Pharmacist, Ms B

Pharmacy

A Report by the

Health and Disability Commissioner

(Case 15HDC01710)

Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

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Executive summary

1. Ms A, aged 48 years at the time of events, previously had a life threatening deep vein thrombosis[1] and bilateral pulmonary embolism.[2] Ms A was travelling overseas and required medication to lower the risk of blood clots forming whilst travelling by aeroplane. Therefore, on 24 September 2015, general practitioner (GP) Dr E prescribed Ms A four enoxaparin sodium 4000IU[3] injections.

2. On 25 September 2015, Ms A had the prescription filled at a pharmacy. Ms B was a pharmacist on duty that day. Ms B mistakenly dispensed epoetin alfa[4] 4000IU (trade name Eprex) in place of enoxaparin sodium 4000IU.

3. On 27 September 2015, Ms A injected herself with two of the Eprex injections and travelled overseas. Ms A advised HDC that the day after she arrived, she felt "breathless, felt weak, dizzy and had flu like symptoms as well as a headache". Ms A said that the backs of her legs were also covered in bruises. On 29 September 2015, Ms A was admitted to hospital.

4. On 12 October 2015, the Pharmacy manager, Ms C, discovered the error. On 13 October 2015, Ms C discussed the error with Ms B. Once the error was confirmed, Ms C attempted to contact Ms A to advise her of the error, but found it difficult to locate her.

5. On 14 October 2015, Ms C obtained a contact number for Ms A and was able to inform her of the error. Also on 14 October 2015, Ms C completed an incident reporting form for the error that occurred on 25 September 2015. On 15 October 2015, via email, Ms C apologised to Ms A for the error.

Commissioner's findings

6. By failing to select the correct medication, and failing to check the selected medication adequately against the prescription on 25 September 2015, Ms B failed to provide Ms A with services in accordance with professional standards and, as such, breached Right 4(2)[5] of the Code of Health and Disability Services Consumers' Rights (the Code).

7. Ms B's error in dispensing the wrong medication to Ms A was an individual clinical error, and cannot be attributed to the pharmacy. Accordingly, the pharmacy did not breach the Code.

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[1] The formation of a blood clot within a deep vein, predominantly in the legs.
[2] A pulmonary embolism is a blood clot that occurs in the lungs; it can be a complication of deep vein thrombosis.
[3] IU stands for "international unit".
[4] Epoetin alfa is indicated for the treatment of severe anaemia of renal origin accompanied by clinical symptoms in patients with renal insufficiency not yet undergoing dialysis. The New Zealand Medsafe data sheet for epoetin alfa states that it has been linked to an increased incidence of thrombotic vascular events (blood clots).
[5] Right 4(2) states: "Every consumer has the right to have services provided that comply with legal, professional, ethical, and other relevant standards."

Complaint and investigation

8. The Commissioner received a complaint from Ms A about the services provided by the pharmacy. The following issues were identified for investigation:

- *Whether the pharmacy provided Ms A with an appropriate standard of care in September 2015 and October 2015.*
- *Whether pharmacist Ms B provided Ms A with an appropriate standard of care in September 2015 and October 2015.*

9. An investigation was commenced on 29 January 2016.

10. The parties directly involved in the investigation were:

Ms A	Consumer/complainant
The pharmacy	Provider/pharmacy
Ms B	Provider/pharmacist

11. Information was also obtained from:

Ms C	Pharmacy manager/pharmacist
Mr D	Pharmacy director/pharmacist
Dr E	General practitioner

Information gathered during investigation

Ms A

12. Ms A, aged 48 years at the time of events, previously had a life threatening deep vein thrombosis[6] and bilateral pulmonary embolism.[7] On 24 September 2015, Ms A consulted with general practitioner (GP) Dr E. Ms A had scheduled return flights overseas and was concerned about blood clots forming during her flights.

Prescription

13. Dr E prescribed Ms A four enoxaparin sodium 4000IU[8] injections (four dosages) to reduce Ms A's risk of blood clots forming during her flights. Enoxaparin sodium is indicated for the prevention of blood clot formation. Dr E advised Ms A that she would need to inject herself with two dosages prior to each flight. The prescription for enoxaparin sodium read: "Rx: Enoxaparin Sodium 40mg/0.4mL Inj[ection] (equiv. 4,000 IU (prefilled syringe))".

14. The New Zealand Medsafe data sheet for enoxaparin sodium states:

[6] The formation of a blood clot within a deep vein, predominantly in the legs.
[7] A pulmonary embolism is a blood clot that occurs in the lungs.
[8] International Unit of measurement. This is equivalent to 40mg.

> "For the prevention of blood clots, the following are the usual doses, which are administered by injection under the skin once a day: … high risk patients: 40mg."

The Pharmacy

15. The pharmacy manager is pharmacist Ms C. Ms C provided information from the Pharmacy in relation to these events.

Arrival at the Pharmacy

16. On 25 September 2015, Ms A visited the Pharmacy to have the enoxaparin sodium dispensed. At 1.27pm the prescription was processed on the computer. Ms C told HDC that only one pharmacist was on duty at this time, as the second pharmacist was at lunch.

17. Ms B was the pharmacist responsible for processing and dispensing Ms A's prescription at the Pharmacy. Ms B has been a qualified pharmacist in New Zealand since 2006.

Dispensing

18. Ms B accepts that she mistakenly dispensed epoetin alfa[9] 4000IU/0.4ml (brand name Eprex) instead of enoxaparin sodium 4000IU/0.4ml. The label generated by Ms B listed: "1.6ml Eprex 4000IU/0.4ml."

19. The Director of the Pharmacy, Mr D, told HDC: "There are physical differences between the two medicines and their packaging … Eprex injections are stored in the fridge and Clexane[10] injections are stored on the shelf."

20. Ms B told HDC that she cannot recall any details of the dispensing except for the fact that it was an extremely busy day in the Pharmacy.

Complaint

21. On 27 September 2015, Ms A injected herself with two of the Eprex injections and travelled overseas. Ms A advised HDC that the day after she arrived she felt "breathless, felt weak, dizzy and had flu like symptoms as well as a headache". She said that the backs of her legs were also covered in bruises. Ms A was admitted to hospital.

Standard Operating Procedures

22. At the time of these events, the Standard Operating Procedure (SOP) in place at the Pharmacy for "Receiving, Dispensing and Recording Prescriptions" stated under the heading "Receiving Prescriptions":

> "Actively set appropriate expectations and encourage patients to return and collect prescriptions during busy periods."

[9] Epoetin alfa is indicated for the treatment of severe anaemia of renal origin accompanied by clinical symptoms in patients with renal insufficiency not yet undergoing dialysis. The New Zealand Medsafe data sheet for epoetin alfa states that it has been linked to an increased incidence of thrombotic vascular events (blood clots).
[10] Trade name for enoxaparin sodium.

23. The SOP also stated, under the heading "Dispensing Prescriptions":

> "Enter medicine details into the computer and generate the required labels … Before printing label check the form of drug, strength, quantity and directions are grammatically correct. Visually check the labels produced against the prescription before signing and passing the prescription for dispensing.
>
> …
>
> Select the appropriate medicine, dose and form and container.
>
> ...
>
> Follow the Dispensing Check below."

24. The SOP also stated, under the heading "Dispensing Check":

> "Check the label and dispensed medicine against the original prescription and stock supply used to dispense the medicine.
>
> …
>
> At every stage compare the original script or CRC to what is on the label and the original container/stock bottle.
>
> …
>
> When self-checking, separate the 'physical' and 'mental' activities by another task e.g. by dispensing or typing another prescription."

25. The SOP also included a process for incident reporting under the heading "Near Misses and Incidents":

> "Keep a log of near misses and errors picked up during the dispensing check. Fill out appropriate forms and file in the folder provided. Note any contributing factors that may have [led] to the near miss or error. Discuss the near misses with dispensary staff and try to eliminate contributing factors leading to the errors. Provide staff training and go over the checking procedures if necessary. Staff need to be highly focussed on avoiding mistakes. Communicate and work as a team with a 'no blame culture'."

Identification of the error by the Pharmacy

26. Ms C told HDC:

> "The dispensing error was discovered by me on Monday 12th October 2015 while I was correcting errors for batch claim period 24th to 30th September 2015. I noticed a wrong medicine was chosen for the Special Authority number. When I checked online, it related to Enoxaparin Injections. I realized the prescription had been processed as Epoetin Injections."

27. Ms C told HDC that on 12 October 2015, she contacted Ms B to see if she could recall the details of the dispensing. Ms C stated:

> "On Tuesday 13th October at 9.30am, [Ms B] came to the Pharmacy to review the prescription. [Ms B] believed that she had most likely dispensed Epoetin 4000iu and not the prescribed Enoxaparin 4000iu injections."

Action taken by the Pharmacy

28. Ms C said that at 9.40am on 13 October 2015, she attempted to call Ms A on her mobile number; however, her calls were unanswered.

29. Ms C documented on 13 October 2015:

> "I rang the medical centre but [Dr E] was not working until Wednesday. Personally visited the [medical centre] and spoke to [a nurse] and asked if she had any further contacts for [Ms A], e.g. next of kin, etc. She told me that [Ms A] was away on holiday. They had no other contact details for her apart from the phone number that I tried ringing."

30. Ms C advised HDC that on 14 October 2015 she was able to make contact with Dr E, who confirmed that the practice had no further contact details, but informed Ms C of the company Ms A worked for. Ms C said that she was able to obtain a cell phone number for Ms A from the payroll department at the company.

31. Ms C told HDC that at 9pm on 14 October 2015, she called Ms A to inform her of the error. Ms C said that she asked Ms A whether she was okay and if she had used any of the injections. Ms A told Ms C that she had used two of the injections prior to her flight.

32. On 15 October 2015, Ms C emailed Ms A with the details of the medication that was prescribed by Dr E, and the medication that was incorrectly dispensed by the Pharmacy. In the email, Ms C also apologised to Ms A for the error. Ms C completed an incident reporting form and informed Medsafe of the error.

33. Ms A told HDC that the Pharmacy has reimbursed her for all medical costs she accrued overseas after she injected the incorrect medication.

Further comment from Ms B

34. Ms B told HDC that when she started working at the Pharmacy in 2008, Ms C and Mr D both stressed the importance of familiarising herself with the SOPs and observing the dispensing process before participating. Ms B said that the Pharmacy has SOPs that cover the entire dispensing process, and stated that she had reviewed them in the month preceding the error.

35. Ms B informed HDC of the changes she has made to her own practice following the error:

> "After typing a prescription through the computer I rip off the labels and place them alongside the prescription and double check that the medicines I have typed through are exactly those written on the prescription, that the correct strength, quantity and instructions have been used. I also check the patient's details and Doctor's details are correct at this point. After dispensing the prescription I then

> conduct my final check as per usual and take time to make sure I am not missing any steps. I would normally leave checking the labels as part of my final checking process but doing it as soon as typing them through helps mistakes to be identified immediately and lessens the likelihood of an error following through. I then check them again as part of my final checking process still."

36. Ms B also told HDC that it can be difficult in a pharmacy, as the number of customers and prescriptions can fluctuate throughout the day. She said that having busy periods during the day can add pressure, but that part of a pharmacist's job is to deal with that pressure and stay focused regardless of how many prescriptions, patient enquiries and other interruptions occur.

Further comment and changes from the Pharmacy

37. Mr D provided HDC with the Pharmacy's staff orientation checklist, which outlines the SOPs that must be reviewed and ticked off by new staff members. The Pharmacy was unable to provide a copy of the staff orientation checklist signed by Ms B.

38. Ms C told HDC that the Pharmacy has made changes to its dispensing procedures and is providing additional training sessions with staff to ensure that a similar mistake does not occur in the future.

Changes made to SOP

39. Ms C provided HDC with a copy of the updated SOP. The updated SOP (changes in italics) requires that, during the dispensing check stage:

> "*A second check is done at this stage and prescription initialled. The second person checking will follow the above procedure. In the rare occasions of self-checking*, separate the "physical" and "mental" activities by another task e.g. by dispensing or typing another prescription."

Response to provisional opinion

40. The pharmacy and Ms B were provided with an opportunity to respond to the provisional opinion. They accepted the findings of the provisional opinion and had no further information to add.

41. Ms A was provided with an opportunity to respond to the "information gathered" section of the provisional opinion. Ms A had no further information to add.

Opinion: Ms B — Breach

42. Ms B was the pharmacist responsible for dispensing the wrong medication to Ms A. Ms B dispensed epoetin alfa to Ms A instead of the prescribed enoxaparin sodium.

43. As a registered pharmacist, Ms B is responsible for ensuring her adherence to professional standards. The Pharmacy Council of New Zealand's Competence Standards for the Pharmacy Profession (2015) states:

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

44. The Pharmacy Council of New Zealand publication "Safe Effective Pharmacy Practice" (2011) provides in its "Code of Ethics" that the pharmacist:

> "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."

45. The SOPs required Ms B to select the correct medication in accordance with the prescription.

46. The SOP in place at the time of the incident also required Ms B, during the checking stage, to "separate the 'physical' and 'mental' activities by another task eg by dispensing or typing another prescription".

47. In light of the Medsafe data sheet, I consider that it was clear from the dosage prescribed to Ms A that she was a high risk patient. Ms B failed to dispense the correct medication to Ms A. Ensuring that the patient is being dispensed the correct medication is a fundamental aspect of pharmacy practice, and is a requirement of the Pharmacy's SOPs.

48. Ms B stated that she could not recall the specifics of the dispensing; however, the label generated by Ms B did not match the prescription presented by Ms A. Therefore, it is apparent that Ms B did not check the label against the prescription adequately, as required by the Pharmacy SOP under the heading "Dispensing Check". Ms B failed to comply with the Pharmacy SOPs.

49. Ms B told HDC that it was very busy in the Pharmacy that day. I note that Ms B accepts that this was a contributing factor in the cause of the error, and not an excuse. I also note that Ms B had the option available to her to ask Ms A to return to the Pharmacy at a later time, when her colleague had returned from lunch.

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

Opinion: The pharmacy — No breach

51. Written SOPs provide the minimum requirements for dispensing medication, and are central to ensuring safe and effective dispensing.

52. There is no doubt that Ms B was aware of the SOPs in place at the Pharmacy at the time of this dispensing error. These clearly require the correct medication to be selected, and for the selected medication to be checked against the original prescription. The SOP also stated that patients should be given appropriate expectations on how long their prescription would take, and to encourage patients to return during busy periods.

53. I am satisfied that the SOPs in place at the Pharmacy for dispensing medications were appropriate, and that Ms B was aware of the dispensing requirements.

54. Although Ms B has told HDC that the Pharmacy was busy that day, she also acknowledged that it is the duty of a pharmacist to stay focused "regardless of many possible interruptions or patient enquiries on top of the prescriptions that need filling".

55. I note the actions that the Pharmacy has taken following the identification of the dispensing error. The Pharmacy proactively attempted to contact Ms A to inform her of the error. This is commendable. The Pharmacy has also updated its SOPs with regard to the dispensing process, and has provided further education to its staff to minimise the likelihood of such a dispensing error occurring again in the future.

56. In my view, Ms B's error in dispensing the wrong medication to Ms A was an individual clinical error, and cannot be attributed to the Pharmacy. I find that the pharmacy did not breach the Code.

Recommendations

57. I recommend that Ms B arrange for an assessment through the New Zealand College of Pharmacists regarding the processing of prescriptions and processes for dispensing and checking medications.

58. I recommend that the New Zealand Pharmacy Council consider whether a review of Ms B's competence is warranted, and report back to HDC on the outcome of that review.

Follow-up actions

59. A copy of this report with details identifying the parties removed will be sent to the Pharmacy Council of New Zealand and the district health board, and they will be advised of Ms B's name.

60. A copy of this report with details identifying the parties removed will be sent to the Pharmaceutical Society of New Zealand, the Pharmacy Guild of New Zealand, the New Zealand College of Pharmacists, the New Zealand Pharmacovigilance Centre, the Health Quality & Safety Commission, and the Ministry of Health.

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