Pharmacy

Pharmacist, Ms C

A Report by the

Deputy Health and Disability Commissioner

(Case 19HDC00059)

Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

Contents

Executive summary

1. This report relates to an error in the dispensing of medication to a woman by a pharmacist and a pharmacy in September 2018. In this report, the Deputy Commissioner highlights the importance of pharmacists checking medications against prescriptions adequately and involving other pharmacists for a second check as necessary.

2. On 15 September 2018, the woman presented to the pharmacy to have a repeat prescription filled. The prescription included 30 tablets (one month's worth) of ropinirole. When the prescription for ropinirole was processed, the correct label for ropinirole was generated, but the label was incorrectly placed on a box of risperidone. The pharmacist did not ask another pharmacist to perform a second check of the medication.

3. The woman took the risperidone for approximately one month and her health was affected adversely.

Findings

4. The Deputy Commissioner found that by failing to check the medication against the prescription adequately and involve another pharmacist for a second check, the pharmacist breached Right 4(2) of the Code.

5. The Deputy Commissioner considered that the dispensing error did not indicate broader systems or organisational issues at the pharmacy, and therefore that the pharmacy did not breach the Code. However, the Deputy Commissioner was critical that the pharmacy's SOPs were not up to date to reflect its current practices.

Recommendations

6. The Deputy Commissioner recommended that the pharmacist undertake an audit of her accuracy in dispensing medication, and report back to HDC. In accordance with the recommendation in the provisional opinion, the pharmacist provided an apology and commenced a near-miss log.

7. The Deputy Commissioner recommended that the pharmacy provide evidence to HDC that it has amended its SOPs to reflect current practices. In accordance with the recommendation in the provisional opinion, the pharmacy provided a written apology to the woman.

Complaint and investigation

8. The Health and Disability Commissioner (HDC) received a complaint from Ms A about the services provided to her by a pharmacist, Ms C, and a pharmacy. The following issues were identified for investigation:

- *Whether the pharmacy provided Ms A with an appropriate standard of care in September 2018.*
- *Whether Ms C provided Ms A with an appropriate standard of care in September 2018.*

9. This report is the opinion of Kevin Allan, Deputy Commissioner, and is made in accordance with the power delegated to him by the Commissioner.

10. The parties directly involved in the investigation were:

Ms A	Consumer/complainant
Pharmacy	Provider
Ms B	Provider/Pharmacy Director
Ms C	Provider/pharmacist

11. Independent expert advice was obtained from a pharmacist, Ms Catherine Keenan (Appendix A).

Information gathered during investigation

Introduction

12. This report concerns an error in the dispensing of medication to Ms A at the pharmacy in September 2018. Pharmacy Director Ms B provided the information from the pharmacy in relation to these events. Ms C, a pharmacist, is an employee of the pharmacy.[1]

Standard Operating Procedures

13. At the time of these events, the Standard Operating Procedures (SOPs) in place at the pharmacy entitled "Labelling Medicines" required Ms C to "check the name, brand, strength and formulation against the prescription, not the label".

14. The Dispensing Procedure also stated that the pharmacist was responsible for checking the final procedure. It required Ms C to:

> "• [C]heck the label and dispensed medicine against the original prescription and the stock supply used to dispense the medicine. This includes
> - correct patient name
> - instructions for use

[1] Ms C obtained a Bachelor of Pharmacy overseas. She is a registered pharmacist in New Zealand.

- formulation, strength and quantity of medicine
- open each dispensed bottle or skillet to compare contents with stock supply

- … Self checking is not recommended — wherever possible the check should be done by a second person.
- If self checking can't be avoided, separate the 'physical' and 'mental' activities by another task eg by dispensing another prescription

…

- Initial each item on the prescription when it has been checked and passed for accuracy … Set aside completed, checked prescriptions in a basket or clear plastic holding bag in a designated collection area."

Standard practice

15. The pharmacy told HDC that a certified repeat copy of a prescription is generated when a prescription is to be dispensed on more than one occasion. It stated that the first item of dispensed medication is checked using the original prescription, and subsequent repeat medication is dispensed without reference to the original prescription.

16. The pharmacy stated that either a pharmacist or a technician process prescriptions, and these are then moved to the dispensing bench to be assembled by a technician. It said that a technician checks the labels with the prescription to make sure the patient, address, doctor, medicine, strength, form, and instructions are correct. Once finished, the prescription is moved to another area in the dispensary for a further check by a pharmacist. The pharmacy said that the pharmacist then checks all the aforementioned information and the stock bottles, prescription, and dispensed medication, and that a dispensed item is checked by a minimum of two dispensary staff members. The pharmacy told HDC that it encouraged pharmacists to tick the strength of the dispensed medication on the prescription or certified repeat copy as part of their checking procedure. At the time of events, this was not reflected in the SOP. In response to the provisional opinion, the pharmacy stated that the ticking process was not a mandatory or enforced process; rather, it was encouraged as the preferred option out of several options that pharmacists could employ while checking a prescription. Other options for checking a prescription included circling, underlining or highlighting, or using a mnemonic.

17. The pharmacy also told HDC that once the final checks have been made by the pharmacist, the prescription items are then placed in a paper bag, to await collection by the customer. The pharmacy stated that dispensed medication was placed in paper bags to observe the privacy of its customers when handing over the medication, and that it prefers to use paper bags rather than plastic bags for environmental reasons. The pharmacy acknowledged that its SOP required checked prescriptions to be placed in a basket or a plastic bag, and that the use of paper bags is contrary to its standard practice. It said that in this case, the use of a plastic or paper bag was not relevant because at this point all the checks have been made by a pharmacist, and the prescription has been signed off and deemed to be correct.

Ms A

18. On 15 September 2018, Ms A visited the pharmacy to have a repeat prescription filled. The prescription included 30 tablets (one month's worth) of ropinirole[2] and 120 tablets of levetiracetam.[3]

19. Ms A told HDC that pharmacist Ms C handed over the medication. Ms A said that the ropinirole was packaged in a box, but that usually it was packaged in a bottle. Ms A stated that she questioned the packaging of the ropinirole, and Ms C advised that the packaging had changed and assured her that it was fine.

20. Ms A took the medication as directed, and said that during this time she experienced paranoia, panic attacks, restlessness, vomiting, nausea, and blurred vision. She stated that after taking the medication for approximately one month, she read the packet and noted that it contained risperidone[4] and not her usual prescription of ropinirole. At this point, Ms A ceased taking the medication.

Ms C — pharmacist

21. Ms C told HDC that on 15 September 2018 she was the only staff member working in the dispensary, and that pharmacist Ms B was working in the retail shop of the pharmacy on this day.

22. Ms C processed Ms A's repeat prescription for ropinirole and dispensed the medication. Ms C told HDC that the label generated was correct, and that it was for ropinirole, but the label was incorrectly placed on a box of risperidone. Ms C stated that the risperidone and the levetiracetam were placed in a labelled paper bag and placed on the shelf in the dispensary in alphabetical order for collection. She said that it was standard practice at the pharmacy to use paper bags, as no plastic bags were available.

23. Ms C told HDC that Ms B was not available to perform a second check because she was busy with the retail sales.

24. Ms C stated that she did not hand out the medication to Ms A, nor was she approached by Ms A about the appearance of her medication. Ms C said that had Ms A raised her concerns about the medication packaging, she would have identified and corrected the error, "as it was clearly a ropinirole label (usually bottled) on a risperidone box". Ms C said that it was either a shop staff member or Ms B who handed the medication to Ms A.

The pharmacy

25. The pharmacy told HDC that on 15 September 2018 Ms C was the only pharmacist involved in the dispensing and checking of Ms A's medication. The pharmacy provided HDC with its sales report for 15 September 2018, which states that two pharmacists (Ms C and a locum pharmacist) and two retail staff were in the pharmacy on this day. It said that a locum pharmacist was in the pharmacy and available to assist Ms C, but he was not

[2] Indicated for the treatment of Parkinson's disease.
[3] Indicated for the treatment of seizures.
[4] A medication used to improve the symptoms of certain types of mental illness.

involved in the dispensing or checking of Ms A's prescription. The pharmacy stated that Ms B was not working on 15 September, and the rosters support this.

26. The pharmacy said that on 15 September, 66 prescriptions were dispensed, of which 13 were dispensed in the hour in which Ms A's repeat prescription was dispensed.

27. The pharmacy told HDC that ropinirole 1mg tablets are dispensed loose in a bottle, whereas risperidone tablets are strip packaged. The pharmacy stated that at the point of collection, should a customer raise questions about their medication, it would expect a pharmacist to open the bag and discuss the medication.

Identification of dispensing error

28. The pharmacy told HDC that it was alerted to the medication error on 8 October 2018, by Ms A's general practitioner. The pharmacy recorded the incident in the Toniq computer system and an incident form was completed. The incident form noted: "Dispensed risperidone 1mg instead of ropinirole 1mg on 15/9/18."

29. On 8 October 2018, Ms B apologised to both Ms A and the GP about the medication error. Ms B told Ms A that she would commence an investigation into the incident and report back to her on 12 October 2018.

30. Ms B met with Ms A on 12 October 2018, and explained that Ms C had made a dispensing error and was very sorry for this. Ms B apologised to Ms A again, and offered to pay for the doctor's expenses incurred.

31. The pharmacy notified the Pharmacy Defence Association[5] (PDA), which provided advice on how to respond to the dispensing error, and reviewed its SOPs. Ms B, on behalf of the pharmacy, told HDC that PDA said that its SOPs were robust and fit for purpose, and provided information on a Root Cause Analysis to follow when a process has "fallen down".

32. Ms C wrote a letter of apology to Ms A, and stated:

> "This has been a personal error as it appears I was distracted and failed to check that the final container contained what was written on the prescription."

33. The pharmacy told HDC:

> "This is an isolated incident which is due to [Ms C] not following the relevant SOPs for dispensing and checking, and not the result of poor practices supported by the pharmacy."

[5] A not-for-profit pharmacy support association in New Zealand.

Actions taken by the pharmacy

34. Following this incident, in September 2018 the pharmacy amended its Dispensing Accuracy Checks SOP. The SOP now states that it is the responsibility of dispensing staff and the pharmacist to:

> "Ensure that every prescription is stamped with the pharmacy stamp at the time of processing …
>
> The more people involved in the dispensing process of every prescription, the smaller the chance of error.
>
> Ensure that all dispensary staff take regular breaks to maintain focus at all times.
>
> Educate all staff to refrain from unnecessary interruptions of dispensary staff during the dispensing process.
>
> Have regular dispensary staff meetings to discuss near misses and ways to improve and streamline the accurate dispensing of prescriptions.
>
> …
>
> When checking repeats — whenever possible it is recommended that the drug name and strength are ticked on the certified repeat copy to confirm the pharmacist has checked both."

35. Ms B stated that since the dispensing error, the pharmacy has put in place the following changes:

- Ms C has reviewed her checking technique.
- Pharmacists are to tick the strength of the dispensed medication on the prescription or certified repeat copy as part of their checking procedure. The SOP has been amended to include this practice under Labelling and Dispensing.
- All stages of the dispensing process (processing the prescription, dispensing the medicine, and checking the medicine) should be signed off by the team member who completes them.
- Staff will initial the sticker that is placed on the prescription or CRC[6] when packaging the items into the bag to confirm that nothing has been left out.
- Its SOP was amended to reflect that once the appropriate checks have been performed, medication is then placed in a paper bag for collection.

36. Ms B also advised that Medicines Control from the Ministry of Health audited the pharmacy and its processes and advised that the SOPs met the Ministry's requirements.

[6] A Certified Repeat Copy (CRC) is a computer-generated record of a repeat prescription item. A CRC can be used for dispensing a repeat item as an alternative to dispensing from the original prescription.

Actions taken by Ms C

37. Ms C told HDC that following these events, she improved her self-checking techniques and adopted strategies to minimise dispensing errors, in addition to the usual checks in place. Ms C said that she takes regular breaks and has undertaken a self-audit of her accuracy for dispensing. Ms C stated that she takes any error very seriously, and apologised for the error in this incident.

38. In response to the provisional opinion, Ms C also said that she has completed a dispensing accuracy workbook assignment from the Pharmaceutical Society of New Zealand, and completed training in 2020 to become a preceptor[7] to an intern pharmacist. Ms C stated: "I believe that teaching will further enhance, refresh and reinforce my dispensing accuracy and standards of practice."

Further comment

Ms A

39. Ms A stated that while taking the incorrect medication, her health deteriorated significantly, and she is still recovering to her previous health status.

The pharmacy

40. The pharmacy told HDC that it has communicated its apologies and explained the situation to Ms A, and believes that it has done its best to ensure that her concerns have been heard and appropriate actions taken.

Responses to provisional opinion

41. Ms A, Ms C, and the pharmacy were all given the opportunity to respond to the relevant sections of the provisional opinion. Where relevant, their responses have been incorporated into this report.

42. In addition, Ms A stated that she has suffered immensely since the medication dispensing error, and that it has cost her and her family financially, physically, and mentally.

43. Ms C stated that she accepts that she made the dispensing error on 15 September 2018 and that her dispensing procedures failed her. She further stated: "I am absolutely committed in upholding my pharmacy standards and ethics at all times to provide a high quality and accurate standard of work at all times."

44. The pharmacy stated:

> "The SOPs were already robust at the time of the error and the addition of ticking the drug name and strength on a CRC was to strengthen our checking processes rather than correct a missing step. Without the requirement of ticks being added while checking a prescription or CRC, our SOPs would remain industry standard as evidenced by our successful Ministry of Health Audit."

[7] An experienced practitioner who provides supervision during clinical practice.

Relevant standards

45. 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.
>
> …
>
> 03.2.5 Accurately records the details of medication incidents and actions taken, including clinical and professional interventions, to minimise their impact and prevent recurrence."

46. 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.
>
> …
>
> Principle 6C Be accountable for practising safely and providing professional services only within their scope of practice."

Opinion: Ms C — breach

47. As a registered pharmacist, Ms C was responsible for ensuring that she provided services of an appropriate standard to Ms A, including complying with the professional standards set by the Pharmacy Council of New Zealand.

Dispensing error

48. The Pharmacy Council of New Zealand's *Code of Ethics (2018)* provides that a pharmacist must "take appropriate steps to prevent harm to the patient and the public" and "be accountable for practising safely and providing professional services only within their scope of practice".

49. Further, the Pharmacy Council of New Zealand's *Competence Standards for the Pharmacy Profession (2015)* require that a registered pharmacist "maintains a logical, safe and disciplined dispensing procedure" and "monitors the dispensing process for potential errors and acts promptly to mitigate them".

50. On 15 September 2018, Ms C incorrectly dispensed risperidone to Ms A instead of ropinirole, the medication that had been prescribed. Ms C stated that the label for the ropinirole was correct, but was incorrectly placed on a box containing risperidone. As per

the practice at the pharmacy, Ms C then placed the medication in a labelled paper bag for collection.

51. I note the conflicting versions of events about whether pharmacist Ms B or a locum pharmacist was present on 15 September 2018. Ms C said that Ms B was in the pharmacy that day. In contrast, the pharmacy told HDC that on 15 September 2018, Ms B was not rostered on, but a locum pharmacist was present. I note that this is consistent with the staffing roster provided to HDC by the pharmacy. Accordingly, I find that Ms C and a locum pharmacist were present that day. However, I accept that neither the locum pharmacist nor any other staff member was involved in the checking of Ms A's medication.

52. Ms A stated that she questioned the packaging of her medication when Ms C handed it to her, noting that it was different to the usual packaging. In contrast, Ms C has no recollection of any discussion with Ms A about the medication. I also note Ms C's comments that Ms B or another staff member handed the medication to Ms A. As stated above, I accept that Ms B was not present at the pharmacy on 15 September 2018. On the evidence available to me, I am unable to determine who handed the medication to Ms A or discussed any concerns that she raised about the packaging. However, this does not affect my findings materially in relation to Ms C's dispensing error.

53. My expert advisor, Ms Catherine Keenan, advised:

> "[Ms C] has given a full account of what happened and does take responsibility for checking and signing off on this dispensing … [Ms A] took the wrong medication, that was dispensed incorrectly and had ill effects from this. There does need to be accountability for this and therefore consequences. As pharmacists we have to be accountable at every dispensing, it is part of our role and cannot be avoided or dismissed (even if busy or overwhelmed)."

54. Ms Keenan advised that the dispensing service has been inadequate because an error has occurred. She noted that the SOP states that self-checking is not recommended, and that another dispensary-qualified staff member was present that day. She observed that 13 items were dispensed in the hour surrounding the error, and said that this is not a significantly high number. Ms Keenan advised that involving another pharmacist in the checking process was realistic and best practice.

55. I agree that the error that occurred on 15 September 2018 indicates that Ms C's checking and signing off on this dispensing was inadequate on this occasion. Ms C failed to select the correct medication, did not check the medication against the prescription adequately, and did not involve another pharmacist to perform a second check. The dispensing error resulted from a failure to follow the pharmacy's SOPs and the Pharmacy Council of New Zealand's Competence Standards for the Pharmacy Profession.

Conclusion

56. By failing to select the correct medication on 15 September 2018, and failing to check the medication against the prescription adequately and involve another pharmacist for a

second check, Ms C failed to adhere to the pharmacy's SOPs and the professional standards set by the Pharmacy Council of New Zealand. As a consequence of the dispensing error, Ms A's health was affected adversely as a result of not taking her correct medication, and taking a medication that was not indicated, for a number of weeks before she was alerted to the medication error. Ms C failed to provide Ms A with services in accordance with professional and other relevant standards and, as such, breached Right 4(2) of the Code of Health and Disability Services Consumers' Rights (the Code).[8]

57. I note that Ms C provided a written and a verbal apology to Ms A promptly following the discovery of the dispensing error. I also note that the written apology acknowledges a deviation from the checking procedure and an assurance by Ms C that she will revisit her procedures. Ms C has since made changes to her practice to improve her dispensing accuracy as a pharmacist. I consider this appropriate.

Opinion: Pharmacy — adverse comment

58. As a healthcare provider, the pharmacy is responsible for providing services in accordance with the Code. The pharmacy has an obligation to ensure that it has adequate policies in place to facilitate safe dispensing.

Adequacy of SOPs

Ticking process

59. The pharmacy in its initial response to HDC stated that it encourages pharmacists to tick the strength of the dispensed medication on the prescription or certified repeat copy as part of their checking procedure, but this was not reflected in the SOPs at the time. In a further response, the pharmacy advised that its SOPs now reflect this practice.

60. My expert advisor, Ms Catherine Keenan, advised that the SOPs cover all aspects and are comprised of industry-standard documents. However, she noted that the pharmacy's comments about a "ticking" process during the checking stages were not reflected in the SOPs. Ms Keenan advised:

> "Having the actual steps taken in dispensing and checking differing from the SOP is a moderate departure from standard practice as it would be advisable and auditable to have the process match the SOP if this 'ticking' is to be the new accepted practice."

61. I accept Ms Keenan's advice that at the time of the error, the pharmacy had in place appropriate dispensing and checking SOPs. However, I note that the pharmacy had preferred practices that it encouraged pharmacists to employ relating to its checking procedures that were not included in the SOPs at the time of events. I am critical of the pharmacy that its SOPs were not up to date to reflect its current practices. It was the

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

responsibility of the pharmacy to ensure that its SOPs were current to guide its staff on its procedures to facilitate safe dispensing.

Dispensing of incorrect medication — no breach

62. In this case, I consider that the dispensing error that occurred on 15 September 2018 was an individual error and did not indicate broader systems or organisational issues at the pharmacy. Therefore, I consider that the pharmacy did not breach the Code directly.

63. 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.

64. Ms C was acting as an employee of the pharmacy when she dispensed risperidone instead of the prescribed ropinirole to Ms A, 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. My expert, Ms Keenan, advised that the SOPs were adequate, and noted that another pharmacist was available to provide a further check of the medication as required by the SOPs. Ms C was individually responsible, in accordance with both the pharmacy's SOPs and the Pharmacy Council of New Zealand's Competence Standards, to ensure that she dispensed the prescribed medication correctly, and that appropriate checks were made before the medication was provided to Ms A. I consider that the pharmacy was entitled to rely on her to do so. I am therefore of the view that the pharmacy took reasonable steps to prevent Ms C's error, and is not vicariously liable for her breach of the Code.

Material of bag for dispensed items — other comment

65. The pharmacy said that the use of a plastic or paper bag was not relevant because at this point, all the checks have been made by a pharmacist and the prescription has been signed off and deemed to be correct. The pharmacy stated that it dispensed medication in paper bags to observe the privacy of its customers when handing over the medication. It also said that for environmental reasons it preferred to use paper bags rather than plastic bags.

66. In my view, the material of the bag (plastic or paper) in which checked prescriptions are placed and handed to customers is not relevant to the dispensing error that occurred in this case. The important component when handing over the medication is checking the patient's identity, reviewing the medications with the patient to ensure they are correct, and ensuring that the patient has an understanding of the use of the medication. I do not consider the use of a paper or a plastic bag to be material to performing adequate dispensing checks or appropriate discussions with a customer. In addition, I note that the use of paper bags may assist with observing patient privacy requirements, and I consider this to be reasonable.

67. While I have found that the material of the bag is not relevant to the dispensing error that occurred, I note that the pharmacy's standard practice of placing the checked prescription

into a paper bag was inconsistent with its SOP, which stipulated that it be placed into a plastic bag or basket. I am critical that, at the time, the SOP had not been updated to reflect standard practice in this regard.

Recommendations

68. In response to the recommendations in my provisional opinion, Ms C:

a) Provided a written formal apology to Ms A for the breach of the Code identified in this report. The apology has been forwarded to Ms A.

b) Reported back to HDC that she has started a near-miss error log, and that this is now an ongoing part of her dispensing practice.

69. I also recommend that Ms C undertake an audit of her accuracy in dispensing medication over a one-month period. I recommend that Ms C report back to this Office regarding the above audit within three months of the date of this report.

70. In response to the recommendations in my provisional opinion, the pharmacy:

a) Provided a written formal apology to Ms A, for the deficiencies identified in this report. The apology has been forwarded to Ms A.

b) Provided evidence to HDC that it has amended its SOP to reflect that checked medications are placed in a paper bag.

Follow-up actions

71. 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.

72. 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 & Safety Commission, and the New Zealand Pharmacovigilance Centre.

73. 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 Mrs Catherine Keenan, Pharmacist:

"17 June 2019

…

Expert Advice Report

I have been asked to provide an opinion to the Commissioner on case number C19HDC00059. I have read and agree to follow the Commissioner's Guidelines for Independent Advisors, and I am not aware of any conflicts of interest.

Expert advice requested (in letter)

Please review the enclosed documentation and advise whether you consider the care provided to [Ms A] by [Ms C] was reasonable in the circumstances, and why.

In particular, please comment on:

1. The adequacy of the dispensing services provided to [Ms A].
2. Actions taken by staff once the dispensary error was identified.
3. The adequacy of the standard operating procedures and changes made following the dispensing error.
4. Changes made by [Ms C] to her dispensing practices following the error.
5. Any other matters you consider amount to a departure from accepted standards.

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).

The Commissioner is subject to the Privacy Act 1993 and the Official Information Act 1982, and your advice may be requested and disclosed under those Acts.

Complaint: [The pharmacy]
Reference: C19HDC00059

Having read over the documents provided by [the] office of the Health and Disability Commissioner I can provide the following information.

1. The adequacy of the dispensing service provided to [Ms A].

[Ms A] has been dispensed the incorrect medication on 15 September 2018 when she came in to [the pharmacy] to get her repeat of Ropinirole and has received Risperidone. The dispensing service has been inadequate because an error has occurred. On reading the correspondence it would seem that only 1 person was involved in the dispensing and checking of this repeat item. The procedure states that self-checking is not recommended and that where possible a second person should do the accuracy check. Since another dispensary qualified staff member was available on that day, best practice would indicate that they should have been involved in the process. 13 items were dispensed in the hour surrounding the error which is not a significantly high number so getting another person to check or dispense was realistic. There is no information on how busy the retail part of [the pharmacy] was on that day as that could account for why the other pharmacist was not available for a second check.

There is mention of a conversation around the fact that the packaging was different.

a. If this conversation did occur, then it should have prompted the pharmacist giving the medication out to have another look at the items. This may have given the pharmacist the opportunity to second check themselves. Best practice is that any change of brand or question about the appearance of medicines would initiate showing the patient the physical items (what they look like and how they are different (or the same)) and how they perceive them to be different. This is mentioned in the notes from [Ms B] and the Document C38 regarding counselling. If this conversation did occur and was brushed aside then this is a major departure from standard care and accepted practice.

b. If this conversation did not occur, it does not excuse the error as patients all have different levels of Health Literacy and understanding of medications. [Ms A] had put her trust in the pharmacist to dispense the correct item. Also, the Document C37 regarding Accuracy Checks mentions about placing completed checked prescriptions in a basket or clear plastic bag. However, [Ms B] says in her notes that '[Ms C] said she would have opened the bag and double checked the prescription if any concerns were raised by [Ms A] about the appearance of her medicine or packaging'. This would indicate that the items had already been put in a bag that was not clear which is a moderate departure from the standard operating procedure and meant that the final opportunity for a further check was lost.

Placing items directly into a brown paper bag to hand to the patient is a moderate departure from standard care and accepted practice. Taking the items out in a basket or clear bag is a much better way of discussing the items with the patient and checking their understanding, even if it is a repeat item. The standard operating procedure must apply to all dispensed items and not just original prescriptions. There is no mention of a deviation from the checking procedure if it is a repeat item, but it seems that this has happened in this instance. Some mention of repeats should be made in the standard operating procedures.

[Ms C's] peers would have some empathy for her situation in making a serious error but would reiterate the need for removing distractions and good support in the dispensary so that the checking process can be standardized every single time. While packing things up in a brown paper bag may have been acceptable some years ago, nowadays showing the patient the medications as they are given out and talked about is viewed by pharmacists as best practice.

Recommendations for improvement:

- Place completed items in baskets or clear plastic bags at all times, as mentioned in the procedure. This is an opportunity for further discussion.
- Somewhere in the procedure should state how repeat items are processed (checking back on dates of collection, interactions with any subsequently prescribed medicines, any other repeat items that may be required).
- Ensure another dispensary trained staff member offers a second check if available. Or ensure that at EVERY dispensing when the same person has dispensed and checked that this is noted on the prescription.

2. Actions taken by staff once the dispensary error was identified.

As soon as [the pharmacy] was notified of the error, they have given a verbal apology to both the prescribing doctor and to [Ms A] and her partner. Also, [Ms B] has given a time frame for further response (12 October 2018) so that an investigation can begin. This is accepted practice. This time frame was met by [Ms B] who met with [Ms A] on 12 October and more verbal communication took place regarding compensation of medical expenses and that a written apology would be forthcoming.

[Ms B] mentions that PDA (Pharmacy Defence Association) was contacted for support and direction in dealing with the dispensing error. There is no documentation as to what that support and direction entailed.

The dispensing pharmacist, [Ms C], has given a written apology dated 11th October 2018. This gives the apology and gives some explanation as to what may have led to the error. She mentions a deviation from the checking procedure and says she will revisit her procedures, but no detail is given as to how this will work, what will be documented and by whom. More detail of the steps being taken to 'revisit' the procedures could have given some certainty that this would happen. This may have been subsequently documented and would be evidence to show [Ms A] how this process of improved performance has unfolded. The offer of compensation for medical expenses is a good idea and would be seen as standard practice.

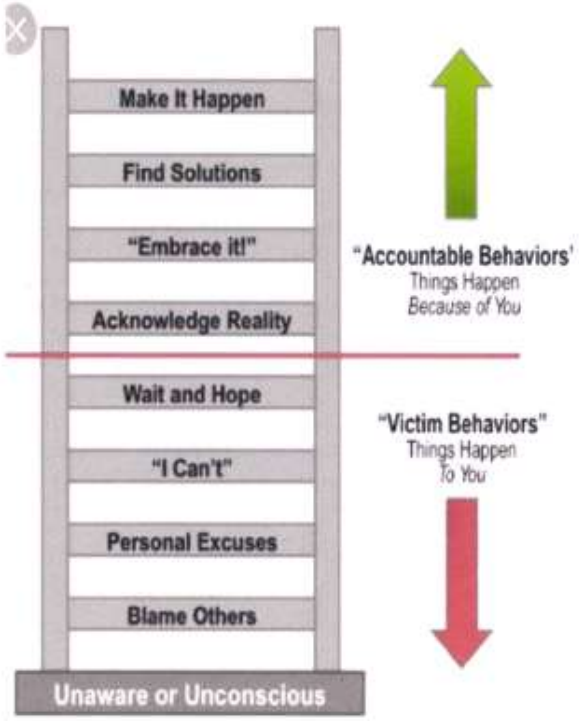
The incident was documented in the Toniq computer system which is standard practice.

The response would be viewed by peers as a standard response to the error and expressing remorse in both verbal and written communication is the common

practice. It is important to back the words up with actions and being able to show the actionable steps being taken to review process would be helpful for the complainant.

Recommendations:

- Have a written policy for handling complaints (they may have this already, just not in the notes I was given) and ensure all staff are trained in how to handle the complaints, particularly regarding documentation.
- Get written information from PDA on processes such as 'Root Cause Analysis' for staff to follow to identify where the process has 'fallen down'.
- Take ownership of the error and never put the blame on the client. The statement 'I am surprised [Ms A] claims to have questioned the packaging only and not the colour and shape of the tablets given her history of collecting Ropinirole from my pharmacy' does appear to try and place some blame on [Ms A] when this should not be the case.



3. The adequacy of the standard operating procedures and changes made following the dispensing error.

The standard operating procedures cover all aspects of the dispensing process and appear to have been reviewed anywhere from 1 day to 6 months after the error occurred. With the SOP Number 37 Accuracy Check, there appears to have been an additional SOP 37b which covers the need to avoid distractions and interruptions, take regular breaks and document and discuss near misses. This goes some way to providing more guidance around the dispensing process and would offer improvement to the process.

On initial reading the SOPs appeared to cover all aspects and are industry standard documents. This would be the view of my peers. In her response to the complaint, [Ms B] mentions that 'she encourages her pharmacists to tick the strength of the dispensed medication on the prescription or certified repeat copy as part of their checking procedure'. This has not been included in the reviewed SOP however and it would be advisable to do so. Not having the original documents, it is tricky to comment if changes have been made. I can only see that the extra 37B SOP has been written.

Having the actual steps taken in dispensing and checking differing from the SOP is a moderate departure from standard practice as it would be advisable and auditable to have the process match the SOP if this 'ticking' is to be the new accepted practice.

Recommendations for improvement:

- Make sure the SOP includes all aspects of the checking process and if this is to include 'ticking' the strength then should be reflected in the SOP.
- Make sure finished items are placed in trays or clear plastic bags for collection or giving out as per the SOP.

4. Changes made by [Ms C] to her dispensing practices following the error.

The new SOP 37b Additional Dispensing Accuracy Checks appears to be the major steps that have been taken by [Ms C] the pharmacist, since the error occurred. This includes minimising distractions, staying totally focused in the dispensary, taking regular breaks and staying hydrated. Not having her cell phone in the dispensary is a good idea and would be standard practice. These are all positive steps.

There is mention of a review of [Ms C's] checking technique but no mention of what this would look like and how this has been documented. Has she kept a log of say 50–100 items in a row without error? Does the near miss log show that [Ms C] is picking up errors before they leave [the pharmacy]? Such documentation is helpful and would provide [Ms A] with some evidence of the steps that have been taken rather than just stating a 'review' has occurred.

Keeping a near miss log is standard and acceptable practice. Documented meeting notes or discussions about near misses should also be kept. The PDA also suggests a Root Cause Analysis report which can break down the process that led up to the error and highlight any areas of concern. Again, this is documentation that could provide some comfort to [Ms A] that concrete steps have been taken to improve performance.

5. Any other matters you consider amount to departure from accepted standards.

All matters have been covered in the above report.

Regards

Mrs Catherine Keenan
…"

Mrs Keenan provided the following further advice by email on 7 October 2019:

> "I have read through the reply documents from both [Ms C] and [Ms B]. It saddens me that they cannot agree on the series of events for the day. Is this an issue for HDC? It seems [Ms B] can attest to the fact that she was not there and had a locum pharmacist working on that day to assist. However, as [the pharmacy] owner she is responsible for high standards of dispensing process.
>
> [Ms C] has given a full account of what happened and does take responsibility for checking and signing off on this dispensing. She has come up with a number of reasons why this may have occurred which probably does not give much comfort to the customer. The reality is that [Ms A] took the wrong medication, that was dispensed incorrectly and had ill effects from this. There does need to be accountability for this and therefore consequences. As pharmacists we have to be accountable at every dispensing, it is part of our role and cannot be avoided or dismissed (even if busy or overwhelmed).
>
> I think the main issue is to do with how things have changed since this happened. Do checked prescriptions still sit in brown paper bags and get given to the customer with no further 'sight' on the items? The SOP mentions that items are placed in a basket or clear plastic bag for collection. Is there visual evidence that this is the case 100% of the time?
>
> I feel this would give [Ms A] and subsequent customers comfort that future errors of this nature would be avoided by showing the items to the customer when giving them out.
>
> [Ms C] could have an independent person assess her accuracy over a period of time. (It seems she has done this herself.)
>
> Having a robust process and supported dispensary staff is the way forward."