Pharmacist, Mr A

A Pharmacy

A Report by the

Deputy Health and Disability Commissioner

(Case 13HDC01618)

Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

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Executive summary

1. In November 2013, Ms B was undergoing a frozen embryo transfer as part of her in vitro fertilisation (IVF) treatment. Ms B was under the care of a fertility clinic. On 4 November, day one of her menstrual cycle, Ms B was prescribed "Oestradiol Valerate 2mg Tab" (brand name Progynova), three times daily to commence that day. At 3.28pm the prescription was faxed to the pharmacy for Ms B to pick up.

2. The pharmacist, Mr A, processed the prescription. Mr A entered the first four letters of the medication — "oest" — into the pharmacy computer software in order to generate the label. The medication that came up on the screen was oestriol (brand name Ovestin), which Mr A selected. The oestriol was then packaged and dispensed to Ms B.

3. Ms B took the oestriol in accordance with the prescription instructions.

4. On 17 November, day 14 of her menstrual cycle, Ms B started spotting. Ms B immediately contacted the fertility clinic, who arranged for an ultrasound scan to be carried out the following day. The ultrasound scan showed that the endometrial lining was not of an optimal thickness. When Ms B questioned the medication she had been taking it was discovered that she had been dispensed an incorrect form of oestrogen (oestriol rather than the correct oestradiol valerate). As a result of taking the wrong medication, Ms B's embryo transfer cycle had to be abandoned.

5. The fertility clinic notified the pharmacy of the error.

6. On 20 November, Ms B returned to the pharmacy to take back the oestriol and pick up the oestradiol valerate. At that time, Ms B spoke to pharmacist Ms C. Ms B recalls Ms C saying that she was sorry for the error, and that it was a computer error. Ms B left the pharmacy feeling very upset, as she did not feel that Ms C had acknowledged the impact the error had had on her or expressed any empathy.

Decision

7. It was held that by failing to check the medication he was dispensing against the original prescription, Mr A failed to provide Ms B with services in accordance with professional standards. Accordingly, Mr A breached Right 4(2) of the Code of Health and Disability Services Consumers' Rights (the Code).[1]

8. It is accepted that the standard operating procedures (SOPs) for dispensing medications in place at the pharmacy at the time of this incident were appropriate, and that Mr A was aware of the dispensing requirements. Furthermore, there is no evidence that the pharmacy was particularly busy at the time of the incident. It was concluded that the pharmacy was not responsible for Mr A's breach of the Code.

9. Adverse comment was made about the pharmacy's incident management in this case.

[1] 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

10. The Commissioner received a complaint from Ms B about the services provided by pharmacist Mr A. The following issues were identified for investigation:

- *The appropriateness of the care provided to Ms B by Mr A in November 2013.*
- *The appropriateness of the care provided to Ms B by the pharmacy in 2013.*

11. An investigation was commenced on 15 April 2014. This report is the opinion of Theo Baker, Deputy Commissioner, and is made in accordance with the power delegated to her by the Commissioner.

12. The parties directly involved in the investigation were:

Mr A	Pharmacist/provider
Ms B	Consumer/complainant
The pharmacy	Provider

Also mentioned in this report:

Ms C	Pharmacist
Ms D	Pharmacist
A fertility clinic	

13. Independent expert advice was obtained from pharmacist Charlotte Schimanski (**Appendix A**).

Information gathered during investigation

Background

14. During 2013, Ms B, aged 35 years at the time, was undergoing in vitro fertilisation (IVF)[2]. In November 2013, Ms B was undergoing a frozen embryo transfer[3] during a manufactured menstrual cycle.[4]

Prescription

15. On 4 November 2013, day one of Ms B's menstrual cycle, she was prescribed oestradiol valerate[5] (brand name Progynova) 2mg, three times daily, to commence that day. The on-duty doctor at the fertility clinic wrote the prescription and, at 3.28pm, it was faxed to the pharmacy.

[2] The process by which the egg is fertilised with sperm outside the body.
[3] During an IVF cycle, more than one embryo can be produced. Embryos can be frozen. Frozen embryo transfer is where a frozen embryo is thawed and then replaced at a certain time in the woman's menstrual cycle.
[4] When the menstrual cycle is controlled by medications.
[5] Oestradiol is the main oestrogen hormone made by developing follicles. It has many actions, including being used to thicken the lining of the uterus.

Mr A

16. Mr A was the pharmacist responsible for processing and dispensing Ms B's prescription. Mr A has been a registered pharmacist in New Zealand since 1979. Mr A is one of the directors of the pharmacy.

Arrival at the pharmacy

17. Ms B arrived at the pharmacy at approximately 4pm to pick up her prescription. Ms B told HDC that after waiting for about 10 minutes she was told by the person at the counter that the prescribed medication was not in stock, and that she would have to come back to pick it up the next day. Ms B replied that she needed to start the medication that day, and was willing to drive to another pharmacy to pick it up. Ms B said that after a short wait she was told that the medication had been located at a local pharmacy, and she waited while the medication was picked up. She was then handed the medication in a bag by the person at the counter. Ms B said that she never spoke to the pharmacist, and no one spoke to her about the medication she was being dispensed.

Dispensing

18. Mr A told HDC that after being given Ms B's prescription to process, he entered the first four letters of the medication — "oest" — into the computer system in order to generate the label. Mr A explained that the first medication that came up on the screen was oestriol 2mg (brand name Ovestin).[6] Mr A selected oestriol on the screen and generated a label.

19. Mr A told HDC that he is unable to recall, and there is no record, that oestriol was not in stock at the time he processed Ms B's prescription, but accepts Ms B's recollection that the medication had to be sourced from another pharmacy. Mr A said that, while he is unable to confirm what actually happened in this case, it is likely that when he found that oestriol was not in stock he requested it from another local pharmacy and someone went to pick it up.

20. The oestriol was then packaged and dispensed to Ms B. Mr A said that he did not re-check the medication being dispensed against the original prescription to ensure that it was correct.

Identification of incorrect medication

21. Ms B told HDC that when she arrived home she noticed an information sheet on oestriol in the bag with the dispensed medication. She said that she had never been prescribed oestradiol valerate (or oestriol) previously, but "had a doubt that the name of the drug [she] was supposed to be on sounded a bit different" from the drug that she had been dispensed. Ms B said that she checked the receipt printed by Mr A, which included a list of the medications that had been dispensed, and it matched the name of the medication that she had been dispensed. She also noted that the information sheet for oestriol clearly stated that it was oestrogen. Ms B said that she never saw the original prescription, and thought that her recollection of the name she had been told must have been incorrect.

[6] A weak oestrogen that is used to treat oestrogen deficiency and hostile cervical mucous.

22. Ms B subsequently started taking the oestriol in accordance with the prescription.

23. On 17 November, day 14 of her menstrual cycle, Ms B started spotting.[7] She immediately called the fertility clinic and spoke to a nurse, who arranged for an ultrasound scan the following day.

24. On 18 November, the duty doctor at the fertility clinic performed an ultrasound scan on Ms B. The scan showed that the endometrial lining was not an optimal thickness. Ms B then asked the doctor about the medication she had been taking (oestriol), and was told that this was the wrong form of oestrogen.

25. The doctor then double checked Ms B's clinical records and confirmed that oestriol was not what Ms B had been prescribed.

26. The doctor overseeing Ms B's care was informed of the situation. The doctor telephoned Ms B a couple of hours later and confirmed that she had been taking the wrong type of oestrogen. The doctor then recommended that the embryo transfer cycle be abandoned because, as a result of taking the oestriol, her endometrial lining was not at an optimal thickness, and the fact that she was spotting indicated that her endometrial lining may have been compromised.

27. Later that day, a fertility clinic nurse contacted Ms B to check that she was all right and to tell her that the pharmacy had been contacted, and had said that the mistake was "a computer error".

28. Because Ms B's embryo transfer had been abandoned she was prescribed Provera, a form of progesterone often used prior to IVF treatment. The prescription was faxed to the pharmacy on 18 November for Ms B to collect. Ms B told HDC that her mother picked up the prescription and, at that time, was also given one box of oestradiol valerate as part of the original prescription, and was told that Ms B should bring back the oestriol and collect the remaining oestradiol valerate left on the prescription.

Further contact with the pharmacy

29. On 20 November, Ms B went to the pharmacy to return the oestriol and pick up the remaining oestradiol valerate as instructed. At this time, Ms B spoke to pharmacist Ms C. Ms B told Ms C that she was very upset about the error as it meant that she had lost an IVF cycle. Ms B recalls that Ms C said that she was sorry and explained that it was a computer error. Ms B said that Ms C did not acknowledge the impact the error had had on her, or express any empathy. Ms B said: "I left the pharmacy crying, feeling quite distressed about the situation, the lack of acknowledgement of the magnitude of this situation for me, and the failure of the pharmacy to accept any responsibility for the error."

Complaint

30. Ms B complained to HDC that she was dispensed the incorrect medication, that she was not given any formal explanation as to how the error had occurred, and that the error was blamed on the computer software. Ms B also complained that the effect of

[7] Spotting is the presence of blood at the wrong part of the menstrual cycle.

the error on her had not been acknowledged by the pharmacy, nor had she received a formal apology.

Standard operating procedures

31. At the time of these events, the SOP in place at the pharmacy for "Dispensing prescriptions" stated under the heading "During the dispensing process":

> "Check you are using the right medication and brand as prescribed …
>
> Check medicine dose, frequency, interactions and contraindications, to ensure the medicine is being given appropriately …
>
> Where possible use another staff member to check prescriptions, labels and calculations.
>
> When working alone in a dispensary, ensure that dispensing and final checking procedures are 'mentally' and 'physically' separated eg documentation procedures require separate steps, product to be checked is lined up with original source and prescription etc. …
>
> **Final check:**
>
> Check the dispensed medicine against the prescription for correct name of contents, formulation, strength and quantity dispensed, correct patient name …
>
> When all items on a prescription have been completed, make sure that all items bagged for the patient are checked off against their prescription, and that any documentation that accompanies the dispensed items (such as prescription records and receipts) belong to the appropriate patient. Ensure that bag labelling matches the prescription contents of the bag."

32. In relation to dispensing errors, the SOP for dispensing prescriptions stated:

> "It is important to deal quickly with dispensing error complaints. If the error is obvious, apologise to the patient …
>
> A written apology, with explanation of how the error occurred and what actions have subsequently been taken to prevent a similar error, should be provided to the patient as soon as the information is available …"

33. There is no reference to incident reporting in the pharmacy SOPs.

Reporting of incident and investigation

34. Mr A told HDC that the fertility clinic advised the pharmacy of the error by telephone. An incident form was completed on 28 November. On the incident form, under "Immediate action taken and by whom" it is documented: "The mistake was partly due to the difference in spelling of the generic names in the TONIQ system." [8] Under "Investigation of incident" it is documented that it was a "typically busy Monday lunchtime at which staff members were on lunch breaks and the dispensary was temporarily short staffed".

[8] Toniq is a pharmacy software system that manages dispensary operations.

35. In relation to the timing of this incident being referred to on the incident form as occurring at lunch time, Mr A advised that the incident form was completed by a third pharmacist, Ms D, who had not previously been involved in the incident. Mr A stated:

> "As the mistake was only noticed 2 weeks after the initial dispensing I think that [Ms D], when writing up the report, had just assumed that it was at a busy break time and had not actually checked the time of dispensing on the computer."

36. Mr A said that he is not sure why the incident form was completed by Ms D, as it is normal process for the person receiving the complaint to complete the incident report. He is also unsure when he became aware of the incident, but said that he was not told about it immediately. Mr A said that he questioned staff about the incident once he became aware of it, and he signed the incident report "as an acknowledgement of the part [he] played in the initial dispensing". Mr A accepts that there are errors in the incident form.

37. Mr A confirmed that the prescription was received at the pharmacy at 3.28pm and entered into the computer at 3.32pm. Mr A told HDC that this "would have been an afternoon tea break time" and that he would have been the only pharmacist working, together with "one or two" dispensary technicians.

38. Mr A told HDC that one of the causes of the error was the way in which the medication was listed on the pharmacy software, Toniq. Mr A said that, in order to achieve international consistency, the medication is listed using the International non-proprietary name (INN), "estradiol valerate", rather than the British Approved Name (BAN), oestradiol valerate. However, the software used by the fertility clinic lists it using the BAN, oestradiol valerate.

39. Mr A said, however, that "this is not an excuse but an explanation as to why this error occurred". Mr A stated: "I failed to adequately check that the label generated was in fact the correct [o]estrogen." Mr A told HDC that this incident has highlighted the importance of critically analysing the question, "Is this medicine appropriate for this patient?"

40. On behalf of the pharmacy, Mr A apologised that Ms B did not consider that Ms C's apology was suitable. Mr A also acknowledged that following the investigation into the incident he should have followed up Ms C's verbal apology personally with a written apology. Following the receipt of Ms B's complaint, Mr A wrote a letter of apology to Ms B.

Nomenclature systems

41. Nomenclature systems are used worldwide to identify the active ingredients of medicines and there are a range of nomenclature systems in existence. New Zealand legislation requires medicine labels to specify active ingredients, but does not specify which nomenclature system is to be used (www.medsafe.govt.nz/profs/RIss/INN.asp). Oestradiol valerate is named using the British Approved Names nomenclature. The medicine is named as estradiol valerate using the International Non-proprietary Names nomenclature system. As noted by Medsafe, "Healthcare professionals have a professional and ethical responsibility to accurately identify the medicine prescribed,

whether it be a new active ingredient, a change of brand name or a different spelling or nomenclature for an active ingredient. Lack of familiarity with a medicine name is not an acceptable reason for dispensing errors to occur."

Action taken by the pharmacy

42. On behalf of the pharmacy, Mr A advised that since this incident he has reviewed the pharmacy SOPs to ensure that the requirement that the dispensed medicine is checked against the prescription is clear. The SOP now states:

> "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. …
>
> When all items have been dispensed, the prescription should be annotated with the dispenser's initials."

43. Mr A has developed an SOP for action following the discovery of a dispensing error, which includes the following requirements:

> "[T]he pharmacist in charge handles the matter. …
>
> Show empathy with the patient. …
>
> At all times remain calm, sympathetic and cooperative. Advise that you will investigate how the incident occurred and revise any procedures to help prevent any reoccurrence. Ensure you let the customer know what measures have been taken, and follow up promptly. …"

44. The SOP also requires the error to be recorded in the pharmacist's Incident Log Book and on the patient's notes on the computer.

45. Mr A told HDC that the pharmacy has regular staff meetings, and that compliance with SOPs is discussed regularly. He said that he has also questioned staff about various SOPs to ensure their understanding of them. He also regularly observes staff during various procedures to ensure they are being carried out correctly.

46. Mr A advised that during a number of staff meetings he has reminded staff of the dispensing and checking requirements and of the importance of checking the medication being dispensed against the prescription, not the label.

47. Mr A stated:

> "At times we are working under quite a lot of pressure and it may be during these times staff are rushing and not fulfilling their job requirements according to the SOPs. For the majority of the time we have two pharmacists in the dispensary but there are times, such as lunch breaks and weekends, where there is only one pharmacist on duty and I guess this has the potential to increase errors. In light of this I have increased the number of pharmacists on duty on some days so as to

provide extra resource to ensure that we can carry out our tasks effectively and efficiently without working under duress."

48. Mr A also advised that all his pharmacists have undertaken research into the different types of oestrogens and when they are used, to ensure they are all aware of when and why particular oestrogens are prescribed.

Further comment and changes

49. Mr A told HDC that when he notified the pharmacy Defence Association (PDA) of Ms B's complaint he was advised that it had been notified of two other incidents in recent weeks involving oestriol being dispensed rather than oestradiol valerate. Mr A advised that on 17 January 2014 the pharmacy Defence Association issued an email warning to all its members alerting them to the issue and advising that pharmacists should be aware of the inconsistencies in the spelling of the generic name for Progynova (ie, oestradiol valerate and estradiol valerate).

50. Mr A also advised that the advisory pharmacist from Pharmacybrands Ltd Professional Services Team[9] subsequently met with the fertility clinic to discuss the issue. Pharmacybrands Ltd has also contacted Toniq and Healthsoft, the suppliers of two of the pharmacy software packages, to request that the software be updated to ensure that either spelling (estradiol valerate and oestradiol valerate) will link to the brand name Progynova. Pharmacybrands Ltd also notified the Pharmacy Guild of New Zealand, the Pharmaceutical Society of New Zealand, the Medical Council of New Zealand, and the Ministry of Health of this issue.

51. HDC has not received any other complaints relating to medication errors involving oestradiol valerate and oestriol.

Action taken by the fertility clinic

52. The fertility clinic advised HDC that since this incident it has changed its processes to ensure that a similar incident does not happen again. It has changed its electronic prescription forms so that practitioners have to select the brand name Progynova, rather than the generic name, oestradiol valerate. In addition, when a patient now calls the fertility clinic on day one of her cycle, the patient is asked to check that the medication she has been dispensed is oestradiol valerate, and to provide a description of the tablet and its colour to double check that she has been dispensed the correct medication.

Response to provisional opinion

53. In response to my provisional opinion, Mr A stated that he accepts that he made a selection error and that this was a breach of the Code, but reiterated that there were a

[9] Pharmacybrands Ltd comprises several pharmacy and medical franchises brands. In total, the company represents 306 retail pharmacy outlets operating throughout New Zealand, and six medical centres.

number of contributing factors. In particular, Mr A said that the prescription was written using the BAN spelling, oestradiol valerate, rather than the INN spelling, estradiol valerate. In addition, Mr A submitted that the spelling of oestriol was similar to oestradiol valerate.

54. Furthermore, Mr A stated: "I accept that I did not handle the situation as well as I should have and I regret that. I have made changes to my practice to ensure a similar situation does not occur again."

Ms B

55. Ms B did not wish to make any further comment in relation to the "facts gathered" section of my provisional report.

Opinion: Introduction

56. On 4 November 2013, Ms B was dispensed the wrong medication — oestriol rather than the prescribed oestradiol valerate. As a result of the error, Ms B had to abandon her IVF cycle for which the oestradiol valerate had been prescribed. She was understandably distressed at the lost opportunity to conceive.

Opinion: Mr A

Dispensing error — Breach

57. Mr A was the pharmacist responsible for dispensing the wrong medication to Ms B.

58. According to Mr A, the error occurred when he entered the medication into the pharmacy computer software. Mr A told HDC that he entered the first four letters — "oest" — into the programme in order to generate a label. The first medication that came up on the screen was oestriol. Mr A selected this medication and, in all likelihood, requested it from another pharmacy.

59. Mr A then dispensed the oestriol to Ms B without rechecking the medication against the original prescription.

60. At the time of this incident, the SOP in place at the pharmacy for "dispensing prescriptions" stated: "Check you are using the right medication and brand as prescribed … Check medicine dose, frequency, interactions and contraindications, to ensure the medicine is being given appropriately …" The SOP also stated that "[w]here possible" the prescription should be checked by another staff member. When this option was not available, the person dispensing the medication should "ensure that dispensing and final checking procedures are 'mentally' and 'physically' separated eg documentation procedures require separate steps, product to be checked is lined up with original source and prescription etc".

61. 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."

62. Furthermore, the Pharmacy Council of New Zealand *Competence Standards for the pharmacy Profession* states:

> "Element 6.6 Fill prescriptions
> …
> 6.2.2 Follows workplace dispensing criteria when dispensing a prescription item
>
> 6.6.2 Maintains a logical, safe and disciplined dispensing procedure
>
> *Examples of Evidence:*
> Selects correct product, dose form & quantity for each prescribed medicine …"

63. Mr A failed to check the medication he was dispensing to Ms B against the original prescription. This is unacceptable. Checking 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. The error in selecting the medication from the pharmacy's computer software is not an excuse for Mr A's failure to comply with these basic requirements. As noted by my expert advisor, pharmacist Charlotte Schimanski: "It is unfortunate that the computer systems were brought into fault — it was incorrect product selection that caused the initial error and it is important that this is recognised, dealt with and learned from." I note that Mr A accepts this and advised that the difference in the spelling was identified as a contributing factor in the cause of the error and not an excuse.

64. By failing to check the medication being dispensed against the original prescription, Mr A failed to provide Ms B with services in accordance with professional standards. I conclude that Mr A breached Right 4(2) of the Code.

Recognition of uncommon dosage — adverse comment

65. Ms B was prescribed oestradiol valerate at a dosage of 2mg three times a day. According to Ms Schimanski, 2mg is an uncommon dosage for both oestradiol valerate and oestriol. In Ms Schimanski's opinion, Mr A should have recognised this and referred to the relevant Medsafe data sheets to check the dose.

66. I do not expect a pharmacist to know the standard dosage for every medication, particularly not uncommonly prescribed medications. However, I consider it wise for a pharmacist to take a proactive approach in a situation such as this and refer to standard prescribing information, which is easily accessible on the Medsafe

datasheets. While I do not consider that Mr A's failure to do so in this case warrants a finding that he breached the Code, it serves as a good reminder of the importance of "[assessing] the effectiveness of the total medicine therapy".[10] As noted by Ms Schimanski, had Mr A checked either of these medications, it may have prompted him to contact the prescriber to double check the medication prescribed.

Opinion: The pharmacy

Standard operating procedures — No breach

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

68. There is no doubt that Mr A was aware of the SOPs in place at the pharmacy at the time of this incident. These clearly state the requirement that the dispensed medication is checked against the original prescription.

69. I note that Ms Schimanski considered that the SOPs for dispensing in place at the time of this incident were adequate.

70. Accordingly, I am satisfied that the SOPs in place for dispensing medications were appropriate, and that Mr A was aware of the dispensing requirements. Although I acknowledge Mr A's belief that he was the only pharmacist working at the time of this incident, there is no evidence that the pharmacy was particularly busy at that time.

71. In my view, Mr A's error in dispensing the wrong medication to Ms B was an individual clinical error, and cannot be attributed to the system in which he was working. Accordingly, I conclude that the pharmacy is not responsible for Mr A's breach of the Code.

72. I note the actions the pharmacy has taken following the receipt of Ms B's complaint, including updating its SOPs with regard to dispensing and dispensing errors, as well as undertaking further education of its staff with regard to the functions and dosages of the various types of oestrogen.

Incident management — Adverse comment

73. On 14 November, the fertility clinic contacted the pharmacy and advised it of the error. Later that day, Ms B's mother attended the pharmacy in order to pick up a new prescription. At that time, Ms B's mother was told that Ms B should return the incorrect medication and pick up the remaining medication left on the original prescription.

74. On 20 November, Ms B went to the pharmacy to return the incorrect medication. At this time she spoke to pharmacist Ms C, who apologised for the error and advised Ms

[10] Element 2.3.3 of the Pharmacy Council of New Zealand *Competence Standards for the pharmacy Profession*.

B that the mistake was a result of a computer error. Ms B did not feel that there was any acknowledgement of the impact this error had had on her, and left feeling very upset. Ms B received no further follow-up from the pharmacy. On 28 November, an incident report relating to the error was completed by a third pharmacist. Under "Investigation of incident" it is documented that it was a "typically busy Monday lunchtime at which staff members were on lunch breaks and the dispensary was temporarily short staffed".

75. This analysis is clearly incorrect. The prescription was received by the pharmacy at 3.28pm, and Ms B was dispensed the medication at approximately 4pm. By way of explanation, Mr A stated:

> "As the mistake was only noticed 2 weeks after the initial dispensing I think that [Ms D], when writing up the report, had just assumed that it was at a busy break time and had not actually checked the time of dispensing on the computer."

76. The fact that the incident report is so clearly incorrect brings into question the incident review process carried out by the pharmacy. Furthermore, it is concerning that Mr A apparently discussed the incident with Ms D and Ms C and signed the incident report as "an acknowledgement of the part [he] played in the initial dispensing" but failed to notice these errors.

77. The pharmacy's dispensing SOP in place at the time of these events required that following an error the consumer should be given a written apology, including details of how the error occurred and the action taken to prevent it from occurring again. There was no specific guidance in relation to the incident review process which, as noted by Ms Schimanski, is concerning. Furthermore, Ms Schimanski stated: "It is easy to get complacent when you are busy. It is also easy to try and ignore when errors are made and not deal with them in an appropriate manner." Ms Schimanski advised that Toniq has an easy-to-use incident reporting form available, which she considers is an "excellent resource when it comes to dealing with such unfortunate situations".

78. It is disappointing that the pharmacy took no steps to follow up the error with Ms B, as required by the pharmacy's dispensing SOP. I consider that an immediate acknowledgement by the pharmacy of the error, and a formal apology, may have provided Ms B with reassurance that the error had been taken seriously.

79. Effective incident management, including direct input from those involved, is important in identifying issues and learning from errors to help prevent a similar incident from occurring. It is also important in reassuring the consumer that the incident is being managed appropriately.

80. In my view, this incident was not well managed, and there are lessons to be learnt. I am reassured that the pharmacy has reflected on the way it managed the error and has reviewed its process for the management of such incidents. Ms Schimanski has advised that the new SOP for dispensing errors is comprehensive and appropriate.

Recommendation

81. I recommend that the pharmacy audit its compliance with its updated SOPs and provide HDC with the outcome of that audit within three months of the date of this report.

Follow-up actions

82.
- 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 district health board, and they will be advised of Mr A's name.

- 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, the Pharmacy Guild of New Zealand, the New Zealand College of Pharmacists, the Health Quality and Safety Commission, and the Ministry of Health, 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 pharmacist Charlotte Schimanski:

"I have been asked to provide a report to the Health & Disability Commissioner on case number C13HDC01618 as an independent advisor.

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

I have no personal or financial connection with the provider or the consumer making the complaint. I have not worked with the provider or with the pharmacists named in the complaint.

I am a Registered Pharmacist, Pharmacy Council registration number: 8500. I completed a Bachelor of Pharmacy at the University of Otago in 2004 and registered as a Pharmacist with the pharmacy Council in 2005.

Currently I am the Manager of the Urgent Pharmacy in Rotorua, which provides experience with a wide variety of prescriptions. I have worked in New Zealand and Australia. I am a member of the Lakes District Health Board Pharmaceutical Advisory Committee, a member of the Pharmacy Council Professional Conduct Committees, and I have helped the Pharmaceutical Society of New Zealand with the new format of Intern Assessment. I am a qualified preceptor for Intern Pharmacists.

The material I examined was as follows:

1. Complaint from [Ms B]
2. Statement from [Mr A], dated 30 January 2014, including
   a. Patient prescription
   b. Incident form
   c. Standard operating procedure (SOP) for dispensing at the time 4 Nov
   d. Revised SOP Jan 14
   e. Copy of email sent by PDA to PDA members
   f. Copy of screen dump for Ovestin and Progynova
   g. Copy of apology letter to [Ms B]
3. Statement from [Mr A] dated 22 May 2014.
4. Statement from [Mr A] on behalf of [the pharmacy] dated 22 May 2014
5. Letter from [the fertility clinic], dated 2 May 2014.
6. During the investigation I requested a copy of the updated SOP for 'Dealing with Dispensing Errors' requested 14/7/14, received 25/7/14.

Key Terms

Oestradiol valerate; also known as estradiol valerate, and known in New Zealand by the brand name Progynova. Oestradiol (E2) is the main oestrogen hormone made by developing follicles. It has many actions, including growing the lining of the uterus (called the endometrium).[i]

Oestriol; also known as estriol, and known in New Zealand by the brand name Ovestin. Oestriol is a weak oestrogen and can be used for infertility due to cervical hostility.[ii]

Summary of Facts

- [Ms B] was in the process of a frozen embryo transfer.
- On the 4th of November 2013 [Ms B] arrived at [the pharmacy] to collect her prescription for Oestradiol (Progynova) 2mg tablets necessary to prepare the endometrium for the transfer.
- [Ms B] was given Oestriol (Ovestin) 2mg in error.
- [Ms B] started spotting (small amount of bleeding) on the 17th of November as a result of taking the wrong oestrogen.
- Her frozen embryo transfer was subsequently abandoned as uterus conditions were not optimal.
- A new prescription for Oestradiol/Progynova was faxed to [the pharmacy] and collected by [Ms B's] mother. The whole quantity was not available so her mother was asked to advise [Ms B] to collect the rest and return the incorrect medication at a later date.
- [Ms B] returned the incorrect medication to [the pharmacy] on the 20th of November. She expressed the distress the error had caused her and was told it was a computer error. She left feeling upset because of the way she had been treated by [the pharmacy].

The questions asked of the Commissioner were as follows:

1. Please comment generally on the standard of care provided by [Mr A].

It is my opinion that [Mr A] did not provide an appropriate standard of care to [Ms B]. [Ms B] had the right to expect her prescription to be dispensed accurately, however this did not happen. [Mr A] deviated from his own SOP's on a number of occasions — with regard to checking prescriptions, counselling patients and dealing with dispensing errors. [Mr A] has acknowledged that he did not follow procedure. I consider that his peers would view this with moderate disapproval, not because of the initial error but because of the way the ensuing situation was handled.

2. Please comment generally on the standard of care provided by [the pharmacy].

It is my opinion that [the pharmacy] did not provide an appropriate standard of care. The Pharmacist dealing with [Ms B] when she arrived to exchange the incorrect medication for the correct medication did not follow the SOP. [Mr A] has acknowledged that procedure was not followed. I consider that this would be viewed with moderate disapproval, because there was no accountability for the error.

3. What standards apply in this case? and

4. Were those standards complied with?

Standards New Zealand
1.11 The right of the consumer to make a complaint is understood, respected and upheld.

[Ms B] was not informed of her right to complain.

5.2 A disciplined dispensary procedure shall ensure the appropriate product is selected and dispensed accurately and efficiently.

The SOP did contain a disciplined procedure; however this was not followed, resulting in an inappropriate product being selected. The SOP at the time did not contain the information relating to sub clause 5.2.4 which advises a full clinical check. It did contain the basic requirements for a clinical check.

Pharmacy Council Competence Standards
1.1.5 Works accurately
The wrong product (Oestriol vs Oestradiol) was selected in the computer and subsequently dispensed to the patient.

1.2.3 Complies with Code of Ethics for Pharmacy Practice
Please see below to the Code of Ethics to see how this standard applies.

2.3.2 For each medicine, checks the dosages and methods of administration are optimal. And

2.3.3 Assess the effectiveness of the total medicine therapy
Here it is necessary to point out that it is not common to see Oestradiol Valerate (Progynova) prescribed at a dosage of 2 mg three times a day. It is equally as uncommon to see Oestriol (Ovestin) prescribed at the same dose. If the relevant Data Sheets[iii,iv] for each medication are checked, the above dose is not mentioned in either Data Sheet. It is only the Ovestin data sheet that mentions use during Fertility Treatment. Had either of these been checked, it may have triggered a phone call to the Prescriber to confirm the correct medication.

6.2.2 Follows workplace dispensing criteria when dispensing a prescription item.
[Mr A] did not follow his SOP entitled 'Dispensing Prescriptions'.

6.5.1 Confirms that each selected medication is suitable for the patient
[Mr A] did not confirm that the medication he had selected was suitable for the patient.

6.9.3 Rectifies dispensing errors immediately
[Mr A], and [the pharmacy], did not follow their SOP for dealing with Dispensing Errors. The situation was not resolved immediately and to date has not been resolved.

Pharmacy Council Code of Ethics

1.2 Take appropriate steps to prevent harm to the patient and the public.
Unfortunately, this error and the subsequent events caused harm to the patient in terms of cost and emotional distress.

1.3 Exercise compassion and care towards patients.
Unfortunately, when [Ms B] returned the incorrect medication, she left in tears. This cannot be described as exercising compassion and care towards patients.

7.6 Ensure that you are able to comply with your legal and professional obligations and that your workload or working conditions do not compromise patient care or public safety.
In the incident report for this event and another that was given as subsequent information, the person completing the report describes both situations as 'typically busy'. If it is 'typically busy' and errors are being made, the workload is too high and better staffing arrangements will need to be considered.

7.8 Ensure that appropriate standard operating procedures are in place, maintained and followed
The SOP's were not followed with regard to dispensing, checking and dealing with dispensing errors. These were not followed by both [Mr A] and other staff members at [the pharmacy].

[…]

[Mr A] should have followed his own SOP and offered [Ms B] a written apology as soon as he became aware of the incident. Unfortunately, his apology after becoming aware of this complaint cannot be described as 'fair, simple, speedy and efficient'.

If not answered above, please comment on the following, giving reasons for your view:

5. The adequacy and appropriateness of the standard operating procedures in place at [the pharmacy] at the time of these events.

The SOP at the time of these events was out of date — the review date was 2/12/11. In the original SOP, the first point under 'During dispensing process' is 'Check you are using the right medicine and brand as prescribed'. [Mr A] selected oestriol instead of oestradiol. The 4th bullet point says 'Check medicine dose, frequency, interactions and contraindications, to ensure the medicine is being given appropriately'. Had [Mr A] followed this point and looked at the contraindications for either medication, he would have seen that both are contraindicated in pregnancy. It would usually be assumed that a script from [the fertility clinic] was either for someone who is trying to get pregnant, or for someone who is pregnant. Although not as comprehensive as the updated SOP's, the basic requirements for a clinical check were in the original SOP. Therefore, the Dispensing SOP was adequate and appropriate at the time of these events.

[Mr A] has used a template for his SOP's, which is very common and saves a lot of time, however it is important to remember that procedures need to be personalised for every Pharmacy.

The procedure for dealing with dispensing errors was covered as a sub section in the original Dispensing SOP, and was inadequate at the time of these events. There is no mention of filling out an Incident Report which is inappropriate. There are some basic steps in place, none of which were followed.

6. The adequacy and appropriateness of the changes made by [Mr A] and [the pharmacy] since this incident.

While the old Dispensing SOP was adequate and appropriate, the updated SOP's for Dispensing are much more comprehensive, particularly with regard to the clinical check and being aware of what is being dispensed.

It is commendable that [Mr A] and his dispensary staff are undertaking continuing education in this confusing area of Oestrogens. It is also commendable to see that [Mr A] has realised he may have been short staffed during some periods of the day and has rectified this.

During the investigation I requested a copy of the 'Dealing with Dispensing Errors' SOP. It was disappointing that the SOP hadn't been updated until a copy was requested, even though when the Dispensing SOP's were updated, any procedure for dealing with Dispensing Errors had been written out.

The updated SOP to deal with Dispensing Errors is ample, although a timeframe for notifying PDA would be a good detail to add. [Mr A] will need to ensure all Dispensary staff are made aware of the new procedures.

Any other comment you wish to make.

This is a regrettable incident and one that is an important situation for all Pharmacists and Dispensary staff to be aware of. Had the situation been dealt with in a more professional manner I suspect that it would have been resolved long before now. I think the most important lesson from these events is how to deal with dispensing errors.

It is unfortunate that the computer systems were brought into fault — it was incorrect product selection that caused the initial error and it is important that this is recognised, dealt with and learned from. It is easy to get complacent when you are busy. It is also easy to try and ignore when errors are made and not deal with them in an appropriate manner. Toniq makes it very simple to fill out a Pharmacy Defence style Incident Reporting Form and Pharmacy Defence is an excellent resource when it comes to dealing with such unfortunate situations. Their advice follows and I think that points 1, 2 and 3 are very appropriate in this situation.

The following details things not to do on becoming aware of an error:

'1. Don't simply dismiss or "brush off" an error, however minor you may view it as being.

A vast majority of the time the person who reports an error simply wants acknowledgement and reassurance. Acknowledgement of what has occurred, and reassurance that steps have been taken to ensure it won't happen again — to themselves or others.

2. Don't ever forget to ask about the patient's wellbeing and to apologise for the situation that they are in.

   Failing to show concern for the patient's wellbeing or forgetting to ask how they are can fuel a fire of resentment from the patient and/or their family. Whilst, as pharmacists, we tend to immediately think through the clinical implications of the error or how it could have occurred, it is critical not to forget the human side of the story.

   Even if you are unsure of the cause of the error, or who is to "blame", don't fail to at least acknowledge the situation, if only addressing the stress and inconvenience caused, e.g.
   "I can appreciate that this must be causing concern and apologise for that."

3. Don't bury your head in the sand or refuse to acknowledge an error.

   Once you are aware of an error you are professionally and ethically obligated to remedy it as quickly as practical. Failure to act can put you in a position where you are seen as both flippant and unprofessional.

4. Don't try to cover up an error.

   Covering up an error is professional suicide. You are actively challenging your professionalism, and, if the error reaches the Health and Disability Commissioner, you will not be viewed favourably.

   Equally important is not hiding errors from your colleagues or employer. Sharing errors is hugely valuable as it may uncover system failures and prevent similar events occurring.

5. Don't make empty promises to the patients concerned.

   If you say that you will follow up an error via letter or phone call by a set time/day, be sure to do it. Many people wait at home precisely for this contact, and if it fails to come it is infuriating. Apart from lack of common courtesy, it is often interpreted as you not taking the error seriously.

6. Don't ever hesitate in reporting the error to Pharmacy Defence.

   We are here to support you through errors/complaints and as such are "on your team".'[v]

Had all these steps been followed, [Ms B] may have felt that this was an innocent mistake, rather than leaving [the pharmacy], after returning the incorrect medication, in a distressed state.

I hope this incident is seen as an important learning experience with regard to correct product selection and assessing suitability of a medication. The most important lesson is recognising when an error has been made, being accountable for that error and dealing with that error in an appropriate and professional manner."

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[i] http://www.fertilityassociates.co.nz/Downloads/0313-1_About-us.aspx

[ii] http://www.medsafe.govt.nz/profs/datasheet/o/Ovestintab.pdf

[iii] http://www.medsafe.govt.nz/profs/datasheet/p/progynovatab.pdf

[iv] http://www.medsafe.govt.nz/profs/datasheet/o/Ovestintab.pdf

[v] www.pda.org.nz