Pharmacy

A Report by the
Health and Disability Commissioner

(Case 18HDC01943)

Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

Contents

Executive summary

1. This report concerns the care provided to a man by a pharmacy and highlights the importance of checking dispensed medication and having appropriate systems and standard operating procedures (SOPs) in place for dispensing medication.

2. In September 2018, the man visited the pharmacy to pick up his repeat medication. One of his medications was Trental 400mg. Tegretol was dispensed instead of Trental. The man consumed Tegretol for the next seven days and suffered adverse reactions as a result.

Findings summary

3. The Commissioner found the pharmacy in breach of Right 4(1) of the Code, as several systemic issues contributed to the dispensing error. The issues included the pharmacist having been appointed the sole charge pharmacist without sufficient training and support, the practice of dispensing repeat medicines off the label (which was inconsistent with the pharmacy's SOPs), and the lack of an alert system for rarely dispensed medications. The Commissioner also made adverse comment about the pharmacist, as he failed to check the dispensed medication adequately.

Recommendations

4. The Commissioner recommended that the pharmacy apologise to the man, conduct an audit of all errors and near misses in relation to dispensing of medicines and staff compliance with the SOPs, arrange training for its staff in relation to dispensing repeat medications, and arrange further training for the pharmacist on his role as the charge pharmacist. The Commissioner also recommended that the pharmacist attend further training.

Complaint and investigation

5. The Health and Disability Commissioner (HDC) received a complaint from Mrs B about the services provided by the pharmacy to her father, Mr A, on 19 September 2018. The following issue was identified for investigation:

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

6. This report is the opinion of the Commissioner.

7. The parties directly involved in the investigation were:

Mr A	Consumer
Mrs B	Complainant
Pharmacy	Provider

Mr C	Pharmacist
Ms D	Pharmacy technician
Mr E	Pharmacy Director

8. Independent expert advice was obtained from a pharmacist, Mr Paul Vester, and is included as Appendix A.

Information gathered during investigation

Incorrect dispensing

9. In August 2018, Mr A was prescribed repeat prescriptions, including Trental[1] 400mg, which was first dispensed by the pharmacy on 9 August 2018. The Pharmacy Prescription Copy stated:

> "Med Pentoxifylline[2] 400mg Tablets
>
> Sig: Take ONE tablet with food, TWICE daily … Repeats: 2"

10. At around 9am on 19 September 2018, Mr A visited the pharmacy to collect his repeat prescriptions.

11. The repeats were processed at 9.14am. Mr C, a pharmacist, processed the prescription and generated the correct Trental label. However, Ms D, a pharmacy technician, incorrectly selected Tegretol[3] 400mg from the medication shelf and put the Trental label on the Tegretol box. Mr C completed the final check of the prescription. Mr A was dispensed the Tegretol 400mg in error.

12. At this time, Mr C, Ms D, and another technician (who began work at 9.10am) were present in the pharmacy.

13. Mr C stated:

> "During the final check of [Mr A's] repeat prescription, another large repeat prescription came in and they wanted to wait … I decided to increase the speed [of] my checking procedure. I proceeded to check the box first (Tegretol) which put Tegretol in the head, I then checked the quantity (60), checked the strength (400mg), read the directions and lastly glanced over the name. As I was trying to speed up my checking procedure and both started with 'T' I inadvertently signed it off thinking Tegretol instead of Trental …"

[1] Trental is used to assist blood flow in patients with vascular disorders.
[2] Generic name of Trental.
[3] Tegretol is an anticonvulsant medication used primarily in the treatment of epilepsy and neuropathic pain.

14. Ms D told HDC:

> "[Mr A] came into the pharmacy during a period in which there were many customers, needing help or waiting upon a prescription. I believe that the wrong medication was selected due to the similar brand names and the low frequency in which they are both dispensed. I believe this is human error."

15. According to the pharmacy's Dispensary Time Zone Report, 39 prescriptions were dispensed from 9am to 10am on 19 September 2018. Mr C told HDC that the number of prescriptions dispensed is only one factor to be considered in the busyness of the pharmacy, and that factors such as customer queries, telephone calls, and prescription interventions should also be considered.

Subsequent events

16. Mr A took Tegretol for seven days. On 26 September 2018, Mr A became very ill and was taken to hospital. He was diagnosed with ataxia (impaired coordination), high blood pressure, and nystagmus (involuntary eye movement), as a result of his unintentional use of Tegretol.

17. On the same day, a doctor called the pharmacy and confirmed the dispensing error and informed Mr C that Mr A had been admitted to hospital. Mr C telephoned Mr A's family to enquire after Mr A and to apologise for the error, and informed the family that he would investigate the matter.

18. On 27 September 2018, Mr C contacted Mr A's medical centre to advise that the pharmacy would be willing to reimburse reasonable costs incurred by Mr A associated with the incident.

19. On 28 September 2018, the clinical pharmacist from the hospital called Mr C regarding the dispensing error, and sent him a photograph of the incorrectly prescribed Tegretol. The photograph was provided to HDC, and shows the prescription label stating "60 TRENTAL Tablets 400mg" on the Tegretol medication packaging, with "Tegretol 400 Carbamazepine 400mg" clearly visible above the prescription label.

20. On the same day, Mr C sent an apology letter to Mr A and explained how the error occurred. The letter stated:

> "I am writing to offer my sincere apologies for the error that occurred with your medication … After reviewing the incident, it is clear that the error was caused by two failures in our dispensing process. Firstly, the dispensary technician has selected the wrong product from the shelf. Secondly, my checking process was not adequate as the error was not detected."

21. On 30 September 2018, Mr C completed the Incident Notification Form for the Pharmacy Defence Association. The incident form described the dispensing error and provided a timeline of what occurred. The form stated:

> "[D]uring the week the error occurred there was an unusual high demand for prescriptions (averaging over 300 scripts daily). Most competent staff member was leaving and allowed the more inexperienced staff to perform her roles … this may have increased the chan[c]e of dispensing error …"

22. On 1 October 2018, Mr A visited the pharmacy and expressed his concerns about the dispensing error. Mr C apologised again and gave him an HDC pamphlet and directions on how to make a complaint.

23. Mrs B told HDC that she would like the pharmacy staff, when dispensing, to "show the client the packaging and prescription before handover [of] the medication to the client". Mr C told HDC:

> "[I]t is a good idea to show patients their medicines at the counter before bagging them and handing them over. This is a final opportunity for both the pharmacy and the patient to pick up on something that is wrong …"

24. Mr C stated: "I am aware I have failed to deliver care to [Mr A] under the Pharmacy Competency Standards Domain O3 Dispense Medicines."

Training of staff

25. Mr E told HDC that he purchased the pharmacy in December 2017 and that he hired all the existing staff, including Mr C (who was an intern pharmacist at the time), Ms D, and a trainee pharmacy technician. Mr E said that all staff had been trained prior to his purchase of the pharmacy. Mr E told HDC that he was not provided with documentation from the previous owner about training provided to staff.

26. Mr C told HDC:

> "Following the change of ownership of the pharmacy, [Mr E] decided to adopt the Standard Operating Procedures (SOPs) of the previous owner. [Mr E] did make a few changes to the way the pharmacy would operate, notably changing to dispensing off [the] labels[4] instead of printed Certified Repeat Copies.[5] He also combined the role of two pharmacists to one sole charge pharmacist. All dispensary staff members were instructed about these changes when they occurred."

27. Mr E said that prior to acquiring the pharmacy he practised in a busy pharmacy, and it was the normal practice to process repeats off the label. He said that when he acquired the pharmacy, he was the sole charge pharmacist, and once Mr C registered as a pharmacist, Mr C became the main pharmacist and Mr E was the second pharmacist only if required.

28. Mr E said that in mid-January 2018, all staff were trained regarding the change to dispensing repeats off the labels instead of Certified Repeat Copies. He provided the Staff

[4] Dispensing a repeat medication from the previous dispensing label.
[5] A Certified Repeat copy is a computer-generated record of a repeat prescription item. It can be used for dispensing a repeat item as an alternative to dispensing from the original prescription.

Training Record to show that Mr C, Ms D, and another technician attended this training. Mr E also told HDC that he "reviewed the SOPs in early June 2018 and retrained staff at the time". This was recorded in the Staff Training Record form.

29. Mr C registered as a pharmacist in 2018. He told HDC:

> "[S]hortly after I qualified as a registered pharmacist, I was given the role of supervising the pharmacy in a sole charge pharmacist capacity with oversight of two to three technicians. [Mr E] did not believe I needed supervision as I was deemed competent to be a pharmacist by the Pharmacy Council, and I had worked at the pharmacy since [2015]."

30. Mr E told HDC:

> "[Mr C], although starting employment in 2015, was a pharmacy student [for a year], an intern [for 18 months], and has since been a registered pharmacist."

31. Mr C also told HDC that "before registration as a pharmacist, intern pharmacists do not conduct the final check of a prescription and so this process was still somewhat new to [him]". There is no evidence that any further training was given to Mr C once he was appointed as the sole charge pharmacist.

32. Ms D acknowledged that she received the training about dispensing repeats off the label in mid-January 2018. She told HDC: "[S]upervision prior to the error is that there is a charge pharmacist who supervises all activity as a broad spectrum in the pharmacy."

The pharmacy's SOPs

33. At the time of events, the pharmacy had current SOPs in place. "Repeat Prescriptions", approved in July 2018, states:

> "When the repeat has been confirmed and dispensed, the prescription should be handed to the patient or carer with appropriate questions and/or advice eg. how do you take the medicine, any problems with the medicine or its effects and reasons why it's important to keep taking the medicine (if appropriate)."

34. "Dispensing 3 — Labelling and dispensing medicines", approved in July 2018, states:

> "Dispense medicines: …
>
> - Check the name, brand, strength and formulation against the prescription, not the label …
> - Double check labels against the original prescription, before attaching them to the container …
> - Leave the prescription (and any attached notes), stock bottles and dispensed items in the designated checking area for an accuracy check by a pharmacist. (See SOP Accuracy Check) …"

35. "Dispensing 4 — Accuracy Check", approved in July 2018, states:

> "Responsible Person(s): Pharmacist manager
>
> Procedure:
>
> Check 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
> - Formulation, strength and quantity of medicine
> - Open each dispensed bottle or skillet to compare contents with stock supply
> - If more than one stock bottle or skillet has been used, check dispensed medicine against all sources supply.
>
> Self checking is not recommended — wherever possible the check should be done by a second person …"

36. The pharmacy's SOPs did not have any reference to an alert system for rarely dispensed medication.

37. It was noted that the above SOPs were created by Mr C in June 2018 and approved by Mr E in July 2018. Mr C told HDC:

> "The SOPs in place at the time were adequate to prevent the error occurring. Ultimately SOP's [Dispensing] and [Dispensing (Accuracy Check)] were not followed correctly."

Changes made since incident

38. The pharmacy told HDC that as a result of this incident, the following changes were made to its SOPs in an attempt to prevent further errors occurring:

a) It is "trialling a system of an additional check before each prescription is bagged and medicines are shown to each patient when they collect them";

b) It is "now using generic names for medicines when dispensing instead of trade names";

c) It "ha[s] gone back to using Certified Repeat Copies when dispensing repeats from a prescription"; and

d) It now "ensure[s] any rarely dispensed medications will be prompted with an alert".

39. Mr C told HDC that as a result of this incident he made changes to his practice. He now gives the prescription a broad overview before and after finishing his regular check of the prescription, he checks the medication name and contents of the medications against the prescription slowly twice, and he avoids rushing the dispensing or checking process. Mr C also said that now "when prescriptions are being collected, [he] go[es] through the

individual items and tells [the customers] what they are used for to confirm their medications".

Relevant standards

40. The Pharmacy Council of New Zealand Competence Standards for the Pharmacy Profession (2015) (the Pharmacy Competency Standards) state:

> "O3: Supply and administration of medicines
>
> … Pharmacists have an independent duty of care to use their professional judgement and apply their expertise to protect and promote the safety, health and well-being of patients and the public …
>
> Competency O3.2 Dispense Medicines
>
> O3.2.1 Maintains a logical, safe and disciplined dispensing procedure
>
> O3.2.2 Monitors the dispensing process for potential errors and acts promptly to mitigate them …"

Responses to provisional opinion

41. Mrs B was provided with an opportunity to comment on the "information gathered" section of the provisional opinion and had no further comments.

42. The pharmacy was provided with an opportunity to comment on the provisional opinion. Where appropriate, its comments have been incorporated into this report.

43. Comments from Mr C were also sought in response to the provisional opinion. The pharmacy also told HDC: "Having reviewed your decision and discussing your report with the staff involved, we have largely agreed with your findings."

Opinion: The pharmacy — breach

44. This opinion concerns the standard of care provided by the pharmacy to Mr A in relation to the incorrect dispensing of Tegretol instead of Trental.

Dispensing error — breach

45. On 19 September 2018, Mr A was incorrectly dispensed Tegretol 400mg instead of Trental 400mg. Ms D was the pharmacy technician who incorrectly selected the Tegretol and placed the Trental label on the Tegretol packaging. Mr C was the pharmacist who then completed the final check of the medication and did not detect that Tegretol had been dispensed incorrectly. Mr A consumed the incorrectly dispensed Tegretol and experienced an adverse reaction.

46. Expert advice was sought from a pharmacist, Mr Paul Vester, who advised that "the adequacy of the dispensing service provided to [Mr A] falls significantly short of the standard of care expected". I agree with this advice.

47. I have carefully considered the extent to which the deficiencies in Mr A's care occurred as a result of individual staff action or inaction, as opposed to systemic and organisational issues. The problems that arose were due to several systemic issues at the pharmacy. Mr Vester identified several systemic factors that contributed to the error, as discussed below.

The pharmacy's SOPs

48. Mr E purchased the pharmacy in 2017, and changed the process to dispense repeat medicines off the labels instead of printed Certified Repeat Copies.

49. The pharmacy's Dispensing SOPs required the medicines to be checked against the prescription, not the label. However, the practice at the pharmacy was for repeat medications to be dispensed off the label, meaning that the pharmacy's practice was not consistent with its SOPs, as the prescription did not need to be checked for off-the-label dispensing.

50. Mr Vester stated:

> "Dispensing off [the] labels rather than a certified repeat copy or the stored original: having worked in environments that dispense in both ways, I found dispensing 'off [the] labels only' did not give me the opportunity to reference as a second check, the written item on separate prescription, so for me, it was a much more insecure way to dispense."

51. Mr Vester noted that Tegretol and Trental 400mg tablets were infrequently or rarely dispensed medicines. He also stated that there was no reference in the SOPs to an alert system to highlight rarely dispensed medicines, which many pharmacies have in place, and he considered this to be a mild departure from accepted standards. Mr Vester advised that ultimately, the pharmacy's SOPs were "barely adequate".

52. I accept Mr Vester's advice. I am concerned that the pharmacy's SOPs were "barely adequate", and that the pharmacy's practice of dispensing repeat medicines off the label was inconsistent with the requirement in the pharmacy's SOPs to check medicines against the prescription. I am also critical that there was no alert system for rarely dispensed medications. I acknowledge that the pharmacy has since rectified these issues.

Appointment of Mr C as charge pharmacist

53. Mr C was an intern pharmacist at the pharmacy from 2015. He obtained his pharmacist registration and was appointed as a sole charge pharmacist.

54. Mr C told HDC that prior to becoming a registered pharmacist, he did not conduct the final check of a prescription, and the process was somewhat new to him. There is no evidence that Mr C was provided training for his appointment as the sole charge pharmacist.

55. The error occurred when Mr C had been a registered pharmacist for only a few months. Mr Vester advised:

> "[T]he practice of a newly qualified pharmacist becoming the charge pharmacist as soon as they qualify … is not unique. However … such a situation would not be seen as wise or something to encourage for both the patients' and pharmacist's wellbeing … [T]he change from intern to Pharmacist is a challenging time for all interns [and] as an employer I would be aware of that choosing not to expose them to charge pharmacist status in that time."

56. I accept this advice. It may be an accepted practice to appoint a newly qualified pharmacist as the sole charge pharmacist, but it is apparent from Mr C's statement that he was still becoming familiar with the new responsibility. I am concerned that Mr C was appointed as the sole charge pharmacist immediately after he qualified. In my opinion, Mr C should have received more training and support in his role as the sole charge pharmacist, and I am critical that this did not occur.

Conclusion

57. I am critical that at the time of the incident:

a) As a newly registered pharmacist, Mr C was appointed as the sole charge pharmacist without sufficient training and support;

b) The practice of dispensing repeat medicines off the label was inconsistent with the pharmacy's SOPs; and

c) There was no alert system for rarely dispensed medications.

58. I recognise that the dispensing error was in part due to the individual mistakes by Mr C and Ms D, and I have commented on this below. Nevertheless, in my view, several systemic issues at the pharmacy contributed to the dispensing error, and accordingly I find that the pharmacy breached Right 4(1) of the Code of Health and Disability Services Consumers' Rights (the Code).[6]

Opinion: Mr C

Dispensing error — adverse comment

59. On 19 September 2018, Mr C was the pharmacist who incorrectly dispensed Tegretol instead of Trental to Mr A. Ms D was the technician who incorrectly selected Tegretol instead of Trental and put the incorrect label on the Tegretol packaging. Mr C was responsible for the final check before the medication was given to Mr A. However, Mr C did not notice the error. Mr C told HDC that it was quite busy on the day, and he had to

[6] Right 4(1) states: "Every consumer has the right to have services provided with reasonable care and skill."

speed up his checking procedure. It also appears that Mr C did not discuss the medication with Mr A when it was handed over.

60. Mr C acknowledged that he failed to deliver care to Mr A as per the Pharmacy Competency Standards. Mr C accepted his error and apologised for his mistake.

61. The pharmacy's SOP on repeat prescriptions states that when a repeat prescription has been confirmed and dispensed, the prescription should be handed to the patient with appropriate questions and/or advice, such as reasons why it is important to keep taking the medicine. The Pharmacy Competency Standards also state that pharmacists should monitor the dispensing process for potential errors.

62. Mr Vester advised: "[Mr C] stated 'I decided to increase the speed of my checking procedure' which I … would not consider a prudent answer to maintaining accuracy when under pressure."

63. Mr Vester stated:

> "[A]s the person holding the responsibility for checking that the prescription item is correctly dispensed, it falls upon that person (the Pharmacist) to take steps to make sure that regardless of time constraints distractions and other responsibilities that this check is given their full attention."

64. Mr Vester said that although in this case Ms D picked up the wrong product and labelled it, which set up the pharmacist for an error, this does not excuse Mr C's error in checking the prescription. Mr Vester also said:

> "[T]he correct label was put on the wrong medication in its original box, with the Brand name of the medication on the original box clearly visible. In this case I would have thought this should have been a further alert."

65. I agree with Mr Vester and, as discussed above, I note that other systemic factors contributed to the dispensing error. Nevertheless, Mr C did not follow the pharmacy's SOPs on repeat prescriptions. Further, had Mr C discussed the medication with Mr A when it was handed over, as per the SOP recommendation, the dispensing error may have been picked up at this time.

66. I am concerned that Ms D selected and prepared the medication incorrectly, but, as advised by Mr Vester, Mr C had the final responsibility to check the dispensed prescription. Accordingly, I am critical that Mr C failed to check the medication adequately.

Subsequent actions following dispensing error — no breach

67. Following the incident, Mr C immediately apologised verbally to Mr A and his family, sent a written apology to Mr A, and completed the Incident Notification Form to the Pharmacy Defence Association. Mr C also directed Mr A on how to make a complaint to HDC.

68. Mr Vester advised that Mr C followed the correct procedures and made a "very prompt acknowledgement and apology". I agree that Mr C acted appropriately and promptly following discovery of the dispensing error.

Recommendations

69. I recommend that the pharmacy:

a) Provide a written apology to Mr A. The apology should be sent to HDC, for forwarding to Mr A, within three weeks of the date of this report.

b) Conduct an audit, for the one-month period prior to the date of this report, on the following matters:

i. All errors and near misses in relation to dispensing of medicines, and common themes or patterns found; and

ii. Staff compliance with three of its SOPs.

The results of the audit, and any actions taken by the pharmacy following the audit, are to be reported to HDC within four months of the date of this report.

c) Arrange refresher training for its staff in relation to dispensing repeat medications, and provide HDC with evidence of the training and any learning, within four months of the date of this report.

d) Arrange further training for Mr C on his role as the charge pharmacist, and provide HDC with confirmation of the training and support provided, within four months of the date of this report.

70. I recommend that Mr C attend training as stated above at paragraph 69(c) and (d), and report to HDC on his key learning from the training, within four months of the date of this report.

Follow-up action

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 the New Zealand Pharmacovigilance Centre and 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 Mr Paul Vester:

"I have been asked to provide an independent opinion on case reference C18HDC01943 ([the pharmacy]).

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

I am now Semi Retired doing some locum work. Until November 2017 I was co-owner of Morrinsville Pharmaceutical Services Ltd in Morrinsville which has the only two pharmacies in Morrinsville. I qualified as a pharmacist with a Diploma in Pharmacy from CIT Heretaunga becoming registered as a pharmacist in 1981. I have worked as a pharmacist since qualifying, first as pharmacist for 2 other Pharmacies before buying my own business in 1989, then forming a partnership in 1999 for the business we sold. I have qualified as a preceptor trainer and had 7 interns over the last 10 years. Before selling we employed 23 staff (including 6 fulltime pharmacists). I was a founding member, and one time chairman of the Midland Community Pharmacy group, which developed many new pharmacy services for not only the Midland area but also New Zealand. This included helping set standards, developing reporting templates, and developing Standard operating procedures and policies. I am currently also engaged by the New Zealand Pharmacy Council as one of the pharmacists developing and critiquing the scenarios for the final assessment day for Pharmacy Interns, and as an assessor on those days.

Please advise whether the care provided by [the pharmacy] was reasonable in the circumstances, and why.

<u>The adequacy of dispensing services provided to [Mr A]:</u>

As a pharmacist myself I recognise this is one of those errors that 'make your blood run cold' and you are left wondering how this could ever happen, but mistakes like this do, and probably will always occur (hopefully very, very, rarely).

The source of this whole error is not recognising that the medication being dispensed was incorrect. The fact that the dose form, strength and dose frequency would be the same for both drugs, in most cases, almost certainly made the error easier to miss.

The reasons given by [Mr C] and [Ms D] appear to be:

1) Busyness: Examining the 'Dispensary Time Zone Report' shows that this was not as busy a time as some others on that day and the next. Each item dispensed averaged 1.5 minutes, which from other cases I have commented on, and personal experience, would be a frequent time frame per item in most pharmacies at some periods of the day. Regardless, as the person holding the responsibility for checking

that the prescription item is correctly dispensed, it falls upon that person (the Pharmacist) to take steps to make sure that regardless of time constraints, distractions and other responsibilities that this check is given their full attention. [Mr C] states 'I decided to increase the speed of my checking procedure', which I myself, and I think my peers, would not consider a prudent answer to maintaining accuracy when under pressure. I would consider this a Moderate departure from accepted standards.

2) Not identifying the correct medicine: Several factors made this more problematic in this case.

   a) Infrequently dispensed medicine. Tegretol Tablets 400mg (not CR, that is Controlled release) would, from my experience, be an infrequently dispensed medicine and Trental Tablets 400mg a very rarely dispensed medicine (most Pharmacies would have no patients receiving this medicine). I do not see any reference in the Standard Operating Procedures (SOPs) to an alert system to highlight that 'this medication is rarely dispensed, please use extra caution' (or some such item) which many Pharmacies do have in place (often set up in the dispensing program to generate a warning on screen and/or a separate label generated to alert to this situation). This would be one change that could be made which may help avoid a similar error in the future. I would consider this a mild departure from accepted standards.

   b) Dispensing off labels rather than a 'certified repeat copy' or the stored original: Having worked in environments that dispense in both ways, I found dispensing 'off labels only' did not give me the opportunity to reference as a second check, the written item on a separate prescription, so for me, it was a much more insecure way to dispense. In this case [the pharmacy] Technician has picked the wrong product and labelled it, which although it does 'set up the Pharmacist for an error' does not excuse the error in the Pharmacist's checking. I would view this as a mild departure from accepted standards.

   c) Dispensing in Brand named medicine labelling:

      As suggested by [Mr C] had the medicine label (especially as there was no Certified Repeat Copy to refer to) been in Generic naming (*Pentoxifylline rather than Carbamazepine*) the chances the Technician would have picked the wrong product, and that it would have gone unnoticed at the checking, would have been much reduced. I must comment though that I have seen an error in our own pharmacies where a rare medicine Disopyramide (an antiarrhythmic medication) was dispensed as Dipyridamol (an antiplatelet agent). I also note the problems all Pharmacists have with the Sulphanylurea antidiabetic group of medications, where the different generic names are very similar (and the dose forms the same in some cases), such as Glibenclamide, Gliclazide and Glipizide. So both methods of labelling have their problems, but I have no

doubt, that in this case generic name labelling, may well have prevented the error.

An additional point I noticed, is that the correct label was put on the wrong medication in its original box, with the Brand name of the medication on the original box clearly visible. In this case I would have thought that this should have been a further alert. I would consider this a moderate departure from accepted standards.

So, in summary, in this case the Adequacy of the dispensing service provided to [Mr A] falls significantly short of the standard of care expected by legislation and my peers.

The actions taken by the staff once the dispensary error was identified:

In this case the parameters of:

Timeliness: the error came to light on the 26th of September upon the hospitalisation of [Mr A] and [Mr C] contacted [Mrs B] (the daughter) that same day to apologise and see if [the pharmacy] could do anything to help. The apology letter sent to [Mr A] is dated 28th September. I would consider this a very prompt acknowledgment and apology (especially compared to many other cases I have seen).

Correctness of procedure: The complainant was offered an apology, some steps advised of how [the pharmacy] would approach preventing a repeat of such an error. An offer of compensation for any 'out of pocket costs' made, and advise as to what further steps the complainant could take (eg. contact HDC) if they felt they would like to.

Advising other health professionals concerned including the general practitioner, and the owner of [the pharmacy] was carried out as soon as practically possible.

There was a verbal apology, and also a written apology which included the offer of a face to face meeting between the pharmacist and the patient and carer. As the complainant made it clear they wanted no more contact with [the pharmacy], I do not see what else could be done.

The error was recorded according to adequate SOPs of [the pharmacy].

In summary, I consider the correct procedures were followed in dealing with the complaint.

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

Having reviewed the SOPs in place at the time of the error (all approved July 2018 by the owner [Mr E]), I feel they did contain adequate detail, which if followed should have prevented the error. However, I note that in [the SOP Document] under Dispensing medicines it states 'Check the name, brand, strength and formulation against the prescription, not the label.' So, in all cases of dispensing repeats, under this SOP, they were being dispensed off label and outside the SOP's parameters. In fact, it states further down 'Double check labels against the original prescription', so this was also not

being followed, and had the prescription been present it may well have alerted the Pharmacist and Technician to the error.

Following the error, the changes made in the SOPs with the additional requirements of 'All labels to be generated under Generic name' and 'Generate a Certified Repeat Copy as a record of the prescription'. This can be used for dispensing repeats or if the original is sent for claiming after the first dispensing, do I feel, bring some needed robustness to the dispensing process. Both additions very likely would have helped prevent the error. So, although I think there was enough detail (as previously stated) in the original SOPs I think that my peers would consider them barely adequate.

3) Recommendations for improvement that may help to prevent a similar occurrence in the future.

Many pharmacies include in their SOPs (as I have stated previously) an alert system to highlight that 'this medication is rarely dispensed, please use extra caution'. This is set up in the dispensing program to generate a warning on screen and/or a separate label generated to alert to this situation. The printing of the label is especially helpful when the pharmacist is not entering the prescriptions into the computer. This would be one change, that could be made, which may help avoid a similar error in the future.

There is a mention of 'staffing issues' such as (quoting from the information presented to me) 'an unusually high demand for prescriptions', 'Most competent staff member was leaving and allowed the more inexperienced staff to perform her roles to get used to it.', 'Technician meant to replace her put a lot of pressure on staff by being late to work and constantly having sick leave leading to 1 pharmacist and 1 or 2 technicians 'to take all responsibilities for the week', 'During the day of the 19th of September [the pharmacy] was down a staff member and had tasks (routine) which need to be completed'. From the information I reviewed I could not determine whether this was a short term congregation of events, or a symptom of long term staffing issues. All Pharmacists can sympathise (maybe in many cases, empathise) with this type of situation where added stress from staffing issues makes the concentration on dispensing even more challenging. Regardless in my opinion, this would not excuse the error the complainant is seeking the HDC review of.

The self review and changes being instituted by both [Mr C] and [Ms D] seem to me to be practical and developmental for them both. These changes in their practice should help prevent such an error from reoccurring.

One difference I noted between [Mr C's] and [Ms D's] letters and other information provided is that [Ms D] states [Mr A] *came into* [the pharmacy] for his repeat, whilst [Mr C] only records undertaking to dispense the repeats at a convenient time as he had noted they had not been ordered, or picked up, by [Mr A]. In either event I do not think this explains the error, even though [Mr A's] presence may have caused more urgency?

In reference to [Mrs B's] desired results 'I want [the pharmacy] to publish in plain sight to the public, their code of compliance, code of ethics, how to lodge a complaint and

when dispensing they must show the client the packaging and prescription before they hand over the medication to the client': In my opinion [Mr C's] letter to HDC on the 9th November 2018 competently answers these two main points. What I don't see written (although it may be present in [the pharmacy]?) is, that there should be displayed in [the pharmacy], advice on how a patient can address any complaints about the service they receive. This should mean there is an HDC pamphlet available on display (as well as advice on who the patient can contact in [the pharmacy] to address their concerns).

The changes made to prescriptions being collected in [the pharmacy], as suggested by [Mrs B], are certainly a further step to preventing an error such as the one that occurred here.

Paul Vester
04 January 2018

…

Please note I have been requested to indicate the level of departure from accepted standards, which I find to be a square peg for round hole type of statement, as all of the components I commented on are processes carried out by many pharmacies, and not illegal. I have tried to apply this system in light of the contribution that the process may have contributed to this error, in this case."

The following further expert advice was obtained from Mr Vester:

"**HDC Complaint C18HDC01943**

I have been asked to provide further independent opinion on case reference C18HDC01943 on which I have originally supplied my opinion on 4 January 2019 ([the pharmacy]).

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

1. *The appropriateness of appointing [Mr C] as the charge pharmacist given his experience.*

There are two points I would comment on here. Firstly, the practice of a newly qualified pharmacist becoming the charge pharmacist as soon as they qualify. I do remember two pharmacists I knew, in the years before and then when I qualified 40 years ago, doing just that, so it is not unique. However, in all my years as a pharmacist I feel I confidently speak for most of my peers in stating that 'such a situation would not be seen as wise or something to encourage for both the patients' and pharmacist's wellbeing'.

[Mr C] comments in his reply to [HDC] on 17th July 2019 notes: 'Before registration as a pharmacist, intern pharmacists do not conduct the final check of a prescription and so this process was still somewhat new to me'. Having been the preceptor to many interns I can confirm that the change from 'intern' to 'Pharmacist' is a challenging time for all interns with the staff observing an almost comical change in output of completed prescriptions, as the responsibility change, causes a dramatic challenge in the level of focus required. I would estimate that most interns, if they were asked, would not feel they have achieved 'maturity' as a pharmacist for a good 6 months to a year, and as an employer I would be aware of that choosing not to expose them to charge pharmacist status in that time. Having worked in [the pharmacy] previously to qualifying, although of some benefit, would not in my opinion shorten this period very much.

[…]

Thirdly, I am not sure if 'He ([Mr E]) combined the role of two pharmacists to one sole charge pharmacist' means the staffing reduced from 2 full time pharmacists on site to just one, or if the two were a shared fulltime equivalent. If it was a reduction in staffing of 2 pharmacists required on site to one then it would raise even more concern in then making the sole pharmacist an inexperienced just qualified intern as the sole pharmacist.

2. *Any systematic issues at [the pharmacy].*

It appears in the replies from the staff and owner that significant changes in process and self development have been made, and these would appear to correct the deficiencies I observed in my original opinion. So, I have no more comment on this topic.

Paul Vester
25th August 2019
…"