Pharmacist, Ms B

GDL Rx No6 Limited
(trading as Countdown Pharmacy Bayfair)

A Report by the

Health and Disability Commissioner

(Cases 20HDC00582 and 21HDC00641)

Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

Contents

Executive summary

1. This report considers the care provided to multiple consumers by GDL Rx No6 Limited (trading as Countdown Pharmacy Bayfair) and its employee at the time of the events, a pharmacist.

2. Following receipt of complaints about multiple dispensing errors made by the pharmacist between August and November 2019, the Commissioner initiated an investigation into GDL Rx No6 Limited's practice and the services provided by the pharmacist. The investigation identified further dispensing errors (up to August 2020).

3. The report discusses the adequacy of GDL Rx No6 Limited's oversight and support of its staff to ensure the provision of accurate and safe dispensing services. The report also discusses the responsibilities of a registered pharmacist in a busy and challenging environment.

Findings

4. The Commissioner identified a number of concerns about the systems in place at the pharmacy at the time of the dispensing errors. In particular, there was a lack of oversight and support, which resulted in multiple staff failing to provide services in accordance with professional standards; staffing levels were inadequate; and there was a lack of adequate monitoring to identify the high number of dispensing errors that were occurring at the pharmacy, and therefore there was no timely action in response. The Commissioner found GDL Rx No6 Limited in breach of Right 4(1) of the Code for failing to provide services to multiple consumers with reasonable care and skill.

5. Whilst acknowledging that following identification of the errors the pharmacist made a number of changes to her practice, the Commissioner found the pharmacist in breach of Right 4(1) of the Code, as she had a professional responsibility to ensure that the services she provided were of an appropriate standard.

Recommendations

6. The Commissioner recommended that GDL Rx No6 Limited provide HDC with a report detailing all incidents that occurred over the six months preceding the date of this report; provide HDC with a review of the effectiveness of its dispensing robot; undertake an audit of staff compliance with the updated dispensing standard operating procedures (SOPs); undertake an audit of staff compliance with the updated incident management SOP; use an anonymised version of this report to provide education to staff across all Countdown Pharmacy sites; add a review date to all its SOPs; and remind its staff that if they are unsure of a dose they should call the prescriber of the medication.

7. The Commissioner recommended that the pharmacist provide HDC with a report detailing any errors made over the six months preceding this report, including actions taken to prevent similar errors in the future.

Names have been removed (except GDL Rx No6 Limited/trading as Countdown Pharmacy Bayfair and the expert who advised on this case) to protect privacy. Identifying letters are assigned in alphabetical order and bear no relationship to the person's actual name.

Complaint and investigation

8. The Health and Disability Commissioner (HDC) received complaints about the services provided by a pharmacist, Ms B, to three consumers. Following an initial assessment, further errors made by Ms B involving a number of consumers over the same time period were identified. Subsequently, a Commissioner-initiated investigation of GDL Rx No6 Limited (trading as Countdown Pharmacy Bayfair) and Ms B was commenced.

9. The following issues were identified for investigation:

- *Whether GDL Rx No6 Limited (trading as Countdown Pharmacy Bayfair) provided Mr A with an appropriate standard of care in 2019.*
- *Whether GDL Rx No6 Limited (trading as Countdown Pharmacy Bayfair) provided multiple consumers with an appropriate standard of care in 2019 and 2020.*
- *Whether Ms B provided Mr A with an appropriate standard of care in 2019.*
- *Whether Ms B provided multiple consumers with an appropriate standard of care in 2019 and 2020.*

10. The parties directly involved in the investigation were:

Mr A	Consumer
Ms B	Pharmacist
GDL Rx No6 Limited	Pharmacy

11. Also mentioned in this report:

Ms D	Countdown Pharmacy Support Manager
Ms E	Consumer
Mr F	Consumer

12. Information from the Pharmacy Manager, Ms C, and the Pharmacy Council of New Zealand was also considered.

13. Independent advice was obtained from a pharmacist, Ms Sharynne Fordyce (Appendix A).

Information gathered during investigation

Introduction

14. The Pharmacy Council of New Zealand notified this Office of three complaints it had received from a GP practice. The complaints related to three separate dispensing errors made by a pharmacist at Countdown Pharmacy Bayfair (the pharmacy), Ms B, between August and November 2019.

15. During initial exploration and assessment of the three incidents, HDC was made aware of multiple other incidents at the pharmacy that had occurred over a similar time period and had involved both Ms B and other staff members. In light of this information, HDC initiated an investigation into the services provided by Ms B, as well as the systems in place at the pharmacy at the time.

16. HDC also commenced an investigation into the services provided to Mr A, the consumer involved in one of the dispensing errors initially notified to HDC. The other two consumers did not wish to proceed with a complaint investigation. However, all the incidents have been considered as part of the wider investigation into the systems in place at the pharmacy.

GDL Rx No6 Limited (trading as Countdown Pharmacy Bayfair)

17. Countdown Pharmacy is operated by a number of registered companies that operate out of Countdown supermarkets nationwide. GDL Rx No6 Limited (GDL) is the registered company that operates Countdown Pharmacy Bayfair, which began trading on 6 December 2018.

18. The pharmacy is situated in the middle of a supermarket. At the time of these events, there was no barrier in place between the pharmacy and the store. The pharmacy dispenses medications between 9am and 8pm, seven days a week, and at the time of these incidents it was staffed with one pharmacist and one pharmacy technician on each shift. GDL noted that under this staffing model there would be times when only one staff member would be processing and dispensing prescriptions, when the other staff member was on a break or engaged in other tasks. However, GDL considered that the staffing levels would be consistent for any pharmacy in New Zealand for the level of weekly dispensing,[1] and noted that an average pharmacy in New Zealand would dispense "close to double this volume over shorter opening hours". GDL said that staffing levels have never been raised as an issue by Medsafe during any of its audits of the pharmacy.[2] GDL also noted that the Countdown Pharmacy Support Office provides support for the in-store operation of the pharmacy, allowing staff to concentrate on customer service and core dispensing tasks.

19. During the time period in question, the pharmacy had four full-time employees, including the Pharmacy Manager, a pharmacist, and two pharmacy technicians.

Standard operating procedures (SOPs)

20. The SOPs in place at the pharmacy are the SOPs used across all Countdown pharmacies, and are reviewed and updated "whenever [Countdown Pharmacy support office] feel that a process can be improved, or in response to a Medicines Control audit review". GDL said that this is the review process it has always followed, and "has led to frequent updates being issued to all Countdown Pharmacies as we share learning experiences across the group,

[1] Between August 2019 and May 2020, the pharmacy dispensed an average of approximately 750–850 prescriptions over a 77-hour trading week.

[2] The Medicines Control team within Medsafe is responsible for regulating the medicine supply chain in New Zealand. As part of this function, Medsafe audits pharmacy premises to ensure that the pharmacy services to the public meet the required standards.

seeking to improve practice and safety". GDL noted that Medsafe requires SOPs to be updated only every two years at a minimum.

21. The SOPs relevant to this investigation are outlined in Appendix B.

Pharmacist Ms B

22. Ms B graduated with a Bachelor of Pharmacy. Ms B then completed an internship, and she registered as a pharmacist with the Pharmacy Council of New Zealand. Ms B is a member of the Pharmaceutical Society of New Zealand and the Pharmacy Defence Association (PDA).

23. In November 2018, Ms B was employed by GDL Rx No6 Limited in the role of pharmacist, working 40 hours a week — three six-hour shifts Tuesday to Thursday, and two 11-hour shifts Friday and Saturday.[3] At the time of these events, during her shifts Ms B was the sole pharmacist, supported by a pharmacy technician.

24. Ms B first starting working at the pharmacy on 19 November 2018, two weeks prior to the pharmacy opening date, during which time Ms B underwent training and induction. Because the pharmacy had not opened at that time, Ms B completed her induction at a different Countdown pharmacy.

25. GDL told HDC that as part of Ms B's induction she read and initialled all the pharmacy's SOPs. Ms B told HDC that although her orientation and induction was some time ago, she recalls reading the SOPs. She also undertook an online induction that included information about the SOPs. The Countdown Pharmacy Support Manager, Ms D, said that in addition she went to the pharmacy for one day and provided one-on-one training to Ms B on the pharmacy dispensary processes and Ministry of Health requirements.

26. Ms B told HDC that although the time period for induction was sufficient, because she completed her induction at a different Countdown pharmacy there were a number of things that were different. In particular, Ms B said that the pharmacy where she undertook her induction was very quiet, so she was unable to practise some things needed for her role. The clientele were also very different, with different needs.

27. In addition, Ms B said that her previous role, in which she had worked for approximately 18 months, was a smaller role, and the pharmacy was located at the back of the store with fewer distractions. Ms B told HDC that starting work at Countdown Pharmacy Bayfair "included a learning curve".

28. Ms B resigned from her role at the pharmacy in 2021.

Individual incidents

29. Below is the factual background of the three complaints that the Pharmacy Council of New Zealand first notified to HDC.

[3] Key accountabilities of Ms B's role included to "[f]ollow Countdown Standard Operating Procedures (SOPs)".

Incident 1 — incorrect strength medication dispensed

30. On 29 August 2019, Ms E was prescribed Accuretic 10/12.5mg (used to treat high blood pressure) for three months (90 tablets). That day, Ms E took the prescription to be filled at Countdown Pharmacy Bayfair, her usual pharmacy.

31. It is unclear who dispensed the prescription, but it appears that a pharmacy technician dispensed the medication, as indicated by the initials on the prescription. Ms B said that while the initials are recorded in her handwriting, this was probably because the pharmacy technician had not initialled it herself, so Ms B added the initials "to complete the record".

32. The incorrect strength of Accuretic was entered into the computer (20/12.5mg instead of 10/12.5mg) and then dispensed.

33. Ms B performed the final check as the pharmacist on duty this day, but failed to identify the strength selection error, and Ms E was dispensed the incorrect strength of Accuretic.

34. Ms E took the medication for one month, when she began to feel "heart attack like symptoms" — dizziness and chest pain. Ms E immediately saw a doctor and was found to have low blood pressure. When being questioned about her blood pressure, Ms E realised that she had been taking the wrong strength of Accuretic, which is a different-coloured tablet from the strength she takes normally.

35. On 8 November 2019, Ms E reported the error to the pharmacy. Ms B immediately provided Ms E with a verbal apology, and contacted Ms E's GP to advise of the error. Ms B later provided Ms E with a written apology, and followed up with Ms E on 12 November and 13 December 2019 to check that she was not having any ongoing health issues.

36. Ms B told HDC that this error was caused primarily because she was distracted while performing her final check. In particular, Ms B noted that Ms E is a very chatty person, and she was not fully focused when checking the prescription because she was also talking to Ms E at the same time. Ms B also said that she was very busy at that time. On the incident from, Ms B recorded that the medication was being dispensed with multiple other medications at the same time, and "[d]istractions and feeling rushed could have contributed to this error".

37. The error was discussed with the Pharmacy Manager, Ms C. On 12 November 2019, the error was discussed during a staff meeting. Subsequently, the two strengths of Accuretic were separated and a note placed on the shelf under Accuretic reminding staff to check the strength before dispensing it.

38. This incident was notified to the Countdown Pharmacy support office, the Countdown Pharmacy partners, and PDA.

Incident 2 — incorrect medication dispensed — Mr A[4]

39. Mr A was prescribed tamsulosin hydrochloride 400mcg (used to treat symptoms of an enlarged prostate) by his GP and advised to take one tablet once a day.

40. On 23 September 2019, Mr A took the prescription to the pharmacy to be filled. The prescription was processed and dispensed by the pharmacy technician on duty,[5] who selected the incorrect medication — tacrolimus 1mg (an immunosuppressant) instead of the prescribed tamsulosin hydrochloride 400mcg. Ms B performed the final check but failed to identify that the incorrect medication and strength had been dispensed.

41. According to the original complaint to the Pharmacy Council of New Zealand, Mr A said that he queried why the medication looked different from usual at the time the medication was being dispensed, but was told by the person handing him the medication that it would do the same job. According to the error incident report, no one at the pharmacy can recall who gave Mr A his medications.

42. It appears that the pharmacy did not have sufficient stock to fill the entire prescription. Accordingly, the remaining part of Mr A's prescription was processed when additional stock was received. On 31 October 2019, when Ms C processed and dispensed the outstanding medications to Mr A, Ms C identified the error. Mr A had been taking the medication for approximately five weeks.

43. Immediately upon identifying the error, Ms C apologised to Mr A and dispensed the correct medication. Ms C advised Mr A to see his GP as soon as possible, which Mr A confirmed he would do. Mr A's GP was informed of the incident the following day, and a written letter of apology was sent to Mr A.

44. On the incident form, the possible causes of the error were noted to be "interruptions in the pharmacy by customers" and "similar names of the medications".

45. At the time of the incident, 29 prescriptions had been processed in that hour, Ms B had just returned from a break, and it was handover time between the two pharmacists.

46. To prevent the error from occurring again, the pharmacy separated the two medications on the shelves.

47. On 5 November 2019, during an all-of-staff meeting, staff discussed "[a]wareness about the closeness of the names" and "the differences between medications". Staff were reminded of "[t]he importance of circling the dosing and underlining when dispensing and checking … as well as having technicians checking as well as the pharmacist where possible". In addition, they discussed that in a situation where the patient questions the medication, the pharmacist should be notified to carry out a further check against the prescription with a second person present. In her response to the provisional opinion, Ms B also recalled that it

[4] HDC complaint 20HDC00582.
[5] HDC does not know the identity of the technician.

was agreed at this meeting that the checking pharmacist would ensure that they reviewed the original script and compared it against the product.

48. This incident was notified to the Countdown Pharmacy support office, the Countdown Pharmacy partners, and PDA.

Incident 3 — incorrect instructions given to patient

49. Mr F was prescribed colchicine (gout medication) by his GP and advised to take one tablet twice a day for six months to prevent a flare-up of acute gout while he was becoming established on allopurinol (long-term gout medication). The prescription was for "ONE tablet twice daily for 3 months".

50. On 26 September 2019, Mr F's prescription was dispensed and checked by Ms B.

51. The label Ms B generated and attached to the medication read: "[T]ake one tablet twice a day or as directed by the doctor. Do not take for more than FOUR days in a row then have a THREE day break."

52. Ms B told HDC that this was the first time she had seen a long-term prescription for colchicine, and so included the warning label that read, "Do not take for more than FOUR days in a row then have a THREE day break," which is relevant for a short-term dose. Ms B said that this is automatically generated on the computer system, Toniq, when generating the label. She said that she included the warning on the label because she thought that this was "best practice".

53. Ms B said that she was the only pharmacist on duty at that time, so was unable to discuss it with anyone else. In addition, she stated: "Despite having a steady day, I didn't check the New Zealand Formulary (NZF) online to confirm this unusual colchicine dosing."

54. Ms B said that at the time of giving the medication to Mr F, she told him to take the medication as directed by his GP, and to ignore the warning on the label. Ms B stated: "As the patient appeared competent and sure of his dose, I did not take the additional step of contacting the prescriber." Ms B made a note on Mr F's record at the time that read:

> "[T]alked patient through dosing of allopurinol and colchicine.
>
> Told patient to take [one tablet twice a day] (despite it being an interesting dose) if that is what he had discussed with the doctor. Informed him that he was to ignore the warnings on the label if he had been told by the doctor otherwise.
>
> I put the warning labels on the label due to the fact that it was a safety warning and from our history he hadn't had it before.
>
> Patient seemed to understand."

55. In the initial complaint made by Mr F's GP to the Pharmacy Council, his GP said that when she saw Mr F one month later, he mentioned that he had not started either the colchicine or the allopurinol because he was confused by the instructions on the bottle.

56. After being notified of the incident, Ms B completed an incident form. Under "Causes", Ms B documented:

> "[A] misunderstanding about the different dosages for colchicine. I had only ever seen the acute dosing and was too busy to look it up (as I was the only staff member on). I should have done this despite being busy."

57. In a statement to the Pharmacy Council in response to the complaint, Ms B stated:

> "I have since looked up and see that NZF list an unapproved usage of colchicine as twice daily for up to 6 months when starting allopurinol. The script was clearly for an increasing (starting) dose of allopurinol so if I had looked it up at the time I would have realised. After conversations with the patient I also should have changed the label to be more accurate to what he had been told."

58. On the incident form, Ms B documented that she discussed the incident with the Pharmacy Manager, and that the pharmacy also held a staff meeting and discussed the need to make sure that patients understand the prescription instructions. In addition, Ms B planned a presentation to all staff at the pharmacy on the use of allopurinol, colchicine and gout treatment.[6]

59. This incident was not notified to the Countdown Pharmacy support office, the Countdown Pharmacy partners, or PDA at the time.

Further errors

60. Following notification of the above three complaints by the Pharmacy Council, HDC asked GDL to provide details of all dispensing errors that had occurred at the pharmacy between August 2019 and August 2020.

61. GDL told HDC that during that time period, the pharmacy dispensed 51,695 prescriptions and recorded a total of 22 dispensing errors. Ms B was responsible for 16 of the incidents,[7] and the Pharmacy Manager, Ms C, was responsible for six of the incidents.[8]

62. The incidents included errors in the number of repeats being recorded on the medication label, calculation errors, mixing up similar-named medications, dispensing the wrong strength of medication, and including unclear instructions on the medication label. Five of

[6] Ms B confirmed that the planned presentation took place on 19 December 2019.
[7] The dates of the errors were 29 August, 20 September, 23 September, 26 September, two on 15 October 2019, two on 26 November, 3 December 2019, 28 January, 30 January, 6 March, 7 April, 14 April, 1 May and 20 May 2020.
[8] The dates of the incidents were 4 December 2019, 10 February, 30 March, 16 April and two on 22 April 2020.

the 22 incidents resulted in the patient either taking the incorrect medication or not taking the prescribed medication at all.

63. All the incidents were recorded on an incident form, and all were reported to the Pharmacy Manager at the time. Four of the incidents, all of which involved the patient either taking the incorrect medication or not taking the prescribed medication at all, were reported to the PDA, the Countdown Pharmacy support office, and the Countdown Pharmacy partners at the time the pharmacy was notified of the incidents (two of which were notified to HDC, as discussed above[9]).[10]

Comment from Ms B

64. Ms B acknowledged that from August 2019 she made a number of dispensing errors, and that prior to these events she "did not have robust checking processes in place". Ms B said that while she had been shown different checking methods by the Pharmacy Manager, "it has taken time for [her] to learn and adopt practices which are effective for her".

65. Ms B told HDC that at the time of starting her role at the pharmacy, she had been going through a number of personal issues, and these likely had an impact on her concentration. She said that she continued to work during that time, "but it was not until matters had settled that the impact of the previous few years began to culminate and become apparent".

66. In addition, Ms B said that the errors "appear to have had a flow-on effect", explaining that with each error her confidence was "severely impacted". Ms B stated that when an error was made, she became anxious to prove herself, which had a spiralling effect in which she was "not confident asking for guidance and further errors resulted".

67. In her response to the provisional opinion, Ms B told HDC that at the time of the incidents, the pharmacy was relatively new and all staff members were relatively inexperienced. Ms B stated that she found Ms C hard to approach and therefore unable to discuss mistakes with her. Ms B also stated:

> "While [the pharmacy] was well resourced, and well supported, it appears it needed time to settle into itself. These 'teething' issues appear to have now settled."

Comment from Ms C

68. All the dispensing errors involving Ms C occurred in 2020. In three of the incidents, the pharmacy technician made a mistake in either entering the prescription incorrectly or selecting the wrong medication from the shelf. Ms C was responsible for the final check but failed to identify the errors. In the other three incidents, Ms C incorrectly entered the prescription and was responsible for checking the medication but failed to identify the error.

[9] The third incident notified to HDC was not reported to the Countdown Pharmacy head office at the time the pharmacy was notified of the incident.
[10] The incidents occurred on 29 August, 23 September, 2 December 2019, and 20 May 2020.

69. Ms C stated: "This number of errors is not characteristic of my usual practice." Ms C noted that many of the errors occurred in March 2020, during a COVID-19-related lockdown. Ms C said that having to work during that time, and the increase in demands from customers, was "mentally exhausting".

70. Ms C also noted that a new technician had started work during that time, while at the same time she was preparing to leave the pharmacy to move to a new job at another Countdown pharmacy. She stated: "I think this all contributed to why there has been a cluster of errors."

71. Ms C said that she has since reviewed the SOPs, and taken her learning from the errors and discussed them with her new team.

72. In relation to why she, as the Pharmacy Manager at the time, did not send all incident reports through to the Countdown Pharmacy support office, Ms C stated:

> "To my memory, I have forwarded incident reports to the support managers and PDA where there has been a patient harm or unsatisfied customer (which we had none) but not where there has been no patient harm and patients were happy with the way they have been dealt with. At the time, I did not think it was an urgent matter to forward it to them as they will be reviewing those errors at the quarterly visit, I did not think it was necessary for me to forward as soon as it happened. There has been no intentions to hide the errors at all, we have documented them to learn from them and to find our ways to reduce errors. We also had a dispensing error log, and near miss log."

73. In relation to the errors made by Ms B, Ms C stated:

> "Countdown Bayfair Pharmacy opened at the end of [2018]. All team members had been gathered up from different pharmacies where there had been different procedures and systems in place. We, as a team, have continuously supported each other and went through a process of trial and error to find the system that worked best for us for efficient flow — this included changing the dispensary layout, changing the way annotations were done, the way labels were printed, and needless to mention the changes made after each internal audit and MOH audit."

Further information from GDL Rx No6 Ltd

74. GDL said that it was not aware of the number of errors that occurred at the pharmacy at the time, and became aware of this only when providing its response to HDC.

75. In a letter from Ms D to the Pharmacy Council dated 14 December 2019, in response to the notification of the initial three incidents, she stated:

> "We would like to advise that we are aware that there have been a number of recent errors made by the same pharmacist at Countdown Bayfair Pharmacy … Countdown Pharmacy Management has contacted the Bayfair pharmacy on the 12th of November to inquire about the recent frequency of errors and how we can, as an organisation, support the pharmacist responsible. Our Bayfair Manager has also spoken to the

> Pharmacist responsible and the Pharmacist recognises that their practice needs to improve."

76. In addition, Ms D noted: "The application of the SOPs is regularly checked during the quarterly operational visits conducted by the pharmacy directors and myself."

77. In a statement to HDC, GDL also noted that after being notified of the initial three incidents by the Pharmacy Council in December 2019, only two of which it was aware of, it updated its incident policy to include the requirement that for all dispensing errors, a copy of the incident form is to be sent to the Countdown Pharmacy Support Manager, the Pharmacy Business Manager, and the pharmacy partners as soon as the pharmacy is aware of the incident (see Appendix B). This change was communicated by email to all Countdown pharmacies on 27 December 2019. However, GDL said that despite this change, "head office was not notified of most of these errors and so we had no idea that [Ms B] was still making this many errors".[11]

78. GDL said that two quarterly site visits on 11 September 2019 and 10 June 2020 were undertaken by Ms D and the pharmacy directors, but it was not made aware of the errors at that time.

79. GDL noted that no significant issues had been identified during any of the Ministry of Health audits[12] carried out over the period in question. GDL stated: "In our opinion this is clear objective evidence that Countdown Pharmacy Bayfair was operating at a high standard of medicines licencing compliance."

80. GDL said that no concerns had been raised previously with either the Pharmacy Manager or Countdown Pharmacy head office in relation to staffing levels, supervision, training, support or work pressures. GDL stated:

> "We feel that the reality is that however comprehensive and regularly reviewed our policies and procedures are, on rare occasions human error can unfortunately occur.
>
> It is clear that the Pharmacists and Technicians involved in these incidents at this time were not complying fully with our Standard Operating Procedures, particularly the reporting of errors to both the PDA and Pharmacy Support Manager."

81. Further, in relation to Ms B, GDL told HDC that it believes Ms B "had plenty of training and support while working at Countdown Pharmacy Bayfair". GDL said that prior to being notified of the dispensing errors:

> "[GDL] had no reason to think that [Ms B] as a qualified pharmacist, registered with the Pharmacy Council could be anything other than competent. Pharmacists are all trained

[11] From the information provided, GDL was notified of one of the 12 incidents that occurred in 2020.
[12] Pharmacy premises in New Zealand are audited by Medsafe to ensure that pharmacy services to the public meet the required standards.

> to a high level at university and then as an intern must pass a variety of assessments to become a registered pharmacist."

Further comment from Ms B

82. Ms B stated:

> "In summary I feel very remorseful about the errors that have occurred, I take full responsibility and am taking on all feedback from all parties on how any future errors can be prevented. I am very grateful to all the staff and support people that have provided me with resources and information that is enabling me to be a better pharmacist. Since finishing the [Pharmaceutical Society of New Zealand] workbooks I have noticed a huge improvement in my checking style and have been more confident in this style. I am constantly looking for opportunities to learn and grow."

83. Ms B said that since these incidents and the changes implemented by the pharmacy (detailed below), she feels more confident in her role as a pharmacist. Ms B stated: "This confidence has empowered me to acknowledge my shortcomings, and ask for guidance where appropriate. My performance anxiety has disappeared."

84. Ms B provided HDC with "a table of errors" detailing the actions she took once the handling error and the consumer had been identified. In most cases, where appropriate, Ms B provided either a verbal or a written apology to the affected consumer, and often implemented practical changes to minimise reoccurrence.

Pharmacy Council of New Zealand review

85. After being notified of the initial three errors, as set out above, the Pharmacy Council undertook an assessment of Ms B. As part of its assessment, the Council undertook a practice visit. The report provided to the Pharmacy Council concluded:

> "[Ms B] must be regarded as a junior pharmacist experience-wise. She has made errors, but has done everything asked of her to rectify these and has sought external help (counselling, College course) to improve herself. Even though [Ms B] likes the small team environment at Bayfair Countdown Pharmacy, the constant interruptions, lack of time away from the pharmacy for breaks (even to get a breath of fresh air) are unreasonable for a sole-charge junior pharmacist. I believe [Ms B] has the makings of a solid pharmacist, but would be better suited to a pharmacy that is small to medium in size, with good support (minimum of trained, competent technicians and retail assistants) where she can fine-tune her dispensing and checking procedures, ask for help or a second opinion where needed (especially for a clinical concern) and have someone working alongside her to both check on her and transition her from a junior pharmacist."

86. After making further enquiries into Ms B's competence and considering this report, the Council decided not to take any further action.

Responses to provisional report

87. GDL and Ms B were given the opportunity to respond to the relevant sections of my provisional opinion.

88. GDL stated that it had no further comments in regard to my provisional opinion, and that it had started work to address my findings.

89. Ms B stated that she accepted my description of her errors and my opinion that she had breached Right 4(1) of the Code.

90. Ms B added that Countdown Pharmacy Bayfair had many SOPs, and they were updated frequently, which was demanding and she struggled to keep up to date on the latest changes. However, Ms B explained that after the mistakes made came to light, changes were made to ensure that updates to SOPs were discussed at staff meetings, which she found helpful for understanding the changes.

Opinion: Ms B — breach

Introduction

91. As a registered pharmacist, Ms B was responsible for ensuring that she provided services with reasonable care and skill. As part of providing services of an appropriate standard, adherence to the Pharmacy Council of New Zealand's *Competence Standards for the Pharmacy Professional (2015),* the Pharmacy Council of New Zealand's *Code of Ethics*, and the Countdown Pharmacy SOPs (appended to this report) is expected.

21HDC00641 — multiple consumers

Failure to perform accurate final check

92. Between August 2019 and August 2020, Ms B made a series of errors. The type and seriousness of the errors varied from entering the incorrect number of repeats on the label to dispensing the incorrect medication. Although some of the errors involved the pharmacy technician making the initial error while processing and dispensing the prescription, Ms B was the pharmacist responsible for performing the final check.

93. The relevant SOP in place at the pharmacy at the time required the pharmacist to perform the final check of the dispensed medication against the prescription, to ensure that the medication, strength, form, quantity, and dose directions were correct.

94. In all but one of the incidents, Ms B performed the final check but failed to identify the various errors in the medication being dispensed.

95. My independent advisor, pharmacist Sharynne Fordyce, advised that the failure to check the medication accurately against the original prescriptions would be viewed as a severe

departure from accepted practice. I accept Ms Fordyce's advice. The pharmacist's final check is an important part of the dispensing process, and failing to complete this step adequately resulted in the incorrect medication being dispensed. I note that this failure was also a departure from professional standards[13] and the pharmacy's SOPs.

96. Ms B told HDC that most of the errors relating to her failure to undertake her final check accurately were caused by her being distracted while undertaking this step. Ms B noted that the pharmacy is located in the middle of the supermarket, with lots of distractions. In particular, the positioning of the pharmacy meant that customers could easily engage with the pharmacist directly, as occurred when Ms B failed to identify that the incorrect strength of Accuretic had been dispensed. In addition, Ms B was relatively junior, and operating as the sole pharmacist in a newly established pharmacy. She had also been going through a number of personal issues at the time. In my view, these factors contributed to the errors, which I discuss below.

Labelling error

97. In relation to Incident 3, in which Ms B included the warning notice on the label for the prescribed colchicine, which contradicted the prescription instructions, Ms Fordyce advised:

> "The accepted practice when labelling a medication is to follow the instructions given by the prescriber unless there is cause to doubt them in any way e.g. unusual dosage, difference to recommended dose in New Zealand Formulary or datasheet. If there is any variance then it is accepted practice to contact the prescriber and clarify the discrepancy before labelling and dispensing the medication to the customer."

98. Ms B said that she had never encountered a long-term dose of colchicine previously, and included the warning because she thought that was best practice. Ms B said that she did not look up the medication in the NZF because she was the sole pharmacist on duty and busy at the time. However, Ms B verbally advised the patient that she had included the warning because it was a safety warning, but that he should take the medication as prescribed. However, the patient was confused by the instructions and did not take either of the medications prescribed.

99. Ms Fordyce advised that Ms B's decision to include the warning on the label would be considered a severe departure from accepted practice, and the pharmacy's SOPs. She stated:

> "[Ms B's] label on the medication did not match her oral instructions, thus confusing the customer, resulting in him not taking his medication at all. Her oral instructions did not match the instructions on the prescription. [Ms B] did not confirm the prescribed dose with any references e.g NZ formulary, or with the prescriber."

[13] 03.2.1 of the Pharmacy Council of New Zealand's *Competence Standards for the Pharmacy Profession (2015)* requires that a registered pharmacist "[m]aintains a logical, safe and disciplined dispensing procedure".

100. I accept this advice. I note Ms Fordyce's view that Ms B being the sole pharmacist on duty influenced her ability to confirm the prescribed dose, which I discuss further in the following section.

20HDC00582 — Mr A

101. Mr A was prescribed tamsulosin hydrochloride 400mcg by his GP. The pharmacy technician processed and dispensed Mr A's prescription but incorrectly selected tacrolimus 1mg instead of tamsulosin hydrochloride 400mcg. Ms B performed the final check but failed to identify that the incorrect medication had been dispensed. As a result, Mr A took the wrong medication for approximately five weeks.

102. Ms Fordyce advised that the accepted standard of care is to dispense the prescribed medication, for the correct patient, at the correct dose, and for the final check to be carried out by the pharmacist checking the dispensed medication against the original prescription. Ms Fordyce advised that Ms B's failure to check the dispensed medication accurately against the prescription when performing the final check before dispensing Mr A's medication would be considered a severe departure from accepted practice. I accept Ms Fordyce's advice. Ms B's failure to carry out the final check accurately also departed from professional standards [14] and the pharmacy's SOPs. Without staff compliance, policies become meaningless, and the failure to adhere to them — as in this case — can amount to a failure to provide services of an appropriate standard.

Conclusions — 20HDC00582 and 21HDC00641

103. While, as detailed above, there were a number of systemic and mitigating factors that influenced Ms B's practice at the time of these events, Ms B had a professional responsibility to ensure that the services she provided were of an appropriate standard. This meant providing safe and accurate services with reasonable care and skill.

104. Overall, I conclude that for failing to ensure that she performed the final check adequately, and making 16 dispensing errors between August 2019 and August 2020, Ms B failed to provide services to multiple consumers, including Mr A, with reasonable care and skill. As such, I find that Ms B breached Right 4(1) of the Code of Health and Disability Services Consumers' Rights (the Code).[15]

105. I am pleased to see that both Ms B and GDL Rx No6 Limited have taken this matter seriously and made a number of changes to improve the working environment, and that Ms B was supported appropriately, both with her professional development and in managing her personal issues.

[14] 03.2.1 of the Pharmacy Council of New Zealand's *Competence Standards for the Pharmacy Profession (2015)* requires that a registered pharmacist "Maintains a logical, safe and disciplined dispensing procedure."
[15] Right 4(1) states: "Every consumer has the right to have services provided with reasonable care and skill."

Opinion: GDL Rx No6 Limited (trading as Countdown Pharmacy Bayfair) — breach

Introduction

106. While there is no dispute that Ms B had an individual responsibility in relation to the 16 dispensing errors, GDL Rx No6 Limited (trading as Countdown Pharmacy Bayfair) also had a duty to ensure that it provided services with reasonable care and skill. This included providing adequate support and oversight to staff to ensure that they provided accurate and safe dispensing services.

107. Between August 2019 and August 2020 there were 22 separate dispensing errors at the pharmacy, involving more than one staff member. Ms Fordyce considered this number of errors to be a severe departure from accepted practice. I agree that this number of errors, made by more than one staff member, is very concerning and is indicative of a systemic failure. In my view, a number of service-level factors contributed to the number of errors that occurred. I discuss my concerns further below.

Staff support and oversight

108. GDL Rx No6 Limited had a responsibility to provide adequate support and oversight to its staff to enable them to provide safe and accurate care that complied with professional standards and the relevant SOPs in place at the time of these events. This was particularly important, as the pharmacy had opened recently and staff were not familiar with the environment, had not worked together previously, and came from different backgrounds.

109. Ms B told HDC that while she underwent a one-week orientation prior to starting work at the pharmacy, including reading all the SOPs, because her orientation took place at a different pharmacy, she did not have the opportunity to practise some aspects of the role. The clientele was also very different. She also said that the pharmacy environment and layout was very different from what she was used to, and it was very easy to be distracted by customers.

110. Ms C noted that because the pharmacy was new and all staff came from different backgrounds, they were used to different procedures and systems. Ms B also noted that at the time of the incidents, "[t]he pharmacy was in its infancy. While it was well resourced, and well supported, it appears it needed time to settle into itself." Ms B said that starting work at the pharmacy was a "learning curve".

111. GDL told HDC that prior to being notified of these complaints, no concerns had been raised in relation to staffing, supervision, training or support at the pharmacy. It considered that Ms B had received adequate training and support, and said that it "had no reason to think that [Ms B] as a qualified pharmacist, registered with the Pharmacy Council could be anything other than competent. Pharmacists are all trained to a high level at university and then as an intern must pass a variety of assessments to become a registered pharmacist." While I am satisfied that Ms B appears to have been provided with adequate orientation

and training, and agree that as a qualified pharmacist she should be considered competent, she still required ongoing support and oversight.

112. Ms B was relatively junior, and this role was clearly a step up in responsibility from her previous role. In addition, the pharmacy was newly opened, with all its staff coming from different backgrounds and experience, and none of them having worked together previously. As the employer, GDL had a responsibility to ensure that all its staff were provided with adequate support and oversight to enable them to provide safe and accurate care that complied with its SOPs. In my view, the multiple incidents that occurred between August 2019 and August 2020, involving more than one staff member, brings into question the systems in place at the pharmacy for oversight and support of its staff to provide safe and accurate dispensing, and comply with its SOPs.

113. In a statement to the Pharmacy Council, Ms D noted: "The application of the SOPs is regularly checked during the quarterly operational visits conducted by the pharmacy directors and myself." However, even after GDL was made aware of the initial errors involving Ms B in November 2019, further errors continued to occur.

114. I consider that GDL should have been alert to the risks of staff adjusting to working in a new environment, and should have taken steps to monitor the operation of the pharmacy closely while staff became more familiar with its operations, in particular Ms B, who was relatively inexperienced at that time.

Staffing levels

115. At the time of the incidents, the pharmacy was staffed by one pharmacist and one pharmacy technician at any one time. GDL noted that while this meant that at times there would be only one staff member on duty while the other was on a break or doing other tasks, the staffing was consistent with other pharmacies in New Zealand for the level of dispensing.

116. Ms Fordyce advised that accepted practice is to have staff numbers that would ensure "prompt and accurate customer service while maintaining minimum levels of stress for staff", and that the aim should be to have two staff available at all times. Ms Fordyce noted that at the time, the pharmacy was staffed with only two staff, with no cover for breaks, which meant that the pharmacist on duty was not able to leave the premises and often was interrupted during breaks. Ms Fordyce advised that taking into account that at times staff were working 11-hour shifts, staffing levels were inadequate for the level of dispensing at the pharmacy. Ms Fordyce considered this to have been a moderate departure from accepted practice. I also note the observations made in the assessment report provided to the Pharmacy Council in relation to Ms B, which stated: "[T]he constant interruptions, lack of time away from the pharmacy for breaks (even to get a breath of fresh air) are unreasonable for a sole-charge junior pharmacist."

117. While I note GDL's submission that the pharmacy, at the time, was not dispensing a high number of prescriptions, I agree with Ms Fordyce that given that staff were working 11-hour shifts, staffing levels were insufficient, particularly given that Ms B was still a relatively junior

pharmacist at that time. In my opinion, at a minimum, GDL should have provided cover for breaks to allow staff to have an uninterrupted break away from the pharmacy.

Oversight and monitoring of errors

118. Following each of the 22 dispensing errors that occurred between August 2019 and August 2020, an incident report was completed, the Pharmacy Manager was advised, and steps were taken by the pharmacy team to prevent the error from reoccurring, such as separating medications on the shelves and staff meetings to discuss the error. However, at no time was a high-level review undertaken to investigate underlying causes for the errors.

119. GDL submitted that it was not aware of the majority of the errors until after HDC requested the information, noting that only four of the 22 incidents had been notified to the Countdown Pharmacy support office. However, I also note that in a statement to the Pharmacy Council after it notified Countdown Pharmacy support office in December 2019 of the initial three errors, GDL said that Countdown Pharmacy management was aware of the "recent frequency of errors" and had contacted the pharmacy to see what support it could provide. Further, in the same statement, GDL said that the application of the SOPs is checked regularly during the quarterly operational visits conducted by the pharmacy directors and head office. I note that Ms C stated that she did not notify the support office of errors that did not involve patient harm because she understood that these would be reviewed during the quarterly site visits conducted by the support office and pharmacy directors.

120. Clearly, GDL was aware of the increase in errors in December 2019, and therefore it was on notice that potentially, underlying systems issues were affecting safe and accurate dispensing, and that errors were occurring without it being notified.

121. Ms Fordyce advised:

> "There has been a severe departure from accepted practice regarding the number of errors that occurred from August 2019 to May 2020. This number of errors, that included more than just one staff member, should have been indicative of underlying issues such as staffing levels, dispensary work flow or incident reporting, that needed prompt and thorough investigation. More importantly it posed a threat to the health and safety of customers."

122. I accept Ms Fordyce's advice. In my view, by December 2019, GDL was aware of issues at the pharmacy and should have taken immediate action to address these. Simply contacting the Bayfair pharmacy staff was not sufficient. In my opinion, at a minimum, GDL should have been monitoring incident trends closely, regardless of whether or not these were being reported by staff actively. GDL's failure to do so led to errors continuing to occur, placing patients at risk of significant harm.

123. I note that the Countdown Pharmacy support office, together with the pharmacy directors, now undertake regular site visits to check compliance with recording of near misses and

dispensing errors, as well as dispensing processes and other Ministry of Health compliance requirements.

Conclusions — 20HDC00582 and 21HDC00641

124. A pharmacy is required to ensure the provision of services that are safe and appropriate. This includes providing adequate support and oversight to its staff to enable them to provide safe and accurate dispensing. As set out above, I have a number of concerns about the systems in place at the pharmacy at the time of these incidents. In particular:

- A lack of oversight and support, which resulted in multiple staff failing to provide services in accordance with professional standards.
- Inadequate staffing levels to support staff in providing safe and accurate dispensing.
- A lack of adequate monitoring to identify the high number of dispensing errors that were occurring at the pharmacy, and therefore a failure to take timely action in response.

125. Overall, for the reasons set out above, I consider that between August 2019 and August 2020, GDL Rx No6 Limited (trading as Countdown Pharmacy Bayfair) failed to provide services to multiple consumers, including Mr A, with reasonable care and skill, and breached Right 4(1) of the Code.

Other matters

SOPs

126. Ms Fordyce advised that the content of the SOPs in place at the time of these events was "very comprehensive and well written". However, she noted that the SOPs were reviewed in an "ad hoc" manner, and that this approach would be considered a mild departure from accepted standards.

127. GDL noted that Medsafe requires SOPs to be updated a minimum of every two years, and that GDL's SOPs, used across all Countdown pharmacies, are reviewed and updated "whenever [GDL] feel[s] that a process can be improved, or in response to a Medicines Control audit review".

128. While I note Ms Fordyce's advice regarding the unstructured way the SOPs are reviewed, I consider it appropriate for changes to be made if and when needed. The Pharmacy Council guidance on writing SOPs states that in the absence of any obvious changes, SOPs should be reviewed, at a minimum, every two years. I have received no evidence to indicate that this did not occur. However, it may be helpful to add a review date to ensure that reviews are always undertaken within the appropriate timeframes. I will be making a recommendation to this effect.

Changes made

Ms B

129. Ms B advised that since these incidents, "with the support of the pharmacy", she underwent counselling, which she believes has had "a profoundly positive impact".

130. In addition, Ms B said that she has been well supported by the pharmacy, and has been provided ongoing support and training from the new Pharmacy Manager.

131. Ms B underwent further training, including:

- The Pharmaceutical Society of New Zealand "Improving Accuracy and Self-Checking Workbook"; and
- Study of the PHARMSI[16] checking process.

GDL Rx No6 Ltd

132. In December 2019, the following changes were made to GDL's SOPs:

- The "Handing the prescribed medicines to the patient and counselling" SOP was updated to include the various actions that can be taken if a patient queries the medication they have been dispensed, including "double-checking the original prescription by the charge pharmacist and reconfirming with the clinic as applicable".
- The Incident Policy was updated to include the requirement for the incident report, recorded on the latest PDA form, to be sent to the Pharmacy Support Manager, the Regional Support Manager, the Pharmacy Business Manager, and the pharmacy partners "as soon as the pharmacy becomes aware of the incident".
- The "Stock control and date checking" SOP was updated to include the requirement for any stock variance "indicating a potential dispensing error" to be investigated by the charge pharmacist, and for the Pharmacy Manager to be notified "as soon as practically possible". The SOP also requires investigation details to be recorded, including the date, item affected, and outcome of the investigation.

133. These changes were communicated to all Countdown pharmacies on 27 December 2019.

134. The Pharmacy Support Manager and one of the pharmacy directors undertook regular site visits to check compliance with recording of near misses and dispensing errors, as well as dispensing processes and other Ministry of Health compliance requirements.

135. On 4 June 2020, an all-of-staff meeting was held in which the recent errors were discussed and staff were reminded of the following:

[16] PHARMSI is a checking system to prevent dispensing errors. A copy can be found on the Pharmacy Defence Association website: https://www.pda.org.nz/Attachment?Action=Download&Attachment_id=1.

- Accuretic has been separated on the shelf.
- Staff should dispense off the prescription rather than the label.
- A plan to focus on the error log and implementation of changes before errors reoccur.
- If there is any confusion with drug names, discuss with the charge pharmacist.
- If a patient queries a medicine, the pharmacist should recheck the prescription.
- If a patient has not had a medication previously, mark on the script "N" or "new".
- If unsure of the dose, check the NZF, discuss with another staff member, or call the medicine centre.
- Record all conversations with patients, doctors, nurses, or other health professionals.

136. The following changes have also been made:

- The layout of the dispensary was changed, including "moving the position of the electronic pill counter to the middle of the bench". GDL stated: "Moving the pill counter to the middle of the bench allows the staff to have specific areas to work in so that prescriptions flow from the start of the bench to the end of the bench left to right." GDL said that "this change helps staff identify what prescriptions are waiting and where patients' prescriptions are in the queue".
- Installation of a dispensing robot to assist with workload.
- Increased resource funding for an extra 40 hours per week of casual pharmacists and technicians to cover busy times.
- Introduction of a system that identifies when a patient will be returning to collect a prescription, or whether the patient is waiting to collect the prescription, to help reduce pressure on dispensary staff.

Recommendations

137. I recommend that GDL Rx No6 Limited (trading as Countdown Pharmacy Bayfair):

a) Provide HDC with a report detailing all incidents that have occurred over the six months preceding the date of this report, including any changes and actions taken in response to these errors.

b) Provide HDC with a review of the effectiveness of the dispensing robot in relation to prevention of incidents since its installation.

c) Undertake an audit of staff compliance with the updated dispensing SOPs. Where any departures are identified, the pharmacy should provide details of what steps it has taken to address the issues identified.

d) Undertake an audit of staff compliance with the updated incident management SOP, in particular the requirement for all incidents to be notified to the relevant people at the Countdown Pharmacy head office, and provide a report to HDC on the results. Where any departures are identified, GDL should provide details of what steps it has taken to address any issues identified.

e) Use an anonymised version of this report to provide education to staff across all Countdown Pharmacy sites on the issues identified in this report.

f) Add a review date to all its SOPs.

g) Remind its staff that if they are unsure of a dose, as well as checking the NZF, discussing with another staff member, and calling the medicine centre, they should also call the prescriber of the medication.

138. GDL should report back to HDC on all recommendations within three months from the date of this report.

139. I recommend that within three months of the date of this report, Ms B provide HDC with a report detailing any errors made over the six months preceding the date of this report, including actions taken to prevent similar errors in the future.

140. Apologies have already been provided to the affected consumers. Therefore, in this instance, further apologies are not recommended.

Follow-up actions

141. I have given careful consideration as to whether Ms B and GDL Rx No6 Ltd should be referred to the Director of Proceedings, and in particular have considered the public interest in ensuring that appropriate proceedings are taken where that public interest requires.

142. I consider the matter finely balanced. While I have serious concerns about the failures in this case, I consider that both Ms B and GDL have taken the matter seriously and made a number of improvements. In particular, Ms B has shown remorse and taken full responsibility for her actions and had apologised to the affected consumers directly. Furthermore, Ms B's competence has been assessed by the Pharmacy Council of New Zealand, which I consider fulfils the public safety interest.

143. GDL has made a number of changes at a systemic level to address the issues raised in this report, and I consider that the public interest in accountability and safety can be met by the further recommendations made above in relation to GDL.

144. I consider that in this case, the public interest in accountability and safety can be met by my breach opinion and recommendations, and therefore a referral to the Director of Proceedings will not be made.

145. A copy of this report with details identifying the parties removed, except the expert who advised on this case and GDL Rx No6 Limited (trading as Countdown Pharmacy Bayfair), will be sent to the Pharmacy Council of New Zealand, and it will be advised of Ms B's name.

146. A copy of this report with details identifying the parties removed, except the expert who advised on this case and GDL Rx No6 Limited (trading as Countdown Pharmacy Bayfair), will be sent to the Pharmaceutical Society of New Zealand, the Pharmacy Defence Association, the Health Quality & Safety Commission, and Medsafe, and placed on the Health and Disability Commissioner website, www.hdc.org.nz, for educational purposes.

Appendix A: Independent clinical advice to Commissioner

The following expert advice was obtained from pharmacist Sharynne Fordyce:

"**Advice for C20HDC00288/C20HDC00582/C20HDC00583**

I, Sharynne Fordyce, have been asked to provide an opinion to the Commissioner on Case numbers 20HDC00288/20HDC00582/20HDC00583 and have read and agreed to follow the Commissioner's Guidelines for Independent Advisers.

My qualifications include a Diploma of Pharmacy, and a Masters of Clinical Pharmacy. I have worked in Retail Pharmacy for over 30 years, both in New Zealand and in England, and also work for the Wairarapa DHB.

Background

[Ms E]
On 29 August 2019, [Ms E] was dispensed accuretic 20/12.5mg instead of accuretic 10/12.5mg, by [Ms B].

It was identified that possible causes could have been interruption by the customer, and feeling rushed.

[Mr F]
On 26 September 2019, [Mr F] was prescribed colchicine 500mcg by his general practitioner (GP). He filled his prescription at Countdown Pharmacy Bayfair with [Ms B]. [Ms B] altered the label so that it reflected the warning note. The label advised to not take the medication for more than four days in a row, and then have a three day break. It is documented that [Ms B] counselled [Mr F] to take the medication twice daily if that is what his GP advised. However, the warning label confused [Mr F] and he did not take the medication until his next GP review.

It is documented that [Ms B] had only seen acute dosing of colchicine and was too busy to find out further information, as she was the only staff member on.

[Mr A]
On 23 September 2019, [Mr A] was dispensed Tacrolimus 1mg instead of tamsulosin 400mcg by [Ms B]. It appears that [Mr A] questioned the medication, but was advised that it would have the same function.

It was identified that possible causes were interruptions by customers, and the similar names of the medications.

Expert advice requested

Please review the enclosed documentation and advise whether you consider the care provided to [Ms E], [Mr A] and [Mr F] by [Ms B] and Countdown Pharmacy Bayfair was reasonable in the circumstances, and why.

In particular, please comment on:

1. The adequacy of care provided to [Ms E] by [Ms B];
2. The adequacy of care provided to [Mr A] by [Ms B];
3. The adequacy of care provided to [Mr F] by [Ms B];
4. The adequacy of the reporting of the above errors and the steps taken after the errors were identified;
5. The adequacy of Countdown Pharmacy Bayfair's policies, both outdated and current;
6. The adequacy of staffing levels at Countdown Pharmacy Bayfair;
7. The number of errors that have occurred from August 2019 to May 2020; and
8. Any other matters in this case that you consider warrant comment.

For each question, please advise:

a. What is the standard of care/accepted practice
b. If there has been a departure from the standard of care or accepted practice, how significant a departure do you consider this to be?
c. How would it be viewed by your peers?
d. Recommendations for improvement that may help to prevent a similar occurrence in future.

If you note that there are different versions of events in the information provided, please provide your advice in the alternative. For example, whether the care was appropriate based on scenario (a), and whether it was appropriate based on scenario (b).

Advice

1. The adequacy of care provided to [Ms E] by [Ms B].

a) The accepted standard of care is to dispense with accuracy, checking the label produced from the computer against the prescription and the patient's history, and the label against the product dispensed. Then ensure a final check is carried out by the pharmacist present, allowing time between dispensing and the final check, for 'fresh eyes' if both processes have been carried out by the pharmacist.

b) There has been a severe departure from the accepted standard of care, as the product did not match the label or prescription, and the error was not picked up in the final check, resulting in the customer taking incorrect medication.

c) My peers would regard this as a severe departure.

d) Recommendations for improvement would include removing the dispensing process away from any potential customer interaction, and physically separating the two strengths of this particular medication on the dispensary shelf, as they appear very similar.

2. The adequacy of care provided to [Mr A] by [Ms B].

a) As above, the accepted standard of care is to supply the prescribed medication, for the correct patient, at the correct dose, with a final check by the pharmacist against the original script for both the label and medication. Accepted practice would also include referring any medication enquiries to the pharmacist, particularly any queries regarding the mode of action of a particular medication.

b) There has been a severe departure from accepted practice. Not only was the incorrect medication supplied to the customer, a drug related query, which would have prevented the customer taking the incorrect medication, was not referred on to the pharmacist on duty.

c) My peers would regard this as a severe departure from accepted practice.

d) Recommendations for improvement would include more emphasis being placed on dispensing accuracy, and the final check by the pharmacist. Separating similar sounding medications on the shelf may help with dispensing accuracy. [Ms B] was working a long shift the day of this error, 9am to 8pm as sole pharmacist, according to the staff roster. A shorter working day could help with accuracy and concentration.

3. The adequacy of care provided to [Mr F] by [Ms B].

a) The accepted standard of practice when labelling a medication is to follow the instructions given by the prescriber on the prescription unless there is cause to doubt them in any way e.g. unusual dosage, different to patient history, different to recommended dose in New Zealand Formulary or datasheet. If there is any variance then it is accepted practice to contact the prescriber and clarify the discrepancy before labelling and dispensing the medication to the customer. This then avoids any potential conflict between information from the prescriber, instructions on the label and information from the pharmacist.

b) There has been a severe departure from accepted practice. [Ms B's] label on the medication did not match her oral instructions, thus confusing the customer, resulting in him not taking his medication at all. Her oral instructions did not match the instructions on the prescription. [Ms B] did not confirm the prescribed dose with any references e.g NZ formulary, or with the prescriber. [Ms B] being the only staff member on at this time did, however, compromise her ability to carry out this important step.

c) My peers would regard this as a severe departure from accepted practice.

d) Recommendations for improvements would include upskilling in knowledge about gout treatment, ensuring the written and oral instructions match and hence avoiding confusion with the patient, always confirming any unusual or different doses with a reference and/or the prescriber, and ensuring adequate staff to reduce stress when dispensing.

4. The adequacy of the reporting of the above errors and the steps taken after the errors were identified.

a) The accepted standard of practice in the reporting of the above errors would involve the completion of a PDA incident form and/or a company incident form by the pharmacist involved. These would then be sent to PDA and the company head office — depending on the line of reporting present in the company. A verbal and written apology would be provided to the customers involved, preferably from both the pharmacist responsible and the company or pharmacy owner. This would also include the offer of any financial compensation needed to cover costs incurred by the customer as a result of the error, such as extra doctor's visits. A staff meeting, preferably minuted, would then be held to discuss the error and the steps to be taken to prevent it reoccurring, including updating SOPs where necessary and appropriate staff training.

b) 1. With [Ms E] all the above practices involved in the accepted standard of care were followed and completed, there was no departure from accepted practice in the reporting of the errors or the steps taken afterwards.

b) 2. With [Mr A] all the above practices involved in the accepted standard of care were followed and completed, there was no departure from accepted practice in the reporting of the errors or the steps taken afterwards.

b) 3. With [Mr F] there was a 6 week delay between the prescriber notifying the pharmacy of the error, and the PDA report being submitted, there was no written apology supplied and the pharmacy did not notify head office of the error. These three items would constitute a mild departure from accepted practice.

c) My peers would agree with me on all three cases.

d) Recommendations for improvement would include, in the case of [Mr F], notifying PDA promptly of the error once being notified by the prescriber, and also notifying head office of the error promptly, as had been done in the previous two cases. Supplying a written apology confirms the verbal apology already made.

5. The adequacy of Countdown Pharmacy Bayfair's policies, both outdated and current.

a) The accepted standard of practice is to have Standard Operating Procedures (SOPs) pertaining to each individual pharmacy within a group of pharmacies such as Countdown. These SOPs are reviewed and maintained up to date within the store, allowing for individual incidents within the store to shape the SOPs where appropriate. SOPs are usually reviewed every two years.

b) There has been a mild departure from accepted practice with a haphazard approach to reviewing of policies since June 2012. This date is rather unusual in that it precedes the start of trading for Countdown Pharmacy Bayfair (6/12/18) by over 6 years. Two of the policies listed were reviewed in September 2019, D2 Stock Control and G8 Incident Policy, in the same month as two of the incidents occurred. The three policies pertaining to the dispensing of medicines, however, were not reviewed until December 2019 (B7 — handing out prescriptions to patients) and March 2020 (B4 — dispensing and labelling of medicines, and B5 — Final check). Given the number of errors occurring over this time, it may have been prudent to review these policies earlier, with maybe less emphasis on Stock Control. The content of all the policies is very comprehensive.

c) My peers would regard the policies as comprehensive and well written. It is the reviewing of these policies that they would consider a mild departure from accepted practice.

6. The adequacy of staffing levels at Countdown Pharmacy Bayfair.

a) Adequate staffing levels can be hard to predict and plan for, given the vagaries of retail practice. The accepted practice is to provide enough staff to ensure prompt and accurate customer service while maintaining minimum levels of stress for the staff. From a safety and stress perspective the aim is always to have a minimum of two staff in the shop working i.e. not one person alone while the other is on a break. There are legal requirements for the number and length of breaks required during the day, particularly when working an 11 hour shift such as on four out of seven days at Countdown Pharmacy Bayfair.

b) There has been a moderate to severe departure from accepted practice at Countdown Pharmacy Bayfair. As mentioned above, four out of seven days involve two staff working 11 hour shifts, with no apparent cover for breaks. In at least one of the incidents, [Ms B] mentions being the only staff member on, and both [Ms B] and her manager acknowledge that staffing levels may have contributed to stress, and the incidents occurring.

The pharmacy has now been allocated an extra 40 staff hours a week to cover 'busy days', a robot is being installed, and there have been changes to the dispensary to improve the dispensing flow — separating it from customers. All of these actions acknowledge the need for adequate staffing levels.

c) My peers would regard the staffing levels as a moderate to severe departure from accepted practice.

d) Recommendations would include all the steps already put in place.

7. The number of errors that have occurred from August 2019 to May 2020.

a) The accepted standard of practice is to work towards the goal of the new manager at Countdown Pharmacy Bayfair where 'he expects zero errors while still supporting us as

a team. This has allowed us to really look at what near misses are happening and action these before they become dispensing errors'. This is quoted from [Ms B] and concurs with the aim of no errors in the dispensing process, but learning from them if they do occur, without excessive personal blame, always looking for underlying trends or causes if the errors reoccur. The health and safety of customers is always paramount.

b) There has been a severe departure from accepted practice regarding the number of errors that occurred from August 2019 to May 2020. This number of errors, that included more than just one staff member, should have been indicative of underlying issues such as staffing levels, dispensary work flow or incident reporting, that needed prompt and thorough investigation. More importantly it posed a threat to the health and safety of customers.

c) My peers would regard the number of errors as a severe departure from accepted practice.

d) Recommendations for improvement would include better reporting to pharmacy management, so they were aware of the problems. Support and training of staff to enable them to learn from the errors, and improve in their practices is also essential. Both of these steps have already been carried out by the company.

8. No other comments.

Sharynne Fordyce.

25/11/2020"

The following further advice was received from Ms Fordyce:

"**Further advice**

Amendments to Advice for 21HDC00641 (20HDC00288/20HDC00582/20HDC00583)

To be read in conjunction with my advice previously submitted on 25/11/2020.

Response 2(b) I have deleted the reference to the drug related enquiry. As mentioned by [Ms B's] lawyer this enquiry did not involve [Ms B] and it is her actions being discussed in this response.

Response 5(b) Adequacy of Policies. I have changed the wording from 'haphazard' to 'ad hoc' as the changes to SOPs were in response to particular events.

Response 6(b) Adequacy of Staffing Levels. In response to the letter from the Directors of GDL Rx No6 (t/a Countdown Pharmacy Bayfair) I will be leaving my comments as they stand but changing my assessment to a moderate departure from accepted practice. Both [Ms B] and her manager at the time, [Ms C], acknowledge that staffing levels would have contributed to the stress and errors. Using the figures supplied by the directors

790 scripts were being done in a 50–55 hour week, not 77 hours as stated by the directors. The breaks provided for [Ms B] were not adequate for the clear and accurate functioning of a health professional, particularly during an 11 hour day.

In a response to a comment from [Countdown Pharmacy], I am presently working in, and have frequently worked in the past, in pharmacies where the only requirements are 'to dispense, serve at counter and answer phone calls'. This would seem to be an industry standard work model, rather than one providing extra support for staff.

Sharynne Fordyce

21/11/2021"

Appendix B: GDL Rx No6 Limited (trading as Countdown Pharmacy Bayfair) SOPs

Dispensing and labelling the prescribed medicine SOP B4

The SOP "Dispensing and labelling the prescribed medicine" (May 2019) states under "Dispensing the correct medicine":

"• Check you are using the right medicine and subsidised brand. …
- Check that the medicine is the right strength.
- Check that the medicine is in the right form.
- Check the expiry date.
- Leave the stock container next to prescription for the final check."

Final check of dispensed medicines against the prescription SOP B5

The SOP "Final check of dispensed medicines against the prescription" (May 2019) states that all prescriptions must be checked by a pharmacist. The pharmacist must:

"[C]heck the dispensed medicine against the prescription for:

Name of the patient
Date
Medicine name, strength, form and quantity
Dose directions
C & A information or labels
Name of prescriber"

It states that the dispenser and checker must be identified on all prescriptions by signing the label. It also states: "Checks are to be made at each step in dispensing, to help eliminate errors."

Handing the prescribed medicines to the patient and counselling SOP B7

The SOP "Handing out prescribed medicines and counselling" (February 2018) states that "it is the usual responsibility of the pharmacist to hand out prescriptions" but that this may be delegated to a pharmacy technician. The SOP states that when handing out prescribed medicines: "It is both good professional and customer service practice to ensure that the patient fully and completely understands the correct way to take their medicines." Further, it states:

"This act [is] a final check that everything is correct and to confirm you have the right patient. It also provides an opportunity for the patient to ask questions about the medicines that [they] are taking, or for you to counsel the patient on their medicines.

> If a patient receives something that looks different to their usual medicine, or asks if there has been a brand change, these should be red flags to investigate further."

Stock control and date checking SOP D2

The SOP "Stock control and date checking SOP D2" (September 2019) requires regular quantity and date checks to be carried out. It states:

> "The dispensary stock check sheet should be completed and signed each week with any stock adjustments made on Toniq to ensure the stock file is kept up to date. Any variances valued more than $50 should be brought to the Pharmacy Manager's attention for investigation."

There is no instruction about what to do where there is a variation in stock quantity indicating a potential dispensing error.

Incident Policy SOP G8

The Incident Policy (September 2019) states:

> "**The appropriate staff member that handles the incident is responsible for completing the incident form** with input from the staff member making the initial assessment. The staff member handling the incident should also contact external agencies if required.
>
> Incident forms are to be used to document all incidents and copies are to be sent to PDA and Pharmacy Support Manager.
>
> Incidents are to be reviewed by the Pharmacy Partner on quarterly operational visits.
>
> …
>
> The **Charge Pharmacist** is responsible for handling incidents concerning **dispensing or** medications" (emphasis in original).

It states that when an incident occurs actions should include notifying the prescriber, assessing the patient for adverse reactions, advising the patient to cease taking the medication, and organising delivery of the correct medication. The pharmacist should also notify the Pharmacy Defence Association (PDA) and complete an incident form, which should be provided to the PDA once completed. In a situation where patient harm has occurred or is suspected, "the Pharmacist partner and the Pharmacy Business Manager must be contacted as soon as practicable by phone". In addition:

> "The Pharmacy Manager must investigate the incident and must consult with the Pharmacy Support Manager regarding revising the SOPs and policies if necessary. Any change in policy or preventative action implemented must be recorded on the incident form. Debrief the incident with the pharmacy team to ensure the correct procedures are followed to avoid repetition and how to deal with the situation if it re-occurs.
>
> The changes implemented must be reviewed by the Pharmacy Manager and recorded in the Dispensing Summary Log every month. This is to assess whether any corrective

actions that have been previously made, have been effective, or whether further action is required. These must be communicated to applicable staff members.

A Pharmacist must follow up with the patient to ensure his/her wellbeing and to advise the patient of [the] outcome of the investigation."

Appendix C: Relevant standards

The Pharmacy Council of New Zealand's *Competence Standards for the Pharmacy Profession (2015)* require that a registered pharmacist:

> "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."

The Pharmacy Council of New Zealand's *Code of Ethics (2018)* requires that a pharmacist:

> "Principle 1F Acts to prevent harm to the patient and the public."