Pharmacist, Ms C

Pharmacist, Ms D

A Pharmacy

A Report by the

Deputy Health and Disability Commissioner

(Case 14HDC00551)

Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

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Executive summary

Factual background

1. On 11 February 2014 and 22 April 2014, Ms B visited a pharmacy to have a prescription filled for her son, Mr A, aged 32 years. Mr A has a disability and is diabetic. On both occasions, Ms B was given the wrong insulin for Mr A, Humulin NPH (a medium-acting insulin) instead of Humulin 30/70 (a mixture of short- and medium-acting insulin).

2. On 11 February 2014, pharmacist Ms C selected, labelled and checked the medication for Mr A. Because of the difference in packaging, Ms B realised that there was an error, and within three days, she contacted the Pharmacy to tell them. The correct medication was then delivered to Ms B.

3. On 22 April 2014, pharmacist Ms D checked the medication dispensed for Mr A. Ms D is not certain who completed the other steps of the dispensing process on this occasion.

4. No medication was taken on either occasion, but had Ms B not discovered the error, it is likely that management of Mr A's diabetes would have been compromised.

5. On 5 May 2014, an incident reporting form for the 11 February 2014 incident was completed by Ms C. On 16 May 2014, an incident reporting form was completed for the 22 April 2014 incident by charge pharmacist Mr E, after receipt of the complaint to HDC.

Deputy Commissioner's findings

6. By failing to select the correct medication and then check the medication being dispensed to Mr A on 11 February 2014 appropriately, Ms C failed to provide Mr A with services in accordance with professional standards and, as such, breached Right 4(2)[1] of the Code of Health and Disability Services Consumers' Rights (the Code).

7. By failing to check the medication being dispensed to Mr A on 22 April 2014 appropriately, Ms D failed to provide Mr A with services in accordance with professional standards and, as such, breached Right 4(2) of the Code.

8. Overall, the Pharmacy did not have appropriate processes in place to support safe dispensing practices. For not supporting a safe dispensing environment appropriately, the Pharmacy breached Right 4(1)[2] of the Code.

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

Complaint and investigation

9. The Commissioner received a complaint about the services provided to Mr A by the Pharmacy in 2014. The following issues were identified for investigation:

- *Whether the Pharmacy provided Mr A an appropriate standard of care.*
- *Whether pharmacist Ms C provided Mr A with an appropriate standard of care.*
- *Whether pharmacist Ms D provided Mr A with an appropriate standard of care.*

10. This report is the opinion of Theo Baker, Deputy Commissioner, and is made in accordance with the power delegated to her by the Commissioner.

11. The parties directly involved in the investigation were:

Mr A	Consumer
Ms B	Complainant, consumer's mother
Ms C	Pharmacist
Ms D	Pharmacist
The Pharmacy	Provider

Also mentioned in this report:

Mr E	Charge pharmacist
Ms F	Technician

12. Independent pharmacy advice was obtained from pharmacist Mr Glenn Mills (**Appendix A**).

Information gathered during investigation

Background

Mr A and Ms B

13. Mr A, 32 years old, has a disability and lives in a residential care home during the week. During the weekends Mr A is cared for by his mother, Ms B. Mr A has insulin-dependent diabetes,[3] for which he is prescribed Humulin Mixture 30/70.[4]

14. Ms B is Mr A's Welfare Guardian, appointed to manage all matters of personal care and welfare for Mr A. Usually Ms B has Mr A's prescriptions filled and then provides these to the residential home for administration when Mr A is under their care.

[3] When the pancreas cannot make enough insulin and the body has too much glucose (sugar) in the blood.

[4] A type of premixed insulin that is a mixture of short-acting insulin (insulin regular) (30 percent) and intermediate-acting insulin (insulin NPH) (70 percent). The premixed insulin starts working 30 to 60 minutes after injection, has its maximum effect between two and eight hours, and stops working after about 18 to 24 hours.

The Pharmacy

15. The Pharmacy has two directors (both of whom are practising pharmacists in the Pharmacy), Mr E and Ms C.

16. The processes for dispensing and checking medications at the Pharmacy are set out in the Pharmacy's Standard Operating Procedures (SOPs) (see below). In particular, the SOPs require that the dispensing of medications is carried out in the dispensing area. The items in a prescription are dispensed in the order that they are written on the prescription, and must be checked against the prescription, not the labels. The dispensed medication must be checked by a pharmacist before it is handed to the patient. The checking pharmacist is required to check each item against the prescription, checking for the correct patient, medication, strength, form, dosage instructions, and quantity. The pharmacist is required to initial the prescription to indicate that he or she has checked the dispensed medication as correct.

First dispensing error (11 February 2014)

Prescription

17. On 7 February 2014, a general practitioner (GP) prescribed Mr A with the following: 38 units (three months' supply) Humulin Mixture 30/70 100 units/1mL injection (cartridge), Optium 5 Second Test Strips (600 original pack)[5] and Bd Micro Fine Needles (32g x 4mm needle).[6]

Dispensing error

18. At approximately 10am on 11 February 2014, Ms B visited the Pharmacy to have Mr A's prescription dispensed. Pharmacist Ms C selected, labelled and checked the medication dispensed for Mr A in accordance with his prescription.[7] Ms C advised HDC:

> "I was dispensing prescriptions at the usual dispensing station on the [morning] of 11th February 2014. [Ms F] (technician) was processing the prescriptions on the computer and I was picking, labelling & checking the prescriptions before handing them out. It was a busy [morning] for prescriptions and pharmacist only enquires and consultations. I believe [Mr E] (charge pharmacist) was not in the dispensary at this time."

19. Ms C told HDC that she was carrying out her normal responsibilities on 11 February 2014, which included "dispensing scripts, staff management, customer consultations, buying decisions (I am the retail manager for the pharmacy), paying bills, [and] data entry for the accounting programme".

20. On 11 February 2014, Ms C inadvertently dispensed Mr A with 38 units (three months' supply) 100units/1mL injection (cartridge) Humulin NPH,[8] instead of

[5] Used to self-test blood insulin levels.
[6] Needles used to inject insulin subcutaneously (ie, into a layer of the skin).
[7] Ms C is a registered pharmacist and has a Diploma in Pharmacy. Ms C is a member of the Pharmaceutical Society of New Zealand Incorporated and the New Zealand College of Pharmacists.
[8] Intermediate-acting insulin (insulin NPH). It takes 1 to 3 hours to begin working after injection, reaches its maximum effect between 5 and 8 hours, and stops working after about 18 to 24 hours.

Humulin 30/70. According to the Pharmacy's electronic dispensary management software, Toniq, the medication was dispensed from the Pharmacy at 10.17am.

Humulin 30/70 and Humulin NPH

21. Both Humulin 30/70 and Humulin NPH insulins are cloudy liquids that are stored in 100mL clear cartridges. Humulin 30/70 packaging is white with blue, black and brown writing with a brown border. Humulin NPH packaging is white with blue, black and green writing with a green border. Both packages contain five clear cartridges each.

22. The manufacturer for both Humulin NPH and Humulin 30/70, package five cartridges of either Humulin NPH or Humulin 30/70 in one pack. Often Humulin NPH and Humulin 30/70 are dispensed in groups of four cartridges (three months' supply). In that case, the Pharmacy repacks the cartridges from the manufacturer's original pack. Ms C informed HDC that the Pharmacy's usual practice is to repackage the cartridges in a plain skillet in groups of four cartridges, therefore losing the manufacturers' packaging with its distinctive style and colouring. As noted above, Mr A's prescription was for four cartridges (3 months' supply).

Ms C's recall

23. Regarding the dispensing of Mr A's medication on 11 February 2014, Ms C advised HDC:

> "I do not particularly remember dispensing this prescription but I must have lost my concentration during the checking procedure and not picked up that I had taken the wrong insulin out of the fridge. Our dispensary fridge at the time was very small and over crowded with medication and [the different branded] insulins were all packed together in the fridge door shelf."

Ms B discovers the error

24. On Friday 14 February 2014 Ms B discovered the error as a result of noticing the different packaging. At 4.55pm she called the Pharmacy to inform them. Ms C was not in the Pharmacy at the time, as she was out of town for business, and so both dispensary technician Ms F and Mr E discussed the matter with Ms B. Mr E advised HDC that he "offered [his] apologies for the error and [Ms F] offered to alter her route to drive home and take the correct Humulin 30/70 out to Ms B". That afternoon, Ms F delivered Humulin 30/70 to Ms B.

25. Upon her return to the Pharmacy the following day, Ms C was informed of the error by Ms F and Mr E.

Incident reporting

26. Mr E advised HDC that he did not fill in an incident reporting form when he became aware of the error. He stated: "I was the sole pharmacist on duty at the time of the error, and for the rest of the working day; I was busy and I forgot." Mr E stated that he appreciates that he did not follow the Pharmacy's SOP for reporting dispensing errors.

27. Once she became aware of the dispensing error, Ms C also did not fill in the incident reporting form right away. On 5 May 2014, following a similar dispensing error

involving Mr A (see below), Ms C completed an incident reporting form relating to the incident on 11 February 2014. Ms C told HDC that when Ms F made her aware of the mistake, she "asked how [Ms B] had been about the error. [Ms F] said that she had been annoyed. I was in the middle of dealing with a sales [representative] at the time and forgot to follow up further about the error." In addition, the incident reporting form of 5 May 2014 states:

> "I did not fill in an Incident Report at the time as per our SOPs as I believed that the matter had been already dealt with, and I regrettably forgot to follow up on the matter with [Mr E] after I had finished my appointment with the Sales rep. I am very sorry that I did not at that time talk to [Ms B] about the incident and apologise on my own behalf to her."

Action taken following error

28. Mr E advised HDC:

> "Following the error on Feb [11] 2014, we placed a warning note on [Mr A's] patient file (electronic version with Toniq software), which appears at every dispensing to [Mr A] after you have selected him as the patient that you are wanting to input dispensing info on; and a message comes up on screen (READ PATIENT WARNING NOTES! The warning note appears on the RHS [right hand side] of the screen and you then need to push Y for Yes). The warning note after the first error in Feb prompted the dispenser to ensure that Humulin 30/70 be dispensed & that a dispensing error had occurred."

Second dispensing error (22 April 2014)

Prescription

29. On 15 April 2014, Mr A's GP prescribed Mr A with the following: 38 units (three months' supply) Humulin Mixture 30/70 100 units/1mL injection (cartridge), Optium 5 Second Test Strips (600 original pack) and Accu-Chek Softclix Li Lancets.[9]

Dispensing error

30. During the morning of 22 April 2014, Ms B visited the Pharmacy to have Mr A's 15 April 2014 prescriptions filled.

31. Pharmacist Ms D[10] was the pharmacist responsible for checking Mr A's filled prescription. There is no record of who processed the prescription through the computer or who selected the medication. Humulin NPH was again dispensed to Ms B instead of Humulin 30/70. Ms D advised HDC:

> "On 22nd April 2014 I was working as locum pharmacist at [the Pharmacy] for 1 week […]. I can recall very little of the day in question other than that it was a very busy day for dispensing. I do not specifically recall dispensing the

[9] Used to self-test glucose levels.

[10] Ms D is a registered pharmacist and has a Bachelor of Pharmacy. Ms D is a member of the Pharmaceutical Society of New Zealand Incorporated and New Zealand College of Pharmacists. At the time of the events in question, Ms D was a locum pharmacist at the Pharmacy. Ms D stated that when she worked as a locum at the Pharmacy, often she was the only pharmacist dispensing and checking prescriptions, with the support of a dispensing technician.

prescription for [Mr A] for Humulin 30/70. From the copy of the prescription I can see that I have signed the 3rd part label (as has always been my custom) to endorse that I have checked the prescription has been dispensed correctly. I cannot tell who processed the prescription through the dispensing computer, or who may have dispensed the items.

I don't believe I processed the prescription through the computer to produce the dispensing labels as I would have seen the alert in the computer regarding the previous dispensing error and the warning to check that Humulin 30/70 is dispensed and my error would not have occurred. The alerts do not print out when a prescription has been processed and so will only be seen by the staff member entering the prescription. It is possible that I both dispensed and checked the prescription for Humulin 30/70, without realising my error.

It appears I have misread the prescription and selected the wrong product from the fridge, then been distracted during my checking process and missed the mistake. At the time of the error the fridge was full and the different types of insulin were stored together on the shelf."

32. At 10.45am when she arrived home, Ms B rang the Pharmacy to inform it of the error. Mr E received the call and advised HDC that he apologised instantly to Ms B and offered to send a staff member to Ms B's house to provide the correct medication. Ms B told Mr E that that would not be necessary as Mr A had enough Humulin 30/70, and she could come in the following week to pick up the correct insulin.

33. Mr E advised HDC that when Ms D returned from lunch he told her of the error and then advised her that he would "deal with the issue". Ms D stated: "I asked if [Mr E] wanted me to complete the incident report and he said he would do it as he received the complaint."

Incident reporting form

34. Mr E advised HDC that following the 22 April 2014 error:

"I prepared an incident report, in note form, but did not follow through on everything in the SOP because:

a. It was a very short week of just three working days between end of Easter and Anzac Day, and we were very busy. Most of my time was dispensing.

b. On Thursday 24th I went on annual leave for 10 days, and unfortunately, completely forgot about it. I was not present for [Ms B] coming in to exchange the incorrectly dispensed drug for the correct one. Indeed receiving the HDC letter made me swiftly recall my error with following my own SOP. I located the incident reports, in notes and refreshed my understanding of the incidents and recorded them electronically."

35. On 16 May 2014, Mr E completed the formal, on-line, incident reporting form. The form outlines the incident and the following actions taken:

"**16 May 2014** after receiving complaint from HDC, changed [one brand] insulin layout in disp [dispensary] fridge.

> **Late May** Introduced new staff procedures to follow in minimising interaction with Dispensing Pharmacist. (Backed up at staff meeting 23 May 2014 to explain why the necessary changes.) Will look at replacing current disp fridge with larger model; currently jam packed! Dispensary staff reviewed checking procedures."

Actions taken as a result of the second dispensing error

36. In addition to the actions highlighted on the incident reporting form, the Pharmacy advised HDC that it has undertaken the following changes to its dispensing practice:

- The warning note on Mr A's file has been amended to read "PLEASE CHECK HUMULIN 30/70!!! 2 dispensing errors made".
- A staff meeting with both the shop and dispensary staff was held to discuss the incidents.
- A new refrigerator was purchased so that the Pharmacy now has two refrigerators to store medication between two and eight degrees.
- Each professional in the dispensary involved in the dispensing process is to sign off that each item has been checked.
- Insulin stocks are segregated as much as possible by storing differing brands and strengths in their own basket. Humulin NPH and Humulin 30/70 are separated by a shelf in addition to their own baskets.

37. Following receipt of a copy of Ms B's complaint to HDC for comment, both Mr E and Ms C spoke with Ms B, tendering their apologies for the errors. In addition, on 27 May 2014, Mr E wrote an apology letter to Ms B. In the letter, Mr E noted that Ms B had decided to continue to use the Pharmacy as the medication provider for Mr A, and that they were grateful for this.

Additional information from Ms B

38. Ms B advised HDC:

> "My son's medicine regime has been carefully formulated over many years, and the potential for hypos or hypers [in blood sugar levels] would have been highly at risk with this error. Added to this is the fact that his insulin is administered by [caregivers], who trust and rely on me to make sure the correct drugs are on hand. The potentially serious situation that could have arisen really concerns me — especially as this error has happened more than once."

Relevant Pharmacy SOPs

39. At the time of these events, the Pharmacy had in place a number of relevant SOPs, including *Recording Prescription Details (9 March 2014)*, *Generating Labels (9 March 2014)*, *Selecting Correct Medications (9 March 2014)*, *Counting or Pouring Medicines (9 March 2014)*, *Checking Prescriptions (9 March 2014)*, *Recording Dispensing Errors (18 December 2012)*, and *Handing Out Prescriptions and Patient Counseling (12 July 2012)*. The dates on a number of the above SOPs were between the first incident on 11 February 2014 and the second incident on 22 April 2014

indicating that they were reviewed on those dates and may not have been the SOPs in place at the time of the first dispensing error on 11 February 2014.

40. HDC requested the Pharmacy provide relevant SOPs in place in February 2014. The Pharmacy advised that it does not keep older versions of the SOPs, but Mr E advised HDC that "by my recall I would say there were perhaps only very minor changes to those SOPs" following the March 2014 update.

Checking Prescriptions SOP

41. The *Checking Prescriptions* SOP outlines that drugs to be dispensed must be checked against the prescription form by the pharmacist, as follows:

> "Stock bottles and the drugs to be dispensed should be side by side with the labelled prescription items and the script form. It is wise to employ a 5 second check to the drug on the Rx [prescription form] against what is about to be dispensed …"

42. The SOP outlines a checklist to review when checking medications to be dispensed:

> "— prescription details: patient details, statutory details, suitability of prescribed medicine.
>
> — past medical history: consistency of treatment, interactions with med, adverse reactions, misuse or abuse potential or history.
>
> — medicine strength and quantity dispensed against prescription, medicine expiry date.
>
> — calculations for compound products.
>
> — label info is correct: medicine name, dose, form, patient name, date, prescription number, directions are clear, concise & correct, caution & advisory labels are attached.
>
> — all containers belong to the prescription."

Handing Out Prescriptions and Patient Counseling SOP

43. The *Handing Out Prescriptions and Patient Counseling* SOP allows for a final check that the right medication is being dispensed to the right patient, by requiring the pharmacist to "check the patients name and address against the prescription to ensure the correct medicine is going to be given to the correct client, or their representative. Points to check include: Is the medicine they're receiving what they expected to be supplied with …"

Recording Dispensing Errors SOP

44. The *Recording Dispensing Errors* SOP outlines the following:

> "If a dispensary error occurs, it is vital to record the event on an incident form (as detailed in Part F8 Incident Reporting, old OQS [operational quality standards] standards), in order to minimise the likelihood of a repeat of the situation, and as a record of what has happened."

45. The SOP identifies the form to be used when recording an error and where to file the completed incident form. The SOP states: "Recording the error & discussion with peers in the pharmacy increases the chances of it not occurring again and discussion can take place in finding ways to lessen the risk of that occurring."

Recording Prescription Details SOP

46. The *Recording Prescription Details* SOP outlines what is to be included on the Pharmacy's Toniq software. The SOP requires that the pharmacist or dispensary technician check the client's personal details against the computer records.

Changes to Ms C's practice

47. Ms C advised HDC:

> "I have reviewed and made changes to my dispensing practice as a result of this dispensing error. I have undertaken an Enhance Group[11] 3 activity to improve my dispensing and checking procedures, this is still underway [as at December 2014] … I have slowed down in my dispensing processes and completely changed the way I do my final check — I now physically mark on the script as I check each separate part of the prescription item — drug name, strength, quantity, repeats, etc. I have found this to be very helpful in catching near misses. When able I also get my work checked by other dispensary staff before it is handed out.
>
> …
>
> I hope the CPD I have undertaken and my commitment to upgrading my dispensing and checking of prescriptions will minimise the risk of error occurring in the future."

Changes to Ms D's practice

48. Ms D advised HDC:

> "Since the dispensing error occurred I have undertaken to review my dispensing and checking process. I have discussed and observed the methods of my colleagues at the pharmacy I now work at part-time … and I have adopted changes as follows:
>
> - I now mark (tick) the prescription of each aspect of an item I have checked — Correct medication, correct strength and form, correct dosage instructions, and only then initial it as correct.
> - Where possible I do not complete all 3 steps of the dispensing process (processing through the computer, dispensing and checking) alone. I ensure at least one other person is involved in the process, preferably that it is dispensed by someone else. Where I have processed and dispensed the items I ask another pharmacist to do the final check.

[11] The recertification programme provided by the Pharmaceutical Society of NZ Incorporated and accredited by the Pharmacy Council of NZ.

- Where possible I prefer to process prescriptions through the computer myself so that I may see any alerts or notes in the patient file and any interactions that are flagged by the program.
- I ensure that every prescription is initialled by the person who dispensed and the person who checked it.
- Where it is not possible to have someone else involved in the dispensing process I will put the prescription aside after I have checked it, do something else, then come back and check it a second time before it is given to the patient. I prefer to initial the second check with a different coloured pen to indicate I have done so …
- Since this error occurred I have ensured that I have familiarised myself with all insulin products available in NZ and have a chart of them all from the Pharmacy Defense Association (PDA). I have also read the PDA's information on insulin dispensing errors.
- As I work part-time I have asked that the full-time staff where I work let me know when they learn of new formulations available in NZ. I also try to keep up to date with Pharmac updates, BPAC [Best Practice Advocacy Centre] magazine and the Interactions publication.

…

As a pharmacist I do my best to ensure that errors do not occur. I hope that my review and alteration of my practice and my ongoing endeavours to keep up to date and refresh my learning ensure that such an error may not happen again."

Response to provisional opinion

49. All the relevant parties were provided with an opportunity to respond to the provisional opinion. Ms C, Ms D and the Pharmacy accepted the findings of the provisional opinion. Ms B provided comment on the information gathered section of the provisional opinion and her comments have been incorporated in the opinion.

Relevant standards

50. The Pharmacy Council of New Zealand publication *Safe Effective Pharmacy Practice* (2011) provides in its *Code of Ethics* that the 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."

51. Furthermore, the Pharmacy Council of New Zealand *Competence Standards for the Pharmacy Profession (2011)* states:

"1.1.5 Works accurately

Examples of Evidence: Minimises mistakes. Acts immediately to rectify harm arising from mistakes. Documents errors and steps taken to prevent their recurrence.

…

6.2.2 Follows workplace dispensing criteria when dispensing a prescription item.

…

6.5.1 Confirms that each selected medicine is suitable for the patient.

Examples of Evidence: Confirms that dosage, route of administration & duration of therapy are suitable.

…

6.6.2 Maintains a logical, safe and disciplined dispensing procedure.

Examples of Evidence: Selects correct product, dose form & quantity for each prescribed medicine. Dispenses off prescription, not label.

6.9.2 Acts to minimise the effects of his/her dispensing errors.

Examples of Evidence: Identifies potential/actual errors in own dispensing. Acts to minimise effect on patient, e.g. contacts patient, contacts prescriber, supplies correct medicine. Documents own dispensing errors & actions undertaken to minimise their effects. Complies [with] workplace procedures for documenting dispensing errors."

Opinion: Ms C

Dispensing error — Breach

52. On 11 February 2014, Ms B took a prescription for medication for her son, Mr A, to the Pharmacy to have the medication dispensed. Pharmacist Ms C selected, labelled and checked the medication dispensed for Mr A before handing the medication to Ms B. Ms C inadvertently dispensed Humulin NPH for Mr A instead of the Humulin 30/70 prescribed. Ms C accepts that she dispensed the incorrect medication for Mr A, and advised that it was a busy day and she felt it likely that she lost concentration during the checking procedure.

53. As a registered pharmacist, Ms C is responsible for ensuring her adherence to professional standards. The Pharmacy Council of New Zealand's *Competence Standards for the Pharmacy Profession (2011)* outlined above state that pharmacists are to work accurately, follow workplace dispensing criteria when dispensing a prescription item, confirm that each selected medicine is suitable for the patient, and maintain a logical, safe and disciplined dispensing procedure.

54. The Pharmacy has a number of SOPs of relevance, notably the *Checking Prescriptions* SOP. Although HDC has not seen the version of the SOP in place in

February 2014, the Pharmacy advised that the SOP in place would have had only minor changes when it was amended in March 2014. The SOP outlines the steps to be taken to ensure medications dispensed are appropriately checked. The SOP outlines that the pharmacist must check the medicine name and dose against the prescription.

55. Ms C selected the wrong medication for Mr A, and then failed to check the medication she was dispensing for Mr A appropriately against the original prescription. This is unacceptable. Checking that the correct medication is being dispensed is a fundamental aspect of pharmacy practice, and is a requirement of both the Pharmacy's SOPs and the Pharmacy Council of New Zealand professional standards. As noted by my expert advisor, pharmacist Mr Glenn Mills:

> "[T]he dispensing of an incorrect medication to a patient distinctly breaches the fundamental standard of care a patient should reasonably expect, when presenting a prescription to a pharmacy for dispensing, i.e. that of receiving the correct medication, at the correct dose, in the correct quantity, with the correct instructions."

56. Mr Mills also advised: "[Ms C's] dispensing process deviated from what would generally be considered reasonable practice to a moderate degree. I consider her peers would view this error sympathetically, with moderate disapproval."

57. By failing to appropriately select and then check the medication being dispensed, Ms C failed to provide Mr A with services in accordance with professional standards and, as such, breached Right 4(2) of the Code.

58. I note that Ms C accepts her error and has been proactive in having undertaken actions to ensure that such a mistake does not happen again. This is commendable.

Failure to report the error — Adverse comment

59. Once a pharmacist has been put on notice of an error having occurred, it is the pharmacist's duty to minimise the on-going harm and take steps to prevent the error from occurring again. This is emphasised in standard 6.9.2 of the Pharmacy Council of New Zealand's *Competence Standards for the Pharmacy Profession (2011)*, as outlined above. An essential component of a pharmacist's duty in this regard is to complete an incident report form.

60. Ms C advised HDC that she did not fill in an incident report when she was first informed of the dispensing error, because she understood that Mr E had completed one. Ms C was busy when she was informed of the error, and advised HDC that she forgot to discuss the incident form with Mr E to ensure it had been completed.

61. I note that the Pharmacy's SOPs do not state who is to record an error, how an error is to be reviewed, or the timeframe in which recording of an error is to occur.

62. However, I consider that it was Ms C's responsibility to fill in the incident reporting form promptly, and I am critical that she did not to so in this case.

Opinion: Ms D

Dispensing error — Breach

63. On 22 April 2014, Ms B took a prescription for medication for her son, Mr A, to the Pharmacy to have the medication dispensed. Pharmacist Ms D checked the medication dispensed for Mr A before handing the medication to Ms B.[12] Ms D did not recognise that Humulin NPH had been selected for Mr A instead of the Humulin 30/70 prescribed. Ms D accepts that she did not identify that the incorrect medication had been selected for Mr A, and advised that it was a very busy day for dispensing on 22 April 2014.

64. As a registered pharmacist, Ms D is responsible for ensuring her adherence to professional standards. The Pharmacy Council of New Zealand's *Competence Standards for the Pharmacy Profession (2011)* outlined above state that pharmacists are to work accurately, follow workplace dispensing criteria when dispensing a prescription item, confirm that each selected medicine is suitable for the patient, and maintain a logical, safe and disciplined dispensing procedure.

65. At the time of the incident, the Pharmacy had a number of SOPs of relevance, notably the *Checking Prescriptions* SOP. This SOP outlines steps to be taken to ensure that medications dispensed are checked appropriately. The SOP outlines that the pharmacist must check the medicine name and dose against the prescription.

66. Ms D failed to check the medication appropriately before giving it to Ms B. This is unacceptable. Checking that the patient is being dispensed the correct medication is a fundamental aspect of pharmacy practice, and is a requirement of both the Pharmacy's SOPs and professional standards. As noted by my expert advisor, pharmacist Glenn Mills:

> "Regrettably, the dispensing of an incorrect medication to a patient distinctly breaches the fundamental standard of care a patient should reasonably expect, when presenting a prescription to a pharmacy for dispensing, i.e. that of receiving the correct medication, at the correct dose, in the correct quantity, with the correct instructions."

67. Mr Mills also advised: "[Ms D's] dispensing process deviated from what would generally be considered reasonable practice to a moderate degree. I consider her peers would view this error sympathetically, with moderate disapproval."

68. By failing to appropriately check the medication being dispensed, Ms D failed to provide Mr A with services in accordance with professional standards and, as such, breached Right 4(2) of the Code.

69. I note that Ms D accepts her error and has been proactive in having undertaken actions to ensure that such a mistake does not happen again. This is commendable.

Failure to report the error — Adverse comment

70. Once a pharmacist has been put on notice of an error having occurred, it is the pharmacist's duty to minimise the on-going harm and take steps to prevent the error

[12] As noted above, the Pharmacy is unable to advise who prepared the medication.

from occurring again. This is emphasised in standard 6.9.2 of the Pharmacy Council of New Zealand's *Competence Standards for the Pharmacy Profession (2011)*, as outlined above. An essential component of a pharmacist's duty in this regard is to complete the incident report form.

71. Ms D advised HDC that she did not fill in an incident reporting form because Mr E advised her that he would complete one.

72. I also note that the Pharmacy's SOPs do not state who is to record the error, how the error is to be reviewed, or the timeframe in which recording of the error is to occur.

73. However, I consider that it was Ms D's responsibility to fill in the incident reporting form promptly, and I am critical that she did not do so in this case.

Opinion: The Pharmacy

Systemic issues — Breach

74. The same dispensing error occurred twice at the Pharmacy within a relatively short period of time. On both occasions the incident was not recorded appropriately. I consider that the repeat in the dispensing error, and the inappropriate recording of the incidences, signal that there were systemic issues at the Pharmacy. My reasons are outlined as follows.

Identification of individuals involved in the dispensing process

75. Following the first incident on 11 February 2014, Ms C recalled that Ms F processed the prescription through the computer, and Ms C selected, labelled and checked the prescription. However, there is no record of who completed which part of the process, except for the check, which was signed off on the prescription by Ms C.

76. Similarly with the 22 April 2014 incident, there is no record of who was involved in the various steps of the dispensing process. Ms D signed the prescription to indicate that she had checked it, but there is no record of who processed the prescription through the computer, selected the medication, and labelled the items to be dispensed.

77. Mr Mills advised:

> "[The Pharmacy] should consider amending their dispensing stamp and Standard operating procedure, to include a section allowing initialling by team members for all specific steps in the dispensing process, **including entering**, dispensing and final checking the prescription. This would generally be accepted as best practice."

78. I consider that the Pharmacy did not have appropriate processes in place to ascertain who was involved in each step of the dispensing process. Being able to identify the individuals involved in the various steps of the dispensing process is critical for quality improvement, and for ensuring that the outcomes of adverse incidents are passed along to the staff members involved.

Standard Operating Procedures

79. Written SOPs provide the minimum requirements for dispensing medication, and are central to ensuring safe and effective dispensing. The Pharmacy's SOPs clearly state the requirement that the dispensed medication is checked appropriately against the original prescription.

80. While Mr Mills advised me that, overall, the Pharmacy's SOPs appear appropriate, he also outlined areas of ambiguity and omission in some of the SOPs. I note the following:

- Recording Dispensing Errors SOP
  The *Recording Dispensing Errors* SOP does not contain information about the timeframe for reporting following an incident. Nor does the SOP outline who should complete, or contribute to completing, the incident reporting form. In addition, there is no formal process for team members to review the error or for the Pharmacy to communicate with the consumer involved in the error. Mr Mills advised me that he would have expected this information to be included in this SOP. Had the information been included, and followed, the risk of the error occurring again may have been reduced.

- Checking Prescriptions SOP
  The Pharmacy has separate SOPs for dispensing processes and checking. Mr Mills considers that checking processes should be incorporated into the dispensing process SOPs.

81. Furthermore, I note that the Pharmacy amended many of its SOPs in March 2014, but did not keep a copy of its previous SOPs.

Incident reporting and review

82. Neither dispensing error was recorded in a timely manner. The 11 February 2014 error was reported on 5 May 2014. The 22 April 2014 error was formally reported on 16 May 2014, after a copy of Ms B's complaint to HDC was provided to the Pharmacy for comment. Mr E, the Pharmacy's charge pharmacist, was involved in the follow-up of both errors. Both Ms C and Ms D understood that Mr E would complete the incident reporting form for their dispensing errors.

83. The Pharmacy's SOPs outline requirements for incident reporting and reviewing the incident with others in the dispensing team at the Pharmacy. While the SOPs have no timeframe on reporting, Mr E did not record the second incident until receipt of Ms B's complaint to HDC. This is unacceptable.

84. Mr Mills advised: "This deviates from both the Pharmacy's SOP and what would be accepted as good practice significantly. It is my opinion that my peers would view this with moderate disapproval."

85. I agree with my expert's advice, and consider that the unsatisfactory reporting of both incidents indicates that the Pharmacy did not have sufficient processes in place to ensure that incidents were reported appropriately and responded to. Had the 11 February 2014 error been reported and reviewed appropriately, it may have reduced the risk of the second error occurring.

Conclusion

86. Ms B trusted the Pharmacy to dispense Mr A's medication accurately. On both 11 February 2014 and 22 April 2014 this did not occur, and Mr A was dispensed Humulin NPH instead of Humulin 30/70. As the pharmacists responsible for checking the dispensed medication, Ms C and Ms D are directly responsible for these individual errors. However, the same error occurred twice. On review of the Pharmacy's SOPs I consider that there were omissions in these, and that overall the SOPs were not followed appropriately. In particular, I note that incident reporting was unacceptable. For the systemic issues identified I consider that the Pharmacy failed to provide services to Mr A with reasonable care and skill and, accordingly, breached Right 4(1) of the Code.

Communication within the dispensing team — Comment

87. Following the 11 February 2014 incident, a note was placed on Mr A's electronic patient file to indicate that an error had occurred. Ms D considered it unlikely that she was involved in processing the prescription through the computer, because she would have seen the note regarding the previous error and been alerted when selecting Mr A's medication. There is a possibility that another member of the dispensing team at the Pharmacy processed the prescription through the computer but did not alert Ms D about the previous error.

88. Mr Mills advised:

> "If indeed she [Ms D] did not enter the prescription, had this alert been communicated through to Ms D, it is highly likely this second dispensing error would have been prevented. It is my opinion that my peers would view this process omission with moderate disapproval."

89. I am unable to make a finding as to who processed the prescription through the computer; however, had someone else in the dispensing team been involved with the processing of Mr A's prescription and not informed Ms D of the alert, I would consider communication in this respect to be substandard.

Recommendations

90. In accordance with the recommendations in my provisional opinion Ms C and the Pharmacy have provided a written apology to Mr A and Ms B.

91. I recommend that Ms C arrange for an assessment through the New Zealand College of Pharmacists regarding the processing of prescriptions and processes for dispensing and checking medications.

92. I recommend that Ms D:

a) Provide a written apology to Mr A and Ms B for her breach of the Code. That apology should be sent to HDC, for forwarding to Mr A and Ms B, within three weeks of the date of this report.

b) Arrange for an assessment through the New Zealand College of Pharmacists regarding the processing of prescriptions and processes for dispensing and checking medications.

93. I recommend that the Pharmacy:

a) Amend its *Reporting Dispensing Errors* SOP to include information on reporting timeframes, personnel requirements for reporting, team incident review, and a process for communicating with consumers following errors. A copy of this amended SOP is to be sent to HDC within three months of the date of this report.

b) Provide all dispensary staff with training on the above (recommendation b) amended SOP and best practice guidelines on incident reporting and review. Evidence of this training, including training handouts, are to be sent to HDC within three months of the date of this report.

c) Amend its *Generating Labels*, *Selecting the Correct Medications*, *Counting or Pouring Medicines* and *Recording Prescription Details* SOPs to include reference to appropriate checking procedures. Copies of the amended SOPs are to be sent to HDC within three months of the date of this report.

d) Ensure that the Pharmacy has a process for saving previous versions of SOPs. Evidence of this is to be provided to HDC within three months of the date of this report.

e) Amend its stamp used for dispensing, or develop another process, so that the Pharmacy can identify who was involved in each step of the dispensing process (entering, dispensing and checking). Evidence of this new stamp or process is to be provided to HDC within three months of the date of this report.

f) Audit its dispensary staffing levels to ensure that pharmacists are not overworked. A copy of this audit is to be provided to HDC within three months of the date of this report.

Follow-up actions

- A copy of this report with details identifying the parties removed, except the expert who advised on this case, will be sent to the Pharmacy Council of New Zealand and the relevant District Health Board, and they will be advised of Ms C and Ms D's names, as well as the name of the Pharmacy.
- A copy of this report with details identifying the parties removed, except the expert who advised on this case, will be sent to the Pharmaceutical Society of New Zealand, the Pharmacy Guild of New Zealand, the New Zealand College of Pharmacists, the Health Quality and Safety Commission, and the Ministry of Health, and placed on the Health and Disability Commissioner website, www.hdc.org.nz, for educational purposes.

Appendix A — Independent expert pharmacy advice to the Commissioner

The following expert advice was obtained from pharmacist Mr Glenn Mills on 23 March 2015.

"**Introduction**
I have been asked to provide an opinion to the Deputy Health and Disability Commissioner on Case Reference 14/00551, regarding [Mr A], and confirm I have read and agree to follow the Commissioner's Guidelines for Independent Advisors. I have no personal or financial connections with the provider(s) or the consumer(s) in this case. I also confirm that no professional connection exists with the provider(s), am free of bias and it is of my opinion that no conflict of interest exists. I am a registered pharmacist with the Pharmacy Council of New Zealand (registration number […]), a member of the Pharmaceutical Society of New Zealand and an Associate Member of the New Zealand College of Pharmacists. I have been registered as a Pharmacist since 2002. I am a shareholder and director [of a large, busy community pharmacy in Auckland.]

Referral Instructions
I have been requested by [HDC's] Investigator, by letter dated 29 January 2015, to provide advice to enable the Deputy Commissioner to determine whether, from the information available, there are concerns about [the Pharmacy] care provided to [Mr A] by [the Pharmacy] and/or its staff, as outlined further in this report. In particular, I have been requested to provide my opinion to the questions below:

1. Whether the [dispensing] processes followed by pharmacists [Ms C and D] were appropriate, as outlined in their subsequent responses to HDC.
2. Whether [the Pharmacy] had appropriate Standard Operating Procedures (SOPS) in place at the time of the events in question. In particular, were there sufficient prescription checking provisions in the SOPs.
3. Whether [the Pharmacy] appropriately stored its supply of Humulin cartridges and Humulin 30/70 mix cartridges.
4. Whether changes undertaken by [the Pharmacy] since the events in question are appropriate.

For each question, I have also been requested to advise:

1. What is the standard of care/accepted practice?
2. If there has been a departure from the standard of care or accepted practice, how significant a departure to you consider it is?
3. How would it be viewed by your peers?

Material Reviewed (as provided)
Please note these Standards have recently been re-published in January 2015, however the Standards valid at the time of these incidents have been referenced.

1. [Ms B's complaint to HDC];
2. [The Pharmacy's] response to complaint (HDC) written by [Mr E], dated 23 May 2014, including;

a. Copy of prescriptions dated 7 February and 15 April 2014
b. Incident reporting forms (x2) completed by [Mr E], each dated 22 April 2014
c. Patient medicine info chart
d. Response to complainant ([Ms B]) dated 27 May 2014
e. Various standard operating procedures (SOP's), including:
    i. SOP Al — Powering up computer system
    ii. SOP A2 — Hand Washing
    iii. SOP A3 — Checking Client Details
    iv. SOP A4 — Accuracy Of Information Input On Computers
    v. SOP A5 — Receiving Prescriptions
    vi. SOP A6 — Priority of Prescriptions
    vii. SOP A7 — Checking Correctness of Prescriptions
    viii. SOP A8 — Recording Prescription Details
    ix. SOP A9 — Generating Labels
    x. SOP A10 — Selecting Correct Medicines
    xi. SOP A11 — Counting or Pouring Medicines
    xii. SOP A12 — Checking Prescriptions
    xiii. SOP A13 — Handing Out Prescriptions and Patient Counselling
    xiv. SOP A14 — Repeat Prescriptions
    xv. SOP A15 — Storage of Prescriptions awaiting Pickup
    xvi. SOP A16 — Delivery of Prescriptions
    xvii. SOP A17— Processing Telephone/fax Prescriptions
    xviii. SOP A18 — Owes/out of Stock
    xix. SOP A19 — Dispensing of Owes on Rx's
    xx. SOP A20 — Medical Practitioner Supply Orders
    xxi. SOP A21 — Recording Dispensing Errors
    xxii. SOP A22 — Recording Near Misses

f. Documentation relating to Pharmacy Quality Audit 4, audited 7 November 2012

3. [The Pharmacy's] response to complaint (HDC) written by [Mr E], dated 17 December 2014, including:
    a. Pharmacist [Ms C's] response to complaint, dated 8 December 2014, including:
    b. Incident reporting form completed by [Ms C], dated 28 May 2014
    c. Pharmacist [Ms D's] response to complaint, dated 17 December 2014;

4. HDC's updated Guidelines for Independent Advisors

Factual Summary

On both 11 February 2014 and 22 Apri1 2014, [Ms B] visited [the Pharmacy] to have an insulin prescription filled for her son, [Mr A]. [Ms B is Mr A's] Welfare Guardian. On both occasions, [Ms B] was given Humulin cartridges instead of Humulin 30/70 mix cartridges. Thankfully, on neither occasion was the incorrect insulin administered to [Mr A].

11 February 2014 Dispensing

The pharmacist involved in the 11 February 2014 incident was [the Pharmacy] shareholder and director, [Ms C].

22 April 2014 Dispensing
The pharmacist involved in the 22 April 2014 incident was locum […] pharmacist [Ms D].

Medication References
Humulin NPH, referred to as Humulin in this case, (also called isophane insulin injection) is a sterile suspension of a white, crystalline precipitate of isophane human insulin (rbe) in an isotonic phosphate buffer adjusted to a pH range of 6.9 to 7.5. Humulin N is an **intermediate-acting insulin** preparation.[1]

Humulin 30/70 (also called biphasic isophane insulin injection) is a **mixture** of human insulin (70% isophane human insulin (rbe), 30% soluble human insulin (rbe)) adjusted to a pH range of 6.9 to 7.5. Humulin Mixture 70/30 is an intermediate acting insulin preparation.[2]

Please find below my opinion and comments, with regard to the specific questions presented for my comment as well as general comments for consideration.

1. Whether the [dispensing] processes followed by pharmacists [Ms C] and [Ms D] were appropriate, as outlined in their subsequent responses to HDC?

Dispensing — 11 February 2014
After reviewing the responses and evidence provided, it appears that pharmacist [Ms C] was responsible for dispensing and checking the dispensing of Humulin (instead of Humulin 30/70 mix) on 11 February, based on annotated initials on the 'dispensed' and 'checked' stamp on the prescription, the internal investigation subsequently held by the Pharmacy and [Ms C's] own response to HDC, dated 8 December 2014. In her response, she states 'I was picking, labelling and checking the prescriptions before handing them out', and 'I do not particularly remember dispensing the prescription but I must have lost my concentration during the checking procedure'.

Regrettably, the dispensing of an incorrect medication to a patient distinctly breaches the fundamental standard of care a patient should reasonably expect, when presenting a prescription to a pharmacy for dispensing, i.e. that of receiving the correct medication, at the correct dose, in the correct quantity, with the correct instructions.

There are a number of relevant professional standards that apply to pharmacists in New Zealand in relation to the completion of the dispensing process. These standards include legislative requirements and, for a process failure such as on this occasion, notably Standards New Zealand's Health and Disability Services

[1] Humulin Datasheet, v4.0, 31/01/13, http://www.medsafe.govt.nz/profs/Datasheet/h/Humulioninj.pdf
[2] Humulin Datasheet, v4.0, 31/01/13, http://www.medsafe.govt.nz/profs/Datasheet/h/Humulioninj.pdf

Pharmacy Services Standard (NZS 8134.7:2010) and the Pharmacy Council of New Zealand's Competence Standards for the Pharmacy Profession. Below, I refer to key standards that in this instance have unfortunately clearly been breached.

Standards New Zealand — Health and Disability Services Pharmacy Services Standard LNZS 8134.7:2010):

Standard 1.7: Consumers receive services of an appropriate standard;
Standard 3.5: Consumers shall receive adequate and appropriate services in order to meet their assessed needs and desired outcomes;
Standard 3.8: Consumers shall receive medicines in a safe and timely manner that complies with current legislative requirements and safe practice guidelines;
Standard 5.2: A disciplined dispensing procedure shall ensure that the appropriate product is selected and dispensed accurately and efficiently.

Pharmacy Council of New Zealand — Competence Standards For the Pharmacy Profession (January 2011)[3]:

Standard 1.1.5: Works accurately;
Standard 6.2.2: Follows workplace dispensing criteria when dispensing a prescription item.
Standard 6.5.1: Confirms that each selected medicine is suitable for the patient;
Standard 6.6.2: Maintains a logical, safe and disciplined dispensing procedure (Evidence Example: Selects correct product, dose form and quantity for each prescribed medicine).

It is my opinion, based on the facts and responses presented, that [Ms C] did not provide an appropriate standard of care to [Mr A] on this occasion. It is reasonable that [Mr A] would expect to receive his prescription to be dispensed accurately, however regrettably this did not occur. [Ms C] failed to accurately complete a final check, as would be considered standard practice, and failed to adhere to a number of the Pharmacy's SOP's, with regard to checking prescriptions. Her dispensing process deviated from what would generally be considered reasonable practice to a moderate degree. I consider her peers would view this error sympathetically, with moderate disapproval.

Dispensing — 22 April 2014
After reviewing the responses and evidence provided, it appears that pharmacist [Ms D] was conclusively responsible for checking the dispensing of Humulin (instead of Humulin 30/70 mix) on 22 April 2014, based on notations on the 3-part label on the prescription, the internal investigation subsequently held by the Pharmacy and [Ms D's] own response to HDC, dated 17 December 2014. In this response, [Ms D] states 'I can see that I have signed the 3rd part label (as has always been my custom) to endorse that I have checked the prescription has been dispensed correctly'. It is important to note that she also states that 'I cannot tell

[3] Please note these Standards have recently been re-published in January 2015, however the Standards valid at the time of these incidents have been referenced.

who processed the prescription through the dispensing computer, or who may have dispensed the items … I don't believe I processed the prescription through the computer to produce the dispensing labels as I would have seen the alert in the computer regarding the previous dispensing error'. She also states 'it is possible that I both dispensed and checked the prescription for Humulin 30/70, without realising my error'. These comments are pertinent to the Pharmacy's dispensing SOPs and are discussed by the writer further in this opinion.

As with the 11 February 2014 dispensing, regrettably, the dispensing of an incorrect medication to a patient unmistakably breaches the fundamental standard of care a patient should reasonably expect, when presenting a prescription to a pharmacy for dispensing, i.e. that of receiving the correct medication, at the correct dose, in the correct quantity, with the correct instructions.

The same relevant professional standards referred to in the 11 February 2014 dispensing also apply to this incident, and are not repeated to avoid repetition. Please refer to these aforementioned standards that in this instance have unfortunately also been clearly breached.

It is my opinion, based on the facts and responses presented, that [Ms D] did not provide an appropriate standard of care to [Mr A] on this occasion. It is reasonable that [Mr A] would expect to receive his prescription to be dispensed accurately, however regrettably this did not occur. [Ms D] failed to accurately complete a final check, as would be considered standard practice, and failed to adhere to the Pharmacy's SOP in this regard. Further, if she was unsure as to who dispensed the prescription as she states, it would be reasonable to expect that she place even more importance on her final check. Her dispensing process deviated from what would generally be considered reasonable practice to a moderate degree. I consider her peers would also view this error sympathetically, with moderate disapproval.

2. Whether [the Pharmacy] had appropriate Standard Operating Procedures (SOPs) in place at the time of the events in question. In particular, were there sufficient prescription checking provisions in the SOPs.

A number of Standard Operating Procedures have been provided for review by [the Pharmacy]. Please note that I have limited my commentary to those with a material relevance to this case.

SOP A1 — Powering up computer system. 9 March 2014
Irrelevant to the nature of this case. I note the issue date proceeds the date of the first dispensing error.

SOP A2 — Hand Washing. 9 March 2014
Irrelevant to the nature of this case. I note the issue date proceeds the date of the first dispensing error.

SOP A3 — Checking Client Details, 9 March 2014
This appears appropriate. I note the issue date proceeds the date of the first dispensing error.

SOP A4 — Accuracy of Information Input On Computers, 9 March 2014
This appears appropriate. I note the issue date proceeds the date of the first dispensing error and precedes the date of the second dispensing error.

SOP A5 — Receiving Prescriptions. 9 March 2014
This appears appropriate. I note the issue date proceeds the date of the first dispensing error.

SOP A6 — Priority of Prescriptions, 9 March 2014
This appears appropriate. I note the issue date proceeds the date of the first dispensing error.

SOP A7 — Checking Correctness of Prescriptions, 7 December 2012
This appears appropriate.

SOP A8 — Recording Prescription Details. 9 March 2014
It is my opinion that this SOP requires significant review and amendment. I note the issue date proceeds the date of the first dispensing error. I am concerned that the SOP does not clearly outline the requirement to refer back to the patient's existing dispensing history, patient notes etc. where applicable, to identify changes to previous drug therapy, omissions, etc. and subsequent processes required, including but not limited to discussion with the prescriber, notation on the prescription to alert the dispenser etc. I also note that SOP Al 2 details the requirement for the dispenser and checker to be identified, but it is my opinion that the person entering the prescription in the dispensing software, and thus responsible for reviewing patient clinical and previous dispensing history etc. needs to be clearly identified and accountable. This is particularly important in a pharmacy with multiple dispensing providers, as in this case, including intern pharmacists, pharmacy technicians etc. The omission of this results in a lack of clear accountability in this crucial step of the dispensing process, and is discussed further in this document.

SOP A9 — Generating Labels, 9 March 2014
This appears appropriate. I note the issue date proceeds the date of the first dispensing error.

SOP A10 — Selecting Correct Medicines, 9 March 2014
This appears appropriate. I note the issue date proceeds the date of the first dispensing error. It is pleasing to see an emphasis to selecting the medicine after referring to the prescription, rather than from the generated prescription labels.

SOP A11 — Counting or Pouring Medicines, 9 March 2014
I note the issue date proceeds the date of the first dispensing error. It would be advisable that this SOP is amended to include an instruction to cross-check the

'stock bottle' against the prescription (not label) as an additional check to ensure the correct medicine has been selected, prior to preparation of the dispensed prescription.

SOP A12 — Checking Prescriptions, 9 March 2014
I note the issue date proceeds the date of the first dispensing error.

This SOP states 'Stock bottles and the **drugs to be dispensed** should be side by side with the labelled prescription items and the script form. It is wise to employ a 5 second check to the drug on the Rx against what is about to be dispensed …' This type of instruction would be more appropriately included in SOP Al 1 — Counting or Pouring Medicines as previously suggested, as the process of 'checking a prescription' should distinctly follow the physical process of counting or pouring and the completion of the entire dispensing process.

This SOP refers to 'additional care being paid to high risk medicines', and lists a range of medicines with narrow therapeutic indices, which is appropriate. It may also be pertinent to include a statement regarding 'medicines with similar presentations, names etc.'.

This SOP refers to checking the 'label info is correct …'. It would be useful to include a reference here to checking the label information against the physical prescription.

This SOP refers to checking 'past medical history, consistency of treatment'. However, it does not detail how this is to occur (face-to-face discussion with the patient, review of client software notes etc.?). This is consistent with my concerns regarding the role of the dispensary team member who processes the prescription through the dispensing software, as previously noted.

This SOP also refers to its author's opinion that 'ultimately it is up to each individual pharmacist to take ownership of their work and find a safe, reliable and duplicable system of prescription checking'. It is my opinion that this is a correct statement, as an exact method of prescription checking successfully adopted by one pharmacist can differ to that successfully adopted by another. However, in this SOP, particularly considering the unfortunate duplicated error that has occurred, it would be prudent to see a revision, which includes reference to:

- An emphasis on the importance of a final, step-by-step 'self-check', particularly if the dispenser and the checker are the same person.
- A recommendation that, where the dispenser and checker are the same person, the SOP refer to a demonstrated 'separation' between the process of dispensing and the process of checking. This separation can assist in the pharmacist assessing the prescription with 'fresh eyes', switching from a process-driven 'dispensing' mode to a disciplined, step-by-step 'checking mode'.

SOP A13 — Handing Out Prescriptions and Patient Counselling, 12 July 2012
This appears appropriate.

SOP A14 — Repeat Prescriptions. 9 March 2014
Irrelevant to the nature of this case. I note the issue date proceeds the date of the first dispensing error.

However, the dispensing of repeats from the original prescription, rather than from the label (after relying on dispensing software) or a Certified True Copy, is best practice, and presents a valuable opportunity to identify errors made in the initial dispensing, thereby preventing recurrent errors.

SOP A15 — Storage of Prescriptions awaiting Pickup, 10 March 2014
Irrelevant to the nature of this case. I note the issue date proceeds the date of the first dispensing error.

SOP A16 — Delivery of Prescriptions, 10 March 2014
Irrelevant to the nature of this case. I note the issue date proceeds the date of the first dispensing error.

SOP A17 — Processing Telephone/fax Prescriptions, 7 December 2012
Irrelevant to the nature of this case.

SOP A18 — Owes/out of Stock, 7 December 2012
Irrelevant to the nature of this case.

SOP A19 — Dispensing of Owes on Rx's, 10 March 2014
Irrelevant to the nature of this case. I note the issue date proceeds the date of the first dispensing error.

SOP A20 — Medical Practitioner Supply Orders, March 2014
Irrelevant to the nature of this case. I note the issue date proceeds the date of the first dispensing error.

SOP A21 — Recording Dispensing Errors, 18 December 2012
It is my opinion that this SOP would benefit from revision, and that the Pharmacy should provide greater attention to the subsequent processes that would be deemed best practice in the event of an error. Please refer to my summary for further opinion. Specifically, the SOP should include reference to:

- A strict timeframe within which an Incident Report is to be completed following an error;
- A formal process for whom should complete or contribute to the Incident Report (generally all team members involved should complete an Incident Form);
- A formal process for advising relevant team members of their involvement in an error;

- A required timeframe for errors/incidents to be discussed with the remainder of the team;
- A formal process that all team members review the error, steps that may have led to it, and possible changes and outcomes that could minimise the chance of such an error occurring in the future;
- Guidelines on the appropriate steps to take and how to interact and communicate with consumers in the event of an error (which often can influence a significant difference in the outcome).

Further information on dealing with dispensing errors is available from the Pharmacy Defence Association (PDA).

SOP A22 — Recording Near Misses, 18 December 2012
Irrelevant to the nature of this case.

It is my opinion that [the Pharmacy] did generally have appropriate Standard Operating Procedures (SOPs) in place at the time of the events in question. It is pleasing to note that these SOPs are personalised to the Pharmacy and its procedures and are not generic templates which can often be encountered in pharmacies. However, it is my opinion that some SOPs, as detailed above, require revision and amendment, particularly those SOPs detailing the entering of prescriptions into the dispensing software, the dispensing process, incident reporting and, most critically, the prescription checking process.

3. Whether [the Pharmacy] appropriately stored its supply of Humulin cartridges and Humulin 30/70 mix cartridges

The storage requirements for medications, including those requiring controlled refrigeration such as Humulin and Humulin 30/70 mix cartridges, are defined in the Standards New Zealand — Health and Disability Services Pharmacy Services Standard (NZS 8134.7:2010), specifically:

Standard 5.13: Storage areas shall be sufficient to permit the effective separation and identification of the various stored materials and products and the environment appropriate to their storage;

This standard also defines specific criterion, including:

5.13.3: Pharmaceutical materials and products shall be stored in a way which prevents cross-contamination. Particular attention shall be paid to items stored in the refrigerator;

5.13.4: The refrigerator maximum/minimum temperature shall be appropriately monitored and recorded to ensure maintenance of correct temperature. Corrective measures shall be taken when specified conditions have not been maintained;

G 5.13.4: Refrigerator temperatures should be maintained between 2 and 8°C.

Pharmacy premises and equipment, including compliance with the requirements defined above for the storage of medications requiring refrigeration, are regularly audited by the Ministry of Health, Medicines Control, Provider Regulation. I note that [the Pharmacy] has provided documentation relating to such an audit that occurred, on 7 November 2012, with subsequent confirmation dated 11 April 2013, that Audit criteria was successfully attained. After reviewing the audit report, I note there were no improvements required relating to the refrigeration of medicines, with audit criterion C.3.1 including 'a refrigerator for storing medicines requiring refrigeration within the range 2 and 8°C' and 'appropriate maximum-minimum temperature reading equipment for monitoring temperatures in refrigerator(s) used to store pharmaceuticals'. Accordingly, it is reasonable to assume, at this date, that the Pharmacy was appropriately storing medication requiring refrigeration, to the minimum requirement as defined.

Following a review by [the Pharmacy] of its dispensing procedures, [Mr E] states in his letter to HDC dated 23 May 2014, that 'we jointly feel that our dispensary refrigerator is not large enough, to store the ever increasing quantity of cold chain medicines and that we may need to replace it'.

In the Incident Reporting Form dated 22 April 2014, prepared by [Mr E], he states 'Will look at replacing current dispensary fridge with larger model currently jam packed'.

In his response to HDC dated 17 December 2014, [Mr E] states 'the insulin products were stored in a under bench refrigerator. This included the door wells …'. In this response, he has also provided photographs of the refrigerator, with a statement 'At the time, it contained all of the medications requiring storing between 2 and 8 degrees centigrade …'.

In her response to HDC dated 8 December 2014, [Ms C] states 'Our dispensary fridge at the time was very small and over crowded with medication and the different [branded] insulins were all packed together in the fridge door shelf'.

I note that [the Pharmacy] has not provided a copy of their SOP for monitoring refrigeration temperatures, but do not believe it is required in order to provide an opinion, as this SOP, as well as the Pharmacy's adherence to it, would have been reviewed as part of their audit on 7 November 2012.

It is my opinion, based on the facts and responses presented, that [the Pharmacy] was appropriately storing its supply of Humulin cartridges and Humulin 30/70 mlx cartridges, to meet a minimum expected requirement, as defined by Standard 5.13 of Standards New Zealand — Health and Disability Services Pharmacy Services Standard (NZS 8134.7:2010). There has been no evidence provided to suggest that these medications were not being refrigerated as required, that cross-contamination of any type occurred, or that staff members were unable to effectively identify the correct stored medication.

However, it should be noted that it is my opinion that, should a larger or secondary refrigerator have been in operation as would be viewed by their peers as best practice, allowing more clearly defined storage and separation of similarly-presented Insulin preparations (e.g. baskets etc.), it is possible that this error may have been in some part prevented, should a dispensing team member have noticed the two similarly named preparations at the time of medicine selection. Whilst potentially a contributing factor to both dispensing errors, it is my opinion that these errors were not primarily caused through the inappropriate storage of the Humulin and Humulin 30/70 mix cartridges, as even with selection of the incorrect medication, this should have been identified on each occasion as part of the final dispensing check.

4. Whether changes undertaken by [the Pharmacy] since the events in question are appropriate.

The following changes have been undertaken by [the Pharmacy] and its pharmacists, subsequent to these unfortunate events:

1. [The Pharmacy] have purchased an additional refrigerator, to complement their existing refrigerator for the storage of medicines requiring refrigeration.
2. [The Pharmacy] now allocate the storage of insulin medications to a dedicated refrigerator, with insulins stored in trays, to assist in the separation of similar preparations.
3. [Pharmacy] staff were alerted to the errors and a staff meeting held to discuss steps to minimise the unnecessary interruption of pharmacists.
4. As a further memory aid to the differing properties of insulin, some reference charts are now attached to this fridge, outlining these.
5. Most importantly, pharmacists [Mr E], [Ms C] and [Ms D] have individually reviewed and made quantifiable changes to their dispensing and checking procedures, as detailed in their individual responses to the HDC. They have also collectively reviewed their dispensing procedures. Notably, [Ms C] has undertaken a Continuing Professional Development activity to focus on continuous review and improvement which includes discussion with other colleagues.

It is my opinion that the changes made by [the Pharmacy] and the individual pharmacists involved in this case are appropriate, and will hopefully assist in the prevention of further dispensing errors, such as within this case. It is commendable to note the self-responsibility demonstrated by [Mr E], [Ms C] and [Ms D], and the importance each have placed on reviewing the factors that may have led to these errors, including their own dispensing practices.

It is also my opinion that it would be appropriate for [the Pharmacy] to review and amend some of its existing SOPs, as previously described, in order to further lessen future dispensing errors, as well as consider some of the further commentary for consideration, as provided below.

Further Commentary for Consideration

It is my opinion that the following statements warrant consideration:

Entering of Prescriptions and Identification of the Person Responsible

The Pharmacy should consider amending their dispensing stamp and Standard operating procedure, to include a section allowing initialling by team members for all specific steps in the dispensing process, including entering, dispensing and final checking the prescription. This would generally be accepted as best practice.

The SOP should also provide guidance on the processes to be followed by the team member entering the prescription into the dispensing software, to ensure that information regarding the patient's previous dispensing history, clinical notes, changes to medication prescribed etc. is communicated clearly to the dispenser and the pharmacist performing the final check (annotation on the prescription a Post-It note etc.). In my opinion, it is particularly distressing to note that following the 11 February dispensing error, a note was placed on [Mr A's] patient file (electronically) but this was not seen by [Ms D] when dispensing for [Mr A] on 22 April, as she 'doesn't believe she processed the prescription through the computer to produce the dispensing labels as she would have seen the alert in the computer regarding the previous dispensing error'. If indeed she did not enter the prescription, had this alert been communicated through to [Ms D], it is highly likely this second dispensing error would have been prevented. It is my opinion that my peers would view this process omission with moderate disapproval.

Timely Completion of Incident Report Forms and Review of Errors

It is my opinion that [the Pharmacy], particularly [Mr E], should place a significantly greater importance on the timely completion of procedures (documentation and review) in dealing with dispensing errors/incidents following the 11 February dispensing error. [Mr E] did not prepare an incident report at the time. Whilst I appreciate he was the sole pharmacist on duty on the day and the challenges this brings ('I was busy, and forgot'), his breach of [the Pharmacy's] SOP on incident reporting is unacceptable, and the completion of an incident report for the 11 February error only on 22 April 2014 in my opinion is unacceptable. Following the second dispensing error on 22 April, [Mr E] prepared an incident report in note form, but 'did not follow through on everything in the SOP'. It was not until receiving the HDC letter did he 'recall his error with following his own SOP'. This deviates from both the Pharmacy's SOP and what would be accepted as good practice significantly. It is my opinion that my peers would view this with moderate disapproval.

It is also important to note that the documentation regarding [the Pharmacy] Audit completed 7 November 2012, specifically [an email] dated 5 March 2013, includes a suggestion to [Mr E] that he may wish to carry out incident report reviews more frequently, 'to provide more immediate feedback and goals to dispensary staff'.

The completion of incident reporting at the time of an incident is fundamentally important, as it demonstrates and documents an acknowledgment by the Pharmacy and pharmacists of the seriousness of an error, and a genuine commitment to

reviewing their practice, associated factors etc. to minimise the potential of repeat errors in the future. Had the first dispensing error been documented, processes reviewed etc. at the time of occurrence, it is possible that subsequent changes to practice, equipment etc. may have prevented the 22 April error from occurring.

Handing Out & Counselling of Prescriptions

There is little contemporaneous evidence provided documenting how, or by whom, the prescriptions in each of these errors were 'handed out' to the patient's caregiver, or the level of counselling that occurred. I note that the Pharmacy's SOP A13 describes specific points to check when handing out completed prescriptions, including 'is the medicine they're receiving what they are expected to be supplied with'. In this case, it is my opinion that, had this SOP been adhered to, it is highly possible, particularly in the 22 April dispensing (given the occurrence of a previous error and [Ms B's] understanding of [Mr A's] medications) that this error could have been identified and rectified, prior to [Ms B] leaving the Pharmacy. I would recommend [the Pharmacy] review this SOP and its current procedures in relation to the handing out and counselling of prescriptions, as this often provides an invaluable opportunity for a final 'check'.

Summary

Any dispensing error, such as those described in this case, is a highly regrettable incident, which all pharmacists fear occurring within their practice. It is commendable to note that the response of all parties concerned, in terms of their interaction with the consumer upon raising her complaint, were professional, apologetic and that all pharmacists accepted self-responsibility, without attempting to divert blame. It is also commendable that, following the second dispensing error, demonstrable appropriate steps were taken to minimise the risk of future repeat errors. I trust these incidents, particularly given the nature of the repeated error, have provided an important opportunity for both the Pharmacy and the Pharmacists involved to review their dispensing processes, particularly with regard to the selection of the correct medication and final checking processes.

Glenn Mills 22/03/15"