A Pharmacy

Pharmacist, Mr B

A Report by the

Deputy Health and Disability Commissioner

(Case 13HDC00819)

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Executive summary

1. Mr A has a history of cardiac problems, and has an artificial pacemaker.[1] On 20 December 2012, Mr A, aged 65 years, received a prescription for 60 1mg warfarin tablets, with two repeats, to be taken twice daily. Mr A filled the prescription at a pharmacy. The prescription was handled by locum pharmacist Mr B.

2. The pharmacy uses industry standard operating procedures (SOPs) templates, which are used throughout New Zealand in many pharmacies. The SOPs outline the steps to be taken in handling prescriptions. Mr B had not been orientated to the pharmacy's processes or made aware of the pharmacy's SOPs. However, Mr B was aware of his job description and expectations as stated in his employment contract, including that he comply with all the pharmacy policies and procedures.

3. Prescriptions are dealt with in a three-step process: processing, dispensing and checking. The pharmacy told HDC that these tasks should be shared between staff members to reduce the possibility of a mistake. In this case, Mr B was the only staff member involved in processing, dispensing and checking Mr A's prescription. Mr B should have dispensed 1mg warfarin tablets in accordance with Mr A's prescription. However, Mr B dispensed 5mg warfarin tablets in error, and the label on the tablet bottle read, "Warfarin sod. Tablets 1 mg", in accordance with the prescription.

4. Mr A took the warfarin tablets twice daily as prescribed. On 31 January he was admitted to hospital with severe generalised abdominal pain and constipation. He was coughing up blood and had blood in his urine. His International Normalised Ratio (INR)[2] level was over 10. Mr A spent five days in hospital and was discharged on 4 February 2013.

Findings

5. Mr B failed to ensure that he dispensed the correct dose of warfarin to Mr A. Accordingly, Mr B failed to provide services in accordance with professional standards and breached Right 4(2)[3] of the Code of Health and Disability Services Consumers' Rights (the Code).

6. Adverse comment is made about the pharmacy's orientation processes.

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[1] A medical device that uses electrical impulses, delivered by electrodes contracting the heart muscles, to regulate the beating of the heart.

[2] International normalised ratio (INR) is a ratio used to determine the clotting tendency of the blood. A normal INR level is between 1.0 and 1.5; however, people taking warfarin generally aim for an INR of between 2.0 and 3.0.

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

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Complaint and investigation

7. The Commissioner received a complaint from Mr A about the services provided to him by pharmacist Mr B, at a pharmacy. The following issues were identified for investigation:

- *Whether the pharmacy provided an appropriate standard of care to Mr A in December 2012.*
- *Whether pharmacist Mr B provided an appropriate standard of care to Mr A in December 2012.*

8. An investigation was commenced on 21 August 2013. This report is the opinion of Deputy Commissioner Rose Wall, and is made in accordance with the power delegated to her by the Commissioner.

9. The parties directly involved in the investigation were:

Mr A	Consumer/complainant
The pharmacy	Provider
Mr B	Pharmacist

10. Information was also reviewed from the following parties:

The District Health Board	
Ms C	Pharmacist and manager of the pharmacy
Dr D	General practitioner

11. Independent expert advice was obtained from a pharmacist, Ms Sharynne Fordyce, and is attached as **Appendix A**.

Information gathered during investigation

Background

12. Mr A has a history of cardiac problems, and has an artificial pacemaker. He had been taking warfarin[4] since September 2008 and, at the time of these events, he took 2mg a day.

13. On 20 December 2012, when he was 65 years old, Mr A received a prescription for 60 1mg warfarin tablets,[5] with two repeats, to be taken twice daily (the prescription is attached as **Appendix B**). Mr A took the prescription to the pharmacy where it was handled by pharmacist Mr B.

[4] Warfarin is an anticoagulant normally used to prevent blood clots. It is a high-risk drug with a narrow therapeutic index (amount of therapeutic agent required to cause the desired therapeutic effect compared with the amount that causes death or toxicity).
[5] The prescription also included six other medications.

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14. Mr A received his dispensed medications on the same day and then took the warfarin tablets twice daily as prescribed.

15. On 31 January 2013 Mr A was in agonising pain, and attended his medical centre, where Mr A's GP, Dr D, assessed Mr A immediately and arranged for Mr A's urgent admission to hospital.

Admission to hospital

16. Mr A told HDC that on admission to hospital he was coughing up blood and had blood in his urine. Clinical notes from the hospital state "no nausea/vomiting", and that Mr A "[felt] like he need[ed] to pass a motion but just [got] blood and water". On examination a small amount of blood and mucus was found in the bowel, and blood tests showed that his International Normalised Ratio (INR) level was over 10. A normal INR level is between 1.0 and 1.5; however, people taking warfarin generally aim for an INR of between 2.0 and 3.0. The increased INR level was noted to be secondary to inadvertent warfarin overdose.

17. Mr A was taken off warfarin and administered vitamin K to assist coagulation. He was diagnosed with diverticulitis[6] and colonic polyps,[7] not associated with the taking of excess warfarin. However, a consultant haematologist stated: "I think [Mr A] was very lucky not [to] have any haemorrhage related to his Warfarin overdose and all he really suffered was some minor bleeding." Mr A was discharged from hospital on 4 February 2013.

Reporting of error to the pharmacy

18. On 4 February 2013, Mr A visited the pharmacy. He advised the pharmacist on duty that he had been admitted to hospital on 31 January 2013 with excessive bleeding as a result of a warfarin dispensing error. Subsequently, an investigation into the incident was conducted. The investigation determined that Mr B was the pharmacist who made the dispensing error.

Mr B

19. Mr B graduated with a degree in pharmacy and was first registered in New Zealand in mid-2010. He was employed by the pharmacy as a locum pharmacist under an individual employment agreement. The pharmacy advised HDC that Mr B was employed via an employment agency.

20. Mr B advised HDC that he was not orientated to the pharmacy's processes or made aware of any standard operating procedures (SOPs) on commencement of employment with the pharmacy. However, Mr B advised that he was "aware of the objectives, job descriptions and expectations" as they were stated in his employment contract. Mr B's employment contract stated:

> "The Employee shall: … (v) Comply with all policies and procedures … implemented by the Employer from time to time."

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[6] Diverticulosis is a common digestive disease that involves the formation of pouches (diverticula) within the bowel wall. Diverticulitis results when diverticula become inflamed.

[7] A growth on the surface of the colon.

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21. Appendix A of the employment contract titled "Job Description" stated:

> "Dispensing: Compounding, checking labelling and dispensing prescription to customers efficiently and within company procedures."

22. Mr B further stated that all pharmacists are required to adhere to their employer's SOPs and he is aware of the processes that pharmacists must undertake in "dispensing and checking prescriptions".

Processing, dispensing and checking

23. Prescriptions are dealt with in a three-step process: processing, dispensing and checking. In brief, these steps should include the following:[8]

    a. Processing includes collecting all relevant information from the prescription and entering this into the computer system. The consumer's previous history should be checked to confirm any possible dose changes or allergies, and labels are printed.

    b. Dispensing includes counting and pouring the correct drugs and dose into the appropriate containers and attaching labels.

    c. Checking refers to checking patient details, labels, and medication. A physical check should also be done to ascertain the correct drugs and doses are in the containers before handing out to the consumer.

24. Mr B does not recall handling Mr A's prescription. However, Mr B confirmed that his signature appears in eight places on the prescription. He stated that two of his signatures indicate that he processed the prescription through the computer, and the other six indicate that he checked each item against the prescription. Mr B stated: "As far as I am aware of, no other signatures are present on the prescription", other than that of the prescribing doctor.

25. Mr B should have dispensed 1mg warfarin tablets in accordance with Mr A's prescription. However, Mr B dispensed 5mg warfarin tablets in error, but the label he printed for the tablet bottle read, "Warfarin sod. Tablets 1 mg", in accordance with the prescription. The 5mg tablets dispensed to Mr A were bright pink with a "5" marked on them, while 1mg tablets are brown and have a "1" marked on them. Mr A told HDC that he "did not take any notice of the difference in the colour of the tablets" because he expected that the pharmacy had "done their job correctly".

26. Mr B told HDC that on 20 December he had severe hay fever, which had not been alleviated by taking medication, and that this may have impaired his judgement in handling Mr A's prescription.

[8] According to pharmacy expert Ms Sharon Fordyce.

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The pharmacy

Staffing

27. From 12.00pm on 20 December 2012 two pharmacists were working at the pharmacy, including Mr B, as well as two technicians and a third-year pharmacy student. The pharmacy advised that between 2.00pm and 4.00pm the pharmacy processed 80 prescriptions. This was a standard day in the dispensary, and this was not the busiest part of the day.

Standard operating procedures

28. The director of the pharmacy told HDC that, both at the time of this incident and currently, the pharmacy uses industry standard SOP templates, which are used throughout New Zealand in many pharmacies. With regard to dispensing prescriptions, the relevant SOP states:

> "Purpose: To describe the process of dispensing in the pharmacy to ensure that prescriptions are dispensed accurately and in accordance with the legislative and ethical requirements.
>
> …
>
> Procedure
>
> - Check all required details are on the presented prescription i.e name, address, age …
> - Check with dispensary staff to ensure that prescription can be dispensed satisfactorily and without delay …
>
> …
>
> - Enter all required prescription details into the dispensary computer dispensing software …
>
> Labelling
>
> …
>
> - Double check labels against the original prescription, before attaching them to the container.
>
> …
>
> Checking procedures
>
> During dispensing process
>
> - Check you are using the right medicine brand as prescribed, the right strength and the right form.
> - Check medicine dose, frequency, interactions and contraindications, to ensure the medicine is being given appropriately.
>
> …
>
> Final check
>
> - Check the dispensed medicine against the prescription for correct name of contents formulation, strength and quantity dispensed …
> - Dispenser and checker must be identified on all prescriptions …

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> - Check each dispensing step and again just prior to dispensing …
> - When all items on a prescription have been completed, make sure that all items bagged for the patient are checked off against their prescription …"

29. The director of the pharmacy told HDC that Mr B was the only person involved in processing, dispensing and checking Mr A's prescription, and that this is "not normal practice". She stated:

> "These tasks should have been shared with other staff members to reduce the possibility of a mistake."

30. The director also advised that "[a]ll staff are trained to follow the SOPs, including locum pharmacists …"

31. In contrast to The director, the pharmacy manager Ms C told HDC:

> "The [SOPs] of [the pharmacy] were not shown to any of the Locum Pharmacists who worked at [the pharmacy] as they would not need to see the SOPs of [the pharmacy] to know how to do their job as a pharmacist as this is related to their training via their relevant degree/diploma and internship/apprenticeship.
>
> …
>
> Each pharmacist will have their own individual way of checking a script item, which may differ to other pharmacists. Checking a prescription is a skill that each pharmacist develops.
>
> …
>
> A locum pharmacist is considered an independent contractor who is fully qualified and should be able to step into the role of pharmacist in a busy pharmacy without being supervised …"

Subsequent events

Actions in response to dispensing error

32. The pharmacy undertook an internal investigation into this incident and advised that as a result of the investigation, it is now standard practice to include the colour and strength of warfarin tablets on all warfarin labels. The pharmacist is also required to check that the consumer has a red warfarin booklet in which to record his or her INR results. the pharmacy has also advised that a Pharmacy Guild "check strength" sticker is now in place on the shelf where warfarin is kept, to prompt the staff member responsible for dispensing to "take extra care" when checking that the correct strength of medication has been dispensed.

33. Mr B advised HDC that he is no longer practising and does not hold a current annual practising certificate with the Pharmacy Council of New Zealand. However, he stated that he has "taken this matter very seriously and [has] taken considerable time to review [his] dispensing and checking processes".

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34. The pharmacy and Mr B advised that following this incident they both sent written letters to Mr A apologising for the error in dispensing his prescription. However, in response to the provisional opinion, Mr A advised HDC that he never received a letter of apology from Mr B, and that he did not consider the pharmacy's letter to be a genuine apology.

Relevant professional standards

Pharmacy Council of New Zealand — Safe Effective Pharmacy Practice, Code of Ethics 2011

35. "*Principles:*

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

…

5.1 Be accountable for practising safely and maintain and demonstrate professional competence relative to your sphere of activity and scope of practice."

Pharmacy Council of New Zealand — Safe and Effective Pharmacy Practice, Competence Standards for the Pharmacy Profession

36. "**Element 6.6 Fill prescriptions**

…

6.6.2 Maintains a logical, safe and disciplined dispensing procedure

Examples of Evidence:
Selects correct product, dose form & quantity for each prescribed medicine …"

Opinion: Mr B — Breach

37. Mr B's signature is the only signature on Mr A's prescription, other than the prescribing provider. Mr B acknowledged that two of his signatures indicate that he processed the prescription through the computer, and six of the signatures indicate that he undertook the final check of Mr A's prescription. Based on this information, I consider it more likely than not that Mr B was the only pharmacist involved with the processing, dispensing, and checking of Mr A's prescription. Mr B erred in dispensing Mr A's warfarin, in that he dispensed 5mg warfarin tablets instead of the prescribed 1mg tablets.

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38. As a registered pharmacist, Mr B is responsible for ensuring his adherence to professional standards. The Pharmacy Council of New Zealand (PCNZ) competence standards, outlined above, requires that registered pharmacists ensure that they "maintain … a logical, safe and disciplined dispensing procedure" including selecting the correct dose of the prescribed medicine. The PCNZ code of ethics requires registered pharmacists to be accountable for practising safety and for "maintaining and demonstrating professional competence".

39. Mr B also had an obligation under his employment contract to "[c]omply with all policies and procedures" of the pharmacy. Mr B stated that he was aware of the "objectives, job descriptions and expectations" as they were stated in his employment contract with regard to the SOPs, that all pharmacists are required to adhere to SOPs, and that he is aware of the processes that pharmacists must undertake in "dispensing and checking prescriptions".

40. The pharmacy advised that on 20 December there were two pharmacists on duty, as well as three additional staff. The pharmacy further advised that it was not a particularly busy day in the dispensary. My pharmacy expert, Ms Sharynne Fordyce, advised that the staffing levels at the pharmacy were adequate. In these circumstances, Mr B should have been able to take appropriate steps, with the support of other staff working in the pharmacy, to maintain a "logical, safe and disciplined dispensing procedure". I do not accept that Mr B's "severe hayfever", which he advised may have impaired his judgement, excuses his actions.

41. Mr B failed to ensure that he dispensed the correct dose of warfarin to Mr A. Accordingly, I consider that Mr B failed to provide Mr A with services in accordance with professional standards and breached Right 4(2) of the Code.

Opinion: The pharmacy — Adverse comment

42. I find it more likely than not that the pharmacy did not provide Mr B with adequate orientation or ensure that he was aware of the relevant SOPs on commencement of his employment with the pharmacy. The pharmacy's manager, Ms C, stated that as a locum pharmacist, Mr B should have been able to "step into the role of pharmacist in a busy pharmacy" without being given orientation. My expert advisor, Ms Fordyce, advised that the pharmacy's SOPs were an industry standard, so Mr B would not have needed to read them before being assumed safe to dispense in the pharmacy.

43. I have carefully considered all the information gathered in the course of my investigation, including Ms Fordyce's advice. In my view, a pharmacy has a responsibility to ensure that all pharmacists working in the pharmacy are appropriately trained and experienced, and aware of the pharmacy's expectations, including the SOPs. I note that the public rely on the pharmacy to protect them, and have no way of ascertaining whether a pharmacist is a locum.

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44. I consider that, as locum pharmacists frequently work at different locations under different systems, it is important to ensure that they are given an appropriate orientation to each pharmacy's processes, especially in light of Ms C's statement that individual pharmacists will have "their own individual way of checking a script item, which may differ to other pharmacists". I consider it unwise for pharmacies to assume that locums supplied by agencies are appropriately trained and experienced. In this case, the pharmacy was unaware of Mr B's relative lack of experience.

45. Therefore, in my view, the SOPs in place in December 2012 should have been brought to Mr B's attention, which the pharmacy failed to do. It also appears that it was the pharmacy's expectation that more than one person would be involved in the processing, dispensing and checking of prescriptions, although there is no evidence that the pharmacy advised Mr B of its expectation in this regard. Although I do not consider that the pharmacy breached the Code, in my view its actions contributed to the overall unsatisfactory care provided to Mr A in this case.

Recommendations

46. I recommend that the pharmacy:

- Update its Standard Operating Procedures (SOPs) and/or other relevant policies to reflect its expectation that, where possible, more than one person must be involved in dispensing, processing and checking prescriptions, and provide a copy of the updated SOP and/or policies to HDC within three months of the date of this report.
- Plan and implement an appropriate training programme for all staff, and provide evidence of an orientation programme to HDC within three months of the date of this report.

47. I recommend that Mr B:

- Undertake to complete training, through the New Zealand College of Pharmacists, regarding accurate dispensing, processing and checking processes, before he returns to work as a registered pharmacist.
- Provide confirmation to HDC that this training has been completed, before returning to work as a registered pharmacist.

Follow-up actions

48. • 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 College of Pharmacists, and they will be advised of Mr B's name.

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- A copy of this report with details identifying the parties removed, except the expert who advised on this case, will be sent to the District Health Board, and it will be advised of Mr B's name.

- 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.

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Appendix A — Independent pharmacist advice to Commissioner

The following expert advice was obtained from Ms Sharynne Fordyce:

"After reading the material provided I consider the care provided to [Mr A] by [the pharmacy] was reasonable in the circumstances, but that the care provided by [Mr B] was not. [Mr B] did not fulfil his ethical and professional responsibilities of providing a service that ensures no harm is done and that the customer receives the best provision of service available.

As commented on by [Ms C], [Mr B], as a registered pharmacist, would have been aware of the dispensing and checking procedures required for the safe dispensing of prescriptions. As [the pharmacy's] standard operating procedures (SOPs) were an industry standard, he would not have needed to read them before being assumed safe to dispense in [the pharmacy]. Unfortunately [the pharmacy] was unaware of [Mr B's] relative lack of experience, which, if known, could have prompted the need for [Mr B] to read [the pharmacy's] SOPs. The employment agencies concerned have been spoken with regarding this lack of information, as it is they who are advertising these pharmacists as being fit for purpose, and the agencies have a professional responsibility to their clients to supply competent locum pharmacists.

Ultimately, however, it is [Mr B] who is contracting himself out as a registered pharmacist, with all the implied skills and knowledge that go with this professional qualification. [The pharmacy] was not overly busy, there were adequate staff levels, but [Mr B] admits to suffering bad hayfever on the day which may have blurred his accuracy. … [Text deleted as not relevant to decision.] I think it was [Mr B] who did not provide an appropriate standard of care, and would view it with severe disapproval due to the nature of the tablets being dispensed, and the potential for harm. I would however question why [Mr A] was able to obtain a 3 month prescription for warfarin 1mg from his doctors on January 29th and have it dispensed at [the pharmacy] without either the doctor or pharmacy commenting on the rapid use of the December prescription dispensed 6 weeks earlier. It also appears unusual that [Mr A] was admitted to hospital only two days after seeing his doctor, January 31, who obviously noticed nothing untoward.

I am aware that in many parts of New Zealand it is very difficult to obtain a locum pharmacist, particularly over the summer months, and that the need for a holiday may override more scrupulous investigation into the suitability of any available locum. [The pharmacy] had used a reputable employment service so should have been safe to assume that [Mr B] would be suitable. I have outlined above what I think to have been mitigating factors, not forgetting the element of human error that is always present. However I do think it should be mandatory for all locums to belong to the Pharmacist Defence Association particularly for situations such as these. Maybe [the director's] letter to [Mr A] could have been a bit more conciliatory; 'inconvenience' understates [Mr A's] experience somewhat, but her improvements after the error sound excellent.

Yours sincerely

Sharynne Fordyce"

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Subsequent independent clinical advice to the Commissioner

The following further expert advice was obtained from Ms Fordyce, dated 12 March 2014:

"1) By referring to the SOPs of [the pharmacy] as 'industry standard' I meant that the dispensing SOP did not appear to differ significantly from the Pharmacy Council Competence Standard 6, which deals with dispensing medicines and the inherent processes involved, with which all pharmacists are required to be familiar, and demonstrate competency in, to facilitate yearly registration. Hence this SOP takes a fairly standard form across pharmacy as an industry. Also, if I remember correctly, [the pharmacy] was a member of [a pharmacy industry] marketing group, and it would appear, judging by the copyright sign at the bottom of each page, that this SOP was based on a template that has been provided by [the marketing group] since at least 2005. Therefore [the pharmacy's] dispensing SOP contained no requirements other than what [Mr B] was required to provide legally in any pharmacy.

2) Having more than one person involved in 'Processing, dispensing and checking' [Mr A's] prescription is more of a safety recommendation than a legal requirement. Having more than one person involved in the process increases the chance of any mistakes being picked up. As [Mr B] was not very experienced in retail pharmacy, and not feeling well, it would have provided another check to have another person involved in the process, and would have been advisable. Local knowledge from regular staff regarding customers and their habits can also be helpful.

Nowhere in [the pharmacy's] dispensing SOP does it specifically state that this process in this pharmacy must involve more than one person, although the reference to the dispenser/checker stamp implies that there *may* be more than one person involved.

3) Processing involves collecting all the relevant patient and prescription details e.g. correct address, all legal requirements, and entering these into the computer. As the details are entered the patient's previous history is checked to confirm any possible dose changes, allergies, date of last dispensing etc. This creates an accurate and legal record and dispensing label.

Dispensing is done reading from the prescription, not the label, and involves counting/pouring/compounding the items needed, putting in appropriate containers — if applicable — checking expiry dates then checking and attaching the appropriate labels.

Checking involves ensuring correct patient, address, age, drug, strength, quantities, brand, and container. The label is then checked for accuracy, that it is easily understood, with the correct drug, dose, quantity, person, address. The whole process must be done with reference to the original script, not off the label. Then a physical check to ascertain the correct drug is in the container before handing out to the customer. The first two processes can be carried out by a technician or pharmacist, but the final check must be carried out by a pharmacist.

This is just a brief overview of the processes involved but the Competence Standard 6 on Dispensing is available to view on the Pharmacy Council's website."

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Appendix B — Mr A's prescription

Item Count:
Subsidy Card:

Rx 20 Dec 2012

Dispense stat list medicines once only unless endorsed close control

Warfarin Sodium 1mg Tab

Sig: Take 2 tablets as directed

Mitte: 60 tabs 2 Repeats

War21
9225969/0
20Dec12
X4 s

CC Initial:

Avoid some medicines - ask pharmacist

180 Warfarin sod. Tablets 1mg (MAR)

Take TWO tablets daily as directed

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