Pharmacy

Pharmacy Technician, Ms B

Pharmacist, Ms C

Pharmacist, Ms D

A Report by the

Deputy Health and Disability Commissioner

(Case 16HDC01665)

Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

Table of contents

Executive summary

1. On 21 September 2016, Miss A was prescribed, among other medications, 15 units (three months' supply) of NovoRapid FlexPen (NovoRapid). At approximately 4.15pm, Miss A visited a pharmacy to have her prescription dispensed. Pharmacy technician Ms B selected NovoMix FlexPen (NovoMix) instead of NovoRapid. Pharmacist Ms C checked Ms B's dispensing but did not read the medication name carefully. As a result, Miss A was dispensed NovoMix instead of NovoRapid.

2. Miss A discovered the error on the same day and reported it to Ms C. Ms C completed an incident report and warning note for the dispensing error, but did not report the incident to the pharmacy management in accordance with the pharmacy's standard operating procedures (SOPs). Ms C informed Ms B of the error on their next shift together.

3. On 31 October 2016, Miss A presented to the pharmacy with a repeat prescription of two medications, one being NovoRapid. Ms B dispensed the repeat prescription, but again erroneously selected NovoMix. Pharmacist Ms D checked Ms B's dispensing but did not read the medication name carefully. As a result, Miss A was dispensed NovoMix instead of NovoRapid for the second time.

4. Miss A discovered the error on the same day and reported it to Ms D. Ms D added on to Ms C's warning note. However, Ms D did not report the incident to the pharmacy management or complete an incident form in a timely manner in accordance with the pharmacy's SOPs. An incident form was not completed until 8 November 2016, after the pharmacy received Miss A's complaint from HDC.

5. NovoRapid and NovoMix are both types of insulin used to treat diabetes mellitus. However, NovoRapid is a fast-acting insulin whereas NovoMix has a mixture of rapid and longer-acting insulin.

Findings summary

6. By failing to check the medication she was dispensing carefully against the prescription in accordance with the pharmacy's SOP, and dispensing the incorrect medication on two occasions, Ms B failed to provide services to Miss A with reasonable care and skill, and breached Right 4(1)[1] of the Code of Health and Disability Services Consumers' Rights (the Code).

7. Ms C failed to check the medication dispensed to Miss A on 21 September 2016 adequately, in accordance with the professional standards set by the Pharmacy Council of New Zealand, and with the pharmacy's SOPs and, therefore, failed to provide Miss A with services in accordance with professional and other relevant standards, in breach of Right 4(2)[2] of the Code.

[1] Right 4(1) states: "Every consumer has the right to have services provided with reasonable care and skill."
[2] Right 4(2) states: "Every consumer has the right to have services provided that comply with legal, professional, ethical, and other relevant standards."

8. Ms D failed to check the medication dispensed to Miss A on 31 October 2016 adequately. She also failed to report the error and complete an incident report form in a timely manner. By doing so, Ms D failed to provide Miss A with services in accordance with professional and other relevant standards, in breach of Right 4(2) of the Code.

9. Criticism is made about the pharmacy not having adequate systems in place to communicate warnings and previous errors to appropriate staff. However, the pharmacy had adequate SOPs in place to ensure safe dispensing, checking, and incident reporting for those who followed them. The errors made by Ms B, Ms C, and Ms D were theirs alone, and not a result of poor or inadequate processes in place at the pharmacy. Therefore, the pharmacy did not breach the Code and is not vicariously liable for Ms B's, Ms C's or Ms D's breaches of the Code.

Recommendations

10. It is recommended that the pharmacy:

    a) Randomly audit, over a period of three months, its staff compliance with its SOPs for dispensing and checking medication, and provide HDC with the outcome of that audit within six months of the date of this report. The pharmacy has provided a written apology to Miss A.

    b) Confirm that training with the local Diabetes Association has taken place for all pharmacy technicians and pharmacists, including Ms D. Confirmation should occur within three weeks of the date of this report.

11. It is recommended that Ms C provide a written apology to Miss A.

12. In response to the provisional opinion, Ms B and Ms D each provided a written apology to HDC for forwarding to Miss A and, therefore, no further recommendations are made in relation to them.

Complaint and investigation

13. The Commissioner received a complaint from Miss A about the services provided by the pharmacy. The following issues were identified for investigation:

- *Whether the pharmacy provided Miss A with an appropriate standard of care in 2016.*
- *Whether Pharmacy Technician Ms B provided Miss A an appropriate standard of care in 2016.*
- *Whether Pharmacist Ms C provided Miss A an appropriate standard of care in 2016.*

- *Whether Pharmacist Ms D provided Miss A an appropriate standard of care in 2016.*

14. This report is the opinion of Meenal Duggal, Deputy Commissioner, and is made in accordance with the power delegated to her by the Commissioner.

15. The parties directly involved in the investigation were:

Miss A	Consumer/complainant
Pharmacy	Provider
Ms B	Pharmacy technician
Ms C	Pharmacist
Ms D	Pharmacist

Information gathered during investigation

Introduction

16. Miss A, aged 24 years at the time of these events, has type 1 diabetes mellitus,[3] for which she is prescribed NovoRapid[4] FlexPen[5] (NovoRapid).

17. On two occasions in 2016, Miss A was dispensed NovoMix[6] 30 FlexPen (NovoMix) instead of NovoRapid at the pharmacy.[7]

NovoRapid and NovoMix

18. NovoRapid is a clear and colourless solution for subcutaneous[8] injection. Its packaging is orange and white, with navy blue text.

19. NovoMix is a white and cloudy suspension[9] for subcutaneous injection. Its packaging is white and navy blue, with navy blue text.

[3] An autoimmune condition in which the body is unable to produce enough insulin, resulting in insulin deficiency.
[4] The drug name for a rapid acting insulin used to treat diabetes mellitus. It lowers a patient's blood sugar level after injection. When injected under the skin, it takes effect within 10 to 20 minutes. Usually, the maximum effect will occur between one and three hours after injection, and the effect may last for up to five hours.
[5] FlexPen is the trade name for a device used to administer insulin. It allows for accurate measurement by dialling the number of units to be administered.
[6] The drug name for a mixture of rapid and longer-acting insulin used to treat diabetes mellitus. It lowers a patient's blood sugar level after injection. When injected under the skin, it takes effect within 10 to 20 minutes, and its effect may last for up to 24 hours.
[7] The pharmacy has two directors.
[8] Applied under the skin.
[9] The difference between a solution and a suspension is in the particle sizes involved. A solution is a mixture of ions or molecules (very small) and is transparent. A suspension has bigger particle sizes and looks cloudy or murky.

First dispensing error — 21 September 2016

20. On 21 September 2016, an internal medicine specialist prescribed Miss A, among other medications, 15 units (three months' supply) of NovoRapid.

21. At approximately 4.15pm on 21 September 2016, Miss A visited the pharmacy to have her prescription dispensed. A pharmacist intern correctly entered the prescription into the computer and generated the label. The intern initialled next to the date stamp on the prescription.

Dispensing

22. Pharmacy technician Ms B[10] dispensed NovoMix instead of NovoRapid. Ms B did not initial next to this item, but initialled next to the previous four items on the prescription. Ms B told HDC:

> "On [21]/9/16 and 31/10/16 I dispensed [Miss A's] prescriptions and incorrectly selected Novomix instead of Novorapid. I do not know why I made this mix up, when checking the prescription and the label I completely misread the name of the product. I [had] not had much experience with these products in the past, however, I do not say this to excuse my mistake, I can only assume that we were extremely busy as usual, and I rushed the procedure and I did not read the product name to the end as I should have."

23. Ms B believes she read only the "Novo" and "Flex" part of the prescription when she went to the fridge. When choosing from the fridge, she believes she was looking for "Novo Flex" and did not register that there were two different types of "Novo Flex". Whilst Ms B underlined "FlexPen" on the prescription, the name of the device used to administer insulin, she did not underline the drug name "NovoRapid" or initial for the dispensing of this item.

Final check

24. Pharmacist Ms C[11] checked Ms B's dispensing and initialled the prescription to show that she had done so. Ms C stated that she does not have a clear recollection of the events that occurred. She told HDC that the dispensing occurred at a busy time of day, and she may have checked the dispensing at the same time as helping Ms B to complete the dispensing. Ms C stated:

> "I think [Ms B] may have already selected the wrong item from the fridge and I labelled it as I checked, hence lack of underlining and signing on the prescription as opposed to the normal procedure for dispensing at the pharmacy."[12]

[10] Ms B trained overseas in 2008 and 2009 and received two certificates of partial completion. Ms B has been employed by the pharmacy since September 2015.

[11] Ms C received her Bachelor of Pharmacy in 2013, and is a member of the Pharmaceutical Society of New Zealand Incorporated. Ms C was employed by the pharmacy as a pharmacist intern in October 2013, and continued as a registered pharmacist from June 2015 until leaving her employment in January 2017. Ms C now lives overseas.

[12] The normal procedure for dispensing at the pharmacy is for each item to be dispensed, one at a time, and for the final check to occur after the dispensing has been completed. See the pharmacy's "Dispensing (Technician or Pharmacist)" and "Final Checking (Pharmacist)" SOPs below.

25. Ms C believes that she did not identify the dispensing error because she only checked that the item was a "Novo" FlexPen, and did not completely check the title to determine whether it was NovoRapid or NovoMix. Ms C stated that, at the time of these events, she was unaware that there were two different types of "Novo" FlexPens. She further stated that she had never dispensed or checked NovoRapid previously. Ms C reported that the pharmacy did not dispense NovoRapid very often, and it had only recently begun keeping stock of this medication, rather than placing a special order each time a prescription was presented.

Discovery of error

26. Upon arriving home on 21 September 2016, Miss A detected the error in her medication. She drove back to the pharmacy the same day to inform the pharmacy of the error. Miss A told HDC that Ms C acknowledged and apologised for the error, and told her that it would not happen again.

27. Ms C stated that she also checked that Miss A had not taken the wrong medication, and Miss A confirmed that she had not. Ms C recalls Miss A telling her that this was the second dispensing error that had occurred at the pharmacy, but that Miss A did not share any further details. Ms C informed Miss A that she would make a clear note on Miss A's file to prevent any further mistakes. Miss A then left the pharmacy with the correct medication.

Incident reporting

28. Ms C completed an incident form stating:

> "We've dispensed NovoMix Flexpen instead of NovoRapid pen (Sorry my bad:(). Patient brought back as soon as found out that she's got the wrong one (not used). She said it happened once before. Dispensed correct [medication]. Apologised and told her I'll make a clear note on her file so it doesn't happen again. 21/9/16 [Ms C]"

29. Ms C created a warning note on Miss A's file in Toniq[13] stating: "Novo*RAPID* FLEXPEN!!!! NOVORAPID FLEX (NOT Novomix) PLEASE BE CAREFUL WE'VE GIVEN OUT WRONG ONE TWICE 21/9/16 [Ms C]". Ms C believed this was sufficient warning for the next staff member dispensing Miss A's insulin.

30. The pharmacy told HDC that, when a warning note is entered in Toniq, the next time a patient file is accessed to enter a prescription, a warning box will come up in the middle of the screen with the words "Warning Note Please Read". The staff member must acknowledge that the note has been read by pressing "Y" before exiting the note. The warning notes are also printed on a Toniq Check Form with the medicine labels and medicine receipt. The pharmacy stated that, at the time of these events, the Toniq Check Form was not required to be attached to the prescription, and this was not part of its standard operating procedures (SOPs).

31. Ms C recalls informing the Charge Pharmacist of the dispensing error and asking another colleague whether they were aware of the two different types of "Novo"

[13] Computer software that manages a pharmacy's dispensary operations.

FlexPens. Ms C stated that, by the time Miss A had come back to the pharmacy to report the dispensing error, Ms B had completed work for the day. Ms C said that she therefore informed Ms B of the error when they next saw each other. Ms C stated that the conversation would have been brief, as she felt much more responsible for the error, given that she had checked the prescription. Ms B recalled being informed by Ms C of her error the following day.

32. Ms C told HDC that she does not believe she informed the pharmacy management of the incident. She explained that she would have discussed the error with management, but there was no one present when Miss A came back to the pharmacy. Ms C reasoned that, because Miss A had not taken the wrong medication, she did not feel it was necessary to notify management of the error the following day.

Second dispensing error — 31 October 2016

33. On 31 October 2016, Miss A presented to the pharmacy with a repeat prescription of two medications, one being NovoRapid. The Dispensary Manager correctly entered the repeat prescription into the computer and generated the label. Her initials are on the medication label. The pharmacy told HDC that the warning note made by the Dispensary Manager on 21 September 2016 would have appeared in the middle of the computer screen, and she would have been required to press "Y" indicating that she had read the note.

34. The Dispensary Manager told HDC that she does not recall processing Miss A's repeat prescription on 31 October 2016. She stated that, if she had followed her usual process, she would have read the warning note and checked that the item she was processing was NovoRapid.

Dispensing

35. Ms B dispensed the repeat prescription, but erroneously selected NovoMix from the fridge. She initialled on the repeat prescription beside each item dispensed, but she did not underline the drug name. Ms B stated that she made this error for the same reasons as the first error, and she does not recall seeing a Toniq Check Form.

Final check

36. Pharmacist Ms D[14] checked Ms B's dispensing. Ms D told HDC that she checked the prescription using her normal process. She ticked "Novo" and "FlexPen" on the prescription, and checked the quantity and instructions on the label. Ms D does not recall whether she checked the "Rapid" part of the prescription. She recalls thinking that the medicine box was a different colour than usual, but, as NovoMix was more commonly dispensed, she assumed that it was correct and thought that the packaging had changed.

37. Ms D told HDC that, as she did not process the repeat prescription on the computer, she was unaware of the warning note. She also stated that she was not advised by anyone of the warning. Ms D stated that she does not recall whether a Toniq Check Form containing Ms C's previous warning note was printed.

[14] Ms D received her Bachelor of Pharmacy in 2014 and is a member of the Pharmaceutical Society of New Zealand Incorporated.

Discovery of error

38. Upon arriving home on 31 October 2016, Miss A detected the error in her medication. She told HDC that, when she returned to the pharmacy the same day to report the error, Ms D gave her a half-hearted apology.

39. Ms D told HDC that Miss A's dispensing error was the first time she had dealt with a customer complaint on her own. Previously, Ms D had always had the assistance of a more senior pharmacist, who would take responsibility for resolving a customer's concerns. Ms D explained that, on the day of these events, the other pharmacists rostered to work with her were unavailable, and therefore unable to advise her on the steps she should take.

Incident reporting

40. Ms D stated that, after speaking to Miss A, she went to add a warning note to Miss A's file on the computer. She then noticed that there was already a note made by Ms C. Ms D told HDC that she attempted to make the note more noticeable by adding "NOVORAPID NOT NOVOMIX!!!" but did not add her initials because she felt that it was unnecessary. Ms D informed Ms B of the error, but did not inform any of her other colleagues or circulate the warning note. Ms D stated that, after she had spoken to Miss A, she assumed that the situation had been resolved and turned her attention back to other prescriptions.

41. Ms D did not complete an incident report for the dispensing error until 8 November 2016, after the pharmacy received Miss A's complaint from HDC. Ms D explained that she had intended to complete an incident report on 31 October 2016 but, because the form takes a while to complete, she decided to prioritise the checking of other prescriptions first. Ms D stated that unfortunately she forgot to complete a report at a later time.

42. Ms D did not inform the pharmacy management of the dispensing error. She stated that she had made a "mental note" to speak to the manager when they next came downstairs, but, because it was busy, she completely forgot about it the next time she saw her manager.

43. The pharmacy told HDC that simply creating a warning note is not sufficient or in accordance with pharmacy procedure.

Further information and changes to Ms B's practice

44. Ms B told HDC that she sincerely apologises for the inconvenience and distress the errors have caused Miss A.

45. Ms B stated that she will ensure that she cross-checks the entire product name of the medication in future.

Further information and changes to Ms C's practice

46. Ms C told HDC that she felt shocked and ashamed of her lack of product knowledge when she was alerted to the dispensing error. She stated that she has improved her knowledge about the different types and formulations of insulin.

47. Ms C stated that she will slow down her dispensing process in future, including checking medicines twice and checking the full name of the product against the description and label. She told HDC that she will also ensure that dispensing has been completed prior to starting her checking. Further, Ms C stated that she will inform management of any dispensing errors as soon as possible in future.

Further information and changes to Ms D's practice

48. Ms D apologised for the dispensing errors. She acknowledged that she failed to perform some crucial steps to ensure that Miss A received the utmost care. Ms D also acknowledged that her handling of the error showed a lack of judgement and professionalism. She has made the following changes:

- Ms D told HDC that she has added steps to her usual checking practice to reduce the chance of potential errors. These include reading the prescription out loud, pointing to the words on the prescription, label or item, and circling points on the prescription likely to be mistaken.

- Ms D stated that, in future, when she is unfamiliar with a medication, she will slow down her process and, if required, stop and research the medication or ask another staff member about the medication.

- Ms D told HDC that, in future, she will ensure that all warning notes are read before an item is approved for handing to the patient. This includes ticking each line in the warning note to confirm that she has read and understood it.

- Ms D stated that she has now been thoroughly trained in the SOP for handling customer complaints. She said that she understands the importance of involving management and completing an incident report. She told HDC that she will give customer complaints her full attention in future and, if necessary, she will ask another pharmacist to assist on the dispensary bench whilst she is handling a complaint.

- Ms D stated that she has identified gaps in her clinical knowledge around medications to treat diabetes mellitus, and has formulated a plan to improve her clinical skill.

- Ms D told HDC that she will be reviewing any errors or near misses made in the next month to identify whether her usual practice is working. If she makes no errors within the next month, she will review her usual practice every three months to ensure that it is continually updated and improved.

Further information and changes to the pharmacy's practice

49. The pharmacy apologised for the distress the dispensing errors have caused Miss A, and stated that all the staff members are very disappointed with the lack of care provided.

50. The pharmacy told HDC that it has updated its SOPs so that the Toniq Check Form is now attached to the prescription and stays with the prescription as the prescription is

dispensed and checked. It is the responsibility of the inputter, dispenser, and checker to ensure that the Toniq Check Form remains with the prescription throughout the dispensing process so that everyone involved in the process is informed of any important information.

51. The pharmacy said that it has also taken the following actions as a result of the dispensing errors:

- Spoken to the dispensary staff involved in these errors.
- Identified where Ms B, Ms C, and Ms D have made the mistakes in their dispensing and checking procedures.
- Updated its procedure on how to handle a dispensary error and trained all pharmacists on this.
- Changed the shelf location of both the medications so that they are on separate shelves with clear signage to check that the correct medication has been chosen.

52. The pharmacy stated that Ms C and Ms D will be completing continuing education on the different types of insulin and their forms. It said that it will also:

- Contact the local Diabetes Association and organise training on the different types of insulins and their forms for all their pharmacists and technicians.
- Re-train all dispensary staff on the importance of circling notes on the Toniq Check Form that prints out, and reading and actioning those notes.
- Re-train the entire dispensary staff on using the "Near Miss" book for reporting all errors and near misses. This will then be summarised weekly at its 9am meetings to learn and pick up and prevent mistakes."

53. The pharmacy told HDC that, on 8 March 2017, it held a full dispensary meeting where detailed discussions took place regarding this incident, and staff were reminded of the changes that have been made.

Relevant Pharmacy SOPs

54. The SOPs were all issued on 10 June 2011. The pharmacy told HDC that it has been unable to confirm when its SOPs were last updated prior to the dispensing errors. The pharmacy asserted that the SOPs had been updated recently, and estimated that this may have occurred approximately two years ago.

"Entering in the Computer" SOP

55. The pharmacy's "Entering in the Computer (Technician or Pharmacist)" SOP states that a prescription can be entered into the computer by either a pharmacy technician or a pharmacist. The steps required for the staff member entering the prescription include:

> "7) Do not ignore warnings
>
> ...

> The inputter having finished entering the prescriptions for a patient should check that the labels are correct and all information is correct and then initial to the left hand side of the directions (Beside the sig).
>
> ...
>
> **<u>As a check on who processed each prescription:</u>**
>
> - The person entering the prescription in the computer must initial the left hand side of each item they are processing.
> - The technician/pharmacist preparing the prescription must initial left side of 3rd part label.
> - The pharmacist who finally checks off must initial to the right hand side of 3rd part label, and then give to patient."

"Dispensing (Technician or Pharmacist)" SOP

56. The pharmacy's "Dispensing (Technician or Pharmacist)" SOP states that the dispensing of a prescription can be carried out by either a pharmacy technician or a pharmacist. The following steps are to be undertaken at dispensing:

> "1) Dispense script from the top of the page, work from the script and <u>not the label</u>.
>
> ...
>
> 5) Peel label off the printer and place small label with item number (3rd part label) on script alongside the medicine name, or in the space provided in the 'Dispensing' column. The instruction label should be placed on the container centred and straight, reading it as you do so to ensure the information printed corresponds with that on the script.
>
> 6) Underline each drug name and strength once dispensed and initial on the left hand side of the 3rd part label."

"Final Checking (Pharmacist)" SOP

57. The pharmacy's "Final Checking (Pharmacist)" SOP states that the final check is to be completed by a pharmacist. The following steps are to be taken:

> "… 2) Read prescription thoroughly, and **tick everything that is read and correct.**
>
> 3) Read the label; ensure that it matches the script.
>
> 4) Read stock label, compare with label on dispensed item.
>
> ...
>
> 7) Initial on the right hand side of the 3rd part label when everything is checked and is satisfactory.
>
> ..."

10) … put on finished shelf or hand directly to patient."

"Receiving and Dispensing Repeats" SOP

58. The pharmacy's "Receiving and Dispensing Repeats" SOP outlines the processes to take place when a patient requests a repeat medication. It states that a pharmacy technician or pharmacist will confirm the repeat by checking the computer, and then print the repeat label. The pharmacy technician or pharmacist will then dispense the item in the normal manner.

"Incident (Dispensing Error)" SOP

59. The pharmacy's "Incident (Dispensing Error)" SOP details how a staff member is to handle an incident. According to this SOP, an "incident" includes a dispensing error. A dispensing error is described as:

> "[A] mistake that is made in the dispensing processes that [is] NOT detected by the pharmacy staff. It is usually detected by the patient, caregiver or doctor. A dispensing error should be given absolute priority to ensure any risk to the patient is dealt with immediately. In items of process and reporting, a dispensing error is treated as an incident."

60. The SOP sets out the steps to be taken when handling and recording an incident:

> "**Handling an Incident**
>
> 1. The pharmacist who has the first contact regarding the incident is to be responsible for recording the incident.
>
> 2. First, apologise sincerely.
>
> 3. Check that the patient is ok. Find out what has happened and resolve issue if possible.
>
> 4. Explain to them that this incident will be reported to management. We will identify how it has happened and will be speaking to staff involved. Also to prevent it from happening again we will put a clear note in the patient's warning note and speak to all staff at 9 o'clock meeting.
>
> 5. Make sure patient leaves feeling satisfied that we are doing something about it to prevent it from occurring again. Ask the patient if there is anything else they would like us to do? Are you satisfied with how it was handled?
>
> 6. Pay for cost if any — with approval from management.
>
> 7. All incidents should be entered in the computer recording reason/action/ outcome with notes to explain.
>
> 8. It is important to document things at the time rather than trying to recall things later.
>
> 9. All incidents are to be reported to Management."

Responses to provisional opinion

Miss A

61. Miss A was provided with an opportunity to comment on the "information gathered" section of the provisional opinion. She expressed her immense dissatisfaction with the actions of the staff involved and felt that both dispensing errors were poorly handled.

Ms B

62. Ms B was provided with an opportunity to comment on the relevant sections of the provisional opinion that related to her. She has provided HDC with a formal letter of apology for Miss A.

63. Ms B advised that she is no longer working in the pharmacy sector as she has decided that the profession is not right for her.

Ms C

64. Ms C was provided with an opportunity to comment on the relevant sections of the provisional opinion that related to her. She advised that she had no further comment to make.

Ms D

65. Ms D was provided with an opportunity to comment on the relevant sections of the provisional opinion that related to her. She advised that she had no further comment to make and has provided HDC with a formal letter of apology for Miss A.

The pharmacy

66. The pharmacy was provided with an opportunity to comment on the provisional opinion. It advised that it accepts the findings in the provisional opinion. It also confirmed that Ms B is no longer employed by the pharmacy and will therefore not be attending the diabetes training.

Other relevant standards

67. The Pharmacy Council of New Zealand's *Code of Ethics (2011)* requires that a pharmacist:

> "1.2 Take appropriate steps to prevent harm to the patient and the public.
>
> …
>
> 5.1 Be accountable for practising safely and maintain and demonstrate professional competence relative to your sphere of activity and scope of practice."

68. The Pharmacy Council of New Zealand *Competence Standards for the Pharmacy Profession (2015)* provides that the pharmacist:

> "Domain O1: Health and medicine management

…

O1.4.3 Acts to optimise health outcomes by identifying and mitigating potential sources of error in service delivery.

…

O1.4.5 Participates in ongoing incident analysis (including 'near misses') and adopts recommendations for resolution or change that come from that analysis.

Domain O3: Supply and administration of 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."

Opinion: Ms B — breach

69. The pharmacy's SOP "Dispensing (Technician or Pharmacist)" required those dispensing medication to read the instruction label, drug name, and strength. It also required the dispenser to underline and initial each drug name on the prescription once it had been dispensed. As a pharmacy technician, it was Ms B's responsibility to dispense medication accurately in accordance with the pharmacy's SOPs.

70. On 21 September 2016, Ms B erroneously selected NovoMix instead of NovoRapid. Whilst she underlined "FlexPen", the name of the device used to administer insulin, she did not underline the drug name "NovoRapid" or initial for the dispensing of this item.

71. Ms B told HDC that she "completely misread the name of the product" and only read the "Novo" and "Flex" part of the prescription when selecting the medication from the fridge. She stated that she did not have much experience with this product and did not register that there were two types of "Novo Flex". Ms B recollected that she was informed of her error by Ms C the following day.

72. Despite being aware of the above error, Ms B went on to make the same mistake on 31 October 2016, and selected NovoMix instead of NovoRapid from the fridge. Although Ms B signed for the dispensing on this occasion, she did not underline the drug name again. The reasons given for Ms B's first error may be understandable given the similarities in the medication names, Ms B's unfamiliarity with the product, and the fact that a pharmacist would carry out a final check. However, her second error demonstrated poor care, a lack of reflection, and a failure to correct her process, which is unacceptable.

73. I am concerned that Ms B twice selected the wrong medication and then failed to compare it to the prescription carefully, particularly as, after the first dispensing error,

she should have been alert to such an error occurring. By failing to check the medication she was dispensing carefully against the prescription in accordance with the pharmacy's SOP, and dispensing the incorrect medication on two occasions, Ms B failed to provide services to Miss A with reasonable care and skill, and therefore breached Right 4(1) of the Code.

Opinion: Ms C — breach

74. As a registered pharmacist, Ms C was responsible for complying with professional standards. The Pharmacy Council of New Zealand's *Code of Ethics (2011)* provides that a pharmacist must "take appropriate steps to prevent harm to the patient and the public" and "be accountable for practising safely and maintain and demonstrate professional competence relative to [the pharmacist's] sphere of activity and scope of practice". Further, the Pharmacy Council of New Zealand's *Competence Standards for the Pharmacy Profession (2015)* require that a registered pharmacist "maintains a logical, safe and disciplined dispensing procedure" and "monitors the dispensing process for potential errors and acts promptly to mitigate them".

75. The pharmacy's SOP "Final Checking (Pharmacist)" requires those checking dispensed items to read the prescription thoroughly and compare the stock label with the label on the dispensed item.

76. There is no dispute that Ms C did not identify Ms B's dispensing error when she checked the dispensing of Miss A's prescription on 21 September 2016. Ms C believes that she did not identify the dispensing error because she checked only that the item was a "Novo" FlexPen, and did not completely check the drug name to determine whether it was NovoRapid or NovoMix. Ms C stated that, at the time of these events, she was unaware that there were two different types of "Novo" FlexPens, having never dispensed or checked NovoRapid previously.

77. I am concerned that Ms C did not read the medication name carefully in accordance with the pharmacy's SOPs, and thus failed to identify that the medication being dispensed did not match the label and prescription. As HDC has noted previously, "checking that the patient is being dispensed the correct medicine is a fundamental aspect of pharmacy practice …".[15]

78. Ms C failed to check the medication dispensed to Miss A on 21 September 2016 adequately, in accordance with the professional standards set by the Pharmacy Council of New Zealand, and with the pharmacy's SOPs. I consider that Ms C failed to provide Miss A with services in accordance with professional and other relevant standards, in breach of Right 4(2) of the Code.

[15] See opinion 13HDC01618.

Reporting incident to the pharmacy management

79. Whilst Ms C completed an incident report and warning note for the dispensing error, the pharmacy's "Incident (Dispensing Error)" SOP also requires the pharmacist to report such incidents to the pharmacy management. I am critical that Ms C failed to tell management in accordance with this SOP so that they could ensure that the mistake was addressed appropriately.

Opinion: Ms D — breach

Dispensing error

80. As a registered pharmacist, Ms D was responsible for complying with professional standards. The Pharmacy Council of New Zealand's *Code of Ethics (2011)* provides that a pharmacist must "take appropriate steps to prevent harm to the patient and the public" and "be accountable for practising safely and maintain and demonstrate professional competence relative to [the pharmacist's] sphere of activity and scope of practice". Further, the Pharmacy Council of New Zealand's *Competence Standards for the Pharmacy Profession (2015)* require that a registered pharmacist "maintains a logical, safe and disciplined dispensing procedure" and "monitors the dispensing process for potential errors and acts promptly to mitigate them".

81. The pharmacy's SOP "Final Checking (Pharmacist)" requires those checking dispensed items to read the prescription thoroughly and compare the stock label with the label on the dispensed item.

82. There is no dispute that Ms D did not identify Ms B's dispensing error when she checked the dispensing of Miss A's prescription on 31 October 2016. Ms D ticked "Novo" and "FlexPen" on the prescription, but does not recall whether she checked the "Rapid" part of the prescription. She recalls thinking that the medicine box was a different colour than usual, but, as NovoMix was more commonly dispensed, she assumed it was correct and that the packaging had changed. Ms D told HDC that, as she did not process the repeat prescription on the computer, she was unaware of the warning note from the first dispensing error.

83. I am concerned that Ms D failed to identify that the medication being dispensed did not match the label or prescription, particularly as she noticed that the packaging was a different colour. This should have put her on enquiry, and I am critical that she did not take further steps to confirm that the medication being dispensed was accurate. As HDC has noted previously, "checking that the patient is being dispensed the correct medicine is a fundamental aspect of pharmacy practice …".[16]

Failure to report the error

84. The Pharmacy Council of New Zealand's *Competence Standards for the Pharmacy Profession (2015)* require that a registered pharmacist "acts to optimise health

[16] See opinion 13HDC01618.

outcomes by identifying and mitigating potential sources of error in service delivery" and "participates in ongoing incident analysis".

85. The pharmacy's SOP "Incident (Dispensing Error)" requires those handling an incident to complete an incident reporting form at the time of the events, and to report the incident to management.

86. While Ms D updated the warning note on Miss A's file on the computer and advised Ms B of the error, she failed to complete an incident report for the dispensing error of 31 October 2016 promptly, and to inform management of the error. Ms D stated that she intended to complete an incident form but prioritised checking other prescriptions first, and then forgot. She said that she also intended to advise management of the error, but later forgot. It was not until after the pharmacy received a complaint from Miss A that an incident report was completed.

87. As HDC has noted previously, "once a pharmacist had been put on notice of an error having occurred, it is the pharmacist's duty to minimise the ongoing harm and take steps to prevent the error from occurring again … An essential component of a pharmacist's duty in this regard is to complete an incident report form."[17] I am concerned that Ms D did not do so until after Miss A made a complaint to the pharmacy.

Conclusion

88. Ms D failed to check the medication dispensed to Miss A on 31 October 2016 adequately. She also failed to report the error and complete an incident report form in a timely manner. By doing so, Ms D failed to provide Miss A with services in accordance with professional and other relevant standards, in breach of Right 4(2) of the Code.

Opinion: Pharmacy — adverse comment

89. The pharmacy told HDC that, when a warning note is entered in Toniq, the next time the patient file is accessed to enter a prescription, a warning note will come up in the middle of the screen with the words "Warning Note Please Read". The staff member must acknowledge that the note has been read by pressing "Y" before exiting the note. The warning notes are also printed on a Toniq Check Form with the medicine labels and medicine receipt. The pharmacy stated that, at the time of these events, the Toniq Check Form was not required to be attached to the prescription, as this was not part of its SOPs.

90. The Toniq Check Form and warning notes act as an important tool in the prevention of repeated errors. The weakness of the system in place at the time of these events was that the person who read and acknowledged the warning note was not the person who dispensed or checked the medication. The SOPs in place at the time also did not

[17] See opinion 14HDC00551.

require the Toniq Check Form to be attached to the prescription and medication labels. As a result, on 31 October 2016, Ms B and Ms D were not alerted to the warning note and the previous error. I am critical that the pharmacy did not have adequate systems to communicate warnings and previous errors to appropriate staff.

91. However, I am satisfied that the pharmacy had adequate SOPs in place to ensure safe dispensing, checking, and incident reporting for those who followed them. I am of the view that the errors made by Ms B, Ms C, and Ms D were theirs alone, and not a result of poor or inadequate processes in place at the pharmacy. Therefore, I do not consider that the pharmacy breached the Code or is vicariously liable for Ms B's, Ms C's or Ms D's breach of the Code.

Recommendations

92. I recommend that the pharmacy:

a) Randomly audit, over a period of three months, its staff compliance with its SOPs for dispensing and checking medication, and provide HDC with the outcome of that audit within six months of the date of this report. The pharmacy has provided a written apology to Miss A.

b) Confirm that training with the local Diabetes Association has taken place for all pharmacy technicians and pharmacists, including Ms D. Confirmation should occur within three weeks of the date of this report.

c) I recommend that Ms C provide a written apology to Miss A. The apology should be sent to HDC within three weeks of the date of this report, for forwarding to Miss A.

d) In response to the recommendations made in the provisional opinion, Ms B and Ms D each provided a written apology to HDC for forwarding to Miss A.

Follow-up actions

93. A copy of this report, with details identifying the parties removed, will be sent to the Pharmacy Council of New Zealand and the district health board, and they will be advised of Ms C's and Ms D's names. The district health board will also be advised of Ms B's name.

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