SOPs. 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

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

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