Pharmacy

Pharmacist, Ms C

A Report by the

Deputy Health and Disability Commissioner

(Case 16HDC00079)

Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

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Executive summary

1. On 22 April 2015, Mrs B visited a pharmacy to have a prescription filled. The prescription included 90 tablets (a three-month supply) of Ferrograd F. Later that day, Mrs B identified that the Ferrograd F that had been dispensed to her by the Pharmacy was due to expire one month into the three-month supply. Pharmacist Ms D replaced the short-dated Ferrograd F and completed an incident report. The Pharmacy performed a check for expired Ferrograd F in the dispensary, but did not perform a check of the stock in the shop.

2. On 14 October 2015, Mrs B returned to the Pharmacy to have another prescription filled. This prescription included 90 tablets of Ferrograd F and four tablets of mercaptopurine 50mg. Pharmacist Ms C mistakenly dispensed cabergoline 500mcg instead of the prescribed mercaptopurine 50mg and dispensed Ferrograd F that had expired in June 2015.

3. On 19 November 2015, the error whereby Ms C had mistakenly dispensed cabergoline 500mcg instead of the prescribed mercaptopurine 50mg was identified by Mrs B and Ms D. Mrs B had not taken the medication at this time.

4. In early January 2016, Mrs B noticed that the Ferrograd F dispensed to her in October 2015 by Ms C had expired in June 2015, and returned it to the Pharmacy. Pharmacist Ms D replaced the expired Ferrograd F.

Deputy Commissioner's findings

5. In dispensing cabergoline 500mg instead of the prescribed mercaptopurine, Ms C failed to select the correct medication and failed to check the selected medication against the prescription adequately. Accordingly, Ms C failed to provide Mrs B with services in accordance with professional standards, and breached Right 4(2) of the Code of Health and Disability Services Consumers' Rights (the Code).[1]

6. The Pharmacy's failure to ensure that the medications in its stock had appropriate expiry dates led to Mrs B receiving expired and short-dated Ferrograd F. Accordingly, the Pharmacy did not provide services to Mrs B with reasonable care and skill, and breached Right 4(1) of the Code.[2]

Deputy Commissioner's recommendations

7. The Deputy Commissioner recommended that Ms C arrange for an assessment through the New Zealand College of Pharmacists regarding her processing of prescriptions and her processes for dispensing and checking medications, and that she provide a written apology to Mrs B for her breach of the Code.

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

8. The Deputy Commissioner recommended that the Pharmacy conduct an audit of three months' compliance with its Standard Operating Procedures for stocktake, and provide a written apology to Mrs B for its breach of the Code.

Complaint and investigation

9. The Commissioner received a complaint from Mrs B about the services provided to her by pharmacist Ms C and the Pharmacy. The following issues were identified for investigation:

- *Whether the Pharmacy provided Mrs B with an appropriate standard of care between April 2015 and November 2015.*
- *Whether Ms C provided Mrs B with an appropriate standard of care between April 2015 and November 2015.*

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

11. Information was reviewed from:

Mrs A	Provider/Pharmacy Director
Mrs B	Consumer/complainant
Ms C	Provider/pharmacist
Ms D	Provider/pharmacist
Pharmacy	Provider/pharmacy

12. Independent expert advice was obtained from pharmacist Mr Paul Vester.

Information gathered during investigation

Introduction

13. This report concerns three errors in the dispensing of medication by the Pharmacy to Mrs B in 2015. Pharmacy Director Mrs A provided the information from the Pharmacy in relation to these events. Pharmacist Ms C is an employee of the Pharmacy.[3]

[3] Ms C has been a qualified pharmacist in New Zealand since 2012.

22 April 2015 — first dispensing error

14. On 22 April 2015, Mrs B visited the Pharmacy to have a prescription filled. This prescription included 90 tablets (three months' supply) of Ferrograd F.[4] Mrs A told HDC that Ms C was the pharmacist responsible for processing and dispensing Mrs B's prescription. However, Mrs A stated that the prescription had been destroyed by the Ministry of Health Sector Services due to the time that had passed, and so she was unable to provide a copy to HDC. Ms C told HDC: "I have no recollection of dispensing and checking that prescription."

Identification of first dispensing error

15. Later on 22 April, Mrs B identified that the Ferrograd F that had been dispensed to her by the Pharmacy was due to expire one month into the three-month supply. Mrs B returned to the Pharmacy and informed pharmacist Ms D of the upcoming expiry date.

16. Ms D replaced the short-dated Ferrograd F and discussed the error with Mrs B. Ms D informed Mrs B that the outcome from taking expired Ferrograd F tablets would be that they would not be as effective.

17. Ms D completed an incident report and recorded: "Pharmacists and stock unpacker(s) need to be more diligent about checking [expiry] dates must be more than 12 months …" Ms D also informed Mrs A of the incident.

18. Mrs A told HDC: "[T]he stock in the dispensary was checked [following identification of the error], there was no further expired stock in the dispensary. The returned medicine was discarded …" Mrs A told HDC that she believes this check would have been conducted by Ms D.

14 October 2015 — second and third dispensing errors

19. On 14 October 2015, Mrs B returned to the Pharmacy to have another prescription filled. This prescription included 90 tablets (three months' supply) of Ferrograd F and four tablets of mercaptopurine 50mg.[5] Ms C processed Mrs B's prescription and mistakenly wrote "Dostinex"[6] on the prescription, which is the trade name for cabergoline rather than mercaptopurine. Ms C then entered the details into the computer, selected the required medication from the shelf, counted the tablets, and performed the final check of the medication for Mrs B. Ms C accidentally dispensed Dostinex (cabergoline) instead of the prescribed mercaptopurine. She also dispensed the Ferrograd F.

Identification of second dispensing error

20. On 19 November 2015, Mrs B telephoned the Pharmacy to request a repeat of the mercaptopurine 50mg. These tablets were dispensed by Ms C. Later that day, Mrs B telephoned the Pharmacy to enquire as to whether there had been a brand change. She explained to Ms D that the mercaptopurine dispensed to her that day looked different

[4] Ferrograd F tablets are used as a source of iron and folic acid for the prevention and treatment of iron and folic acid deficiency.
[5] Mercaptopurine is an immunosuppressive medication. It is used to treat acute lymphocytic leukaemia, Crohn's disease, and ulcerative colitis.
[6] Used to treat hormone imbalances.

in appearance to the mercaptopurine that had been dispensed on 14 October 2015. Mrs B had not taken the mercaptopurine dispensed on 14 October 2015.

21. Ms C informed the pharmacist in charge, Ms D, who advised Mrs B to return to the Pharmacy with both bottles of mercaptopurine. It was identified that, on 14 October 2015, Mrs B had received cabergoline 500mcg instead of the prescribed mercaptopurine 50mg. Ms D exchanged the medications so that Mrs B would have mercaptopurine in accordance with her prescription.

22. Following the identification of the error, an incident report was completed by Ms C. The incident report noted: "Cabergoline 500mcg was given despite the label printed mercaptopurine 50mg." Ms C also wrote a letter of apology to Mrs B and stated: "I understand this is a serious mistake for which I take full responsibility." Ms C explained to Mrs B that the error had occurred as a result of her selecting the wrong medication and then failing to recognise the mistake when checking the tablets in the repacked bottle against the stock bottle.

23. Ms C told HDC:

> "The only thing that I think could have led to making this mistake was that the dose of both of the medicines are similar (both are taken as a weekly dose) and that both products are packaged in a small amber glass bottle."

24. Ms C also told HDC:

> "This incident where I mistakenly checked off cabergoline as mercaptopurine has taught me a painful lesson of not to assume that the brand name is the medicine of the generic name that I have in mind but to always sight the generic name and underline it, or in its absence to write it down."

25. Mrs A told HDC:

> "We have run through various scenarios that may have led to the error … An incorrect brand name was written on the prescription by the person who dispensed the prescription … Both medicines are in a small brown glass bottle, the products are stored in different areas of the Dispensary (ordered generically) however because the bottles look similar the cabergoline bottle may have been put incorrectly on the shelf in the tray that the mercaptopurine tablets are stored in. Cabergoline and mercaptopurine are both given as weekly doses, [Ms C] is unsure but the frequency of dosing may have contributed to the confusion when writing down the wrong trade name (Dostinex) on the prescription."

26. In addition, Mrs A told HDC that the error occurred during the Pharmacy's rush hour.

19 November 2015 staff meeting

27. On 19 November 2015, a staff meeting was held to discuss the dispensing error and checking system. The meeting minutes state: "Checking — MUST always check against generic name, in this instance the Brand name (Dostinex) was written on the [prescription]."

28. The meeting minutes also documented: "NOTED [Ms C] is serving 75% of customers as she is most often dispensing, therefore at the front dispensing computer — need to reduce this to 50% which will result in less interruptions for [Ms C]."

29. Mrs A told HDC:

> "[Ms C] is often the first person people see when they enter the pharmacy — so she meets and greets, she receives prescriptions, she offers assistance. The design of the pharmacy is that the patients move straight towards the dispensary to receive assistance. All staff have been instructed to reduce those interruptions for [Ms C] or whoever is at the main dispensing computer."

30. The Pharmacy also decided during the staff meeting that, when possible, two pharmacists will perform checks of medication dispensed and, in instances when this is not possible, the dispensing pharmacist is to perform a separate task before checking that the selected medication is correct.

Identification of third dispensing error

31. In early January 2016, Mrs B noticed that the Ferrograd F dispensed to her in October 2015 by Ms C had expired in June 2015, and returned it to the Pharmacy. Mrs B had not taken any of the Ferrograd F dispensed to her in October 2015. The Pharmacy does not have a record of the day on which Mrs B informed them of the expired medication. Ms D replaced the expired Ferrograd F and told Mrs B that, had she taken them, she might not have received the amount of iron that her doctor intended her to receive.

32. On 11 January 2016, Ms C returned from holiday and was informed of her error. She wrote a letter of apology to Mrs B and stated:

> "I would like to apologise for dispensing a medicine (Ferrograd F) that has passed its expiry date … This mistake should not have occurred, as the exact same mistake where we dispensed an expired batch of Ferrograd F happened to you 5 months prior. For the same mistake to happen again, shows that our system of managing our dispensary stock has failed us miserably."

33. Ms C also completed an incident report and documented:

> "Ferrograd F was placed in 2 separate locations of the pharmacy (dispensary and in Shop). We have addressed the first expiry date incident by removing all short dated stock from the dispensary but might have failed to do so for the Ferrogard F in the Shop.
>
> Failure to take expired products off the shelf occurred when stock rotation and checking of stock's expiry date have not been reinforced."

21 January 2016 staff meeting

34. On 21 January 2016, a staff meeting was held to discuss the third dispensing error. The meeting minutes documented that a full dispensary stock check for expiry dates was to be done immediately and that the Ferrograd F would be relocated so that it

would all be in one location in the Pharmacy. The minutes also recorded that Ms C was to establish a system in the Pharmacy to identify stock due to expire within six months.

Standard Operating Procedures

Dispensing

35. At the time of these events, the Standard Operating Procedure (SOP) in place at the Pharmacy entitled "The Dispensing Procedure" required Ms C to select the correct medicine and to:

> "[C]heck the selected medicine against the prescription to ensure it is the correct medicine, dosage, form and strength … [and] check the expiry date of the medicine."

36. The Dispensing Procedure SOP also stated that the pharmacist was responsible for the final check of the prescription. It required Ms C to:

> "[C]heck for label accuracy — name, date, medicine strength and form, instructions … and contents accuracy — correct medicine, dose, form and quantity."

37. In January 2016, the Pharmacy amended its Dispensing Procedure SOP to state:

> "[T]wo pharmacists check and initial the prescription where possible, if a single pharmacist is responsible for checking the prescription, the pharmacist must complete an unrelated task prior to the final check to ensure the final check is with a clear head."

Stocktakes

38. At the time of these events, the SOP in place at the Pharmacy entitled "Stock" relevantly stated: "Stock expiry dates are checked when products are used and surveyed as a whole when carrying out a physical stocktake." The Stock SOP also required pharmacy staff to put the stock in the correct place and "put the new stock BEHIND old every time".

39. The Pharmacy updated its Stock SOP in January 2016. It now states:

> "Stock expiry dates are checked when products are used and surveyed as a whole when carrying out a physical stocktake. Products arriving in store should have at least 12 months expiry, if not, check with Dispensary Manager whether to accept or return the goods."

40. The new Stock SOP also states: "Products that are both dispensed and over the counter should be kept in one location and ensure stock is rotated."

41. The SOP in place at the Pharmacy at the time entitled "Subject: Rolling Stocktakes" stated:

> "A rolling stocktake of 20 active items in the dispensary must be performed and cleared daily by the pharmacist and or intern pharmacist … During stocktake check the expiry dates of products. Short dated (<6 months) expiry must be brought to the Manager's attention immediately … Expired product must be removed and discarded appropriately … During March of each year a complete stocktake must be completed for the end of the financial year."

42. The Pharmacy updated its Rolling Stocktakes SOP in January 2016. It now also states:

> "All products with less than 6 month expiry must be marked with a green dot to highlight that it is getting close to expiry date."

43. Mrs A told HDC that the systems in place at the Pharmacy, and the seriousness of not following those systems, have been reinforced with all staff during staff meetings and daily dispensing.

Stocktake in 2015

44. Mrs A told HDC that stocktake records for 2015 are unavailable as "the intern and retail staff who performed the stocktake wrote the products and stock on hand (SOH) on pieces of paper and adjusted stock cards manually". She told HDC that the stocktake took place in the weeks prior to 31 March 2015. Mrs A said that "this function is performed by both shop and dispensary staff over a 4 week period — during this period as well as our pharmacists we employed a pharmacy student and a pharmacy intern".

45. Mrs A told HDC: "Expired products being overlooked on the shelf and dispensed to a patient is unacceptable and correct adherence to robust dispensing and stock rotation systems recorded in our SOPs is required to prevent this occurring."

Actions taken by the Pharmacy

46. Mrs A told HDC that the changes the Pharmacy has put in place following the dispensing errors include:

- Ms C now attends 10–15% fewer customers.
- A new system has been established whereby green sticker dots are placed on short-dated stock to allow it to be identified easily.
- When possible, two pharmacists are to check medication to be dispensed and sign the prescription. When this is not possible, the dispensing pharmacist is to perform an unrelated task prior to performing the final check on the prescription.
- Support staff will now provide the first point of contact to customers on their arrival rather than the pharmacists.
- All Ferrograd F stock has been relocated to one area in the Pharmacy to improve stock rotation.
- The dispensary area is being redesigned to provide a larger area for stock storage.

- The generic name of each medication is to be written on the prescription as part of the checking mechanism.
- Every 10th prescription by Ms C is independently checked by Mrs A or Ms D, both senior pharmacists.
- Weekly meetings are held between Mrs A and Ms C during which "a random selection of 20 prescriptions" is reviewed and processes and concerns are discussed.
- In July 2016, a pharmacy technician was employed to assist the pharmacists.
- Stock rotation and daily stocktakes are managed and conducted by the pharmacy technician with a pharmacist overseeing the process.

Action taken by Ms C

47. Ms C told HDC that, following these events, she will "never sign off a prescription without checking that the expiry date is appropriate and without viewing the generic name of the medicine".

48. Ms C also created the green dot sticker system in place at the Pharmacy to identify short-dated stock.

Response to provisional opinion

49. Mrs B was provided with an opportunity to respond to the "information gathered" section of the provisional opinion. Mrs B had no further information to add.

50. The Pharmacy and Ms C were provided with an opportunity to respond to the provisional opinion. They had no further information to add.

Opinion: Ms C — breach

Dispensing errors

51. On 22 April 2015, a pharmacist dispensed a three-month supply of Ferrograd F to Mrs B. Later that day, Mrs B identified that this Ferrograd F was due to expire one month into the supply. Mrs A told HDC that Ms C was the pharmacist responsible for processing and dispensing Mrs B's prescription that day. However, Ms C has no recollection of doing so, and the signed prescription has been destroyed owing to the time that has passed. Accordingly, I am unable to determine who dispensed the short-dated Ferrograd F to Mrs B on 22 April 2015.

52. On 14 October 2015, Ms C dispensed a further three-month supply of Ferrograd F to Mrs B. Ms C later discovered that this Ferrograd F had expired in June 2015. On 14 October Ms C also incorrectly dispensed cabergoline to Mrs B instead of mercaptopurine, the medication that had been prescribed. This error was discovered on 19 November 2015, at which point the Pharmacy exchanged the cabergoline for

the prescribed mercaptopurine. Prior to discovery of these errors, Mrs B had not taken the cabergoline or the expired Ferrograd F.

Professional standards

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 (2015) state:

> "03.2 DISPENSE MEDICINES
>
> 03.2.1 Maintains a logical, safe and disciplined dispensing procedure
>
> 03.2.2 Monitors the dispensing process for potential errors and acts promptly to mitigate them."

54. The Pharmacy Council of New Zealand publication *Safe Effective Pharmacy Practice* (2011) provides in its "Code of Ethics" that pharmacists must:

> "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."

55. Furthermore, the Pharmacy's SOPs required Ms C to select the correct medication to be dispensed, check the selected medication against the prescription, and check the expiry date of the medication.

Dispensing expired Ferrograd F

56. My expert advisor, Mr Paul Vester, advised that, whilst there is a responsibility for the pharmacist to check the expiry date of medication, often this is done only in the case of rarely used medications. Mr Vester advised that stock turn and pharmacy systems should ensure that products have appropriate expiry dates.

57. I accept that, had the SOPs in the Pharmacy been adhered to in relation to stock management and rolling stocktakes, the expired Ferrograd F would not have been available to be dispensed on 14 October 2015. However, I am critical that Ms C dispensed expired Ferrograd F to Mrs B, particularly given that the Pharmacy's SOP required her to check the expiry date of the medication before dispensing it.

Dispensing incorrect medication

58. Mr Vester advised:

> "The error with the dispensing of Dostinex (generic name Cabergoline) instead of Mercaptopurine is a serious error, for which Pharmacist [Ms C] holds the responsibility, as regardless of work load and distractions it is still within the expected scope of her practice as Pharmacist to avoid such a mistake."

59. Ms C failed to select the correct medication, as required by the SOP, and failed to check the medication against the prescription adequately prior to dispensing it to Mrs B.

60. By failing to select the correct medication, and by failing to check the selected medication against the prescription adequately, I consider that Ms C failed to provide Mrs B with services in accordance with professional standards and, as such, breached Right 4(2) of the Code.

61. I note that Ms C apologised to Mrs B promptly following the discovery of her dispensing errors. Ms C has also worked on improving the stock system in the Pharmacy and her own practice as a pharmacist. This is commendable.

Opinion: Pharmacy — breach

Stocktakes

62. The Pharmacy was responsible for ensuring that services were provided to Mrs B with reasonable care and skill. On two separate occasions, Mrs B was dispensed expired or short-dated Ferrograd F.

63. My expert advisor, Mr Vester, considers the Ferrograd F errors to be largely a failure of the Pharmacy's systems, and that in this respect the care provided to Mrs B was inadequate. He noted that stock turn and systems should ensure that products have appropriate expiry dates.

64. I acknowledge that the stocktake SOPs in place in the Pharmacy at the relevant time appear to have been satisfactory. Mr Vester advised: "Had the SOPs been followed, then they contain within them sufficient procedures to ensure that the expired stock should have been found, so were appropriate as documents." Mr Vester further advised:

> "Had … Rolling Stocktakes, been carried out, every 6 weeks then all the stock should have been checked for expiry. The SOP states stock older than 6 months should be brought to the manager's attention, so no expired stock should have been available to dispense … Clearly this SOP has not been followed correctly."

65. Mrs A told HDC that the 2015 stocktake was performed in the weeks prior to 31 March, and that both shop and dispensary staff were involved. She said: "Expired products being overlooked on the shelf and dispensed to a patient is unacceptable and correct adherence to robust dispensing and stock rotation systems recorded in our SOPs is required to prevent this occurring."

66. I consider that it was the responsibility of the Pharmacy to ensure that the 2015 stocktake was carried out by staff correctly and in accordance with the SOPs. I also note that the Pharmacy missed a further opportunity to remove the short-dated Ferrograd F from its stock after the first dispensing error was identified in April 2015.

67. The Pharmacy's failure to ensure that the medications in its stock had appropriate expiry dates led to Mrs B receiving expired and short-dated Ferrograd F. Accordingly, I consider that the Pharmacy did not provide services to Mrs B with reasonable care and skill, and breached Right 4(1) of the Code.

68. I acknowledge that the Pharmacy has now introduced a green dot system to mark short-dated stock. Mr Vester has advised that the system "is useful and visual, which should be of help in managing expired stock".

Dispensing of incorrect medication

69. In addition to any direct liability for a breach of the Code, under section 72(2) of the Health and Disability Commissioner Act 1994 (the Act), an employing authority is vicariously liable for any act or omission by an employee. However, a defence is available to the employing authority under section 72(5) if it can prove that it took such steps as were reasonably practicable to prevent the act or omission.

70. Ms C was acting as an employee of the Pharmacy when she dispensed cabergoline instead of the prescribed mercaptopurine to Mrs B, in breach of Right 4(2) of the Code. However, I am satisfied that the Pharmacy took all such steps as were reasonably practicable to prevent Ms C's error. Ms C was required by both the Pharmacy's SOPs and the Pharmacy Council of New Zealand's Competence Standards to ensure that she dispensed the prescribed medication correctly. I consider that the Pharmacy was entitled to rely on her to do so. I am therefore of the view that Ms C's breach of Right 4(2) was an individual clinical error, and the Pharmacy is not liable for it.

Recommendations

71. I recommend that Ms C:

a) Arrange for an assessment through the New Zealand College of Pharmacists regarding her processing of prescriptions and processes for dispensing and checking medications, and provide evidence confirming the outcome of that assessment to this Office within three months of the date of this report.
b) Provide a written apology to Mrs B for her breach of the Code. The apology is to be sent to HDC within three weeks of the date of this report, for forwarding to Mrs B.

72. I recommend that the Pharmacy:

a) Conduct an audit of three months' compliance with the SOPs for stocktake, and report the results of the audit to HDC within four months of the date of this report.
b) Provide a written apology to Mrs B 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 to Mrs B.

Follow-up actions

73. 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 it will be advised of Ms C's name.

74. 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 (College Education and Training Branch), the Health Quality and Safety Commission, and the New Zealand Pharmacovigilance Centre.

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

Appendix A: Independent advice to the Commissioner

The following expert advice was obtained from pharmacist Mr Paul Vester:

"I have been asked to provide an independent opinion on case number 16HDC00079 Complaint: [the Pharmacy]/[Ms C]

I have read and agreed to follow the Commissioner's Guidelines for Independent Advisors.

I am a current practising pharmacist and co-owner of Morrinsville Pharmaceutical Services Ltd in Morrinsville which has the only two pharmacies in Morrinsville. I qualified as a pharmacist with a Diploma in Pharmacy from CIT Heretaunga becoming registered as a pharmacist in 1981. I have worked as a pharmacist since qualifying, first as pharmacist for 2 other Pharmacies before buying my own business in 1989, then forming a partnership in 1999 for our current business. I have qualified as a preceptor trainer and had 6 interns over the last 10 years. We currently employ 23 staff (including 6 fulltime pharmacists). I was a founding member, and one time chairman of the Midland Community Pharmacy group, which developed many new pharmacy services for not only The Midland area but also New Zealand. This included helping set standards, developing reporting templates, and developing Standard operating procedures and policies. I am currently also engaged by the New Zealand Pharmacy Council as one of the pharmacists developing and critiquing the scenarios for the final assessment day for Pharmacy Interns, and as an assessor on those days.

1) The adequacy of the care provided to [Mrs B] by [the Pharmacy] and, if appropriate, please include specific comment on the care provided by the individual pharmacists.

When considering my response to this (and the other questions) I need to clarify that there are many different issues with different risks to patient and possible causes, which makes a general statement on adequacy of care difficult. They are:

(a) the risk from expired Ferrograd F tablets versus the risk from the Mercaptopurine/Dostinex error.

(b) the repetition of the expired Ferrograd F tablet error.

(c) three errors in 7 months to the same patient

(d) the repeated failure of the systems

(e) stock management issues

(f) work load, support and distractions for pharmacist/s?

In relation to the Ferrograd F tablets being dispensed when expired, I see this as mostly a failure of [the Pharmacy's] systems leading to this error, and in this the care was inadequate (Moderate departure from standard practice). Whilst there is a responsibility for the Pharmacist to check the expiry date on dispensing, in reality for almost any dispensing, except those of rarely used medications (where I think

all pharmacists should check the expiry date!) I do not think I know of any Pharmacist who would do this on every item, as stock turn and systems should ensure that correct product expiry is expected.

The error was replicated, and it would seem likely, that the stock from the first error was not removed from the pharmacy stock after the first error. In this [the Pharmacy's] care was inadequate and would be viewed as such by our peers (moderate departure from standard practice).

I must point out though, that the danger to the patient in these errors was if not non-existent, at least very low, in relationship to this product. This would of course not be the same risk for other products, hence the need for robust stock expiry management.

The error with the dispensing of Dostinex (generic name Cabergoline) instead of Mercaptopurine is a serious error, for which Pharmacist [Ms C] holds the responsibility, as regardless of work load and distractions it is still within the expected scope of her practice as a Pharmacist to avoid such a mistake. That being said, there will not (within my experience and knowledge of other pharmacists' practice) be a Pharmacist who has not made an error, although many will not have dispensed completely the wrong medication. The dispensing of this error did not provide adequate care to the patient.

2) The appropriateness of the Pharmacy's relevant Standard Operating Procedures in place at the time of the incident on 22 April 2015.

Had the SOPs been followed, then they contain within them, sufficient procedures to ensure that the expired stock should have been found, so were appropriate as documents.

Had SOP 6.1.12; Rolling Stocktakes, been carried out, every 6 weeks then all the stock should have been checked for expiry. The SOP states stock older than 6 months should be brought to the manager's attention, so no expired stock should have been available to dispense. To clarify, assuming 260 working days a year and the stock items in our pharmacy (which dispenses bigger prescription numbers than the majority of Pharmacies in New Zealand) is 1022, then the stock should have been checked 5 times in 1 year. Clearly this SOP has not been followed correctly. Whilst this is a departure from accepted practice, it would seldom cause any significant risk to the public so would be viewed as moderate departure from accepted practice.

3) The appropriateness of the Pharmacy's relevant Standard Operating Procedures following the incident on 14 October 2015.

I note the inclusion of the system of 'green dots' to mark products with less than 6 months expiry, which is useful and visual, which should be of help in managing expired stock. I note also the increasing of stock items checked for stock holding and expiry per day from 20 to 25, which would shorten the time frame for all stock being checked.

My comment on this SOP in regards to daily stock checking of 25 items is that in a busy pharmacy, with Pharmacists already doing multiple tasks (dispensing and all that entails, answering patient and staff queries, 'monitoring' the retail environment, managing stock) I feel it offers an extra task which I think is unlikely to be done (and historically has most likely not been done, as in my observations in question 2).

Many pharmacies, including the Pharmacies I am responsible for, utilise the computer reports to generate a list of items in the dispensary that have not been dispensed in 3 months. This list is not usually very large, providing the most likely candidates for products that may have an expiry issue and can then be checked quickly. A system such as this, is briefly mentioned but not expanded on (so I am unable to say whether it includes the idea above) in SOP 4.2 STOCK, under the heading General 'A system of computerised stock control is in place which monitors the turnover of stock, creates orders in anticipation of demand, maintains a record of total stock holding and identifies slow moving stock lines'.

Added to this, as stated by [Mrs A] in her Reply to the HDC on 14 August 2016, '... Propharma (the wholesaler to the pharmacy) are obliged to notify the pharmacy if they are sending out short dated stock … where they send a coloured slip if stock is short dated …' which should aid in the expiry date of stock management. In addition the 'End of financial year March stock take for the dispensary and shop stock' and the responsibility of the pharmacist dispensing to at least check expiry on rarely used items, should also help prevent an error such as this.

4) The appropriateness of the Pharmacy's relevant Standard Operating Procedures following the incident on 14 October 2015.

I have reviewed the changes found in 4.2 Stock and these give clarity to ways in which stock expiry can be better supervised. The issue of having stock used in both dispensing and OTC sale is addressed and rules set out, although this does not necessarily clarify who checks the expiry date. With the addition of who is responsible for joint stock expiry checking being clarified in the SOP then these SOPs are adequate.

The changes made to 6.2.3 The dispensing procedure, give better direction on processes to check generic and brand name on each item, which is acceptable. The addition of 'if the expiry date is less than 6 months, highlight the expiry date' is a good idea, but on a practical level it does not tell how to do this, and in my experience this would be hard to see. Maybe a way to do this, would be to rubber band a coloured 'close expiry' note to the product, as this would be possible with almost all products.

5) The Pharmacy's management of the incident on 22 April 2015

From the information given to me it seems that the error was managed as most one off errors of this nature would be managed by most pharmacies (that is, the medication, dose and form were correct but the medication expiry date was going to be past after the first month's consumption by the patient). The patient was

spoken to face to face, an apology offered, the medication was replaced with suitable dated stock and the error was recorded and stored. I did note though that the recording of the incident was in a different format on this error, as it was hand written and on a photocopied template form, whereas the subsequent errors are recorded in the computer on an internal form.

I think this was an acceptable standard of practice, and would be viewed as such by our peers.

6) The Pharmacy's management of the incident on 14 October 2015

On being advised of the two errors (when the patient picked up a repeat for Mercaptopurine on 19th November and returned expired Ferrograd F tablets 11th January) the resolution of the problems were undertaken promptly, the patient was encouraged to bring the medications back immediately, the errors were confirmed, the patient's safety ascertained (she had taken none of the Dostinex tablets), the medication errors rectified and the patient apologised to. This is all expected standard of care and practice. There is no record of [Mrs B] being offered information as to her avenues of making a formal complaint, which is expected practice, but this may simply not have been recorded.

An urgent staff meeting was held on the same day as the Mercaptopurine error was recognised (19th November) which shows how seriously the error was taken and a real intention to prevent such an error happening again. This I feel is excellent practice. An apology letter from the Dispensing Pharmacist [Ms C] was sent to [Mrs B] on 23rd November which is prompt. The letter accepts responsibility and offers explanation of how [the Pharmacy] may prevent a recurrence which is accepted practice but not always undertaken to such a high standard by many pharmacies (as past HDC cases I have reviewed will attest).

A staff meeting to address stock rotation and stock expiry dates was held on 21st January, the content which seems to be quite thorough, to start rectifying the problem. Pharmacist [Ms C] sent an apology letter regarding this repeat of the expired Ferrograd F stock, once again it accepts responsibility and offers explanation of changes being undertaken to prevent a recurrence of this problem, including an acknowledgement of the patient's right to take the matter further. The only matter I could not resolve was that [Ms C]'s letter of apology to [Mrs B] on 11th January mentions an urgent staff meeting being held, but the recorded staff meeting is on 21st January?

7) Whether changes undertaken by [the Pharmacy] and [Ms C] since the events in question are appropriate.

I feel that [the Pharmacy's] engagement with identifying issues that may lead to errors occurring and undertaking processes to rectify as much as possible these issues has been of a high standard. They have addressed staffing levels, dispensing processes, physical conditions and undertaken extra support, checking and training for Pharmacist [Ms C]. I feel these changes are appropriate.

Pharmacist [Ms C] has throughout this process, undertaken responses to the Patient affected in a professional manner. [Ms C] has also shown a mature attitude to admitting her errors and undertaking a thorough review of her dispensing processes, and according to [Mrs A's] submission to HDC on 14 August 2016 complied with conforming to the practice reviews being undertaken. I believe this exhibits a high level of professional practice.

8) Any other aspects of the care provided to [Mrs B] by the Pharmacy and/or [Ms C] that you wish to comment on.

I do have a few observations I would like to make:

1) [Mrs A] states in her submission to HDC on 19 February 2016 that 'I have reviewed the pharmacy errors log and over the last six months there have been 3 errors (all for [Mrs B]) and 2 near misses.' The pharmacy has done 35000 prescriptions in that time and [Mrs A] herself notes that for every 10,000 prescriptions dispensed International literature suggests they could expect 4 errors and 22 near misses. Therefore we could have expected up to 14 errors and 77 near misses. Whilst I have no evidence to show there were more errors in this time, I frankly find it hard to believe there would be only 3 errors and all for the same person.

One simple suggestion, that I do not see in the information given to me, that I would offer to [Ms C], that may help prevent errors such as the Mercaptopurine/Dostinex error, is that, particularly on less common prescription medications, she ask herself what the medication is for (its pharmacology) which may then alert her to such an error.

Paul Vester"