A Pharmacy

Pharmacist, Mr B

Pharmacist, Ms C

A Report by the

Deputy Health and Disability Commissioner

(Case 13HDC01718)

Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

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Executive summary

Effexor-XR dispensing error

1. On 6 May 2013, Ms A was prescribed Effexor-XR 37.5mg capsules by her general practitioner, Dr E. She presented her prescription at a pharmacy.

2. On 14 June 2013, Ms A returned to the pharmacy to collect her first repeat for Effexor-XR, but was dispensed 75mg capsules instead of 37.5mg capsules. She brought this to the attention of pharmacist Mr B, who apologised for the error and provided the correct capsules. He acknowledged to HDC that he was the dispensing pharmacist who made the error, and was also the charge pharmacist at the time of the error. Mr B did not complete an incident report form at the time the error was identified detailing how the Effexor-XR error occurred.

Nadolol dispensing error

3. On 29 July 2013, Dr E prescribed Ms A nadolol 40mg tablets. She presented her prescription at the pharmacy that same day, and collected her medication. Ms A noticed that the tablets she was dispensed were green in colour, whereas her previous nadolol tablets had been white in colour.

4. On 15 October 2013, Ms A was dispensed a further supply of nadolol tablets at the pharmacy. On 21 November 2013, she opened this supply and discovered that the tablets were white in colour. Ms A queried the colour changes with Dr E, who discussed the issue with Mr B.

5. Mr B established that the pharmacy had incorrectly dispensed propranolol 40mg tablets instead of nadolol 40mg on 29 July 2013. Further investigation by Mr B identified Ms C as the dispensing pharmacist on that occasion. Ms C was unable to recall how the error occurred, owing to the time that had elapsed between dispensing the medication and being notified of the error.

Labelling and documentation errors

6. On 16 September 2013, Ms A was prescribed Konsyl-D powder by her gastroenterologist, Dr F. On 18 September 2013, Ms A presented the prescription for Konsyl-D at the pharmacy. She was dispensed the correct medication by Mr B, but the label did not include the complete dosage instructions. The computer records were subsequently updated to document incorrectly that Ms A had two repeats available on Dr F's prescription.

7. On 15 October 2013, Ms A obtained a prescription from Dr E for further supplies of Konsyl-D powder. She presented her prescription at the pharmacy on the same day, and was incorrectly advised that she had a repeat for Konsyl-D remaining on Dr F's prescription. Mr B dispensed the Konsyl-D powder as per Dr E's prescription. The dosage instructions on the label were consistent with Dr E's instructions, but the label incorrectly stated Dr F's name as the prescriber.

8. On 26 November 2013, Ms A collected Konsyl-D from the pharmacy. Ms A was given a repeat, accurately documented in the pharmacy's computer records as owing

from Dr E's prescription. However, Dr F was again incorrectly identified on the label as the prescriber. On this occasion, Ms A was also dispensed a repeat incorrectly documented in the pharmacy's computer records as owing to her from Dr F's prescription.

Findings

Mr B

9. Mr B failed to ensure that he dispensed the correct strength of Effexor-XR to Ms A on 14 June 2013, incorrectly labelled the Konsyl-D medication on 18 September, 15 October and 26 November 2013, and failed to complete incident report forms in a timely manner. Furthermore, by amending the records without ensuring that he kept a record of those amendments, Mr B acted in an unprofessional and misleading way, and failed to minimise the potential harm to Ms A, contrary to the Pharmacy Council of New Zealand's Code of Ethics. The number of errors relating to one consumer, within a six-month period, along with the failure to complete incident forms in a timely manner, is of significant concern.

10. Accordingly, Mr B failed to provide services to Ms A that complied with professional standards and breached Right 4(2) of the Code.[1]

Ms C

11. Ms C failed to ensure that she dispensed the correct medication to Ms A on 29 July 2013, and failed to provide services that complied with professional standards. Accordingly, Ms C breached Right 4(2) of the Code.

The pharmacy

12. The pharmacy's failure to ensure staff compliance with its SOPs played a significant part in Ms A receiving the incorrect medication on two occasions, and her medication being labelled incorrectly on three occasions. Accordingly, the pharmacy did not provide services to Ms A with reasonable care and skill and breached Right 4(1) of the Code.[2]

13. Adverse comment is made with regard to the pharmacy not having a system in place to ensure that any amendments to documentation were recorded.

[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

14. The Commissioner received a complaint from Ms A about the services provided to her at the pharmacy. The following issues were identified for investigation:

- *Whether the pharmacy provided Ms A with an appropriate standard of care in 2013.*
- *Whether pharmacist Mr B provided Ms A with an appropriate standard of care in 2013.*
- *Whether pharmacist Ms C provided Ms A with an appropriate standard of care in 2013.*

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

16. The parties directly involved in the investigation were:

Ms A	Consumer/Complainant
The pharmacy	Provider
Mr B	Pharmacist
Ms C	Pharmacist
Ms D	Pharmacist
Also mentioned in this report:	
Dr E	General practitioner
Dr F	Gastroenterologist

Information gathered during investigation

17. Ms A complained that she experienced both dispensing and labelling errors when filling prescriptions at the pharmacy.

Dispensing Errors

Effexor-XR

18. On 6 May 2013, Ms A was prescribed Effexor-XR[3] 37.5mg capsules by her general practitioner (GP), Dr E.[4] The prescription was for a one-month supply plus two repeats. Ms A was instructed to take one capsule once daily.

[3] Effexor-XR is indicated for the treatment of major depression, generalised anxiety disorder, social anxiety disorder and panic disorder.
[4] Dr E is vocationally registered in general practice.

19. On 14 June 2013, Ms A went to the pharmacy and collected her first repeat for Effexor-XR. When she opened the box at home, she discovered that she had been incorrectly dispensed 75mg capsules.[5]

20. Ms A contacted the pharmacy the same day and advised the pharmacist, Mr B, of the error. She returned the incorrect capsules to the pharmacy the following day and was dispensed the correct 37.5mg capsules.

Description and storage of Effexor-XR

21. Mr B advised that Effexor-XR capsules are available in three strengths, which are blister-packaged in foil. The packaging for each strength capsule is different:

- The 37.5mg packet is yellow and black.
- The 75mg packet is pink and black.
- The 150mg packet is green and black.

22. According to Mr B, at the pharmacy the different strengths of Effexor-XR are stored next to each other on the dispensary shelves in ascending order of strength.

Incident reporting

23. The pharmacy's standard operating procedure (SOP) for incident reporting states:

> "An appropriate incident form should be completed immediately after an incident has occurred and all steps taken to minimise or exclude harm to persons or property."

24. Mr B did not complete an incident form immediately when he became aware of the Effexor dispensing error on 14 June 2013. Mr B completed an incident form in December 2013, following Ms A's request that he document the incident.[6]

How the error occurred

25. Mr B acknowledged that he was the pharmacist who made the dispensing error on 14 June 2013, and was also the charge pharmacist on duty at the time of the error. Mr B explained that he incorrectly selected the Effexor-XR 75mg capsules from the dispensary shelves.

26. According to the information in the incident form, Mr B was working alone, and the pharmacy was busy at the time of the error. The incident form noted that Mr B was probably in a hurry and did not perform the required checks and, therefore, failed to identify the error.

27. However, Mr B advised HDC that he did check his own work, but failed to identify the error. Mr B stated that "[his] error with the Effexor was caused by [his] lack of care and attention in selecting the correct strength of the drug and not adequately making the final check that [he] should have".

[5] Ms A did not take any 75mg Effexor capsules.

[6] Ms A advised that on 26 November 2013, she requested that Mr B document the incident. The incident reporting form is dated 5 December 2013. Page two of the incident reporting form records a further date of 2 December 2013 as the date the form was completed.

Nadolol

28. On 29 July 2013, Dr E prescribed Ms A 23 nadolol[7] 40mg tablets for migraine prophylaxis. The dosage prescribed was one quarter of a 40mg tablet (10mg) once daily. Ms A filled her prescription from Dr E at the pharmacy that same day.

29. Ms A noticed that the tablets dispensed by the pharmacy were green in colour. The nadolol tablets usually dispensed to her were white, apart from on one previous occasion when she was dispensed green tablets.[8] Ms A advised HDC that she had "taken the colour changes on trust", and she was reassured that the tablets dispensed were nadolol because the green tablets had "Apo 40" written on them. She said that she thought Apo 40 written on the tablets meant that they must be Apo-nadolol, the brand of nadolol she was usually dispensed. She was unaware that all drugs produced by the pharmaceutical company Apotex have "Apo" included in the name. Ms A took the dispensed medication[9] for the next two and a half months.

30. On 15 October 2013, Ms A was dispensed a further supply of nadolol from the pharmacy. On 21 November 2013, she opened this supply of tablets and discovered that the tablets were white.

Discovery of error

31. Ms A researched the tablets using the internet, and concluded that the green tablets she was dispensed were not nadolol.

32. On 25 November 2013, Ms A consulted Dr E to discuss the apparent dispensing error. Dr E visited Mr B to discuss the matter, and it was established that the pharmacy had dispensed another beta-blocker, propranolol 40mg tablets, instead of nadolol 40mg.[10]

33. Mr B advised HDC that he was not involved in the dispensing error involving propranolol and nadolol on 29 July 2013, but he became aware of it when Dr E notified him of the error on 25 November 2013. According to Mr B, Dr E visited him and brought a green, quartered tablet that required identification. Mr B advised Dr E that he would discuss the matter further with Ms A once it had been investigated.

Ms A's concerns regarding the error

34. Having discovered the dispensing error, Ms A visited Dr E regarding concerns about potential side effects having taken Apo-Propranolol instead of Apo-Nadolol which she had been prescribed. Ms A told Dr E that she was experiencing headaches, insomnia, shakiness, nausea and constipation. Ms A stated that her symptoms improved once the propranolol was discontinued.

[7] Nadolol is a nonselective beta-blocker used in the treatment and prevention (prophylaxis) of high blood pressure and chest pain. It is also often prescribed in the treatment and prevention of atrial fibrillation, migraine headaches, and complications of cirrhosis.

[8] Ms A advised that she is not sure when this occurred.

[9] Ms A told HDC that the tablets were quartered to provide 92 10mg tablets. Ms A recalls taking one quarter tablet once daily between August and November 2013.

[10] Propranolol and nadolol are both beta-blockers but have differences in action, meaning that in some patients one may be contraindicated while the other is suitable. There is no evidence that Apo-Propranolol was contraindicated in Ms A's circumstances.

35. On 3 December 2013, Dr E wrote to the pharmacological clinic at the public hospital to request advice regarding possible side effects for Ms A. In his letter he noted that Ms A was "very sensitive to medications" and had been taking Apo-Nadolol and rizatriptan[11] for headaches (Ms A took 10mg of each, daily). He requested advice regarding possible interactions between Apo-Propranolol and rizatriptan.

36. On 10 December 2013, a general physician and clinical pharmacologist responded to Dr E's letter stating that while rizatriptan is not contraindicated when taking propranolol, the maximum dose of each tablet should be only 5mg, rather than the 10mg that Ms A was taking. He agreed that a drug interaction had occurred between Ms A having taken propranolol and rizatriptan. However, he stated that Ms A's symptoms were "relatively common", and "[i]t is unclear whether the symptoms that she was complaining of … are due to this interaction. However, it certainly cannot be ruled out."

Description and storage of Apo-Nadolol and Apo-Propranolol

37. Mr B advised that Apo-Nadolol tablets are white and marked with APO/N40, whilst Apo-Propranolol tablets are green and marked with APO/40. Both medications are packaged in white containers with blue lids. Photos of the packaging provided by Mr B are attached as **Appendix A**.

38. According to Mr B, at the pharmacy Apo-Nadolol and Apo-Propranolol are stored on opposite ends of the dispensary and on different shelves.

39. Mr B advised that all the medicines shelved in the dispensary are arranged alphabetically by the generic name of the drug. He said that the medicines are always stored in the same place, and are separated from adjacent drugs by a small space.

40. Mr B stated:

> "All pharmacists are aware of similarities of packaging produced by the generic drug manufacturers as they use the same containers with very similar labels, usually in the same corporate colours, with the only major difference being the name of the drug. This is an issue that pharmacists are aware of and the SOPs are designed to avoid or prevent error or confusion."

Reporting of nadolol dispensing error

41. On 26 November 2013, Ms A visited Mr B to discuss the dispensing error. She advised HDC that Mr B told her that the wrong beta-blocker was mistakenly put in the bottle. According to Ms A, she was also advised that "it was another medicine of the same type (i.e. beta blocker) and the difference between the two was not that significant".

42. Mr B explained to Ms A that he considered that a selection error[12] had occurred. According to Mr B, he told Ms A that Apo-Propranolol and Apo-Nadolol are both

[11] Used for severe headaches and migraines.
[12] Selecting the incorrect medication from the shelf.

beta-blockers, 40mg in strength and manufactured by Apotex NZ Limited. He advised Ms A that both medications are similar in size, and their containers are also very similar.

43. Mr B checked the original prescription and determined that charge pharmacist Ms C had made the dispensing error.

Ms C's response

44. In her response to HDC,[13] Ms C acknowledged that she was the pharmacist who dispensed and checked the prescription on 29 July 2013, as the prescription contains only her signature.

45. Ms C advised HDC that she worked at the pharmacy for over two years. Ms C no longer works at the pharmacy. She said that usually she worked as part of a team of two or three pharmacists, but had also worked as a sole charge pharmacist when required.

46. Ms C stated that due to the time that has lapsed since the dispensing error, and the large volume of prescriptions she has dispensed, she cannot recall the particular dispensing error pertaining to Ms A or what may have been happening at the time of the error that may have distracted her. Ms C explained that the pharmacy's stock of propranolol may have been placed in the section where nadolol should have been, or the wrong medicine may have been picked owing to their proximity or location on the dispensary shelf.

Documentation incidents

Konsyl-D powder prescribed — 16 September 2013

47. On 16 September 2013, Ms A consulted gastroenterologist Dr F with regard to gastrointestinal symptoms. Dr F prescribed 500g Konsyl-D powder[14] for Ms A. The dosage prescribed was one dessertspoon (10g) twice a day for two weeks, followed by one teaspoon (5g) daily for the following two weeks.

Konsyl-D powder dispensed — 18 September 2013

48. On 18 September 2013, 1x 500g of Konsyl-D powder was correctly dispensed to Ms A at the pharmacy, in accordance with her prescription from Dr F.

49. In the course of this investigation, HDC was provided with two copies of labels relating to the medication dispensed on 18 September 2013 (**Appendix B**). One label was provided to HDC by Ms A (label S1, which Ms A obtained from Mr B at her request on 27 November 2013), and one was provided to HDC by the pharmacy (label A1 provided to HDC on 17 February 2015). Labels S1 and A1 do not match:

Label S1	Label A1
States: "… Follow with additional fluid."	States: "… Follow with additional fluid as directed".

[13] Dated 2 February 2014.
[14] A dietary fibre that promotes normal bowel activity.

50. Furthermore, neither label S1 nor A1 includes reference to the reduced dose of Konsyl-D powder after the first two weeks, in accordance with Dr F's prescription, and both S1 and A1 incorrectly state that there were two repeats available to Ms A, in reference to Dr F's prescription. Ms A told HDC that when she received the medication on 18 September 2013, the dispensing label did not refer to her having repeats for the Konsyl-D powder, which was consistent with her prescription from Dr F (Ms A was not able to provide a copy of that dispensing label to HDC).

51. With regard to the labelling errors, Mr B accepted that:

> "[t]here were no repeats ordered by [Dr F] and their appearance on the label [S1] was incorrect. We also omitted to include reference [on the dispensing label] to a reducing dose from after the first two weeks …"

52. Ms A told HDC that she believed that Mr B had attempted to mislead her by providing her with a copy of the dispensing label on 27 November 2013, which she does not believe was the same as the original dispensing label on the Konsyl-D that she received on 18 September 2013. In this respect, Mr B told HDC:

> "Athough the prescription did not prescribe any repeats, when it was entered into our computer it recorded repeats as owing. The dispensing label has not been amended since it was first entered. I cannot understand why [Ms A] would suggest that I would amend the label as this would deliberately create an error which I am now required to explain.
>
> …
>
> I … vehemently deny [Ms A's] assertion that I deliberately tried to mislead her. This is simply untrue."

53. However, when questioned by this Office regarding the differences between the labels provided to this Office by Ms A, and those subsequently provided by the pharmacy, Mr B stated that owing to the passage of time he could not recall "with any degree of accuracy what was done". Mr B stated:

> "I can only assume that the words 'as directed' were added after the label was printed for [Ms A] [on 27 November 2013]. I cannot confirm whether it was me or another person that made those amendments, or when they were made."

Konsyl-D powder prescribed — 15 October 2013

54. On 15 October 2013, Ms A consulted Dr E for a further prescription for Konsyl-D, as her gastrointestinal symptoms had not abated. Dr E prescribed 2 x 500g of Konsyl-D powder, one tablespoon to be taken twice daily or as required. Dr E's prescription included two repeats.

Konsyl-D powder dispensed — 15 October 2013

55. On 15 October 2013, Ms A presented Dr E's prescription for 2 x 500g of Konsyl-D powder, at the pharmacy. She was advised that she still had a repeat for Konsyl-D owing on Dr F's prescription. Ms A explained to staff that this was incorrect, as Dr F had prescribed her only one bottle. Ms A explained to HDC that the reason she had

consulted Dr E and requested a new prescription from him was because the original prescription from Dr F did not indicate repeats, and neither did the label on the medication that she received from the pharmacy on 18 September 2013.

56. Ms A's prescription from Dr E was dispensed the same day by pharmacist Ms D. Ms D told HDC that while she cannot specifically recall her involvement with dispensing Ms A's prescription, she confirmed that she dispensed the prescription.

57. In the course of this investigation, HDC was provided with copies of four labels relating to the medication dispensed for Ms A on 15 October 2013 (**Appendix B**): two from Ms A (photographs of two medication bottles — labels S2 and S3), and two from the pharmacy (label A2, provided to HDC on 17 February 2015 and label A3, provided to HDC on 25 March 2015). Labels S2 and S3 do not match labels A2 and A3:

Label S2	Label S3	Label A2	Label A3
"1000g" total of Konsyl-D is recorded and it is noted that the bottle is "pack 1 of 2".	"1000g" total of Konsyl-D is recorded and it is noted that the bottle is "pack 2 of 2".	"500g" of Konsyl-D is recorded.	"1000g" of Konsyl-D is recorded.
The dosage instructions were consistent with Dr E's instructions, and two repeats were correctly recorded. However, Dr F is incorrectly identified as the prescriber.	The dosage instructions were consistent with Dr E's instructions, and two repeats were correctly recorded. However, Dr F is incorrectly identified as the prescriber.	Two repeats were correctly recorded and Dr E is correctly identified as the prescriber.	Two repeats were correctly recorded and Dr E is correctly identified as the prescriber.

58. With regard to the differences between the labels dated 15 October 2013, Mr B told HDC:

> "I can only assume that the original computer record was amended after I became aware of the errors. In particular, the changes are to correct the name of the doctor and to inaccurately change the quantity (i.e to introduce another clerical error). Though I cannot specifically recall having done this, I believe that it would have been me that made those changes."

59. Mr B told HDC that he could not explain the difference between labels A2 and A3.

Konsyl-D powder dispensed — 26 November 2013

60. On 26 November 2013, Ms A collected a repeat for Konsyl-D at the pharmacy.[15] She was also dispensed a repeat, which had been recorded incorrectly as owing to her from Dr F's 18 September 2013 prescription, for 1 x 500g of Konsyl-D powder.

61. On 26 November 2013, Ms A's repeats were dispensed by Mr B.

62. In the course of this investigation, HDC was provided with two copies of labels relating to the medication dispensed for Ms A on 26 November 2013 (**Appendix B**) — one from Ms A (label S4, a photograph of the medication bottle that was provided to Ms A on 26 November 2013), and one from Mr B (label A4, provided to HDC on 17 February 2015). Both labels appear to be dispensed from the same repeat from Dr E's prescription, but labels S4 and A4 do not match:

Label S4	Label A4
Dr F is incorrectly recorded as the prescriber.	Dr E is correctly recorded as the prescriber.

63. In relation to the differences between the labels dated 26 November 2013, Mr B told HDC:

> "I believe that the name of the doctor has been altered [in the computer records] (to correct the name of the prescriber). … I assume that the changes were made by me after my meeting with [Ms A] on 26 November [2013] but cannot be sure of that …"

How the labelling errors occurred

64. With regard to all Konsyl-D labelling errors, Mr B told HDC that he was responsible for checking the Konsyl-D prescriptions, as he was the charge pharmacist at the time the errors relating to Konsyl-D occurred. In relation to the incorrect prescriber's names appearing on the labels, Mr B told HDC:

> "In producing the labels for [the] prescription from [Dr E], we used a function on our computer system[16] which enables us to duplicate the original label from a previous dispensing. This had the effect of replicating a label with [Dr F's] name on it and not that of [Dr E] as it should have had."

65. Mr B further told HDC with regard to changes made to the labels:

> "I am confident that any changes would have been to ensure that the records were accurate, and would not have been done for any other purpose that I can imagine."

[15] Repeat owing from Dr E's prescription for 2 x 500g of Konsyl-D powder.
[16] The LOTS computer system.

66. The pharmacy advised HDC that information relating to the tracking of any amendments to Ms A's records was not available. However, the pharmacy provided information relating to the tracking of occasions on which the pharmacy staff accessed Ms A's records on the computer system. The pharmacy stated that "it appears that this audit function is not operating correctly".[17]

Incident reporting

67. Mr B failed to complete an incident form for the Konsyl-D labelling errors. He told HDC that he did not believe it was justified or required in these cases.

Standard operating procedures

68. The Pharmacy Council of New Zealand (PCNZ) stated that "SOPs are necessary to ensure the continuity of processes to achieve quality performance and quality products/preparations. They form part of clinical governance, and in particular, show that pharmacists are putting in place strategies for risk management and harm minimisation."[18]

69. At the material time, the pharmacy had an SOP for dispensing in place. The purpose of this SOP, as stated in the document, is to "provide an accurate, clear checklist of the procedure when dispensing a prescription". The pharmacy's SOP for dispensing is at **Appendix C**.

70. As noted above (paragraph 23), the pharmacy also has an SOP for incident reporting, including dispensing errors and customer complaints. The SOP (in place at the time of these events) states that an incident form and a Pharmacy Defence Association[19] form should be completed in relation to dispensing errors.

Actions taken after each error

Effexor-XR error

71. In relation to the Effexor-XR dispensing error on 14 June 2013, Mr B apologised to Ms A and placed a note on her file as a reminder to check the dosage of her medication in future.

72. The incident form completed for the Effexor-XR dispensing error records that the pharmacy's SOP for dispensing was reviewed following the error. The pharmacy's SOP for dispensing was updated on 13 May 2014 to recognise the situation of a pharmacist working alone:

[17] The pharmacy stated: "For example, it demonstrates the record being accessed up to 7 or 8 times in one day. [Ms A's] prescription records have been accessed a number of times when first [Ms A] and then your office has made enquiries of the pharmacy. However, it has not been accessed 7 or 8 times a day …"

[18] Writing Standard Operating Procedures (SOPs): http://www.pharmacycouncil.org.nz/cms_show_download.php?id=316.

[19] A pharmacist support organisation that seeks to protect the interests of pharmacists, primarily against actions of professional indemnity.

> "If the pharmacist is working on their own and does not have another pharmacist available to check their work, ensure that an extra final check is done just prior to handing the prescription out to the patient."

Nadolol error

73. In relation to the nadolol error on 29 July 2013, Mr B apologised to Ms A, explained that a review of what happened would be conducted and an incident form completed, and that Ms C would be contacted.

74. Having subsequently been contacted by the pharmacy, Ms C reviewed her checking procedures. She told HDC that she is confident that her current procedures are compliant with professional standards. She also advised that she will ensure that she checks that the name and appearance of each dispensed product matches the product in stock bottles (or boxes).

75. Ms C stated that she continues to endeavour to minimise errors in her everyday practice, both by following protocols set out for the dispensing process, and by making it a personal priority to up-skill and maintain a high standard of care in all aspects of pharmacy practice. However, she advised that there is always the potential for human error, and this may occur at any point in the dispensing process. She stated: "I am not exempt from the possibility of making human error and for this, I am extremely sorry."

Konsyl-D error

76. During the course of this investigation, Mr B apologised to Ms A for the part he played in relation to the Konsyl-D labelling errors on 18 September 2013, 15 October 2013 and 26 November 2013.

77. Mr B advised that the pharmacy's SOP for dispensing was reviewed on 20 February 2014 following the Konsyl-D labelling error. The SOPs were updated to include a note regarding the copy function of the LOTS computer system.[20] The note states:

> "If using the 'copy' function of the LOTS computer system, check carefully there are no subtle differences — e.g. prescriber's name, slight changes to instructions or change in strength etc …
>
> OR: do not use this function and enter the prescription as a new one."

78. Mr B further advised that a discussion was held with all pharmacy staff on the use of the copy function of the LOTS computer system. It is noted in the incident report form that staff agreed that the use of the copy function should be done with extreme care, and preferably not used at all.

[20] The updated dispensing SOP is undated. However, the pharmacy advised that it was updated on 13 May 2014.

79. In later correspondence, Mr B advised HDC that staff at the pharmacy no longer use the copy function in the computer software. He considers that this will help to prevent a similar error from occurring.

Responses to provisional report

80. The parties were given an opportunity to comment on the relevant sections of the provisional report. These responses have been incorporated into the report where relevant. Further responses have been outlined below.

81. Having received the provisional report, the pharmacy sought a review of its dispensing processes at the pharmacy from two pharmacists. The reviewers spent four hours at the pharmacy reviewing current practice and auditing past prescriptions to monitor adherence to the pharmacy's SOPs for dispensing and incident reporting.

82. Having reviewed the current processes at the pharmacy, the reviewers advised HDC that Mr B currently maintains a "logical and disciplined dispensing procedure".

83. The reviewers advised HDC that Mr B has undertaken to review the pharmacy's dispensing SOP to ensure that it adequately reflects "good checking practice".

84. With regard to incident reporting, the reviewers advised HDC that following their review of the pharmacy's processes:

> "[Mr B] has undertaken to amend his processes with respect to: more formalised logs of errors and near misses; specified robust definitions of both what consists of a 'near miss' or of an 'error'. He also undertook to institute reporting processes that allow easy entry, and subsequent regular systematic review of why and when such incidents occur, in order to prevent their recurrence."

85. The reviewers further advised HDC:

> "… [T]he confusion around what happened, and at what time, with two Konsyl-D scripts, largely arises because the activities undertaken to remediate errors do not appear as changes or amendments in the dispensing log. Neither brand of New Zealand pharmacy dispensing software has this function currently, or has had in the past."

86. In response to the provisional report, Mr B told HDC that he intends to arrange for a support pharmacist to visit the pharmacy on at least three occasions in order to assist him to develop and monitor improvements in his checking processes. Mr B confirmed that he intends to provide HDC with the outcome of the review by the support pharmacist, including any changes made as a result of that process.

Relevant professional standards

87. **Pharmacy Council of New Zealand Competence Standards for the pharmacy Profession 2010 (PCNZ Competence Standards):**

"**Element 4.2 Work effectively within the workplace organisation**
4.2.1: Works with the documented procedures and systems.

…

Element 6.2 Assess prescriptions

…

6.2.2: Follows workplace dispensing criteria when dispensing a prescription item.

Element 6.6 Fill prescriptions

…

6.6.2: Maintains a logical, safe and disciplined dispensing procedure.

Examples of Evidence:

Selects correct product, dose form & quantity for each prescribed medicine …"

…

Element 6.7 Package medicines to optimise safety and compliance

…

6.7.2: Produces comprehensible and complete labels for medicines.

…

Element 6.9 Minimise dispensing errors

…

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

Examples of Evidence:
Identifies potential/actual errors in own dispensing

…

Documents own dispensing errors & actions undertaken to minimise their effects.
Complies with workplace procedures for documenting dispensing Errors."

88. **Pharmacy Council of New Zealand Safe Effective Pharmacy Practice Code of Ethics 2011 (PCNZ Code of Ethics):**

"**Principles**

…

1.2 Take appropriate steps to prevent harm to the patient and the public.

…

7.8 Ensure the appropriate standard operating procedures are in place, maintained and followed."

Opinion

Introduction

89. This investigation relates to two dispensing errors, and a number of matters relating to incorrect documentation, which occurred at the pharmacy, in relation to one consumer. Pharmacists Mr B and Ms C have accepted their roles in the errors and offered their apologies to Ms A. The pharmacy also has a responsibility to ensure that consumers receive the correct medications in accordance with the strength and quantity specified in their prescriptions. Furthermore, patients should be told what dose they should take and for how long to take a medicine in accordance with their prescriptions, and this should be recorded clearly on the medicine label.

90. In my view, a pharmacist's dispensing practice does not occur in a vacuum, isolated from a pharmacy's structure and procedures. I consider that a pharmacy's procedures are essential components in ensuring the safe dispensing of medication by pharmacists.

91. I have therefore considered the extent to which the errors may have occurred as a result of individual staff actions, as well as possible systemic and organisational issues.

Causation

92. Ms A is concerned that taking Apo-Propranolol instead of Apo-Nadolol may have led to adverse side effects for her. For the avoidance of doubt, my role does not extend to determining the cause of symptoms or adverse effects experienced by consumers. My role is to assess the quality of care provided to Ms A. Accordingly, my opinion should not be interpreted as having any implication regarding the cause of symptoms experienced by Ms A.

Factual findings

Dispensing errors

93. On 6 May 2013, Ms A was prescribed Effexor-XR 37.5mg capsules. On 14 June 2013, Ms A collected her first repeat for Effexor-XR from the pharmacy. However, Mr B incorrectly dispensed 75mg capsules instead of 37.5mg capsules.

94. On 29 July 2013, Ms A was prescribed nadolol 40mg tablets. She presented her prescription at the pharmacy that same day, and collected her medication. However, Ms C incorrectly dispensed propranolol 40mg tablets instead of nadolol 40mg.

Labelling and documentation errors

95. With regard to the labels provided to HDC in respect of the Konsyl-D dispensed to Ms A between 18 September 2013 and 26 November 2013, I make the following findings:

Labels for medication dispensed on 18 September 2013

96. Ms A told HDC that when she received Konsyl-D from the pharmacy on 18 September 2013, the dispensing label did not refer to her having repeats for the Konsyl-D powder, which was consistent with her prescription from Dr F. Ms A was not able to provide a copy of that dispensing label to HDC. Ms A explained that she sought a further prescription from Dr E on 15 October 2013, as Dr F had not provided her with repeats, and there were no repeats on the label for medication she received on 18 September 2013.

97. I have considered the information provided by Ms A, the pharmacy and Mr B. Given that the information provided by the pharmacy is inconsistent, I consider that neither label S1 (which Ms A obtained from Mr B at her request on 27 November 2013), nor A1 (provided to HDC by the pharmacy on 17 February 2015) is an accurate copy of the dispensing label that was on Ms A's medication dispensed on 18 September 2013. I consider it more likely than not that:

a) the label on the medication dispensed on 18 September 2013 did not include reference to the reduced dose of Konsyl-D powder after the first two weeks, as instructed on Dr F's prescription;
b) the label on the medication dispensed on 18 September 2013 did not refer to repeats, consistent with Dr F's prescription;
c) repeats were added to the records after the medication was dispensed to Ms A, producing S1, which was subsequently provided to Ms A by Mr B; and
d) the records were further altered after S1 was provided to Ms A on 27 November 2013, to include the words "as directed" (and A1 subsequently produced).

Labels for medication dispensed on 15 October 2013

98. Ms A provided HDC with photographs of the labels on the Konsyl-D that she was dispensed on 15 October 2013 (labels S2 and S3). With regard to the differences between labels S2, S3 and A2, Mr B told HDC: "I can only assume that the original computer record was amended after I became aware of the errors … I believe that it would have been me that made those changes." Mr B told HDC that he could not explain the differences between labels A2 and A3.

99. I accept that S2 and S3 are accurate records of the labels on the medication dispensed to Ms A on 15 October 2013. Therefore, I consider that:

a) it was accurately recorded on the dispensing label that a total of 1000g of Konsyl-D was dispensed in two separate packs;
b) the dosage instructions were consistent with Dr E's instructions;
c) Dr F was incorrectly identified as the prescriber; and
d) it is more likely than not that the records were amended since the medication was dispensed to Ms A on 15 October 2013, to produce label A2 and subsequently label A3. The amendments include recording the correct prescriber, Dr E, and incorrectly recording the amount of Konsyl-D provided to Ms A as "500g" and "1000g" (rather than a total of 1000g).

Labels for medication dispensed on 26 November 2013

100. Ms A provided HDC with a photograph of the label on the medication that she was dispensed on 26 November 2013 (S4). With regard to the differences between labels S4 and A4, Mr B told HDC:

> "I believe that the name of the doctor has been altered (to correct the name of the prescriber) … I assume that the changes were made by me after my meeting with [Ms A] on 26 November [2013] but cannot be sure of that."

101. I accept that S4 is an accurate record of the label on the medication dispensed to Ms A on 26 November 2013. Therefore, I consider that:

a) on S4, Dr F was incorrectly recorded as the prescriber; and
b) it is more likely than not that the records were altered (to produce label A4), since the medication was dispensed to Ms A on 26 November 2013, in order to record the correct prescriber, Dr E.

Opinion: Mr B — Breach

102. Mr B failed to ensure that he dispensed the correct strength of Effexor-XR to Ms A on 14 June 2013, incorrectly labelled the Konsyl-D medication on 18 September, 15 October and 26 November 2013, and failed to complete incident report forms in a timely manner. Furthermore, Mr B amended Ms A's records without ensuring that he kept a record of those amendments. While each of these errors in isolation might appear relatively minor, any one of the errors could have had serious consequences in different circumstances. Furthermore, the number of errors relating to one consumer over a short period of time causes me to question Mr B's practice overall.

Effexor-XR dispensing error

103. Pharmacists are responsible for maintaining a logical, safe and disciplined dispensing procedure, in accordance with the Pharmacy Council of New Zealand's (PCNZ) Competence Standards outlined above. Mr B acknowledged in relation to the dispensing of Effexor-XR on 14 June 2013 that he incorrectly selected Effexor 75mg capsules, and did not make a final check of the medication adequately prior to dispensing it to Ms A, and therefore failed to identify his error. By way of explanation for the error, Mr B noted in the incident form (completed in December 2013) that he was working alone at the time of the error, the pharmacy was busy, and he was probably in a hurry. In my view, that is a poor explanation. A pharmacist should never compromise patient safety and professional obligations.

104. Principle 1.2 of the PCNZ Code of Ethics requires a pharmacist to "[t]ake appropriate steps to prevent harm to the patient and public". In my view, there were safety measures that Mr B could have implemented during busy periods. For example, PCNZ has stated that instead of attempting to dispense a prescription in a short period

of time, it may be appropriate to explain to the patient that he or she can return at a later time.[21] By discussing this matter with the patient, the pharmacist will not feel pressured to dispense the prescription in a short period, can take the time to consider each step of dispensing carefully, and therefore ensure that the correct medication is dispensed.

105. I therefore consider that Mr B should have exercised his professional judgement and managed the situation so that he was not under pressure. I accept that pharmacies have busy times; however, in my view, it is the responsibility of the pharmacist to have strategies in place to ensure that patient safety is not compromised.

Konsyl-D documentation issues

Labelling errors

106. Mr B accepted that he was the charge pharmacist responsible for checking the labels in relation to the Konsyl-D labelling errors on 18 September 2013, 15 October 2013, and 26 November 2013.

107. On 18 September 2013, the dispensing label relating to Dr F's prescription for Konsyl-D did not include the reduced dose after the first two weeks. Furthermore, on both 15 October 2013 and 26 November 2013, Dr F was incorrectly identified as the prescriber on the dispensing labels when the prescriber on both occasions was Dr E.

108. On 18 September 2013, Mr B failed to adhere to the SOP for dispensing when the label for Ms A's Konsyl-D did not include the reduced dose. The SOP for dispensing clearly instructs the pharmacist to check the label against the prescription for dosage. Had Mr B followed the SOP, he would have identified that the label did not contain the complete dosage instructions.

109. On 15 October 2013 and 26 November 2013, there were further labelling errors concerning Konsyl-D while Mr B was the charge pharmacist. The Konsyl-D labels incorrectly identified Dr F as the prescriber, rather than Dr E. Mr B advised HDC that on 15 October 2013 the label was generated using the LOTS system to duplicate the original label from the previous dispensing, resulting in Dr F's name being replicated on the label instead of Dr E's. However, it is unclear who was responsible for generating the label. On 15 October 2013, the prescription was dispensed by pharmacist Ms D, and checked by Mr B. As stated above, the SOP for dispensing requires the pharmacist to check the label against the prescription. As the wrong prescriber was recorded on the Konsyl-D labels, it appears that Ms D and Mr B both failed to follow the SOP for dispensing adequately on both occasions, by failing to perform an adequate check of the label against the prescription to ensure that the correct information was recorded.

Amending records

110. Of significant concern is that records regarding the labels have been altered with regard to medication dispensed to Ms A between 18 September 2013 and 26

[21] www.pharmacy.council.org.nz, Workplace pressures in pharmacy. Practical advice for New Zealand pharmacists, pharmacy staff and employers (2012).

November 2013. Furthermore, there is no documentation identifying details of retrospective alterations to the records.

111. With regard to labels S1 and A1 dated 18 September 2013, Mr B initially told HDC:

> "The dispensing label has not been amended since it was first entered. I cannot understand why [Ms A] would suggest that I would amend the label as this would deliberately create an error which I am now required to explain.
>
> …
>
> I … vehemently deny [Ms A's] assertion that I deliberately tried to mislead her. This is simply untrue."

112. However, Mr B subsequently accepted that the words "as directed" were added to the computer records after the dispensing label was printed for Ms A on 27 November 2013. Mr B was unable to confirm when the alteration was made or by whom.

113. With regard to labels S2, S3 and A2, dated 15 October 2013, Mr B told HDC that he "assume[s]" that the original computer record was amended after he became aware of the errors. Mr B accepted that it "would have been [him]" who made those changes. With regard to label A2, Mr B told HDC:

> "I believe that the name of the doctor has been altered (to correct the name of the provider) … I assume that the changes were made by me after my meeting with [Ms A] on 26 November [2013] but cannot be sure of that."

114. Mr B told HDC that he could not explain the difference between labels A2 and A3. With regard to all of the alterations made to the records, Mr B told HDC:

> "I am confident that any changes would have been to ensure that the records were accurate, and would not have been done for any other purpose that I can imagine."

115. In response to my provisional report, the pharmacy advised that neither brand of pharmacy dispensing software used in New Zealand has a function that allows for the identification of retrospective amendments to records.

116. I am unable to ascertain whether Mr B was responsible for the changes made to records regarding the dispensing label dated 18 September 2013. However, Mr B accepts that it is more likely than not that he changed the records relating to the labels dated 15 October 2013 and 26 November 2013, and I agree with that assessment. Mr B stated that the changes would have been made in order to "ensure that the records were accurate …".

117. I have carefully considered Mr B's alterations to the records, and am not persuaded that these were motivated by an intention to mislead. I also acknowledge that the dispensing software used by Mr B does not have a built-in function that identifies retrospective amendments. However, I remain of the view that the alterations made to the records regarding the dispensing labels do not accurately reflect what occurred with regard to the dispensing of medication to Ms A, but rather what should have

occurred. Amending records in this way without identifying that the amendment has been made retrospectively is very poor practice. Furthermore, by making amendments to the records in this way, Mr B removed the record of what actually occurred, which is also unacceptable.

Documentation conclusion

118. This Office has frequently emphasised the importance of accurate record-keeping.[22] The failure by a pharmacist to keep an accurate record of medications dispensed is poor practice, affects continuity of care, and puts patients at real risk of harm, and is contrary to standard 1.2 of the PCNZ Code of Ethics and 6.7.2 of the Competence Standards, outlined above. In this case, incorrect record-keeping led to Ms A being dispensed medication in excess of her prescription on 26 November 2013, when she was dispensed a repeat incorrectly recorded as owing to her from Dr F's 18 September 2013 prescription for 1x 500g of Konsyl-D powder. While I acknowledge that Konsyl-D is an over-the-counter medication, and that therefore a prescription is not required, I am concerned that documentation errors such as those exhibited in this case could lead to serious dispensing errors in different circumstances. It also demonstrates poor practice and a lack of care.

119. The clinical record is essential to enable other providers to provide accurate, consistent and appropriate care. The records as amended by Mr B present a false picture of what occurred with regard to the dispensing of medication to Ms A. Furthermore, there is no documentation identifying details of retrospective alterations to the records. Subsequently I have been reliant on the recollection of parties and Ms A's own records in order to determine what medication was dispensed to her between 18 September 2013 and 26 November 2013, and the information provided to her on the dispensing labels. Repetitive errors such as are demonstrated in this case is indicative of very poor practice.

Incident reporting

120. Once a pharmacist has been put on notice of an error having occurred, it is the pharmacist's duty to minimise on-going harm and take steps to prevent the error from occurring again. This is emphasised in standard 6.9.2 of the PCNZ Competence Standards, outlined above, as well as the pharmacy's incident reporting policy. An essential component of a pharmacist's duty in this regard is to complete an incident form.

121. In my view, it is unacceptable that an incident form was not completed for the Effexor-XR error until Ms A requested that the error be recorded, approximately five months later, and that incident forms were not completed at all regarding the Konsyl-D labelling errors. This is an indication that Mr B did not appreciate the potential gravity of the errors and the importance of learning from them and preventing the same type of error from happening again.

[22] See Opinions 08HDC10236, 10HDC00610, 12HDC01019 and 12HDC01483, available at www.hdc.org.nz. See also: Hill, A, "Systems, Patients, and Recurring Themes", *New Zealand Doctor* (9 March 2011), available at www.hdc.org.nz.

Conclusion

122. As a registered pharmacist, Mr B is responsible for ensuring that he adheres to professional standards. The PCNZ Code of Ethics requires registered pharmacists to ensure that they are able to comply with their legal and professional obligations, and that their workload or working conditions do not compromise patient care or public safety.[23] Mr B failed to comply with professional obligations in the following ways:

- By failing to ensure that he dispensed the correct strength of Effexor-XR to Ms A on 14 June 2013, incorrectly labelling the Konsyl-D medication on 18 September, 15 October and 26 November 2013, and not completing incident report forms in a timely manner. In these respects, Mr B did not comply with his professional obligations or the pharmacy's SOPs.

- By amending the records without ensuring that he kept a record of those amendments, Mr B acted in an unprofessional and misleading way and failed to minimise the potential harm to Ms A, contrary to the PCNZ Code of Ethics.

123. The number of errors relating to one consumer, within a six-month period, along with the failure to complete incident forms in a timely manner, is of significant concern. I consider that Mr B failed to provide services that complied with professional standards, as outlined above, and breached Right 4(2) of the Code.

Opinion: Ms C — Breach

124. Ms C accepts that she was the only person involved in the processing, dispensing and checking of Ms A's prescription for nadolol on 29 July 2013. However, owing to the length of time that had elapsed between the error occurring and the error being brought to her attention, Ms C is unable to recall the events surrounding the dispensing of propranolol instead of nadolol.

125. Ms C stated that the error may have occurred because of the medications being placed in the wrong sections of the dispensing shelves, or the wrong medication may have been picked by her owing to their proximity or location on the dispensary shelf. However, according to Mr B, at the pharmacy nadolol and propranolol are stored at opposite ends of the dispensary and on different shelves.

126. Regardless of where the medication was located, the pharmacy's SOP for dispensing clearly sets out what is required at each step of the prescription handling process. Ms C stated that she is confident that her checking procedures are compliant with professional standards. However, the fact remains that on this occasion Ms A was dispensed propranolol instead of nadolol.

127. As a registered pharmacist, Ms C is responsible for ensuring that she adheres to professional standards. The PCNZ Code of Ethics requires registered pharmacists to

[23] Principle 7.6.

ensure that they are able to comply with their legal and professional obligations, and that their workload or working conditions do not compromise patient care or public safety.[24]

128. By failing to ensure that she dispensed the correct medication to Ms A, Ms C failed to comply with the relevant professional standards outlined above, and did not adhere to the pharmacy's SOPs.

129. As a pharmacist, Ms C is expected to be fully cognisant of her obligations and comply with the standards set by the profession. Accordingly, I consider that Ms C breached Right 4(2) of the Code, as she did not provide services that complied with professional standards.

Opinion: The pharmacy— Breach

Failures of staff to adhere to SOPs

Dispensing errors

130. A pharmacy has an obligation to ensure that it has adequate policies in place to facilitate safe and disciplined dispensing. It is also responsible for ensuring that staff adhere to policies. The pharmacy had an SOP for dispensing, outlining the pharmacist's responsibility to select the correct medication and to perform a check against the prescription to ensure that the correct medication is dispensed. On 14 June 2013, Ms A was dispensed the incorrect strength of Effexor-XR and, on 29 July 2013, she was incorrectly dispensed propranolol instead of nadolol.

131. It is very concerning that two dispensing errors relating to the same consumer occurred within six weeks of each other. The SOP for dispensing provides for a number of opportunities to check the medication against the prescription. If each step of the SOP had been adhered to, it is likely that both errors may have been identified and corrected before Ms A left the pharmacy with the medication.

Labelling errors

132. On 18 September, 15 October and 26 November 2013, there were a number of labelling errors in relation to Ms A's prescriptions for Konsyl-D. The SOP for dispensing instructs the pharmacist to check the label against the prescription to ensure that the label contains the correct information. It is clear that staff did not adhere to the SOP on each of these occasions.

Incident reporting

133. At the time of the error, the pharmacy also had an SOP for incident reporting in place. The SOP instructs that an incident form should be completed immediately in relation to dispensing errors.

[24] Principle 7.6.

134. The completion of incident forms is an essential learning tool to help prevent errors from recurring. It provides an opportunity for staff to learn from the mistake and provide a safe and effective service in future, as well as ensuring that the consumer has been informed of the incident, and has been given follow-up advice or treatment where appropriate. Incident forms should be completed as soon as possible following the error while the incident is fresh in the minds of those involved, so that the details recorded will be as accurate as possible.

135. The error regarding Effexor-XR was discovered on 14 June 2013. However, an incident form was not completed as per the SOPs until Ms A requested it in November 2013. Furthermore, it does not appear that incident forms have been completed for the dispensing error relating to nadolol, or the labelling errors relating to Konsyl-D. The multiple failures by the pharmacy staff to complete an incident form in these circumstances is unacceptable.

Conclusion

136. In my view, the number of errors at the pharmacy, and the fact that these have been made by more than one staff member, indicate a systemic problem with regard to staff failing to follow the pharmacy's SOPs. Consumer safety is of utmost importance, and I consider that it is the responsibility of the pharmacy to ensure that every staff member complies with SOPs in order to prevent harm to patients. The PCNZ, in its document "Writing Standard Operating Procedures", has stated that procedures are the cornerstone of a strong quality system, and support meeting the overall goal of providing the public with safe and effective medical products.[25]

137. I acknowledge that, for the most part, the pharmacy's policies and procedures appear to be satisfactory. Accordingly, the gap appears to be in the pharmacy's systems for ensuring that staff were complying with those policies. Without staff compliance, policies become meaningless. Ultimately, the pharmacy had a responsibility to ensure that all staff complied with policies and provided services of an appropriate standard.[26] As stated in a previous report:[27]

> "The inaction and failure of multiple staff to adhere to policies and procedures points towards an environment that does not sufficiently support and assist staff to do what is required of them. [The organisation] must bear overall responsibility for this."

138. At the time of these events there appears to have been a culture of non-adherence to SOPs at the pharmacy. In my opinion, the pharmacy's failure to ensure staff compliance with its SOPs played a significant part in Ms A receiving the incorrect medication on two occasions, and her medication being labelled incorrectly on three occasions. Accordingly, I consider that the pharmacy did not provide services to Ms A with reasonable care and skill and breached Right 4(1) of the Code.

[25] http://www.pharmacycouncil.org.nz/cms_show_download.php?id=316.
[26] Opinion 08HDC17309 (26 May 2010) p 23.
[27] Opinion 09HDC01783 (28 March 2011) p 23.

System for ensuring that amendments to records are documented — Adverse comment

139. The pharmacy advised HDC that information relating to the tracking of amendments to records was not available. In response to my provisional opinion, the pharmacy advised that pharmacy dispensing software does not currently have a function that allows for "activities taken to remediate errors [to] appear as changes or amendments in the dispensing log".

140. I acknowledge this, but remain of the view that it is crucial to be able to ascertain whether amendments have been made to records, and, if so, details of such amendments, including when the amendments were made and by whom. It is equally crucial to maintain accurate records of what has occurred. Accordingly, any amendments to records should not have the effect of overriding any existing documentation relating to what actually occurred.

141. As outlined above, the clinical record is essential to enable other providers to provide consistent and appropriate care. Furthermore, the lack of information regarding details of amendments made to records relating to the dispensing of medication to Ms A has meant that I have been reliant on the recollections of parties and Ms A's own records to determine what occurred.

142. I am critical that the pharmacy did not have in place a system to ensure that any amendments to documentation were recorded appropriately.

Changes to SOPs — Other comment

143. The pharmacy updated its SOP for dispensing in May 2014. The SOP for dispensing now includes the instruction that a sole charge pharmacist perform an "extra final check" just prior to handing out the prescription to the patient. I am concerned at the length of time taken to amend the SOP to include this instruction. The Effexor-XR error occurred in June 2013. Therefore, it took the pharmacy almost a year to update the SOP.

144. While I am pleased that the pharmacy now has an updated SOP, I consider that the pharmacy has the responsibility to ensure that a sole pharmacist has a robust method of self-checking the medications he or she is dispensing. As stated in a previous opinion of this Office:[28]

> "[The HDC pharmacy expert] suggested a number of methods a sole pharmacist can use to self-check. These include creating a slight delay in the dispensing procedure to 'psychologically reset' before confirming the relevant prescription details.
>
> In my view, in order to ensure public safety, [the pharmacy] has an obligation to make sure that a sole pharmacist does have a robust method of self-checking the medications he or she is dispensing …"

[28] 07HDC21772 at www.hdc.org.nz.

145. I am of the view that the pharmacy's SOP for dispensing could be improved in this respect.

Recommendations

The pharmacy

146. In my provisional report, I recommended that the pharmacy:

a) Update its SOPs to reflect that staff should no longer use the copy function in the computer software.

In response to the provisional report, Mr B advised HDC that the SOP has been updated in this respect. I look forward to receiving evidence of this change having been made, within **three weeks** of the date of this report.

b) Seek an independent review of its dispensing processes, including its SOPs. As previously outlined, in response to my provisional report, the pharmacy sought a review of its dispensing processes by two expert pharmacists, which I consider an appropriate response to this recommendation.

147. I also recommend that the pharmacy:

a) Apologise to Ms A for its breach of the Code. The apology is to be sent to HDC within **three weeks** of the date of this report, for forwarding.

b) Conduct a training session for staff, which discusses the importance of following SOPs at all times and completing incident forms in a timely manner, and report back to HDC within **one month** of this report.

c) Review its SOP for dispensing with regard to self-checking by a sole pharmacist, and report back to HDC within **one month** of this report regarding the outcome of that review, including any changes made as a result.

d) Put in place systems to ensure that an audit trail or record is available to track changes made to records retrospectively, including who made the change and when, and report back to HDC within **three months** of the date of this report.

148. I also recommend that the pharmacy conduct the following audits, and report back to HDC regarding the outcome of the audits, within **six months** of this report:

a) Audit its incident reporting, including regarding the accuracy and timeliness of its incident reporting.

b) Audit compliance with its SOPs over a three-month period.

c) Audit its dispensing and dispensing processes, including its SOPs, the arrangement of medication on the shelves, and staffing resource.

Mr B

149. In my provisional report, I recommended that Mr B:

a) Review and familiarise himself with the pharmacy's SOPs and arrange an assessment through the New Zealand College of Pharmacists, regarding accurate dispensing, processing and checking processes, and report back to HDC.

150. In light of Mr B's advice that he intends to engage a practice support pharmacist to help develop and monitor improvements in his checking processes and report to HDC regarding the outcome of this process, I do not consider it necessary that he arrange an assessment, as outlined above, through the New Zealand College of Pharmacists. However, I remain of the view that Mr B should familiarise himself with the pharmacy's SOPs, and I look forward to receiving his report to HDC in this respect, within **three months** of the date of this report.

151. I also recommend that Mr B provide a written apology to Ms A for his breach of the Code. The apology is to be sent to HDC within **three weeks** of the date of this report, for forwarding.

Ms C

152. In my provisional report I recommended that Ms C provide a written apology to Ms A for her breach of the Code. In response to the provisional opinion, Ms C provided a written apology to HDC for forwarding to Ms A.

Follow-up actions

153.
- A copy of this report with details identifying the parties removed will be sent to the Pharmacy Council of New Zealand and the relevant district health board, and they will be informed of Mr B's and Ms C's names, and the name of the pharmacy.

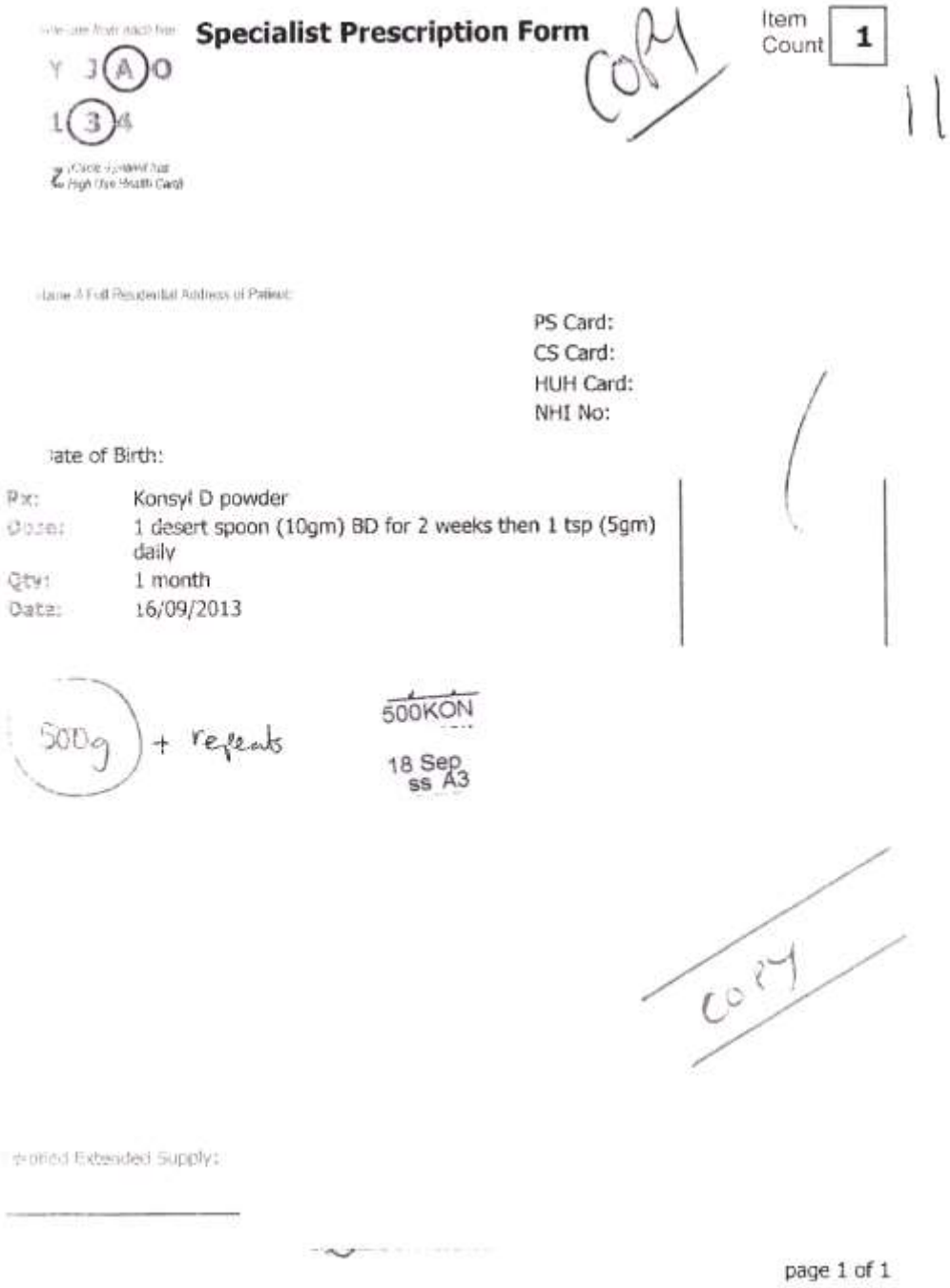
- Mr B will be referred to the Pharmacy Council of New Zealand, and the Council will be asked to consider whether Mr B should undergo a competency review. I recommend that the Council determine any necessary conditions on his practice, supervision and monitoring, and training needs, and advise HDC accordingly.

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

Appendix A — Photos of APO/40 and APO/N40

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

Appendix B — Labels provided by Ms A and Mr B



Specialist Prescription Form

COPY

Item Count 1

Y J A O

L 3 4

PS Card:
CS Card:
HUH Card:
NHI No:

ate of Birth:

Rx: Konsyl D powder
1 desert spoon (10gm) BD for 2 weeks then 1 tsp (5gm) daily
Qty: 1 month
Date: 16/09/2013

500g + repeats

500KON

18 Sep
ss A3

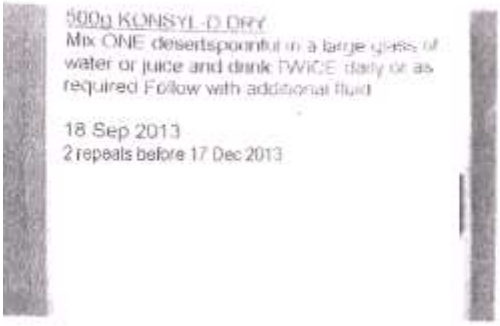
COPY

page 1 of 1

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

18 September 2013

S1



500g KONSYL-D DRY
Mix ONE desertspoonful in a large glass of water or juice and drink TWICE daily or as required Follow with additional fluid

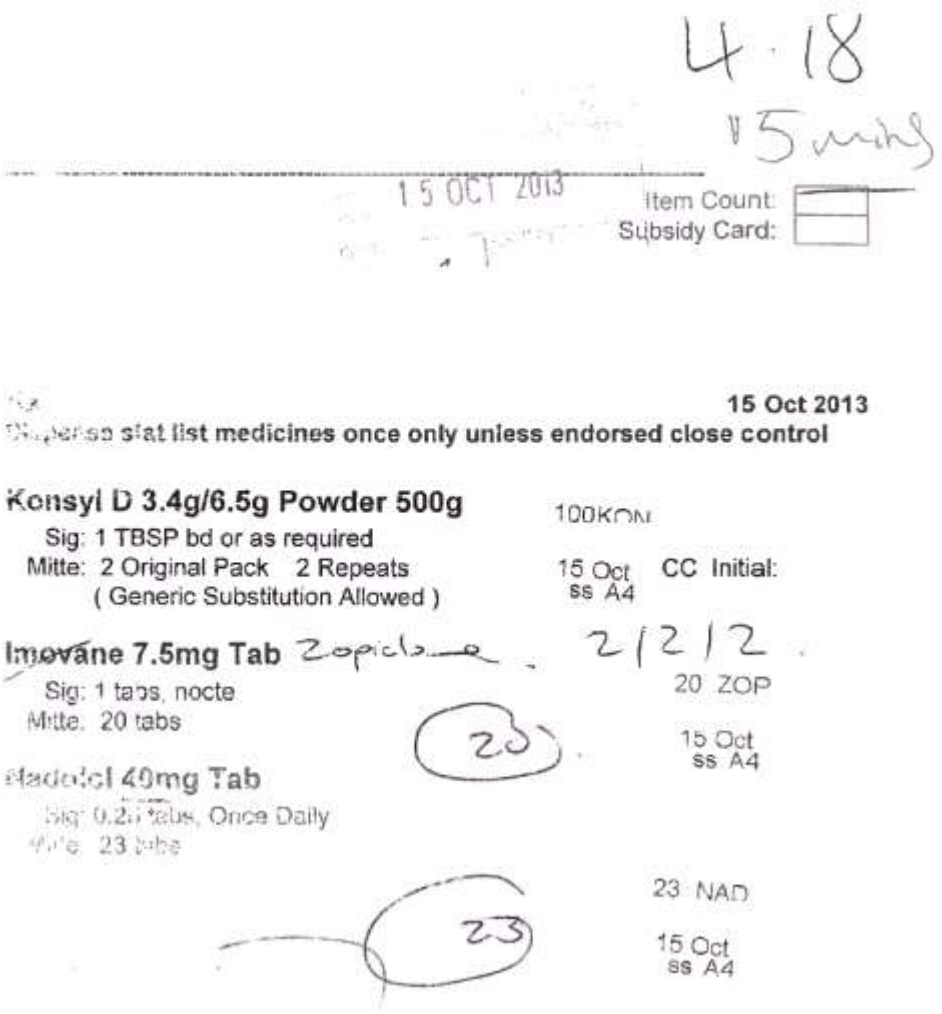
18 Sep 2013
2 repeats before 17 Dec 2013

A1

500g KONSYL-D DRY
Mix ONE desertspoonful in a large glass of water or juice and drink TWICE daily or as required Follow with additional fluid as directed

18 Sep 2013
2 repeats before 17 Dec 2013

15 October 2013



4·18

15 mins

15 OCT 2013

Item Count:
Subsidy Card:

15 Oct 2013

Unless stat list medicines once only unless endorsed close control

Konsyl D 3.4g/6.5g Powder 500g
Sig: 1 TBSP bd or as required
Mitte: 2 Original Pack 2 Repeats
(Generic Substitution Allowed)

100KON

15 Oct
ss A4

CC Initial:

Imovane 7.5mg Tab Zopiclone

2/2/2

Sig: 1 tabs, nocte
Mitte: 20 tabs

20 ZOP

20

15 Oct
ss A4

Nadolol 40mg Tab
Sig: 0.25 tabs, Once Daily
Mitte: 23 tabs

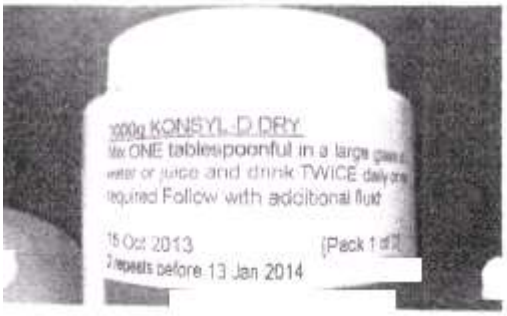
23 NAD

23

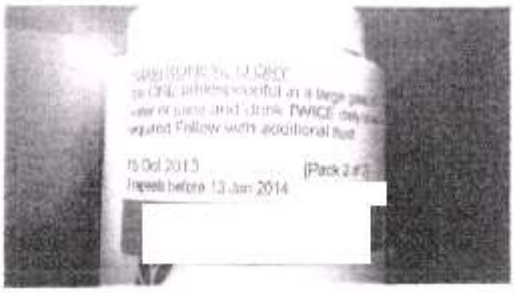
15 Oct
ss A4

15 October 2013

S2



S3



A2

500g KONSYL-D DRY
Mix ONE tablespoonful in a large glass of water or juice and drink TWICE daily or as required Follow with additional fluid

15 Oct 2013
2 repeats before 13 Jan 2014

500KON

15 Oct
ss A4

A3

1000g KONSYL-D DRY
Mix ONE tablespoonful in a large glass of water or juice and drink TWICE daily or as required Follow with additional fluid

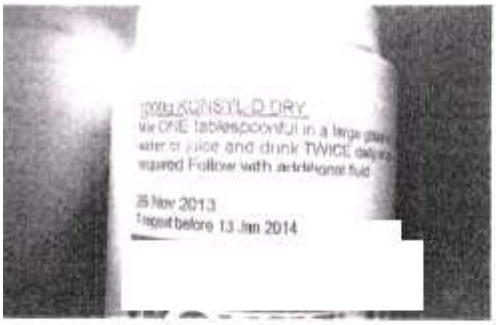
15 Oct 2013
2 repeats before 13 Jan 2014

100KON

15 Oct
ss A4

26 November 2013

S4



A4

1000g KONSYL-D DRY
Mix ONE tablespoonful in a large glass of water or juice and drink TWICE daily or as required Follow with additional fluid

26 Nov 2013
1 repeat before 13 Jan 2014

100KON

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Appendix C — The pharmacy's dispensing SOP

12.0 Dispensing Procedures

PURPOSE: To provide an accurate, clear checklist of the procedure when dispensing a prescription

12.1. PROCEDURE FOR DISPENSING NEW PRESCRIPTION

12.1.1 RECEIVING THE PRESCRIPTION

1) In person
Greet the patient and take prescription
2) Fax/email/phone
Ensure the prescriber is known to you
Check the prescriber's signature for authenticity
If phoned, obtain all prescription details and repeat to prescriber to ensure information is accurate

12.1.2 LEGALITY AND VALIDITY OF PRESCRIPTION

Check the prescription has:

Patient's title, name (initial and surname) and address	
Patient's date of birth (if under 13y)	
Doctor's name, address and registration number	
Valid date (3m=Subsidised (6m for OCs) 6m=NSS, CD=7 days)	
Doctor's signature (check it is authentic)	
Name, strength and form of medicine(s)	[ ]
Dose and frequency of medicine(s) (including directions for use)	[ ]
Period of supply/quantity of medicine(s)	[ ]
Check if medicine is stat/close control/repeats	[ ]
Check restrictions on period of supply (e.g. CD=1 month, OCs=6 months)	[ ]
Check restrictions on certain prescribers (e.g. dentists, midwives)	[ ]
Check prescription is correctly endorsed (certified condition/special authority number/ specialist recommendation) with valid expiry dates	[ ]
If special authority number is missing or date has expired, ring 0800 number to obtain current details	[ ]
Patient code (not legally required but essential for funding)	[ ]
Check if patient has CSC or subsidy card	[ ]
Patient's NHI number (not legally required but an important identifier)	[ ]
If patient requests single supply, stamp prescription with single supply stamp and get the patient to tick reason for single supply and sign prescription.	[ ]
Notify patient of approximate waiting time for prescription	[ ]
If any of the legal requirements are missing from the prescription, contact the prescriber	[ ]

12.1.3 PREPARE A LABEL USING LOTS DISPENSING PROGRAMME

Select the correct patient (if already in database) by checking their name/address/date of birth	[ ]
OR add the patient to the database (if new patient)	
Read the patient's history and additional notes for allergies, past medications (brand), evidence of misuse	[ ]
Ensure the medicine is appropriate for the patient (with regards to dose, interactions)	[ ]
If it is not, contact the prescriber to discuss alternative medicines/dose changes	[ ]
Enter in the details of prescription (Doctor's name, medicine, directions for use etc.)	[ ]
If generic substitution is permitted, select the funded brand of medicine	[ ]

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

Check if the medicine is in stock (if not, order more) [ ]
NOTE: If using the 'copy' function of the LOTS computer system, check carefully there are no subtle differences – e.g. prescribers name, slight changes to instructions or change in strength etc..
OR: do not use this function and enter the prescription as a new one. [ ]
If any medicines are owing, replicate label and make up when stock arrives [ ]
Check the price on the computer [ ]
For phoned scripts, tick "phoned" box and print out phoned prescription [ ]

12.1.4 FILL THE PRESCRIPTION

Select the correct medicine (name, brand, strength) using the prescription [ ]
Check the expiry date of the stock [ ]
Count/pour correct amount of medicine required [ ]
Put the medicine in a suitable container (with CRC if appropriate) [ ]
If it is a controlled drug, fill in the Controlled Drugs Register [ ]
If extemporaneous:
- Prepare compounding sheet [ ]
- Ensure all equipment is clean before and after making the product [ ]
- Accurately weigh out/measure ingredients [ ]
- Ensure the pharmacist checks the weights/volumes are correct before proceeding further [ ]
- Ensure the pharmacist checks the final product [ ]

Label the medicine (include expiry date if extemporaneous) [ ]
Add Cautionary and Advisory labels where appropriate [ ]
Check once more the correct medicine has been selected by comparing contents of container to stock bottle and prescription [ ]
Double-check that the label matches the prescription [ ]
Stamp the prescription with pharmacy name, address and date [ ]
Put the sticker (from the label) on the prescription [ ]
Annotate and initial each prescription item with different coloured pen to prescriber [ ]

12.1.5 PHARMACIST CHECK

Get the pharmacist to check the medicine, label and receipt against the prescription for:
- Patient's name, address (and age if <13y) [ ]
- Name, brand, strength, dosage and quantity of medicine [ ]
- Doctor's name, registration number and address [ ]
- Prescription fee [ ]
- Expiry date of prescription [ ]

Once they are satisfied, the pharmacist should initial each prescription item to indicate it is ready to dispense to the patient
If the pharmacist is working on their own and does not have another pharmacist available to check their work, ensure that an *extra* final check is done just prior to handing the prescription out to the patient. [ ]
File the prescription in a safe and secure place [ ]
- If a faxed script, put aside until original prescription is received [ ]
- If a phoned script, obtain the prescriber's signature before filing [ ]
- If a CD script, separate the pharmacy, healthpac and medicines control copies [ ]

12.1.6 GIVING THE MEDICINE TO THE PATIENT

Ensure the patient receives the correct medication (by asking patient their name & address) [ ]
Ascertain what knowledge the patient already has about their medicine [ ]
(e.g. if they have taken it before)

If necessary, explain to the patient:	
What the medicine is being used for	[ ]
How often to take the medicine	[ ]
Advice on taking the medicine (e.g. With a large glass of water)	[ ]
Expected side effects	[ ]
Precautions when taking the medicine (e.g. Don't drink alcohol)	[ ]
How many repeats left	[ ]
How to store the medicine (e.g. keep refrigerated)	[ ]
Expiry date of medicine	[ ]
Appropriate lifestyle advice	[ ]
Find out what other medications/supplements (including OTC) the patient is taking and notify them of possible interactions	[ ]
Ensure the patient understands what you have told them - encourage them to ask questions about their medicine	[ ]
Receive payment for prescription and farewell patient	[ ]