Napier Balmoral Pharmacy Limited

A Report by the

Deputy Health and Disability Commissioner

(Case 13HDC01235)

Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

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Executive summary

1. In 2012 Ms A underwent a bilateral mastectomy and chemotherapy due to breast cancer. Consequently, she was prescribed a five-year course of tamoxifen.

2. On 27 March 2013, Ms A presented her prescription to a dispensing pharmacy for a further three-month supply of tamoxifen. She noticed that the tablets she was dispensed were different from previous ones. However, she attributed the difference in appearance to funding changes.

3. From April to July 2013, Ms A took the tablets she was dispensed.

4. In August 2013, Ms A returned to the pharmacy to collect a further supply of tamoxifen tablets. Upon collecting the tamoxifen tablets, she noticed a return to the round white pills she was used to.

5. Ms A queried staff at the pharmacy about the changes in the medication she was dispensed. It was then established that, on 27 March 2013 she had been dispensed tenoxicam instead of tamoxifen. Tenoxicam is described as an antirheumatic, anti-inflammatory and analgesic agent.

6. Napier Balmoral Pharmacy Ltd (NBP Ltd) undertook an investigation to determine how the error occurred. It was noted that on 27 March 2013, Ms A's prescription was correctly entered into the computer, as a label for 20mg tamoxifen was generated. However, tenoxicam 20mg was incorrectly selected from the shelf and subsequently dispensed to Ms A.

7. At the time of the error, NBP Ltd had standard operating procedures (SOPs) in place, which required that the dispenser and checker must be able to be identified at all times. However, NBP Ltd was unable to identify the pharmacist responsible for the dispensing error, as Ms A's prescription was not initialled by the dispenser.

8. It was held that NBP Ltd's failure to have sufficient measures in place within the pharmacy environment to ensure knowledge of, and compliance with, its SOPs played a significant part in Ms A receiving the incorrect medication. In particular, NBP Ltd failed to place an alert or precaution notice near the tamoxifen and tenoxicam, did not regularly review and update its SOPs, was unable to demonstrate that staff read the SOPs and, despite being aware of ongoing non-compliance with the dispensing SOP, failed to enforce compliance. Accordingly, NBP Ltd did not provide services to Ms A with reasonable care and skill and breached Right 4(1) of the Code.

Complaint and investigation

9. On 24 September 2013 the Commissioner received a complaint from Ms A about the services provided to her at a pharmacy. The following issue was identified for investigation:

- *The adequacy and appropriateness of the care Napier Balmoral Pharmacy Limited provided to Ms A.*

10. An investigation was commenced on 5 February 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.

11. The parties directly involved in the investigation were:

Ms A	Consumer
Napier Balmoral Pharmacy Limited	Provider

12. Information was also reviewed from:

Mr B	Former Pharmacist and Director of NBP Ltd
Mr C	Pharmacist and Director of NBP Ltd
Mr D	Pharmacist and Director of NBP Ltd
Ms E	Pharmacist at NBP Ltd

Information gathered during investigation

Napier Balmoral Pharmacy Limited

13. Napier Balmoral Pharmacy Limited (NBP Ltd) is the owner/operator of a dispensing pharmacy. NBP Ltd employs registered pharmacists, pharmacy technicians and retail staff. The pharmacy is open seven days a week and operates from 8.30am to 7.00pm during weekdays and 9.00am to 7.00pm on weekends.

Ms A

14. In 2012 Ms A was diagnosed with breast cancer and underwent a bilateral mastectomy and chemotherapy. Consequently, she was prescribed tamoxifen[1] to reduce the risk of reoccurrence of the cancer. She commenced taking tamoxifen in June 2012, and is to remain on this treatment for a period of five years.

Dispensing error

15. On 26 March 2013, Ms A's general practitioner provided her with a further prescription for tamoxifen 20mg, one tablet daily. She was also prescribed 500mg paracetamol caplets, two caplets four times a day as required for pain. The prescription instructed that 90 tamoxifen tablets (3 months' supply), and 100 paracetamol caplets were to be dispensed in total.

16. On 27 March 2013, Ms A presented her prescription at the pharmacy for the three-month supply of tamoxifen. She noticed immediately that the tamoxifen tablets were

[1] Tamoxifen is a non-steroidal, triphenylethylene-based drug. It is indicated for the treatment of breast cancer and prevents oestrogen binding to the oestrogen receptor.

different from the ones she had been dispensed previously.[2] However, she attributed the difference in appearance to funding changes, and considered it to be a generic substitute supplied by a different company. Ms A explained that previously she had experienced funding changes with her other medication, but was always reassured that the medication was the same.

17. From April to July 2013, Ms A took the tablets she was given. During this time, Ms A noticed that a lump in her reconstructed breast had started to change. Her specialist arranged for a biopsy followed by removal of the lump in August 2013. It was found that Ms A's cancer had returned. An MRI scan was performed, which showed that the cancer may have spread to Ms A's lymph nodes.

18. In August 2013, Ms A returned to the pharmacy to collect another supply of tamoxifen tablets. Upon collecting the tamoxifen tablets, she noticed a "return to the green carton and round white pills". Ms A discussed the difference in the medication's appearance with her specialist, who was unaware of any funding changes or changes to the medication from previous prescriptions, and suggested that Ms A check with the pharmacy.

19. Ms A then returned to the pharmacy to query the medication she had been dispensed. She discussed the matter with pharmacist Ms E. Ms A took her medication cartons with her, and it was ascertained that the one dated 27 March 2013 and labelled as tamoxifen, was actually tenoxicam.[3] It was then apparent that Ms A had been dispensed a three-month supply of 20mg tenoxicam in March instead of 20mg tamoxifen.

20. In September 2013, Ms A's lymph nodes were removed, and her oncologist arranged for her to undergo six months of chemotherapy, followed by radiation therapy.

NBP Ltd's response

21. NBP Ltd Director and pharmacist Mr D advised HDC that NBP Ltd was informed of the error on 21 September 2013 and, upon hearing of it, staff were devastated that it had occurred and offered Ms A their apologies.

22. Mr D stated that NBP Ltd undertook an investigation to determine how the error occurred. It was noted that on 27 March 2013 Ms A's prescription was entered into the computer at 1.49pm and recorded as paid for at 2.07pm. It appears that the information was correctly entered into the computer, as a label for 20mg tamoxifen was generated. However, tenoxicam was incorrectly selected from the shelf and subsequently dispensed to Ms A.

23. NBP Ltd Director and pharmacist Mr C advised that staff routinely check prescriptions the day after dispensing to ensure they are correct. He explained that this is performed electronically, but as Ms A's prescription had been entered into the

[2] Tamoxifen tablets are white and round and packaged in silver foil and green film, whereas tenoxicam tablets are ochre coloured and oval and packaged in silver foil and clear film.
[3] Tenoxicam is an antirheumatic, anti-inflammatory and analgesic agent.

dispensing software correctly and this was a selection error, nothing untoward was picked up during that routine check.

24. Mr D explained that dispensary stock is organised in alphabetical order on the shelves according to the generic name of the drug. Consequently, at the time of dispensing, the tamoxifen and tenoxicam were close together. Mr D noted that although these two medications were on the same shelf with "a couple of products in between", the medications are physically different.

Differences in tamoxifen and tenoxicam

25. Mr C advised HDC that although the tablets remain in their foil strip packaging when dispensed, the physical differences between tamoxifen and tenoxicam would be apparent to a dispensing pharmacist.

26. According to the Medsafe website, there are two brands of tamoxifen approved for distribution in New Zealand — Sandoz and Genox. Based on the information provided by NBP Ltd, Genox was the brand it stocked.

27. Tamoxifen is a non-steroidal, triphenylethylene-based drug. It is indicated for the treatment of breast cancer and prevents oestrogen binding to the oestrogen receptor. The initial dose is 20mg once daily. The dosage may be increased to 40mg daily if no response is seen in patients with advanced breast cancer.[4]

28. Mr C provided the following description of tamoxifen and the way it is packaged:

> "Tamoxifen 20mg tablets are strip packaged with five strips of twenty tablets in each strip, 100 tablets in a box. The strips have silver foil on one side and a green film on the other. The silver foil has the words Genox 20mg over Tamoxifen 20mg over as citrate in brackets printed on it. This is repeated several times on the foil backing. The tablets are white and round, scored on one side with TN over 20, and the reverse side has a G marked on it. When dispensing these tablets they remain in the foil strip, with the strips being cut to dispense the required quantity for each prescription."

29. The Medsafe website advises that tenoxicam is available as a tablet and a powder for injection. Ms A was dispensed the 20mg tablet and the brand was Tilcotil.

30. Tenoxicam is described as an antirheumatic, anti-inflammatory and analgesic agent. It is indicated for the symptomatic treatment of various painful inflammatory and degenerative disorders of the musculoskeletal system, including rheumatoid arthritis, osteoarthritis, arthrosis, and ankylosing spondylitis. It is also indicated for postoperative pain, acute gout and primary dysmenorrhea. For all indications except postoperative pain, acute gout and primary dysmenorrhea, a daily dosage of 20mg should be taken at the same time each day.[5]

31. Mr C described tenoxicam as follows:

[4] http://www.medsafe.govt.nz/profs/datasheet/g/genoxtab.pdf.
[5] http://www.medsafe.govt.nz/profs/datasheet/t/tenoxicaminj.pdf.

> "Tenoxicam 20mg tablets are strip packaged with 10 strips of 10 tablets in each strip, 100 tablets in a box. The strips have silver foil on one side and clear film on the other. The silver foil has the words Tilcotil over Tenoxicam over 20mg printed on it. This is repeated several times on the foil backing. The tablets are ochre coloured, oval, and scored on one side and marked '20' on the other. When dispensing these tablets they remain in the foil strip, with the strips being cut to dispense the required quantity for each prescription."

32. According to Mr C, the similarities between the products are the strength, dosage regimen for treatment, the fact that they are both taken with food, and that they are similar sounding and looking in written form.

Dispensing pharmacist

33. According to the incident notification form that was sent to the Pharmacy Defence Association, the same pharmacist "processed, picked[6] and checked items". A review of Ms A's prescription revealed that it was not initialled as dispensed or checked by a pharmacist.

34. Mr C advised that it was the registered pharmacist's exclusive duty to take the prescription from the dispensing/checking counter. He explained that the pharmacist provides the final check, then immediately files the prescription for claiming. According to Mr C, the prescription is bagged immediately prior to taking the prescription item(s) out to the patient. He said that no exceptions have ever been made to this procedure, and for this reason they are certain that Ms A's prescription would have been checked by a pharmacist.

35. Mr D advised that there were four pharmacists working on 27 March 2013 — Ms E, Mr C, Mr B and himself. Ms E, Mr B and Mr D worked from 8.30am to 5.30pm, and Mr C worked from 5.30pm to 7pm.

36. NBP Ltd initially concluded that Mr B was the pharmacist responsible for the dispensing error on 27 March 2013 for the following reasons:

- Mr B did not routinely sign the prescriptions he checked and dispensed despite frequent reminders to do so, and the technicians at NBP Ltd had ceased to follow up with Mr B to ensure that he correctly marked prescriptions.

- Ms E, Mr C and Mr D signed the prescriptions they checked, and had built this into their checking procedures.

- On 27 March 2013, NBP Ltd dispensed 547 prescription items, of which 239 were new items[7] and 308 were repeat prescriptions.[8] Mr C advised that between 1.48pm and 2.30pm there were 11 prescriptions dispensed. He found that four were initialled by Mr D and seven were not initialled.

[6] Selected from the shelf.
[7] Physical prescriptions either brought in by patients or faxed from doctors' surgeries.
[8] The reissuing of medicines from previously presented prescriptions.

- Mr C reviewed all the prescriptions dispensed for the entire day and found that no prescriptions were initialled by Mr B, although he had worked a full day.

37. According to Mr C, he and Mr D had raised the issue of non-compliance with SOPs with Mr B on a number of occasions over the years. Mr C stated that "this did not result in any change to [Mr B's] practice and I think it is fair to say that we had given up a long time ago".

38. Although NBP Ltd concluded that Mr B was the pharmacist most likely to have made the dispensing error, Mr C acknowledged that it was possible that another pharmacist made the error and failed to sign the prescription. He said that they could not exclude anyone who was working at the pharmacy that day, but can work only with what they definitely know, recognise their failure, and make improvements.

Individual responses

Ms E

39. Ms E said that during the time the error occurred, "there were a lot of meetings taking place outside of the pharmacy… This meant that [Mr D] and [Mr B] would often have to leave the pharmacy for periods of time. In order to do this, they would swap, shorten, or even split their individual lunch breaks."

40. Ms E advised that she normally took her lunch breaks to fit around those of Mr D and Mr B. Ms E said that she viewed the prescription log for 27 March 2013 and there were no prescriptions processed between 12.15pm and 3.18pm that carried her signature or annotations.

41. According to Ms E, she always signs her prescriptions and annotates 99% of them. She stated that she follows this process as she wants to be held accountable if she makes a mistake and, conversely, does not want to be held accountable for someone else's mistake. In addition, Ms E advised that signing prescriptions is part of her internal checking process and a requirement as per the SOPs.

42. Ms E stated that in her two years at NBP Ltd, she rarely saw Mr B sign a prescription unless it was a controlled drug script. She also stated that it was "always generally assumed that an unsigned prescription had been checked by [Mr B]" and it "was that way from the day [she] started working at NBP".

Mr D

43. Mr D agreed that start times and lunch breaks varied, and that the roster during the month of March 2013 was extremely vulnerable to last-minute changes. This was because he and Mr B had appointments with their lawyers or he had other personal appointments. However, Mr D noted that a review of the dispensing records showed that he may have taken his lunch break before the error was made.

44. Mr D advised that he worked with Mr B in the same dispensary for seven years and rarely witnessed him sign a prescription. Mr D stated that while still an intern pharmacist 14 years ago, he built into his dispensing procedure the practice of signing prescriptions, and has never had any reason not to sign his work.

Mr B

45. Mr B acknowledged that on occasion he has failed to initial the prescriptions, but explained that he would still check prescriptions. According to Mr B, he usually initialled prescriptions with the first letter of his name or this initial twice. He stated that other dispensers at the pharmacy were also "not 100% in their initialling". In addition, he disagreed that technicians had to follow up with him for failing to initial prescriptions and eventually ceased to do so.

46. Mr B considered that NBP Ltd's logic in concluding that he was the dispensing pharmacist who made the error was flawed. He advised that on 27 March 2013, he took his lunch break from approximately 1.00pm to 2.00pm, and can state with confidence that he was not on the premises when the error occurred. According to Mr B, the prescriptions dispensed before and after Ms A's were initialled by someone else. He advised that this is further evidence to suggest he was not present in the dispensary when the error occurred.

Questions from Ms A

47. Ms A questioned whether a leaflet or instructions should have accompanied the tenoxicam she was incorrectly dispensed, as she had not taken this medication previously. Mr D explained that it is not compulsory for consumer information to be included with medicines, either by the manufacturer or the pharmacy. He stated:

> "[NBP Ltd] provide[s] Med-Info sheets on request for patients, but as this was a picking error[9] and the incorrect medicine given this would not have resulted in the production of an information sheet, which is generated at the time the prescription is processed. Once requested, it is our policy to provide consumer information to the patient (with or without a prescription being presented)."

48. Ms A queried why the dispensing error was not identified by NBP Ltd's stocktake procedures, and whether there were any discrepancies in the stock. According to Mr D, NBP Ltd's stock orders are generated by computer from usage. He explained that the tamoxifen would have been ordered, as that is what the computer label recorded as being dispensed.

49. Mr D advised that whoever placed the stock on the shelf did not realise the significance of having 90 more tablets on hand than usual. He stated:

> "[W]hen we do re-order Tamoxifen, it is common to re-order 300 to 600 tablets at a time and having 90 more tablets on hand would not raise alarm bells unless checked against electronic stock levels, a practice which is only mandatory with Class A and B controlled drugs, which are kept in the safe and recorded in a manual register."

50. Mr C stated that when orders are generated, the person who generated the order is tasked with looking for anomalies in the order, and stock checks are done once the order is generated (as time permits). He explained that sometimes there are significant variances between the stock level in the computer and what is on the shelf, which

[9] Selecting the medication from the shelf.

prompts further investigation. Mr C reiterated Mr D's comments and advised that Ms A's dispensing error would not have resulted in sufficiently incorrect levels of stock so as to warrant investigation.

51. According to Mr C, NBP Ltd performs rolling stocktakes on areas of the dispensary as time permits.

Standard Operating Procedures

52. The Pharmacy Council of New Zealand (PCNZ) defines standard operating procedures (SOPs) as living documents that detail written instructions describing specific steps to follow in all activities under defined conditions. PCNZ states that "SOPs are necessary to ensure the continuity of processes to achieve quality performance and quality products/preparations. They form part of clinical governance, and in particular, show that pharmacists are putting in place strategies for risk management and harm minimisation".[10]

53. In March 2013, NBP Ltd had a dispensing SOP in place. The purpose of this SOP is to help ensure that "the pharmacist maintains a disciplined dispensing procedure which ensures that the appropriate product is selected and dispensed correctly and efficiently. This includes the acceptance of prescriptions by shop staff, initiating the dispensing process and time frames for prescription processing."

54. NBP Ltd's dispensing SOP outlines instructions for recording the prescription details, generating a label and selecting the correct medicine. The SOP clearly instructs staff to "check that the right medicine and brand is used", as well as "check the strength, form and quantity of the medicine against the prescription".

55. According to the dispensing SOP, a pharmacist must "check the dispensed medicine against the prescription" to ensure the correct medication is being dispensed.

56. The SOP also states that the "dispenser and checker must be able to be identified at all times. Each item must be initialled appropriately to reflect this".

57. In addition to the dispensing SOP, NBP Ltd has SOPs for stock ordering and incident reporting. The stock ordering SOP[11] confirms Mr D's comments that stock is generated electronically. The incident reporting SOP advises that a reported complaint should be reviewed, and procedures changed where possible to avoid a similar complaint.

58. Mr C advised that NBP Ltd's SOPs were reviewed by a Medsafe Auditor in 2010 and were found to be lacking some detail. He explained that these issues were rectified and the procedures updated accordingly.

59. The dispensing SOP dated 23 August 2006 was in place in March 2013. However, according to Mr C, NBP Ltd's SOPs are reviewed constantly in order to improve the

[10] http://www.pharmacycouncil.org.nz/cms_show_download.php?id=316.
[11] The stock ordering SOP at the time of the error was dated 26 June 2006.

procedures and systems. He noted that on some occasions there has been a failure to record the review dates.

60. Mr C signed the dispensing SOP on 23 August 2006, as he had inspected it. There are two further signatures present, which Mr C advised belong to Mr B. The most recent signature is dated 20 November 2009. No other staff have signed the SOP.

Other measures in place to prevent errors

61. Mr C advised that there are a number of medicines that have "look alike–sound alike names" and the following measures were in place in March 2013 at NBP Ltd to avoid mistakes:

- A notice attached to the shelf where medications identified as potentially confusing are located, eg, doxepin 25mg capsules and dothiepin 25mg capsules have a similar presentation and function. NBP Ltd has a notice attached to the shelf highlighting the similarity of the products as a prompt for the dispenser.
- Notes are added to particular medicines in the dispensing software programme alerting the person who is entering the prescription of the possibility of errors or likely areas of confusion with these medicines.
- NBP Ltd's software has a function incorporated into the programme that alerts the person entering the prescription of a similarly spelt medicine or similar strength medicine with a confusing or similar name. This function looks at what previous medicines have been dispensed for a patient as the trigger point.

Actions implemented since the dispensing error

62. Mr D stated that tamoxifen and tenoxicam have very similar names, and extra care should be taken with medicines that have "look alike–sound alike names". He advised that NBP Ltd accepts that it failed Ms A in this instance. As a result of this error, there have been three staff meetings where the error was discussed as a group, including what went wrong and what more could be done to avoid a similar error in future. NBP Ltd has also reviewed and updated its dispensing and checking SOPs in light of this error.

63. According to Mr C, there was no specific alert or precaution in place for tenoxicam and tamoxifen in March 2013, as NBP Ltd has never previously experienced a situation where these two medications have been confused with each other. Since the dispensing error involving Ms A, a notice has been placed beneath both these medications on the shelf. Tenoxicam and tamoxifen have also been relocated on the shelves, so that they are not in close proximity to each other.

64. On 24 September 2013 a dispensary meeting was held where Ms E explained the dispensing error. The following changes were communicated at this meeting and subsequently implemented:

"a) Branded labelling for similar generically named medicines which makes it harder to mix up the medicines. This means that Tamoxifen/Tenoxicam would now be labelled as Genox/Tilcotil respectively. Other medicines included in this branded labelling are Doxepin/Dothiepen, Carbamazepine/

Carbimazole, and different brands of medicines with the same generic name e.g. lamotrigine tablets supplied as Lamictal and Arrow-Lamotrigine tablets, salbutamol inhalers supplied as Respigen, Salamol, and Ventolin inhalers.

b) Branded labelling was also extended to non-interchangeable brands of the same medicine i.e. Lithium tablets became Priadel/Lithicarb tablets, warfarin tablet labels became Marevan/Coumadin tablets, levothyroxine tablets became Eltroxin/Goldshield-levothyroxine/Synthroid tablets.

c) Discussion of the need for more care when dispensing medicines was insisted on for both the person picking the item off the shelf and the person checking the item.

d) Sub-shelf labels were put up to draw attention to similar generically named items.

e) More physical shelf space was put between the similar generically named items."

65. On 14 October 2013, an NBP Ltd Directors' meeting was held and a decision was made to implement further preventative measures:

"a) Two people are now required to check every prescription (preferably two pharmacists, but alternatively a technician could provide a second check). The only exception was late night and weekend shifts where pharmacists are sole charge in the dispensary.

b) No exceptions would be tolerated in regard to failure to initial/sign work. Both checkers were to place their initial in the designated place under the date stamp.

c) It was emphasised that there was to be no compromise in the new policy while a second checker was onsite, even if they were temporarily unavailable. E.g. in the toilet or speaking to customers etc.

d) Standard Operating Procedures (SOPs) were reviewed and updated to reflect the new procedures.

e) We decided that though we did not think we were deliberately rushing our dispensing of prescriptions on a day to day basis, waiting time expectations were to be raised from 5–10 minutes when quiet and 10–15 minutes when busy, to 10–15 minutes when quiet and 15–20 minutes when busy.

f) Staff were advised that though we would still be available to speak to the public/shop customers/telephone calls, delays in requests for the pharmacist's time were to be expected as they must be allowed to make their final checks without interruption.

g) Retail staff were notified of the changes to procedure, and these were implemented immediately."

66. On 11 November 2013, electronic notes were placed in the files of the similar generic named medicines, to draw attention to their higher than usual potential for error. Running stock checks were implemented on similar generic named medicines. Mr C

advised that this was done by the person picking the product off the shelf, by using information printed on the third part of the dispensary label. He explained that since Ms A's dispensing error, any stock discrepancies are to be reported immediately to the checking pharmacist. Mr C said that this practice would ensure that the chances of stock being incorrect were minimal and will trigger "alarm bells" for the checking pharmacist, if the wrong item has been selected off the shelf.

Response to Provisional Opinion

67. NBP Ltd advised that it contacted the Pharmacy Guild to discuss better ways of managing the SOPs. The Guild advised that it is in the process of introducing a web-based process for managing and reviewing SOPs, and anticipates that this will be available in the next two to three months. The Guild suggested that NBP Ltd wait until this is available rather than purchase the current outdated software.

68. NBP Ltd advised that once the new web-based system is available, all staff will be asked to review and sign the relevant SOPs at the relevant review dates. It also proposes to incorporate this as part of the staff induction process.

Opinion: Breach — Napier Balmoral Pharmacy Limited

Introduction

69. NBP Ltd is responsible for ensuring that consumers attending the pharmacy receive the correct medications. I have considered the extent to which the medication error in this case may have occurred as a result of individual staff action or inaction, as opposed to systemic and organisational issues. Based on the information gathered, I am unable to make a factual finding on which individual pharmacist dispensed the incorrect medication to Ms A. However, it appears that NBP Ltd's SOP for dispensing was not followed. I am concerned that aspects of the organisational processes in place at NBP Ltd, when taken together, indicate that inadequate systems were in place to ensure that the dispensing SOP was followed and that services were provided to Ms A with the expected level of care and skill.

Physical setup

70. NBP Ltd's dispensary stock is organised in alphabetical order on the shelves according to the generic name of the drug. Therefore, at the time of the error, tamoxifen and tenoxicam were in close proximity.

71. NBP Ltd advised HDC that it did have notices attached to the shelf where medications identified as potentially confusing are located. Additionally, notes are added to particular medicines in the dispensing software programme alerting the individual entering the prescription of the possibility of errors or likely areas of confusion with

these medicines. However, at the time of the dispensing error in March 2013, there was no specific alert or precaution in place for tenoxicam and tamoxifen. This was because NBP Ltd had never previously experienced a situation where these two medications had been confused with each other.

72. Look-alike sound-alike medication names are one of the most common causes of medication errors throughout the world.[12] Insufficient systems within the pharmacy environment increase the chances of these types of medication errors occurring. The issue of look-alike sound-alike medication names, as well as suggested strategies to reduce these types of errors, is well publicised both in New Zealand and internationally. The September 2008 PCNZ newsletter featured an article on patient safety and look-alike sound-alike medicines. It provided measures that pharmacists can implement to reduce these errors. The article also listed the medications that have been involved in near-misses or reported errors, which included tenoxicam and tamoxifen (see **Appendix A**).

73. In light of the above, I consider that it was suboptimal that the tenoxicam and tamoxifen had been placed in close proximity at the pharmacy without a specific alert or precaution notice attached to the shelf.

Standard Operating Procedures not enforced

74. At the time of the dispensing error, NBP Ltd had a dispensing SOP in place to help ensure that "the pharmacist maintains a disciplined dispensing procedure which ensures that the appropriate product is selected and dispensed correctly and efficiently".

75. NBP Ltd's dispensing SOP outlined instructions for recording the prescription details, generating a label and selecting the correct medicine. The SOP advised that the "dispenser and checker must be able to be identified at all times. Each item must be initialled appropriately to reflect this".

76. Mr D, Mr C and Ms E asserted that Mr B did not routinely sign the prescriptions he checked and dispensed despite frequent reminders to do so. Mr D stated that he, Ms E and Mr C did all sign the prescriptions they checked, and had built this into their checking procedures. Mr B acknowledged that on occasion he had failed to initial prescriptions, but noted that he would still check the prescriptions.

77. According to Mr C, he and Mr D raised the issue of non-compliance with SOPs with Mr B on a number of occasions over the years. Mr C stated that "this did not result in any change to [Mr B's] practice and I think it is fair to say that we had given up a long time ago". Mr C advised that the technicians at NBP Ltd had also ceased to follow up with Mr B to ensure that he marked prescriptions correctly. However, Mr C acknowledged that NBP Ltd should have enforced the SOPs with a greater degree of vigilance.

[12] Lambert BL et al, "Similarity as a risk factor in drug-name confusion errors." *Medical Care*, 1999, 37(12):1214–1225.

78. According to the incident notification form NBP Ltd sent to the Pharmacy Defence Association, the same pharmacist "processed, picked and checked items". During NBP Ltd's investigation of the error, all the prescriptions on 27 March 2013 were reviewed. It was noted that some prescriptions that day were not initialled and none of the prescriptions were initialled by Mr B, although he had worked a full day.

79. A pharmacy has an obligation to ensure that it has adequate policies in place to facilitate safe and disciplined dispensing. NBP Ltd had a dispensing SOP outlining the pharmacists' responsibility to select the correct medication and to perform a check against the prescription to ensure the correct medication is being dispensed. The SOP also clearly instructed the pharmacist to initial prescriptions, so that the dispenser and checker could be identified at all times. Clearly the SOP was not followed in Ms A's case, as she was dispensed the wrong medication and the prescription was not initialled.

80. Based on the information gathered, I am unable to make a factual finding on whether Mr B was the pharmacist who dispensed the incorrect medication to Ms A. However, I note the comments from Mr C, Mr D and Ms E regarding Mr B's frequent non-compliance with SOPs. It is disappointing that NBP Ltd acknowledged that not everyone at the pharmacy initialled the prescriptions they dispensed, yet it did not enforce compliance with the dispensing SOP. I consider that NBP Ltd should have enforced this requirement. Consumer safety is of utmost importance and, in my view, it is the responsibility of the pharmacy to ensure that every staff member, regardless of position, is compliant with SOPs in order to prevent harm to patients.

81. Although NBP Ltd had an adequate dispensing SOP in place, NBP Ltd was aware that a staff member was not complying with that SOP. Without staff compliance, SOPs become meaningless. NBP Ltd had a responsibility to ensure that all staff complied with the SOPs and therefore provided appropriate services. I consider that NBP Ltd failed to fulfil its obligations in this regard.

Review of SOPs

82. In August 2008, the PCNZ published a document on drafting SOPs,[13] which includes information on who should write SOPs, what information should be included, and when SOPs should be reviewed. The PCNZ recommends:

> "All SOPs should be numbered and should be clearly marked with the date of preparation and/or date of review/amendment. They should be kept up to date and relevant at all times and should be regularly reviewed to allow for changes in practice or circumstances, for example, legislative changes or changes of staff. In the absence of any obvious changes, reviews should be undertaken at least once every two years.
>
> When SOPs are first drafted, or when new members of staff are appointed, it is good practice to ask staff to sign to say that they have read and understood them. As well as clarifying staff roles, this can also offer an opportunity for staff training

[13] Writing Standard Operating Procedures: http://www.pharmacycouncil.org.nz/cms_show_download.php?id=316

and development. Pharmacists should ensure that any changes to SOPs are brought to the attention of relevant staff."

83. NBP Ltd's dispensing SOP in place in March 2013 was dated 23 August 2006. Mr C last signed the dispensing SOP on 23 August 2006, as he had inspected it then. There are just two further signatures present, which Mr C advised belong to Mr B. The most recent signature is dated 20 November 2009.

84. According to Mr C, NBP Ltd's procedures are reviewed constantly in order to improve the procedures and systems, but he agreed that there had been a failure to record the review dates. The failure to record the review dates does not support Mr C's claim of regular reviews. In my view, if the dates of the reviews are not recorded it can reasonably be concluded that such reviews did not take place.

85. In addition, as there were only two signatures on the dispensing SOP it is difficult to ascertain whether all staff working at the pharmacy were aware of that SOP. If staff are unaware of the required procedures they cannot adhere to them. It is NBP Ltd's responsibility to ensure that all staff, new and existing, are familiar with the SOPs and kept up to date with any changes.

Conclusion

86. I consider that it was suboptimal that tamoxifen and tenoxicam had been placed in close proximity at the pharmacy without a specific alert or precaution notice attached to the shelf.

87. I further find that it was poor practice that NBP Ltd did not document regular reviews and updates of its SOPs, was unable to demonstrate that staff read the SOPs and, despite being aware of ongoing non-compliance with the dispensing SOP, failed to enforce compliance. The PCNZ has stated that procedures are the cornerstone of a strong quality system and support meeting the overall goal of providing the public with safe and effective medical products.[14] I agree and further note that without staff awareness of, and compliance with, SOPs they become meaningless.

88. In my opinion, NBP Ltd's failure to place an alert or precaution notice near the tamoxifen and tenoxicam and to ensure staff knowledge of, and compliance with, its dispensing SOP played a significant part in Ms A receiving the incorrect medication.

89. NBP Ltd did not provide services to Ms A with reasonable care and skill and breached Right 4(1) of the Code.

[14] Writing Standard Operating Procedures: http://www.pharmacycouncil.org.nz/cms_show_download.php?id=316.

Recommendations — Napier Balmoral Pharmacy Limited

90. I note the actions taken by NBP Ltd since the dispensing error.

91. In my provisional report, I recommended that NBP Ltd apologise to Ms A for breaching the Code. NBP Ltd provided a formal written apology, which has been forwarded to Ms A.

92. In addition, I recommend that NBP Ltd undertake the following:

- Audit compliance with its SOPs related to consumer safety over a three-month period on three separate days and provide HDC with the outcome of that audit.
- Ensure that SOPs and updates of SOPs related to consumer safety are signed by all staff to indicate that they have read and understood the procedures, and advise HDC that this has been completed.
- Ensure that SOPs are reviewed at least every two years, and that the date of review is clearly documented.
- Ensure that all medications with look-alike sound-alike names stocked in the pharmacy are associated with specific measures to prevent dispensing errors, and advise HDC that this has been completed.

Please confirm by **29 August 2014** that the recommendations have been met.

Follow-up actions

93.
- A copy of this report with details identifying the parties removed, except the name Napier Balmoral Pharmacy Limited, will be sent to the Pharmacy Council of New Zealand and the District Health Board.
- A copy of this report with details identifying the parties removed, except the name Napier Balmoral Pharmacy Limited, will be placed on the Health and Disability Commissioner website, www.hdc.org.nz, for educational purposes.

Appendix A — List of look-alike sound-alike medicines[15]

The concern surrounding LA/SA names is international and although it may not be obvious in some of the following, most have been involved in near-misses or reported errors. Generics are in *italics*.

Aci-dex and Aci-jel
amantadine and *amlodipine*
aminophylline and *amitriptyline*
Atropt 1% and Azopt 1%
baclofen and Bactroban
beclomethasone and *betamethasone*
carbamazepine and *carbimazole*
ceftriaxone and *cefotaxime*
chlorpromazine and *clomipramine*
daunorubicin and *idarubicin*
digoxin and *Diamox*
docetaxel and *paclitaxel*
Frumil and Frisium
Humalog and Humulin
ketoprofen and *ketotifen*
Lamictal and Largactil
lanzoprazole and *latanoprost*
levothyroxine and *liothyronine*
Logem and Loten
metformin and *metronidazole*
olanzapine and *omeprazole*
Plavix and Paxol
quinine and *quinidine*
tramadol and Travatan
Tobradex and Tobrex
Zostrix and Zovirax

Adacel and Adalat
amlodipine and *amitriptyline*
Aratac and Arava
Avandia and Coumadin
baclofen and Batrafen
budesonide and *bumetanide*
Cardiprin and Cardizem
Celebrex and Zyprexa
clonidine and *clomiphene*
Diflucan and Diprivan
Dilatrend and *diltiazem*
doxepin and *dothiepin*
gliclazide and *glipizide*
imipramine and *trimipramine*
lamivudine and *lamotrigine*
Lamictal and Lamisil
Leukeran and Alkeran
Lexapro and Loxamine
mercaptamine and *mercaptopurine*
methotrexate and *methotrimeprazine*
Oxycontin and *oxycodone*
Progout and Prograf
Seretide and Serevent
tamoxifen and *tenoxicam*
Xenical and Xeloda
Zyprexa and Zyrtec

Hospital pharmacists also have difficulty with packaging similarities for many injectables e.g. Morphine amps (DBL) (all strengths), Fentanyl amps/Sodium chloride amps, many AstraZeneca Polyamps, Heparin injection. If you dispense any of these products, be aware that extra care is required.

[15] http://www.pharmacycouncil.org.nz/cms_show_download.php?id=57.