**District Health Board**

**Paediatric Registrar, Dr C**

**Pharmacy**

**Pharmacist, Ms B**

**Pharmacist, Ms D**

**A Report by the**

**Health and Disability Commissioner**

**(Case 15HDC01542)**

Health and Disability Commissioner
*Te Toihau Hauora, Hauātanga*

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## Executive summary

1. Miss A, aged two years and 11 months, experienced painful and difficult urination following bladder surgery. She was reviewed for this on 8 September 2015 by paediatric registrar Dr C at the Day Stay Unit of a public hospital (the hospital). After discussion with a senior colleague, Dr C prescribed some medications for Miss A including oxybutynin, which is primarily indicated for the management of urinary urgency and incontinence.

2. Dr C chose a dose of 2mg oxybutynin, "because [Miss A's] weight was mid-range for her age, the dose is mid-range for dosage and 2mg would be manageable for dispensing and administering". Instead of writing "oxybutynin 2mg" three times daily for ten days on the prescription form, Dr C wrote "oxybutynin 20mg", three times daily for ten days, which was a ten times higher dose.

3. Miss A's father took the prescription forms to the pharmacy that evening for the medications to be dispensed. Pharmacist Ms B noticed that the oxybutynin dose seemed high but did not question it at the time. The oxybutynin and one other item were not in stock, so they were ordered for the next day.

4. The following day, the oxybutynin and the other item were delivered to the pharmacy. Ms B and the pharmacy owner, pharmacist Ms D, were on duty. The prescription forms are not initialled to show who completed the dispensing. The medications were placed in a bag, and the bag was placed in the delivery basket at the pharmacy. Ms D delivered the medication to Miss A's mother. Ms D said that she omitted to discuss the medication for Miss A with Miss A's mother, but discussed a separate health issue.

5. Three days later, Miss A's mother gave Miss A the prescribed dose of oxybutynin after she had ongoing pain with passing urine. Miss A experienced side effects and was taken to the hospital's Emergency Department, where she was monitored and discharged later that day. Miss A experienced ongoing side effects.

### Findings

6. It was Dr C's responsibility to ensure that she prescribed a clinically appropriate dose of oxybutynin to Miss A. By failing to do so, Dr C did not provide services with reasonable care and skill, and the Commissioner found that she breached Right 4(1) of the Code of Health and Disability Services Consumers' Rights (the Code).[1]

7. The Commissioner considered that if electronic prescribing had been available to Dr C when she prescribed the medication to Miss A, it could have minimised the risk of this error occurring.

8. Ms B failed to take steps to contact the prescriber when she noticed that the oxybutynin dose seemed high. Ms B also did not sign on the date stamp to indicate that she had dispensed and/or checked Miss A's prescriptions in accordance with the

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

pharmacy's Dispensing Prescriptions Standard Operating Procedure (SOP). The Commissioner found that Ms B did not provide Miss A with services in accordance with professional standards, and breached Right 4(2) of the Code.[2]

9. The Commissioner was critical that Ms D did not check the prescriptions, calculations and labels on 8 September 2015, did not ensure that the Dispensing Prescriptions SOP was followed, and missed an opportunity to check the appropriateness of the prescription for Miss A at the time of delivery of the medications to Miss A's mother. The Commissioner found that, in all the circumstances, Ms D did not provide services to Miss A with reasonable care and skill, and breached Right 4(1) of the Code.

10. Non-compliance with the Dispensing Prescriptions SOP played a part in Miss A receiving an inappropriate dose of oxybutynin. Accordingly, the Commissioner found that the pharmacy did not provide services to Miss A with reasonable care and skill and breached Right 4(1) of the Code.

11. The Commissioner was critical that the pharmacy intern did not sign the prescription to indicate her involvement in the dispensing process.

**Recommendations**

12. The Commissioner recommended that Dr C, Ms B, Ms D and the pharmacy each provide a written apology to Mr and Mrs A.

13. The Commissioner recommended that the DHB introduce systems to allow a specific space for the recording of a child's weight on prescriptions; give feedback to HDC on the implementation of its new electronic prescribing system, and use this case as an anonymised case study for education for paediatric medical staff.

14. The Commissioner recommended that the pharmacy undertake two audits of compliance with its Dispensing Prescription SOP, and use this case as an anonymised case study for education for future pharmacist or pharmacy intern employees of the pharmacy.

15. The Commissioner recommended that the Pharmacy Council of New Zealand consider whether a review of Ms B's competence is warranted.

16. The Commissioner recommended that the Ministry of Health actively continue to support the rollout of electronic prescribing across New Zealand's DHBs in both inpatient and outpatient settings, and work with the sector to progress an integrated approach to medicines management.

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

## Complaint and investigation

17. The Commissioner received a complaint from Mrs A about the services provided to her daughter, Miss A. The following issues were identified for investigation:

- *The appropriateness of the care provided to Miss A by Dr C in September 2015.*
- *The appropriateness of the care provided to Miss A by the DHB in September 2015.*
- *The appropriateness of the care provided to Miss A by the pharmacy in September 2015.*
- *The appropriateness of the care provided to Miss A by Ms B in September 2015.*
- *The appropriateness of the care provided to Miss A by Ms D in September 2015.*

18. An investigation was commenced on 31 March 2016.

19. The parties directly involved in the investigation were:

| | |
|---|---|
| Mrs A | Complainant/consumer's mother |
| District Health Board | Provider |
| Pharmacy | Provider |
| Ms B | Pharmacist |
| Dr C | Paediatric registrar |
| Ms D | Pharmacist |
| Ms E | Pharmacy intern |

Also mentioned in this report:

| | |
|---|---|
| Mr A | Miss A's father |
| Dr F | Paediatric surgeon |

20. Information was also reviewed from:

The Medical Council of New Zealand
The Pharmacy Council of New Zealand

21. Independent expert advice was obtained from consultant paediatrician Dr Roger Tuck (**Appendix A**) and pharmacist Sharynne Fordyce (**Appendix B**).

## Information gathered during investigation

### Background

22. On 25 August 2015, Miss A, aged two years and 11 months, had an operation by paediatric surgeon Dr F to remove a urachal cyst[3] from her bladder. Miss A was discharged the following day. A urinary catheter was inserted during surgery and then removed three days later. Miss A experienced worsening dysuria (painful/difficult urination) following the catheter removal and was prescribed a dose of oxybutynin[4] that was too high for a toddler. This report is about the care Miss A received in relation to the prescribing and dispensing of oxybutynin in September 2015.

### 8 September 2015

*Day Stay Unit*

23. On 8 September 2015, Miss A was seen at the Day Stay Unit for review of her dysuria by paediatric registrar Dr C.

24. Dr C examined Miss A and found that her abdomen was soft and non-tender. Miss A had an ultrasound scan, which showed thickening of the top of the bladder and a small volume of free fluid adjacent to the bladder wall, which was likely a result of her recent surgery. Dr C discussed Miss A's case with Dr F, and they decided to start Miss A on a course of antibiotics,[5] analgesia (pain relief medication)[6] and oxybutynin.

25. Dr C handwrote the prescriptions for Miss A on two separate DHB prescription forms (see **Appendix C**). Regarding the oxybutynin prescription, Dr C stated:

> "I … split the analgesia onto a separate prescription sheet and referred to the appropriate medication dose in the New Zealand Formulary for Children (NZFC).[7] I split the analgesia because this is commonly prescribed and administered whereas the other medication is less so and I wanted to reduce the risk of an error. The dose range [for oxybutynin] for patients 2–5 years is 1.25–2.5mg and I chose 2.0mg because [Miss A's] weight was mid-range for her age, the dose is mid-range for dosage and 2mg would be manageable for dispensing and administering. I documented the on-call contact number which is routine practice to enable checking of the medication if there is a query about the medication or dosage or frequency by either the pharmacy or parents. The on-call phone is manned 24/7 by a surgical registrar."

26. Instead of writing "oxybutynin 2mg" three times daily for ten days on the prescription form, Dr C wrote "oxybutynin 20mg", three times daily for ten days, which was a ten

[3] A urachal cyst occurs in the remnants between the navel and the bladder.
[4] Oxybutynin chloride is primarily indicated for the management of urinary urgency and incontinence.
[5] Amoxicillin (Augmentin) and clavulanate suspension. In a suspension, the medication is mixed with a liquid in which it cannot dissolve.
[6] Paracetamol, ibuprofen, tramadol, and lignocaine gel.
[7] The NZFC is an independent resource providing healthcare professionals with clinically validated medicines information and guidance on best practice, enabling healthcare professionals to select safe and effective medicines for individual patients.

times higher dose. Dr C also documented Miss A's weight, 14kg, on both prescription forms. Dr C later told HDC that "the prescription read 20mg rather than 2.0mg".

27. The DHB confirmed that Dr C received an orientation booklet as part of her registrar training, which included guidelines on safe prescribing and links to the hospital's prescribing guidelines. The hospital's prescribing guidelines state: "Never write a trailing zero[8] after a whole number ie 8mg, not 8.0mg."

28. Miss A was discharged with a plan to review her in one week's time (on 15 September 2015) at the registrar clinic.

*The pharmacy*

29. Miss A's father, Mr A, took the prescriptions to the pharmacy[9] at around 5pm on 8 September 2015 for the medications to be dispensed. Ms B[10] was the pharmacist on duty and was working with pharmacy intern Ms E.

30. Ms B said that Ms E took the prescriptions from Mr A and began processing them through the computer. Ms E told HDC that she does not recall whether she entered the prescriptions into the computer, but does recall being involved in the dispensing of some medications for Miss A that were in stock.

31. Ms B said that she informed Mr A that the oxybutynin and the lignocaine gel were not in stock and could be ordered for the next day, but that the rest of the medications could be dispensed at that time.

32. Ms B said that Ms E began working on dispensing the medications. Ms B stated: "I had to help [Ms E] calculate the volume required for the doses of Augmentin, Paracetamol, Ibuprofen and Tramadol, because she was struggling to convert the [milligrams] on the prescription to [millilitres] required for dosing." Ms B stated that she reconstituted the antibiotic suspension[11] while Ms E dispensed the other items on the prescription.

33. Ms B told HDC that, as she was checking the medication labels, she noticed that oxybutynin had been entered into the computer as tablets, rather than as the liquid that had been prescribed. Ms B told HDC that she "noticed that the dose seemed high, but did not question it at the time". Ms B stated: "I acknowledge that I should have attempted to contact the prescriber regarding the high dose of oxybutynin at that time instead of leaving it for later, regardless of what time of day it was."

34. Ms B generated a new oxybutynin label to read a liquid formulation and put it to one side with the prescriptions, to complete the dispensing when the new stock arrived the next day. Ms B then ordered the oxybutynin and the lignocaine gel.

[8] A trailing zero is where a whole number is followed by a decimal point and then a zero (eg, 2.0 instead of 2).
[9] Pharmacist Ms D is the sole director.
[10] At this time, Ms B had been a registered pharmacist for nearly one year.
[11] Mixed the antibiotics into liquid.

35. Pharmacy owner and pharmacist Ms D told HDC that she was out of the pharmacy on 8 September 2015 when the prescription was received, but that she arrived back at around 5.30pm, just as the last of the in stock medications for Miss A were being dispensed. Ms D said that she helped by dealing with other prescriptions that were waiting to be completed, so that Ms B and Ms E could concentrate on Miss A's prescriptions.

36. Ms D said that, after the medications were given to Mr A, Ms B expressed frustration to her regarding Ms E's inability to calculate the volumes required accurately. Ms D stated: "In hindsight, this should have been my [c]ue to check the entire prescription but I didn't." Ms D also told HDC: "I have faith in [Ms B's] capabilities that she would have corrected any errors. At the time I had no need to double check her work."

37. The prescriptions for Miss A's medications are not initialled or signed to show who carried out the dispensing or checking. However, there are some annotations on the prescriptions. Ms D advised HDC that these are mainly written by Ms B, but that some had been written and scribbled out by Ms E. Ms D stated that often Ms E wrote calculations on scrap bits of paper and discarded them, rather than annotating them on the prescription as instructed, "mak[ing] it very difficult to prove who did what on the prescription". Ms D stated that the annotations by Ms B indicate that she had to take over because Ms E was unable to do the calculations.

**9 September 2015**

38. On 9 September 2015, Ms B and Ms D were the pharmacists on duty at the pharmacy, and there was also a pharmacy student present. Ms E was not working, as it was her regular day off.

39. The oxybutynin liquid and lignocaine gel were delivered to the pharmacy at around 11am. The medications were then labelled and bagged for delivery. However, the prescriptions are not initialled or signed to show who dispensed or checked these items. Ms B and Ms D both told HDC that they are unsure who completed the dispensing by labelling and bagging the medications, and whether a final check was carried out. Ms D stated: "As there are no signatures on the prescription for the dispensing of this item, as the owner I will take responsibility as it was either [Ms B] or myself, we just cannot be certain."

40. The bag of medications was placed in the delivery basket at the pharmacy. That afternoon, Ms D delivered the medications to Miss A's mother, Mrs A. Mrs A told HDC that the medications were delivered to her house in a brown bag. She stated:

> "[The pharmacist] knew I had two very sick kids so I think they were saving me a trip back with one vomiting baby and one toddler beside herself in pain after having bladder surgery. I asked the pharmacist about the oxybutynin and she said they very rarely use it, that it can cause sedation."

41. Ms D stated that she "chatted with [Mrs A] in regards to a separate health issue concerning her other daughter … At no point did I discuss the prescription for [Miss

A].” Ms D said that, while she omitted to discuss the medication for Miss A, she told Mrs A that if she had any questions she could call her or Ms B at any time.

**12 September 2015**

42. On the morning of 12 September 2015, Mrs A administered Miss A 20ml of oxybutynin. Mrs A told HDC that she was nervous about using the oxybutynin, and that she recalls having the medication for a few days before she gave it to Miss A.

43. Mrs A stated:

> “As soon as I gave it, I thought that is an awful lot of medicine to get in to a child. I […] quickly googled, and discovered that this was an almost TEN TIMES overdose of a very dangerous drug. I rushed her to [the hospital] which is 15 minutes from my house. By the time I got there, she was blind from dilated pupils, was hallucinating and was starting to slur her words.”

44. Miss A was reviewed in the Emergency Department (ED) at 8.10am by a paediatric registrar, who recorded on the discharge summary:

> “Almost 3 year old girl presents after taking a 7 x the standard dose of oxybutynin at home as per the prescription. This equates to 1.4mg/kg (normal dose is 0.2mg/kg). Mother feels that [Miss A is] finding it difficult to see looking at toast closely, pupils dilated. Starting to sway. Not her normal self … [Miss A] has ongoing pain with passing urine last night. Therefore, mother gave oxybutynin this morning.”

45. The paediatric registrar examined Miss A and noted that her heart rate was 126 beats per minute, her respiration rate was 30 breaths per minute, her oxygen saturation was 100%, her temperature was 37.3°C, and her blood sugar level was 5.1mmol/L. These observations are all within the normal range for a child of Miss A’s age.

46. The paediatric registrar’s impression was that Miss A had some signs of mild anticholinergic[12] toxicity. Miss A had initial and repeat electrocardiograms,[13] which were normal.

47. Mrs A told HDC that Miss A had tremors and jerky movements, was sedated and difficult to rouse, she could not speak, and she had a high heart rate.

48. At 1.30pm, Miss A was reviewed by a paediatric surgical registrar,[14] who recorded that he would follow up with the pharmacy and prescriber to find out how the error had happened, to stop it happening again.

[12] Anticholinergics are a class of drugs that inhibit nerve impulses. Oxybutynin is an anticholinergic drug.
[13] These record the electrical activity of the heart over a period of time using electrodes placed on the skin.
[14] The registrar’s name is indecipherable from the clinical notes.

49. Ms D told HDC that she was contacted by the registrar, who told her what had happened. Ms D said that she then left a telephone message for Mrs A apologising for the error.

50. It is documented in the clinical notes that Miss A had myoclonic jerks[15] while she was asleep in the ED that afternoon. Miss A was discharged from the ED at around 5pm. The discharge summary states that Miss A was alert and comfortable at rest and had bilaterally dilated pupils. The discharge advice was to continue taking the appropriate dose of oxybutynin the next day if required (2.8ml[16] three times daily or as needed) and to return for review if Miss A had any abnormal behaviour, vomiting, urinary retention, or worsening vision, or if her parents were at all concerned.

**13–15 September 2015**

51. Dr C told HDC that, on 13 September 2015, the registrar told her about Miss A's admission to the ED the previous day, and that the registrar had contacted the pharmacy, had a photocopy of the prescription emailed from the pharmacy to the ED, and had alerted Dr F to the error. Dr C said that she discussed her error with the Clinical Director of Paediatric Surgery on Monday 14 September 2015.

52. Ms D told HDC that, on 14 September 2015, all pharmacy staff involved in the dispensing of Miss A's prescriptions convened to discuss what had happened and establish how the error had occurred, and to discuss how to prevent further incidents such as this occurring.

53. On 15 September 2015, Dr C reviewed Miss A with Mrs A at the registrar clinic, as had been arranged previously. Dr C said that she apologised for the error at this time, and that Mrs A was understandably very upset.

**Subsequent events**

54. Mrs A told HDC that Miss A had the following side effects after the overdose of oxybutynin: several days of lethargy; confusion and slurring her words; four days of severe abdominal pain, restlessness and difficulty urinating; two weeks of low grade fever; three days later, vomiting; and, four weeks later, bleeding from her rectum. Mrs A was also concerned that the overdose caused slow healing at Miss A's bladder surgery site, and urinary retention. Miss A was seen for those issues in the ED on 17 September, 28 September, and 4 October 2015.

**Further information — the pharmacy**

*Apology letter*

55. On 16 September 2015, Ms B wrote a letter of apology to Mr and Mrs A, which stated:

> "As a pharmacist, it was my responsibility to query the high dose of oxybutynin that was on the prescription and I failed to do that.

[15] Brief involuntary twitching of a muscle or group of muscles.
[16] This dose was calculated based on a rate of 0.2mg per kg.

> As a result of this incident, we have reviewed our dispensing procedures to ensure that similar mistakes won't happen to you or anyone else in the future …
>
> Once again I am very sorry that this occurred and offer my humble apologies for the distress and inconvenience caused. I would like to offer to pay for any ambulance fees or medical expenses that were incurred as a direct result of my error."

*Incident Notification form*

56. On 17 September 2015, Ms B filled in an Incident Notification form. She recorded that Mrs A contacted her on 13 September 2015 to inform her of the error. The Incident Report form states:

> "*Details of the incident* [Prescription] from hospital with lots of doses to be calculated. Oxybutynin dose written as 20mg [three times daily for ten days]. I noticed the dose was high but didn't check it. The stock needed to be ordered so was dropped off by [Ms D] on the 9th Sep. The first dose was given on the 11th Sep and [Miss A] experienced anticholinergic [side effects] so was taken to hospital. [Mrs A] called the pharmacy on Sunday to notify [Ms D] of what had happened …
>
> *Action requested by customer* Letter of apology and review processes. Contact registrar that was responsible at hospital.
>
> *Action taken by pharmacy after the event and by whom* … [Ms D] and [Ms B] went through the dispensing SOP and updated the procedures relating to suspensions and child doses. Wrote a letter of apology …
>
> *Investigation of incident* … Pharmacy was busy -> 3 [prescriptions] happening at the same time. [Prescription] had 6 doses that needed calculating. Intern made an error when processing [prescription] -> tablets rather than suspension. Dose was not checked / discharge summary was not looked at.
>
> *Outcome: correction action taken* … Letter of apology written and given to parents. SOP updated."

*Dispensing Prescriptions Standard Operating Procedure (SOP)*

57. The Dispensing Prescriptions SOP (issue date 7 March 2014) in place at the time of the error stated:

> "Purpose: To describe the process of dispensing in this pharmacy to ensure that prescriptions are dispensed accurately and in accordance with legislative and ethical requirements …
>
> Checking Procedures
> During dispensing process: …
>
> - Check medicine dose, frequency interactions and contraindications, to ensure the medicine is being given appropriately (e.g. correct dose for age or condition) …

- Dispenser and checker must be identified on all prescriptions and original dispensing, by signing on the date stamp …

Handing out procedures / Giving advice to customers

- It is the sole responsibility of the pharmacist to hand out prescriptions, or delegate this task ensuring that the necessary information and counselling is given to the patient."

58. The SOP was updated on 16 September 2015 to include the following section on calculations for child doses:

"Calculations for child doses

- Write out the full calculation on the prescription so that it can be checked at each step of dispensing.

  Dose (ml) = Dose (mg)
  X mg/kg = X mg/dose
  X mg/dose = X ml/dose

- If no weight is available for the child, calculate the expected weight for the prescribed dose and leave a 'check weight' label with the medication.
- Check that the dose is appropriate for the child's weight and age according to the Paediatric Pharmacopoeia or NZF.
- If the dose is low or high, notify the pharmacist on duty to deal with it appropriately."

*Ms D*

59. Ms D stated that "the prescriber should have been contacted and [oxybutynin] not dispensed until this could occur and the dose been discussed". She told HDC:

> "I must remind all pharmacists that clinical checks need to be done on every prescription to ensure the dose is appropriate for the patient. This was a prescribing error that was not picked up, and as pharmacists we are responsible for the last check."

60. Ms D told HDC: "I cannot explain why the prescriptions were not initialled as being dispensed and checked, as this is part of the pharmacy SOPs. I admit that we had not been very good at making people accountable for this, but we are now." Ms D acknowledged that as the owner and director of the pharmacy, it is her responsibility to ensure that all dispensary staff follow the SOPs in place.

61. Ms D stated that she continues to monitor all dispensary staff to ensure they follow the SOPs in place at the pharmacy, and that staff are more diligent in ensuring that all prescriptions are initialled by the dispenser and checker, and that all calculations are recorded on the prescriptions, rather than on scrap bits of paper. Ms D said that, in future, she will undertake random checks on prescriptions dispensed to ensure that the pharmacy SOPs are being followed.

62. In September 2014, the pharmacy had undergone a quality audit for the Ministry of Health. The audit found that many of the pharmacy's prescriptions did not include the name of the pharmacist responsible for the final check for completeness and accuracy. Following the audit, Ms D had confirmed in writing to the auditor that "all prescriptions, including repeats and owes, will be initialled by the checking pharmacist". Following this confirmation (and clarification of some other matters), all audit criteria were fully attained on 24 November 2014.

**Further information — Ms B**

63. Ms B told HDC that she has been involved in reviewing the Dispensing Prescriptions SOP, has become much more cautious in her dispensing, has improved her practice regarding initialling prescriptions, makes sure that she calculates the exact dose by weight for prescriptions for children, asks to read any discharge summary available to ensure it aligns with the prescription, and writes out all calculations in full on the prescription. She stated that the pharmacy has placed a list of the usual doses that require calculation[17] next to the dispensing computer to make it easier to check doses, now keeps the paediatric pharmacopoeia[18] on hand for other doses, and has "check weight" and "check dose" labels to put with prescriptions where the weight is listed on the prescription.

64. Ms B told HDC:

> "The incident … has made us all strive to improve our pharmacy practice and communication with each other. I am so incredibly sorry that this happened and I'm doing everything I can to ensure that I don't do it again."

**Subsequent events — Dr C**

65. Dr C told HDC: "I would like to apologise again for [the] distress that this has caused [Miss A] and her family."

66. Dr C told HDC that she raised the error through her department's morbidity and mortality meeting, and it was discussed as a team. She stated:

> "There was discussion regarding contributory factors; ensuring safeguards are reviewed and the whole team learns from the mistake to minimise the risk of this incident occurring in future.
>
> The following points were discussed as learning points which I have put into practice:
>
> 1. Trailing zeros — I don't usually use trailing zeros, but I believe I did in this case because the range as specified in the NZFC had fractions of a mg in each case with a decimal point in each dose (eg. 1.25 and 2.5mg).

[17] That is, where the dose is based on the person's weight.
[18] The Paediatric Pharmacopoeia advises prescribers, pharmacists, nurses and other healthcare professionals on doses for paediatric patients.

2. Using digital prescribing where possible — currently, there are 2 systems of prescribing — a paper system and a digital system. I previously used the 2 interchangeably, but in an effort to ensure accuracy, I will use the digital system in future. However, this is not possible in the outpatient clinic due to the way the computer system is set up. The electronic prescription system does require the weight of a patient to be manually written after printing as it is not currently considered essential when prescribing.

3. Re-review the prescriptions before handing them to patients.

4. Continue to refer to prescription guides e.g. NZFC.

5. Continue to include a contact telephone number and patient's weight on prescriptions to facilitate checking.

Once again, I was deeply saddened by [Miss A's] experience; it has provided me with invaluable education for my future. I will do everything possible in future to ensure this situation is not repeated."

67. Dr C also told HDC that she has carried out a literature review on medical error, which emphasised the importance of optimising the prescribing environment, checking mechanisms and improving systemic factors to reduce error. She stated that she has since avoided prescribing in noisy or busy environments, printed prescription guidelines and placed them in medication charts, encouraged an open dialogue with nursing staff, become more engaged with the Riskpro[19] risk alert system, and progressed her active involvement with hospital audits.

68. In May 2016, a senior pharmacist from the DHB audited Dr C's prescribing while Dr C was working in the Neonatal Intensive Care Unit. She reviewed 51 of Dr C's prescriptions over the period of two weeks and, without exception, found these to be clinically appropriate, legible, legally complete, and in accordance with standard prescribing practice and relevant protocols. The pharmacist told HDC that she discussed safe prescribing practices with Dr C, and stated:

"[I] am confident that she has a good understanding of the importance of prescribing legibly and completely, minimising distractions during prescribing, and utilising appropriate dosing resources for the clinical situation, as well as being aware of the availability of various prescribing resources."

**Subsequent events — the DHB**

69. The Clinical Director of Paediatric Surgery told HDC:

"On behalf of our department, I too apologise to the family for this error occurring. We recognise[d] the seriousness of the error at the time and as a result, the following actions were taken:

[19] Electronic incident reporting system.

1. [Dr C] self-reported this error promptly through our departmental morbidity review processes.
2. We have addressed the error through rigorous peer review in our department and agreed with [Dr C's] actions, as outlined above.[20]
3. We are confident that this does not represent a systemic problem or an educational omission in registrar training.
4. This incident provided us with the opportunity to discuss and reflect on safe prescribing practices. We have ensured that all members of our team know where to access prescribing information and advice. However, this was not an issue in this case.
5. We have activated a Riskpro so the incident can be reviewed … with our departmental protocols.
6. We are satisfied that [Dr C] has learned from this event including discussion through the Morbidity and Mortality process. This event has highlighted to all members of our medical team, the critical importance of accurate prescribing using accepted methodologies and terminology and the consequences of inattention to detail."

70. The DHB agreed with HDC's expert advisor that having a space to document the weight of a child on outpatient prescriptions would be a useful addition for safety. In the provisional opinion, I recommended the DHB introduce systems to allow a specific space for the recording of a child's weight on prescriptions. In response to the provisional opinion, the DHB advised that it has now amended its prescription form to include a space to document the weight of a child under 13 years of age.

71. The DHB's electronic prescribing and administration (ePA) programme started being introduced from mid-2016 to cover both inpatient and outpatient prescribing. the DHB advised that the MedChart[21] ePA system has now been implemented on two wards, and a project plan for further roll-out of ePA is being developed, aligned to the Electronic Health Record strategy (to implement a single electronic health record for the whole region and sector).

72. The DHB has since introduced a paediatric prescribing memory aid in the form of a safe prescribing reference card, which is given to all house surgeons and registrars. This is a small card that is clipped in with identity and swipe cards. It states:

"**Right patient** correct sticker on all pages AND clearly written name and weight

**Right medicine** document generic name … LEGIBLY

**Right dose and route** calculate per kg (or m²) — sensible rounding, don't exceed adult dose … document mg/kg dose for ease of checking

[20] See paragraph 66.
[21] MedChart provides hospitals with an end-to-end electronic medication management solution, helping healthcare organisations reduce clinical risk and improve medication safety.

> **Right time** indication for [as needed] meds, date/time for once-only meds, consider dose interval …
>
> **Identify yourself!** Signature + surname + date when starting AND ceasing medicines …"

The back of the card then directs staff to websites for resources for prescribing in children.

73. The DHB told HDC that it is developing its clinical excellence and safe care programmes to ensure that minutes are taken at its morbidity and mortality meetings,[22] and the learnings from adverse events are disseminated throughout the DHB.

**Further information — electronic prescribing**

74. In the Ministry of Health's National Health IT Plan Update 2013/14 it specified that all DHBs were expected to have electronic prescribing and administration (ePA)[23] in place by 2016, and a national contract has been signed that supports a standardised approach to implementing electronic prescribing. Nine of New Zealand's 20 DHBs have implemented, or are in the process of implementing, ePA.

75. The Ministry of Health told HDC that the ePA system, MedChart, is currently being enhanced to enable its use in outpatient settings, and this will be available for early adopter testing in early 2017. Following the successful early adopter testing in outpatient settings, the Ministry of Health said that it will continue to work with DHBs to progress the rollout of ePA across hospital inpatient and outpatient settings. The Ministry of Health stated that it is also working with the sector (hospital and community) to develop a more integrated approach to medicines management across the New Zealand health system.

**Responses to the provisional opinion**

76. Responses to the provisional opinion were received from all parties, and a response to the "information gathered during investigation" section of the provisional opinion was received from Mrs A. Where appropriate, responses have been incorporated into the "information gathered during investigation" section above.

77. Ms B, Ms D, the pharmacy and Ms E confirmed that they had no comments in response to the provisional opinion.

78. Dr C confirmed that she would write a letter of apology to the family as recommended. She also stated that she continues to maintain heightened levels of

[22] In the past, it was recorded that the meetings occurred, but minutes were not taken for data protection (patient privacy) purposes.

[23] ePA allows medication to be prescribed and administration to be recorded electronically in hospitals. It reduces the potential for errors by including "electronic system support", eg, there are alerts if a medication is likely to cause an adverse reaction with another medication. Common errors such as mistakes in patient identification, unreadable medicine names and incorrect or missing prescriber information are significantly reduced.

vigilance over her practice, and uses the digital prescribing system at the DHB where possible.

79. The DHB confirmed that it would advise HDC of further actions undertaken in due course.

80. Mrs A told HDC that, following the overdose, Miss A struggled to urinate for days and would scream in pain for hours at a time without being able to sleep or eat much. Mrs A said that it took Miss A three to four months to be able to urinate properly, and that she had been doing reasonably well up until the overdose. Mrs A is concerned that Miss A may now have autonomic dysfunction[24] as a result of the medication reactions.

## Relevant professional standards

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

> "M1.2 Comply with ethical and legal requirements …
>
> O1.3.3 Uses professional judgement to determine whether changes to the medication treatment regimen are needed to improve safety, efficacy or adherence
>
> O1.3.4 Liaises with and provides recommendations to the prescriber and/or the other healthcare professionals to ensure optimal use of medicines by patients …
>
> O3.1.3 Applies knowledge in undertaking a clinical assessment of the prescription to ensure pharmaceutical and therapeutic appropriateness of the treatment and to determine whether any changes in prescribed medicines are warranted
>
> O3.1.4 Initiates action, in consultation with patient/carer and/or prescriber to address identified issues."

82. The PCNZ Code of Ethics (2011) states:

> "1.2 Take appropriate steps to prevent harm to the patient and public …
>
> 5.1 Be accountable for practising safely and maintain and demonstrate professional competence relative to your sphere of activity and scope of practice."

[24] Nerve damage that interferes with the autonomic nervous system.

## Opinion: Introduction

83. This case is an unfortunate example of errors occurring in tertiary hospital outpatient clinic and community pharmacy settings, which allowed for a child to be administered medication in a dose that was clinically unsafe.

84. It is essential that all providers involved in the prescribing and dispensing of medication remain attentive to the possibility of errors occurring at different steps in the process. Providers must take great care to ensure they have performed their role in the process accurately.

## Opinion: Dr C — Breach

85. Under Right 4(1) of the Code, Miss A had the right to have services provided by Dr C with reasonable care and skill.

86. On 8 September 2015, after discussing Miss A's case with Dr F, Dr C handwrote Miss A's prescriptions on two prescription forms. Dr C explained that she wrote the oxybutynin prescription on a separate form because it is less commonly prescribed than the other medications. Dr C told HDC that she referred to the appropriate medication dose in the NZFC and that she chose a 2mg dose because "[Miss A's] weight was mid-range for her age, the dose is mid-range for dosage and 2mg would be manageable for dispensing and administering".

87. Instead of writing "oxybutynin 2mg" on the prescription form, Dr C wrote "oxybutynin 20mg" — a ten times higher dose. Dr C also documented Miss A's weight, 14kg, on both prescription forms. Dr C told HDC that she does not usually use trailing zeros (eg, 2.0mg instead of 2mg), but believes she did in this case because the range as specified in the NZFC had fractions of a milligram with a decimal point in each dose (eg, 1.25 and 2.5mg). Dr C later told HDC that "the prescription read 20mg rather than 2.0mg".

88. The DHB confirmed that Dr C received an orientation booklet as part of her registrar training, which included guidelines on safe prescribing and links to the prescribing guidelines. The prescribing guidelines state: "Never write a trailing zero after a whole number ie 8mg, not 8.0mg." Despite Dr C's explanation, I am concerned that she did not follow the prescribing guidelines regarding trailing zeros in this case.

89. I am satisfied that Dr C's error was a transcribing error that occurred when she wrote the dose on the prescription form, as she had taken steps to choose a clinically appropriate dose. Nevertheless, Dr C recorded on the prescription form a dose that was significantly higher than recommended for a child of Miss A's age and weight. My expert advisor, paediatrician Dr Roger Tuck, advised:

> "The prescription error, as with all prescription errors, was unacceptable … prescribing and dispensing errors are unquestionably serious departures from acceptable standards of care."

90. I accept Dr Tuck's advice. It was Dr C's responsibility to ensure that she prescribed a clinically appropriate dose of oxybutynin to Miss A. By failing to do so, she did not provide services with reasonable care and skill and breached Right 4(1) of the Code.

91. I consider that, once Dr C was aware that the error had occurred, she took appropriate steps to disclose it and to minimise the risk of such an error occurring again.

## Opinion: DHB — Adverse comment

92. At the time of these events, Dr C was an employee of the DHB. In addition to any direct responsibility for a breach of the Code, under section 72(2) of the Act, employers are responsible for ensuring that their employees comply with the Code. Pursuant to section 72(5) of the Act, it is a defence for an employing authority to prove that it took such steps as were reasonably practicable to prevent the acts or omissions leading to an employee's breach of the Code.

93. At the time of these events, electronic prescribing was available at the DHB but not in the outpatient clinic setting. I consider that, if electronic prescribing had been available to Dr C when she prescribed the medication to Miss A in the Day Stay Unit, it could have minimised the risk of this error occurring.

94. The DHB confirmed that Dr C received an orientation booklet as part of her registrar training, which included guidelines on safe prescribing and links to the prescribing guidelines. Accordingly, I do not consider that this error represents a failure with regard to orientation or training provided to Dr C. I am satisfied that the error in failing to prescribe a clinically appropriate dose of oxybutynin to Miss A was Dr C's alone, given that she had taken steps to choose a clinically appropriate dose, but failed to transcribe this accurately.

95. My expert advisor, paediatrician Dr Roger Tuck, advised: "Digital systems are in their infancy in NZ. In the meantime, continuing education of clinical staff on manual prescribing with continuing innovation to mitigate risks is essential."

96. The DHB told HDC that its new e-prescribing programme, which is being introduced from mid-2016, will cover both inpatient and outpatient prescribing. I consider it both necessary and appropriate that this is being introduced. The DHB has advised that it has also introduced a paediatric prescribing memory aid in the form of a safe prescribing reference card, which is given to all house surgeons and registrars. I am satisfied that the actions taken by the DHB following the error are appropriate in the circumstances.

## Opinion: Ms B — Breach

97. As a registered pharmacist, Ms B is responsible for ensuring her adherence to professional standards. The PCNZ competence standards require that a registered pharmacist "[a]pplies knowledge in undertaking a clinical assessment of the prescription to ensure pharmaceutical and therapeutic appropriateness of the treatment and to determine whether any changes in prescribed medicines are warranted". The PCNZ Code of Ethics requires registered pharmacists to be accountable for practising safely and for maintaining and demonstrating professional competence.

98. The Pharmacy Dispensing Prescriptions SOP required Ms B to: "Check medicine dose, frequency interactions and contraindications, to ensure the medicine is being given appropriately (eg. Correct dose for age or condition)."

99. Ms B was the pharmacist on duty on 8 September 2015, and was working with pharmacy intern Ms E. Ms B told HDC that, as she was checking the medication labels for Miss A's prescriptions on 8 September 2015, she "noticed the dose [of oxybutynin] seemed high, but did not question it at the time". Ms B stated: "I acknowledge that I should have attempted to contact the prescriber regarding the high dose of oxybutynin at that time instead of leaving it for later, regardless of what time of day it was." Ms B put the oxybutynin label to one side with the prescription, to complete the dispensing when the new stock arrived the next day.

100. My expert advisor, pharmacist Sharynne Fordyce, advised:

> "This dose of 20mg three times daily is three times the maximum dose for an adult, and is not recommended for use in children under 5 years of age. Therefore accepted practice would have been to contact the prescriber and not to dispense the medicine until the dose had been clarified. Not to have done so would be viewed by myself and my peers as a serious departure from the accepted standard of care."

101. I accept Ms Fordyce's advice. I am particularly concerned that, despite Ms B noticing that the oxybutynin dose seemed high for a child Miss A's age, she did not take steps to contact the prescriber as required by the PCNZ Competence Standards for the Pharmacy Profession and the Pharmacy's Dispensing Prescriptions SOP.

102. The prescriptions for Miss A's medications are not initialled or signed to show who carried out the dispensing or checking. The Dispensing Prescriptions SOP required Ms B to sign on the date stamp to indicate whether she dispensed and/or checked the prescription. I am critical that she did not do so.

103. Ms B was one of two pharmacists working at the pharmacy on 9 September 2015 when the oxybutynin stock arrived at the pharmacy and was labelled and bagged for delivery. Given that there are no signatures on the prescription to indicate who completed the dispensing or carried out the final check, and neither Ms B nor Ms D can recall who did this, I am unable to make a finding as to whether Ms B completed the dispensing of this prescription or carried out the final check.

104. In conclusion, Ms B failed to take steps to contact the prescriber when she noticed that the oxybutynin dose seemed high, as required by the PCNZ Competence Standards for the Pharmacy Profession and the pharmacy's Dispensing Prescriptions SOP. Ms B also did not sign on the date stamp to indicate that she had dispensed and/or checked Miss A's prescriptions on 8 September 2015 in accordance with the pharmacy's Dispensing Prescriptions SOP. Accordingly, I consider that Ms B did not provide Miss A with services in accordance with professional standards, and breached Right 4(2) of the Code.

## Opinion: Ms D — Breach

105. On 8 September 2015, Ms D arrived back at the pharmacy as the last of the in stock medications were being dispensed for Miss A. Ms D said that, after the medications were given to Mr A, Ms B expressed frustration to her regarding Ms E's inability to calculate the volumes required accurately. Ms D stated: "In hindsight, this should have been my [c]ue to check the entire prescription but I didn't."

106. My expert advisor, pharmacist Sharynne Fordyce, advised:

> "[Ms D] had been made aware of [Ms B's] concern for [Ms E's] inability to independently complete the calculations involved with the doses on the prescription. As [Ms E's] preceptor, and the senior pharmacist present, good practice would have suggested [Ms D] check the prescription, calculations and labels, as she herself admitted later."

107. In the circumstances, I am critical that Ms D did not check the prescriptions, calculations and labels on 8 September 2015.

108. Ms D was one of two pharmacists working at the pharmacy on 9 September 2015 (the other was Ms B) when the oxybutynin stock arrived at the pharmacy and was labelled and bagged for delivery. There was also a pharmacy student working at the pharmacy that day. Given that there are no signatures on the prescription to indicate who completed the dispensing or carried out the final check, and neither Ms D nor Ms B can recall who did this, I am unable to make a finding as to whether Ms D completed the dispensing of this prescription or carried out the final check. I am critical that, as the owner and director of the pharmacy, Ms D did not ensure that the Dispensing Prescriptions SOP was followed in this regard.

109. The oxybutynin and lignocaine gel were put aside in a bag for delivery and, on the afternoon of 9 September 2015, Ms D delivered the medications to Miss A's mother, Mrs A. Mrs A told HDC that the medications were delivered to her house in a brown bag. She stated:

> "[The pharmacist] knew I had two very sick kids so I think they were saving me a trip back with one vomiting baby and one toddler beside herself in pain after

> having bladder surgery. I asked the pharmacist about the oxybutynin and she said they very rarely use it, that it can cause sedation."

110. However, Ms D said that she "chatted with [Mrs A] in regards to a separate health issue concerning her other daughter". Ms D stated: "[A]t no point did I discuss the prescription for [Miss A]." Ms D said that she told Mrs A that if she had any questions she could call Ms D or Ms B at any time.

111. I note Ms Fordyce's advice:

> "Not discussing the contents of the bag before handing over the prescription is … a departure from good practice … I would consider this departure to be a moderate to severe one as it was another lost chance to check the dose, and talk to the parents."

112. In my view, the discussion on delivery of the medications to Mrs A was a missed opportunity for Ms D to check the appropriateness of the prescription for Miss A, and I am critical that she did not do so.

113. Accordingly, in the circumstances, I find that Ms D did not provide services to Miss A with reasonable care and skill, and breached Right 4(1) of the Code.

## Opinion: Pharmacy — Breach

114. The pharmacy was responsible for ensuring that the pharmacy provided services to Miss A with reasonable care and skill. This includes the need to ensure staff compliance with its SOPs. Pharmacies are responsible for the operation of services provided by their staff, and can be held responsible for individual failures by staff. While the individual pharmacists in this case also bear responsibility for the deficiencies in the care provided to Miss A, I am of the view that the deficiencies were also a result of issues at the pharmacy.

115. Consumer safety is of the utmost importance, and I consider that it is the responsibility of the pharmacy to ensure that every staff member complies with its SOPs, in order to prevent harm to patients. PCNZ, in its document "Writing Standard Operating Procedures", 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.

116. I accept Ms Fordyce's advice that, at the time of the error, the pharmacy had in place an appropriate Dispensing Prescriptions SOP. However, I am concerned that more than one staff member failed to follow the Dispensing Prescriptions SOP, as there are no initials on the prescription to indicate who dispensed, and who performed the final check of, the medications dispensed on 8 September 2015, and of the oxybutynin and lignocaine gel dispensed the next day.

117. Furthermore, I am concerned that the high dose of oxybutynin was dispensed without the dose first being clarified with the prescriber, despite the Dispensing Prescriptions SOP stating: "Check medicine dose, frequency interactions and contraindications, to ensure the medicine is being given appropriately (eg. correct dose for age or condition)."

118. Without staff compliance, policies become meaningless. Ultimately, the pharmacy had a responsibility to ensure that all staff complied with its SOPs and provided services of an appropriate standard. I consider that the pharmacy is responsible for the person who completed the dispensing and final check of the oxybutynin on 9 September 2015 not being identifiable. In my opinion, non-compliance with the Dispensing Prescriptions SOP played a part in Miss A receiving an inappropriate dose of oxybutynin. Accordingly, I consider that the pharmacy did not provide services to Miss A with reasonable care and skill and breached Right 4(1) of the Code.

119. Ms Fordyce advised me that the actions taken by the pharmacy and its staff following these events were timely and appropriate. She stated that the changes made to the Dispensing Prescriptions SOP are very detailed, particularly in regard to dosage calculations for children, and are appropriate. I accept this advice.

## Opinion: Ms E — Adverse comment

120. Ms E was the pharmacy intern working on 8 September 2015 when Mr A attended the pharmacy with the prescriptions for Miss A's medications. Ms E was working with pharmacist Ms B.

121. Ms B said that Ms E took the prescriptions from Mr A and began processing them through the computer.

122. Ms B stated: "I had to help [Ms E] calculate the volume required for the doses of Augmentin, Paracetamol, Ibuprofen and Tramadol, because she was struggling to convert the [milligrams] on the prescription to [millilitres] required for dosing." Ms B stated that she reconstituted the antibiotic suspension while Ms E dispensed the other items on the prescription.

123. Ms E told HDC that she does not recall whether she entered the prescriptions into the computer, but does recall being involved in the dispensing of some medications for Miss A that were in stock.

124. The pharmacy's Dispensing Prescriptions SOP required Ms E to sign on the date stamp to indicate that she dispensed the prescription. My expert advisor, pharmacist Sharynne Fordyce, stated that all persons involved in the dispensing process "were responsible for initialling or signing for the process they carried out, so as to identify the processor, dispenser and checker". I am critical that Ms E did not sign the prescription to indicate her involvement in the dispensing process.

## Recommendations

125. I recommend that Dr C, Ms B, Ms D and the pharmacy each provide a written apology to Mr and Mrs A, and send this to HDC for forwarding to Mr and Mrs A within three weeks of the date of this report.

126. I recommend that the DHB:

a) Give feedback to HDC, within three months of the date of this report, on the implementation of its new e-prescribing system.
b) Use this case as an anonymised case study for education for paediatric medical staff, and report back to HDC on this within three months of the date of this report.

127. I recommend that the pharmacy :

a) Undertake two audits of compliance with its Dispensing Prescription SOP by taking two random selections of 30 prescriptions processed during a three-month period, and report back to HDC on the results of these audits at three and six months from the date of this report.
b) Use this case as an anonymised case study for education for future pharmacist or pharmacy intern employees of the pharmacy.

128. I recommend that the Pharmacy Council of New Zealand consider whether a review of Ms B's competence is warranted, and report back to HDC with the results of any review.

129. I recommend that the Ministry of Health actively continue to support the rollout of ePA across New Zealand's DHBs in both inpatient and outpatient settings, and work with the sector to progress an integrated approach to medicines management.

## Follow-up actions

130. A copy of this report with details identifying the parties removed, except the experts who advised on this case, will be sent to the Medical Council of New Zealand, and it will be advised of Dr C's name in covering correspondence.

131. A copy of this report with details identifying the parties removed, except the experts who advised on this case, will be sent to the Pharmacy Council of New Zealand, and it will be advised of Ms B's and Ms D's names in covering correspondence.

132. A copy of this report with details identifying the parties removed, except the experts who advised on this case, will be sent to the Health Quality Safety Commission, the New Zealand Pharmacovigilance Centre, the College of Education and Training branch of the Pharmaceutical Society of New Zealand, and the Paediatrics and Child Health Division of the Royal Australasian College of Physicians, and placed on the Health and Disability Commissioner website, www.hdc.org.nz, for educational purposes.

## Appendix A: Independent paediatric advice to the Commissioner

The following expert advice was obtained from consultant paediatrician Dr Roger Tuck:

"My name is Roger Tuck and I am a consultant paediatrician currently employed by the Northland District Health Board. I obtained my basic medical degree from the University of London in 1972. I obtained Membership of the Royal College of Physicians (UK) in 1974, Fellowship of the Royal Australasian College of Physicians in 1981 and Fellowship of the Royal College of Physicians (Edinburgh) in 1994. I have been a consultant general paediatrician in New Zealand since 1983.

I have no personal or professional conflict of interest in regard to this case.

As a general paediatrician, I have considerable experience with renal and urological conditions of childhood and am familiar with the surgical procedures described for this young child, and the drugs used, particularly oxybutynin, the drug in question in this case.

I have read the material provided by your office including the guidelines for independent advisors which I will do my best to follow.

**Reasonableness of care provided by [Dr C]:**
The information provided would suggest that with the exception of the prescription error, the care provided both pre and post-event was of a good standard. The prescription error, as with all prescription errors, was unacceptable. It would appear that this was a simple transcription error as there is evidence that [Dr C] had taken care to calculate an appropriate dose of oxybutynin for her patient. [Dr C's] subsequent response to this error was prompt and professional including an approach to the family to apologise. She has clearly reflected on this error and will undoubtedly take measures to reduce the risk of further prescribing errors in her own practice.

**Digital prescribing/e prescribing:**
As the Commissioner is aware, iatrogenic harm from prescription and dispensing errors is one of the main causes of avoidable morbidity and mortality in health systems worldwide. New Zealand is no exception and as far as I am aware there is no active national strategy on the implementation of standardised e prescribing in DHBs throughout NZ, and certainly no significant implementation of systems nationally. I am aware however that there are piecemeal efforts in various DHBs. My own view is that a standardised national system for electronic/digital prescribing throughout New Zealand's health care settings is well overdue. In the meantime, patients will continue to be at unnecessary risk of iatrogenic medication related morbidity and mortality due to inevitable human error and the risks of manual prescribing and dispensing.

**Follow up actions:**
This prescribing error was clearly taken seriously and appropriate internal reviews took place. Basic issues such as legibility, the use of decimal points and 'trailing zeros' have been re-visited. Many of the risks of manual prescribing are open to mitigation using digital systems. Ideally digital/e prescribing should be available in all health care settings where prescribing takes place. Algorithms can be embedded in such systems to aid appropriate medication choices, avoid adverse medication effects and interactions, and ensure appropriate dosages of medications.

With particular respect to prescribing for children, a safety and quality improvement that I am currently pursuing in my own DHB is the addition of a box on the DHB prescription pad for the patient's weight. I note that this is also absent from [the DHB's] prescription pad. Many medications are prescribed on a dose per weight basis in all age groups, but this is particularly important in children where doses of medications should be routinely checked on a dose per weight basis. The addition of a box on the prescription pad for the patient's weight would provide both a prompt for careful medication dose calculation and also provide an important additional check for the dispensing pharmacy to minimise the risk of inappropriate dosing in the context of manual prescribing. A digital system could include a mandatory field for weight.

**Community Pharmacy:**
I am aware that I have not been asked to comment on this, but I would like to point out that as prescribing clinicians we rely on our pharmacy colleagues both within hospital settings and in community pharmacies to audit our prescriptions. … When [Miss A's] medication was dispensed there should have been an opportunity to check the appropriateness of the prescription.

**Summary:**
Prescribing and dispensing errors are unquestionably serious departures from acceptable standards of care and can be responsible for avoidable morbidity and mortality. In [Miss A's] case, had her parent not been as vigilant and professionally knowledgeable, the outcome could have been much worse. Technology, in the form of digital or e prescribing, is available to mitigate the risks of manual prescribing. Digital systems are in their infancy in NZ. In the meantime, continuing education of clinical staff on manual prescribing with continuing innovation to mitigate risks is essential.

[Dr C's] error would appear to be a simple human error of transcription. Her response to this was prompt and professional and elicited the appropriate cascade of enquiry and reflection both personally, and within the department of paediatric surgery at [the hospital].

Fortunately in [Miss A's] case, the outcome was largely favourable and my sympathies and best wishes go to her and to her family for what must have been a very difficult and upsetting time. My sympathies also go to [Dr C] as I am aware of the distress that such an event can cause the involved clinicians.

Dr Roger Tuck. FRACP. FRCP. Consultant Paediatrician."

## Appendix B: Independent pharmacy advice to the Commissioner

The following expert advice was obtained from pharmacist Sharynne Fordyce:

"I, Sharynne Fordyce, have been asked to provide an opinion to the Commissioner on Case number C15HDC01542. I have read and agreed to follow the Commissioner's Guidelines for Independent Advisers.

My qualifications include a Diploma of Pharmacy, and a Masters of Clinical Pharmacy. I have worked in Retail Pharmacy for over 30 years, both in New Zealand and in England, and also locum for the Wairarapa DHB. I have also been involved in training and assessing intern pharmacists.

*Expert advice requested*
Please review the enclosed documentation and advise whether you consider the care provided to [Miss A] was reasonable in the circumstances, and why. In particular, please comment on:

1. The reasonableness of the care provided by each of the following:
   a. [Ms B]
   b. [Ms D]
   c. [Ms E]
   d. [The pharmacy]
2. In this case, who and/or which entity was responsible for ensuring the correct dose of oxybutynin was dispensed for [Miss A].
3. Who and/or which entity was responsible for ensuring the dispensing prescriptions SOP was followed, in particular, that the prescription was initialled/signed to identify the dispenser and checker?
4. Was the dispensing prescriptions SOP, in place at the time of these events, appropriate?
5. Are the changes made to the dispensing prescriptions SOP, in light of these events, appropriate?
6. Were the other actions taken by the pharmacy and its staff, following these events, appropriate?
7. Any other matters in this case that you consider warrant comment.

For each question, it would be helpful if you would advise:

a. What is the standard of care/accepted practice?
b. If there has been a departure from the standard of care or accepted practice, how significant a departure do you consider this to be?
c. How would this be viewed by your peers?
d. Recommendations for improvement which may help prevent a similar occurrence in future.

If you note that there are different versions of events in the information provided, please provide your advice in the alternative. For example: whether the care was appropriate based on scenario (a), and whether it was appropriate based on scenario (b).

*Document copies provided*

1. Letter of complaint dated […]
2. Prescription form dated 8 September 2015
3. Incident notification form dated 17 September 2015
4. Apology letter from [Ms B] dated 16 September 2015
5. [The pharmacy's] 'Dispensing Prescriptions' Standard Operating Procedures (SOPs) (old and new)
6. [The pharmacy's] response and all enclosures dated 17 April 2016
7. [The pharmacy's] further response dated 13 May 2016
8. [Ms B's] response dated 7 April 2016
9. [Ms E] response dated 26 May 2016

*Background summary*

8 September 2015 a public hospital registrar wrote a prescription for [Miss A] for, among other things 'Oxybutynin 20mg TDS oral 10/7'.

8 September 2015 [Miss A's] father [Mr A] presented the prescription to the pharmacy to be filled. [Ms B] was the only pharmacist on duty at the time, working with [Ms E], intern pharmacist. Oxybutynin and one other item were not in stock, could be ordered for next day, father informed by [Ms B]. Rest of prescription could be dispensed.

[Ms E] started to work on the prescription, generating a label for oxybutynin. [Ms B] checked the label, which had been put through for tablets instead of liquid. Noted also 'dose seemed high', retyped label for liquid and put aside to await stock. Discussed high dose of oxybutynin with father, who replied [Miss A] had just come out of surgery. [Ms B] did not check dose further.

9 September 2015, [Ms B] and [Ms D] on duty, [Ms E] on day off. Oxybutynin liquid arrived, labelled and bagged for delivery. No initials on prescription form for dispenser or checker. Delivered that afternoon by [Ms D] to [Miss A's] mother, [Mrs A], prescription not discussed.

12 September 2015 morning, mother administered 20ml of oxybutynin liquid to [Miss A]. Concerned about large volume for young child, internet search revealed overdose, rushed [Miss A] to hospital.

12 September 2015, later in day [Ms D] received a telephone call from a surgical registrar at the hospital, explaining what had happened. [Ms D] sights script, and left a telephone message for [Mrs A] apologising for error.

14 September 2015 all staff involved told of error.

15 September 2015 Pharmacy Defence Association (PDA) contacted for advice.

16 September 2015 [the pharmacy] updated its dispensing prescriptions SOP. [Ms B] wrote letter of apology to [Mr and Mrs A].

17 September 2015 apology letter delivered to [Mr and Mrs A] and [Ms B] filled in an incident notification form.

*1 .STANDARD OF CARE PROVIDED*

a) [Ms B]. Working from [the pharmacy's] training records, it would appear that in 2015 [Ms B] was in her first year as a registered pharmacist. On the day of the incident she was in sole charge of an intern pharmacist, a person a year behind her in training and experience. [Ms B] followed good prescription and dispensing practices (in accordance with [the pharmacy's] SOP) by keeping the customer informed of stock shortages, potential delays and expected stock arrival time. She allowed [Ms E] to process the prescription, part of an intern's training, and by [Ms B's] own admission, helped [Ms E] with calculations she appeared unsure of. When checking the labels produced by [Ms E] she noticed the mistake with the dosage form of oxybutynin (tablets not liquid) and noted the high dose, but did not confirm this dose with the prescriber. The prescription was written by a registrar from [the hospital], with the associated implications of specialist knowledge and potentially unusual doses. Hospital doctors are frequently difficult to locate, to do so can take hours and many phone calls. However this dose of 20mg three times daily is three times the maximum dose for an adult, and is not recommended for use in children under 5 years of age. Therefore accepted practice would have been to contact the prescriber and not to dispense the medicine until the dose had been clarified. Not to have done so would be viewed by myself and my peers as a serious departure from the accepted standard of care. Receiving assurance from the father re the 'high' dose is not sufficient. Depending on which pharmacist checked and labelled the bottle of oxybutynin when it came in the next day means either [Ms B] or [Ms D] missed another opportunity to check the unusual dose. This behaviour is also at odds with the 2014 dispensing prescriptions SOP of [the pharmacy].

b) [Ms D], although not involved in the actual processing and dispensing of the script on 8 September, was present in the dispensary before it was handed out. She had been made aware of [Ms B's] concern for [Ms E's] inability to independently complete the calculations involved with the doses on the prescription. As [Ms E's] preceptor, and the senior pharmacist present, good practice would have suggested [Ms D] check the prescription, calculations and labels, as she herself admitted later. It has been noted that there is no completed training log for [Ms E] as regards knowledge of SOPs. Not discussing the contents of the bag before handing over the prescription is also a departure from good practice.[25] As the child had been in hospital, the parents were likely to be distressed and may have been confused about drugs and doses. There are no signatures on the prescription to

[25] On 26 June 2016, Ms Fordyce clarified: "I would consider this departure to be a moderate to severe one as it was another lost chance to check the dose, and talk to the parents."

indicate who processed, dispensed or checked the prescription. This goes against the 2014 dispensing prescriptions SOP, and lack of identifying signatures had also been noted on the otherwise excellent audit of [the pharmacy]. With the volume of prescriptions being dispensed nationally, accountability for every item dispensed is viewed as extremely important by the profession.

c) [Ms E] was working as an intern pharmacist at [the pharmacy], with [Ms D] as her preceptor, when this error occurred … All of these tasks [entering the prescription into the computer, producing labels, or completing any dosage calculations] should have been within the capabilities of an intern. This does not agree with the description of the incident by either [Ms B] or [Ms D]. Due to the lack of identifying signatures on the prescription this discrepancy is hard to solve. However there are annotations (calculations) visible on the copy of the prescription which may be able to be linked to either [Ms E] or [Ms B]. … At some stage after this incident [Ms E] appears to have left the employ of [the pharmacy], to finish her internship elsewhere. While there is no doubt that full responsibility must lie with the qualified pharmacists involved, all interns are trained to dispense each prescription as if they were solely responsible for the final product, including attention to dosages.

d) [The pharmacy], at the time of the incident, had in place appropriate dispensing prescriptions SOPs. It had passed a Ministry of Health Pharmacy Quality Audit 4 which evaluated procedures, systems and processes, in September 2014. It employed legally qualified staff and provided a wide range of services to the local community. It was able to order in, supply stock and deliver prescriptions within an appropriate time frame, thus providing an acceptable standard of care.

2. In this case [Ms B] and [Ms D] were responsible for ensuring the correct dose of oxybutynin was dispensed for [Miss A]. (Competence Standards for Pharmacy M1.2, O1.3.3, O1.3.4, O3.1.3 and O3.1.4). The departure from the accepted standard of care was very significant.

3. [Ms D], as the owner of [the pharmacy], is the person primarily responsible for ensuring the dispensing prescriptions SOP is communicated and followed, or the pharmacist on duty at the time, being [Ms B]. All three women were responsible for initialling or signing for the process they carried out, so as to identify the processor, dispenser and checker. (Competence Standards M1.2, O1.3.3, O1.3.4, O3.1.3 and O3.1.4). There has been a considerable departure from acceptable practice in this instance.

4. The dispensing prescriptions SOP, in place at the time of these events, was entirely appropriate and adequate.

5. The changes made to the dispensing prescriptions SOP, in light of these events, are very detailed, particularly in regards to dosage calculations for children, and are appropriate.

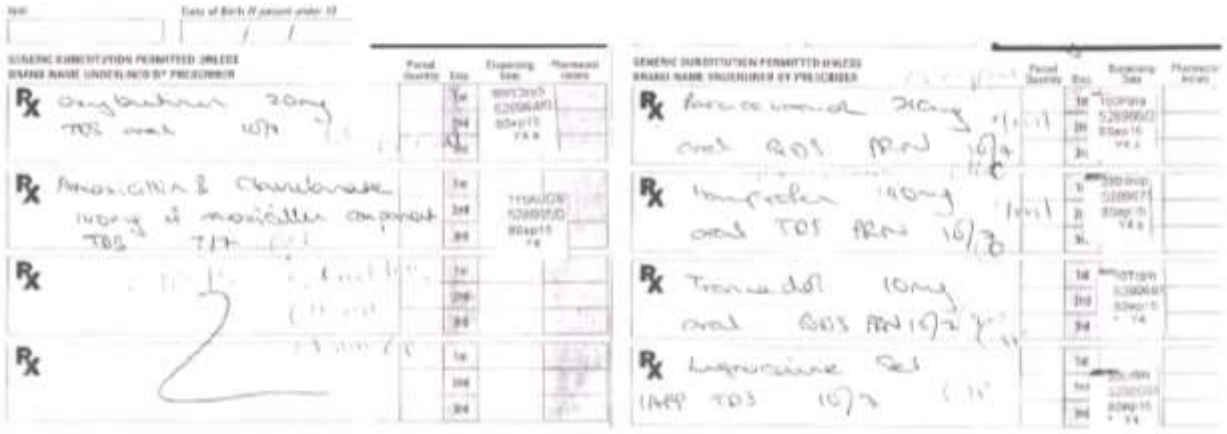
6. The actions taken by [the pharmacy] and its staff, following these events, were timely and appropriate. An earlier involvement of the Pharmacy Defence Association may have been helpful, and initiated an earlier filing of the incident

> notification form. This may have potentially prevented minor discrepancies in the pharmacists' reports.
>
> The discrepancies in the recollection of events is disconcerting. … That neither [Ms B] or [Ms D] could remember whether or not [Ms E] was present at work on 9 September (her regular day off for which she was not paid) is surprising. Also unusual is that neither pharmacist could remember labelling, checking and bagging the oxybutynin liquid, ready for delivery — a significant departure from accepted practice. This later omission denied both pharmacists the chance to investigate a significant and harmful overdose."

Ms Fordyce provided the following further expert advice on 4 August 2016:

> "Having read [Ms D's] reply to my comments I and all my peers would very much agree with her regarding the need for shared blame for consequences. As a profession, pharmacists accept that they are the final barrier between any prescriber errors and the patient, however both professions have a responsibility to ensure that there are enough checks and balances in place to limit errors occurring as much as possible.
>
> In response to [Ms D's] comment regarding the structure of the intern year and their assignments, I do have a reasonably good idea of the programme involved. However I was unaware of [Ms E's] progress through it as it can sometimes differ depending on the intern and their circumstances. In light of [Ms D's] information I would like to add the following sentences to my previous comments on [Ms E].
>
> By September [Ms E] would have been a significant way through her internship, and only two and a half months away from undergoing her final assessment for registration in November. Processing a script such as [Miss A's], with a bit of supervision, should have been within her capabilities, as should have been the calculations. …
>
> In summary, throughout the document I have been asked to comment on how my peers would regard actions that were taken. I think, almost without exception, my peers would regard this as a tragic incident, both for [Miss A] and her family, and the pharmacists involved. In spite of audits, SOPs, checks and balances, human frailties will always be present."

# Appendix C: Prescription form





*Names have been removed (except the experts who advised on this case) to protect privacy. Identifying letters are assigned in alphabetical order and bear no relationship to the person's actual name.*