Pharmacist, Ms B

A Pharmacy

A Report by the

Deputy Health and Disability Commissioner

(Case 06HDC09528)

Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

Parties involved

Baby A	Consumer
Mr A	Baby A's father
Mrs A	Baby A's mother
A pharmacy	The Pharmacy
Ms B	Charge pharmacist
Ms C	Pharmacy technician
Ms D	Pharmacy technician
Dr E	General practitioner

Complaint

On 28 June 2006, the Commissioner received a complaint from Mr and Mrs A about the services provided by a pharmacy to their daughter Baby A. The following issue was identified for investigation:

Whether the pharmacy and registered pharmacist Ms B provided services of an appropriate standard to Baby A on 8 June 2006.

An investigation was commenced on 16 August 2006.

Information reviewed

Information from:
- Mr and Mrs A
- Ms B
- Dr E
- The Pharmacy

Independent expert advice was obtained from Mr John Fraser.[1]

[1] Mr Fraser provided independent expert advice for the investigations of Opinions 06HDC01037 and 06HDC12613. These complaints relate to dispensing errors that occurred at the Pharmacy in 2006.

Summary

This case involves the dispensing of a prescription for ranitidine, a drug prescribed for the treatment of gastric reflux. The pharmacy staff involved in the dispensing process incorrectly calculated that Baby A, a 9-week-old baby, was to receive 5*ml* rather than 5*mg* of ranitidine. This resulted in Baby A receiving approximately five times the prescribed dosage for 15 days, when the error was noticed.

Information gathered during investigation

Chronology

Nine-week-old Baby A had been having feeding problems. On 8 June 2006, Mr and Mrs A took her to their general practitioner, Dr E, who diagnosed gastric reflux. Dr E prescribed ranitidine syrup, 5mg, twice a day. The prescription was sent by facsimile to the Pharmacy, and received at 11.47am.

At 12.47pm, pharmacy technician Ms C entered the prescription onto the computer. Ms C erroneously entered that Baby A was to have 5*ml* twice a day.

The prescription was then dispensed by a second pharmacy technician, Ms D, who failed to notice the error, and placed the label (created following Ms C's entry of the prescription onto the computer) onto a 300ml bottle of ranitidine.

The third step in the dispensing process involved a check by charge pharmacist Ms B. Ms B failed to notice the error, and the ranitidine was dispensed with the incorrect dose of 5ml, twice a day.

Ms B advised that between 12 and 2pm on that day, 80 prescriptions were dispensed.

Later events

On 21 June, Baby A was taken by her parents for a further visit to Dr E. As part of this assessment, a repeat prescription for ranitidine was provided, at the same dose as previously prescribed (5mg, twice a day).

Mr A went to a different pharmacy to fill this prescription. He noted after it had been dispensed that it was in a smaller bottle, with different instructions. The pharmacist at this pharmacy contacted Dr E's practice, but because she was in a meeting and unavailable, a message was relayed to the pharmacy that Baby A was to have the same dosage as previously dispensed. Accordingly, the pharmacy dispensed ranitidine at 5ml, twice a day.

On 23 June, Dr E reviewed what had been dispensed, became aware that an incorrect dose had been dispensed, and immediately contacted Mrs A to check Baby A's condition. Dr E also contacted the National Poisons Centre and the first pharmacy. Ms B stated:

> "I was away on [23 June] but was absolutely mortified to discover I had made an error and could have compromised a child's health. I did not follow this up with the family as [Dr E] informed [the Pharmacy] that she had resolved the issue and was just making [the Pharmacy] aware of the situation and that we did not need to do anything further."

Mrs A stated:

> "Having contacted the Poisons Centre, [Dr E] informed me that the side effects of an overdose of ranitidine include vomiting, headache, sore stomach, and drowsiness. It is difficult to state whether or not any such symptoms [Baby A] suffered were a direct result of the ranitidine overdose, however [Baby A] did suffer from frequent excessive vomiting, and obvious discomfort. [Dr E] instructed me to cease giving [Baby A] any ranitidine for at least two weeks to get the excess medication out of her system, after which time she may be able to take the correct, much lower, dose. As [Baby A] currently can not take the medication, she is experiencing considerable pain from her silent reflux, which significantly affects her feeding and sleeping. This is distressing for her, and is emotionally draining on my husband and myself."

Actions taken by the Pharmacy
Ms B described the actions taken by the Pharmacy following discovery of the dispensing error:

> "We conducted a staff meeting and all dispensary staff were shown the prescription in question. The outcome of this meeting was that the following changes have been implemented:
>
> - It was re-iterated that all prescriptions for children MUST have the date of birth highlighted to alert the dispenser and checker to check the dose.
> - We have also changed our procedures to ensure that the dose per kg is checked to ensure it is within the accepted guidelines. We are to use the BNF Paediatric Guide for these checks.
> - Any calculations are to be written on the prescription, or if necessary on a separate piece of paper. Any concentration calculations are to be checked by a second person and initialled as correct."

Ms B wrote to Baby A's parents on 21 July 2006, apologising for the dispensing error and advising the actions taken by the Pharmacy to prevent a similar error occurring.

Independent advice to Commissioner

The following expert advice was obtained from Mr John Fraser:

"1. Introductory comments

1.1. Introduction
I would like to thank the Commissioner for asking me to review this case, number 06/09528, regarding [Baby A] and [the Pharmacy]. This matter was referred to me for my opinion on 11 October 2006.

1.2. Qualifications, training and experience of expert advisor
I am John Fraser, a registered pharmacist. I am a member of the New Zealand Pharmaceutical Society with a Diploma in Pharmacy, and I also hold the degree of Bachelor of Science in Physiology (Otago). I am a practising rural pharmacist with about 45 years' experience working in pharmacy in New Zealand, the United Kingdom and the United States. I have worked in pharmacy at all levels from junior apprentice to proprietor/manager.

I am a Past President of the Southland Pharmacists' Association; a Pharmacy Preceptor (a person involved in the tuition of pharmacy interns); a Member of the Southland Rural Health Committee; and a Member of the Joint Trans-Tasman Expert Committee on Drug Labelling.

I have had a long-standing professional interest in the safe and effective labelling and use of pharmaceutical agents. I have been involved as a label safety consultant to the pharmaceutical industry although at the present time I have no financial interests in this area.

In June 2006, my work in developing an error prevention program for New Zealand Pharmacies led to me receiving the New Zealand Pharmacy Award for Innovation in Pharmacy Practice, and also the Overall Pharmacy Award.

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

I understand that my report is subject to the Privacy Act 1993 and the Official Information Act 1982, and that under those statutes my advice may be requested and disclosed. I understand that the Commissioner's policy is to name his advisors where any advice is relied upon in making a decision.

I have previously entered into a formal confidentiality agreement relating to any advice I give the Commissioner.

I have compiled this report in good faith, based on the information available to me. Although I may have consulted professional colleagues in preparing aspects of this report, all opinions stated herein are solely my own.

[At this point Mr Fraser lists the questions asked of him, which he repeats in his advice.]

…

1.5. Material examined

In providing my opinion, I have examined the following material supplied to me by the HDC:

1. Letter of complaint (pages 1 to 3);
2. Notification letter (pages 4 to 7);
3. Information from GP practice (pages 8 and 9);
4. Information from [the Pharmacy] (pages 10 to 47);
5. Information from [Ms B], including interview transcript (pages 48 to 62).

I have also referred to the following resources:

6. *Zantac Manufacturer's Prescribing Information* (GlaxoSmithKline, 2006).
7. *British National Formulary for Children* (BMJ Publishing Group, 2006).
8. *Martindale: The Complete Drug Reference* (Sweetman, 2006).

2. Summary of Facts

On Thursday, 8 June 2006, [Mr and Mrs A] took their 9-week-old daughter, [Baby A], to see their General Practitioner, [Dr E]. [Baby A] had been having feeding problems and was diagnosed with 'silent reflux,' a painful condition in which acidic stomach contents may move back up the oesophagus. [Dr E] prescribed ranitidine hydrochloride syrup, which is a powerful inhibitor of stomach acid production; it helps to reduce the unpleasant symptoms when reflux occurs. The prescription was for '2–4mgs/kg 12 hrly,' meaning about 10–20 milligrams (i.e. 0.66–1.33 millilitres) every 12 hours.[2]

While [Dr E's] prescription was not a particularly common one for a baby, it was entirely within well-established dosage guidelines for an infant of [Baby A's] age and condition.[3,4,5]

[2] This assumes [Baby A] weighed about 5 kilograms, a fact which is stated on her prescription form.
[3] GlaxoSmithKline (2006). Zantac Prescribing Information, p.13.
[4] Paediatric Formulary Committee (2006). "Ranitidine." BNF for Children. 2006. London: BMJ Publishing Group. On-line version.

The prescription was faxed to [the Pharmacy] at about 11.57am on 8 June. It was entered into the pharmacy computer at 12.47pm by pharmacy technician [Ms C]. [Ms C] made a mistake in preparing the directions, indicating that 5 millilitres of ranitidine were to be taken every 12 hours. This was roughly five times the amount of medicine that the doctor's prescription indicated.

The prescription was dispensed by technician [Ms D], who failed to notice the labelling error and prepared a 300mL bottle of Zantac (a brand of ranitidine hydrochloride).

Finally, the dispensing was checked and approved by pharmacist [Ms B], who also failed to notice the error.

The pharmacy was quite busy at the time the error occurred, having dispensed 80 prescriptions between 12–2pm that day.

The medication was subsequently picked up by [Baby A's] father, and was administered to her according to the instructions on the label. This regular administration continued until 23 June (15 days after the error occurred), at which time [Baby A's] parents requested an identical prescription from another pharmacy. When they noted differences in the amount of the medicine dispensed and the accompanying directions, they made inquiries, and the mistake was realised.

It is not clear whether [Baby A] suffered any adverse affects from the overdose. While she suffered from vomiting and abdominal discomfort (which are known side effects of ranitidine), these symptoms may have been caused by the underlying reflux condition, rather than the overdose. However after the mistake was discovered, [Baby A's] doctor said she should not take any medication for at least two weeks. This meant her painful reflux was left untreated, causing distress for her and her parents.

After being informed of the incident, [the Pharmacy] undertook a full investigation of the error. All staff were informed of the mistake and changes were made to the pharmacy standard operating procedures to minimise the chance of such an error recurring. The error was further discussed at a Pharmacy staff meeting on 11 July. A letter of apology was sent to [Baby A's] family on 21 July.

This mistake was the second significant dispensing error to occur at [the Pharmacy] in 2006.

[5] Sweetman, S. (2006). 'Ranitidine.' Martindale: The Complete Drug Reference. London: Pharmaceutical Press. On-line version.

3. Commissioner's questions

3.1. Please comment generally on the care provided to [Baby A].

The standard of care provided to [Baby A] by [the Pharmacy] on 8 June 2006 was quite clearly not appropriate or acceptable. [Baby A] and her parents had the right to expect her prescription to be dispensed in an accurate manner, but that did not happen in this case.

3.2 Please comment on the standard of care provided by [Ms B].

[Ms B], the supervising pharmacist, has in part been let down by her two technicians. Technician [Ms C] committed an error in calculating the label instructions, and technician [Ms D] failed to detect that error when preparing the medicine. However, in situations where such errors occur, and barring exceptional circumstances, the responsibility falls entirely on the supervising pharmacist.[6]

I have several observations on the standard of care provided in this case.

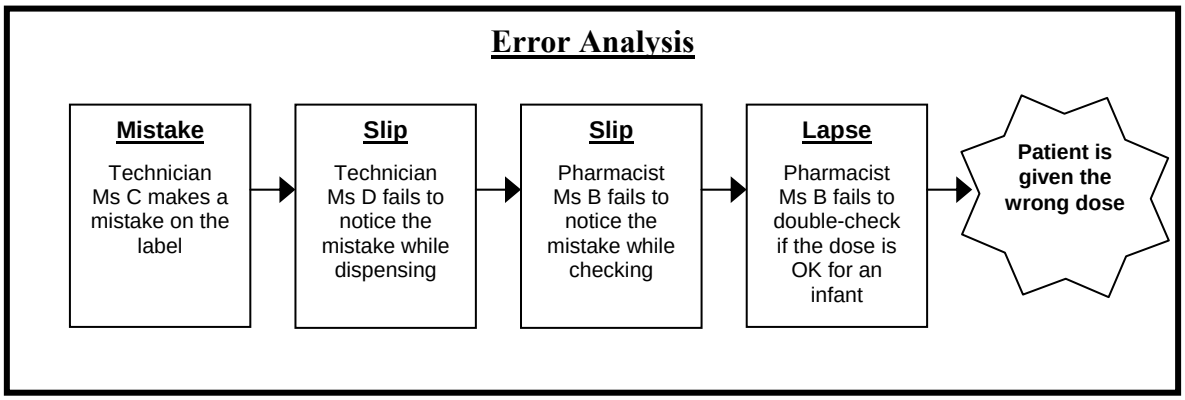
1. While *all* pharmacy patients are entitled to an appropriate level of care, there are certain patients who deserve a special standard of care. This category includes neonates and infants, who are vulnerable and often require specially calculated doses. In this case, the pharmacist did not seem to link the patient's age with the need for extra care.

2. The error seems to have occurred because pharmacy staff, including the supervising pharmacist, failed to notice the difference between mg (milligrams) and ml (millilitres). While this might seem like an easy mistake to make, it is a basic and important distinction that all pharmacy staff should make without difficulty.

3. In defence of the pharmacy staff, I note that this prescription was, in my opinion, a fairly uncommon one for a community pharmacy to encounter. In my experience it is not often that a very young child is prescribed ranitidine, so staff would not be very familiar with the prescribing procedure involved. Furthermore, it is clear that the pharmacy has been under a considerable amount of stress in recent months, and at the time of the error the dispensary was very busy. These observations do not completely excuse the error, but place it in context.

4. [Ms B], as supervising pharmacist, is clearly responsible for the actions of her technicians and failed to detect an error that was made.

[6] I believe there are cases where exceptions to this rule exist, but they are rare. For more details on this aspect, refer to my answer to question 3.4 below.



In my opinion, [Ms B] clearly did not provide [Baby A] — a vulnerable infant — with an adequate standard of care. I believe pharmacy peers would regard the departure from care with mild disapproval.

While it is not strictly within my brief from the Commissioner, I have thoroughly investigated the safety and therapeutic index of ranitidine in infants. Based on the references I have consulted, I am reasonably confident that a moderate overdose of ranitidine, of the type taken by [Baby A], is usually quite benign. I feel it is very unlikely that the overdose caused [Baby A] any significant or long-term harm. I mention this aspect of the case only for the peace of mind of all individuals involved in the error.

3.3. What professional standards apply in this case? Were these standards met?

The standards that apply in this case are the standards that would apply to all practising pharmacists in New Zealand at the time that the incident occurred. There are a very large number of applicable rules and regulations affecting pharmacy, including at least 20 separate statutes; but the following are particularly relevant to this case:

- Pharmacy Council of New Zealand Code of Ethics 2004[7]
- Pharmacy Council of New Zealand Quality Standards, Second Edition 2004[8]
- Pharmacy Practice Handbook 2003[9]
- Medicines Regulations 1984[10]

[7] Pharmacy Council of New Zealand (2004). *Code of Ethics 2004*. Available on the worldwide web at http://www.pharmacycouncil.org.nz/pharmacists/standard/documents/CODEofEthics20044preps.pdf.
[8] Pharmacy Council of New Zealand Competence Standards Available on the world wide web at http://www.pharmacycouncil.org.nz/pharmacists/standard/documents/Standards1-7Sept04.pdf.
[9] Pharmaceutical Society of New Zealand (2003). *Pharmacy Practice Handbook 2003.* Wellington: Pharmaceutical Society of New Zealand.
[10] New Zealand Government Legislation, available online at http://legislation.govt.nz

While most aspects of these standards **were** met, there were unfortunately some breaches of these standards. I have outlined the precise areas of concern and explained why I think the cited standards were not complied with.

(Note that I will further discuss regulations relating to pharmacy technicians in section 3.4, below.)

Pharmacy Council of New Zealand Code of Ethics 2004

Obligation 2.6 — Dispensing

'The pharmacist who is responsible for the dispensing of a prescription must verify its authenticity, interpret and evaluate the prescription, ensure that it is correct and complete, assess its suitability for the patient within the limitations of available information, and dispense it correctly.'

This standard was not complied with. The prescription was clearly not dispensed correctly.

Obligation 4.1 — Standards of service

'The pharmacist must provide high standards of service and patient focused care within the resources available.'

This standard was not complied with. Although the resources of the pharmacy may have been under strain due to stress and heavy workload, this does not excuse the lapse in the standards of service.

Obligation 6.4 — Supervision

'The pharmacist must provide appropriate direct supervision for other personnel for whom they have responsibility.'

The error that occurred resulted from a basic mistake made by a technician, which was neither detected nor corrected by supervising pharmacist [Ms B], despite her being in a position to do so. Therefore, the level of supervision on this occasion cannot be said to be appropriate, and thus this part of the standard was technically not complied with.

Obligation 10.2 — Special needs

'The pharmacist must take necessary and reasonable additional steps to ensure a patient with special needs receives an appropriate standard of pharmaceutical care.'

The patient was only nine weeks old, and receiving a reasonably unusual prescription for an infant. Therefore, I would categorise her as someone with special needs. In spite of this, it does not appear that the pharmacist took

reasonable additional steps (e.g. double-checking the dosage calculation or confirming the appropriateness of the dose for an infant), so in my opinion this standard was not complied with.

Pharmacy Council of New Zealand Competence Standards 2004

Sub-element 1.1.2 — Maintains a consistent standard of work

'Examples of evidence: expects consistent standard of work from self and others; leads by example; explains quality systems and who is responsible in workplace.'

This error cannot be seen as a consistent standard of work — especially when viewed in the context of other significant errors which have occurred in the same pharmacy in 2006.

Sub-element 1.1.5 — Works accurately

'Examples of evidence: minimises mistakes; acts immediately to rectify harm arising from mistakes; documents errors and steps taken to prevent their recurrence.'

Unfortunately, the error that occurred cannot be described as an accurate standard of work, so in that aspect the standard was not complied with. However, the actions taken by the pharmacy following the mistake (documenting the error and taking steps to minimise a recurrence of the error) appear to have been thorough and did comply with this standard.

Sub-element 2.2.2 — Evaluates the available medicines, dose forms and methods of administration

'Examples of evidence: using readily available references, determines the advantages and disadvantages of different medicines, their dosages and dose forms for specific situations or patients.'

In the situation I believe the pharmacist should have consulted with other references to confirm that the dose was safe and appropriate for a nine-week-old infant. This evidently did not occur, so the standard was not complied with.

Sub-element 2.3.2 — For each medicine, checks the dosages and methods of administration are optimal

'Examples of evidence: assesses efficacy and safety of medicine recognising pharmacokinetic factors, e.g. age, weight, pregnancy, other therapies; assesses the suitability of dosage form with respect to efficacy, safety and compliance, e.g. tablets in a child, inhaler type for asthmatic.'

As with sub-element 2.2.2, it does not appear this standard was complied with.

Sub-element 6.3.3 — Interprets prescription instructions

'Examples of evidence: interprets abbreviations of dosage and dose forms; interprets the prescriber's intention.'

The primary mistake in this incident was not interpreting the doctor's dosage instructions accurately — there was confusion between 'mg' and 'ml.' Therefore this standard was clearly not complied with.

Sub-element 6.4.4 — Identifies patient factors likely to affect the efficacy or safety of specified medicines

'Examples of evidence: e.g. age, weight, pregnancy, breast-feeding, disabilities, allergies, risk factors, other medicines.'

While the pharmacist was aware that the patient was a baby, she did not seem to identify the patient's age as an important factor affecting the safety of this particular dispensing, which required more diligent checking. In my opinion this standard was not complied with.

Sub-element 6.5.1 — Confirms that each selected medicine is suitable for the patient

'Examples of evidence: confirms that dosage, route of administration and duration of therapy are suitable; identifies possible interactions or incompatibilities.'

As already mentioned, I am of the opinion that the pharmacist should probably have double-checked the dosage to ensure it was appropriate for an infant. She could have done this by referring to sources such as *Martindale* or an internet-based drug information service. It does not appear that this happened. As such, I think that this standard was not complied with.

Sub-element 6.6.2 — Maintains a logical, safe and disciplined dispensing procedure

'Examples of evidence: selects correct product, dose form and quantity for each prescribed medicine; dispenses off prescription, not label.'

This standard was not complied with, as dispensing a five-fold overdose cannot be considered a safe procedure; and failing to double-check the safety of the dose for an infant is, in my opinion, a lapse in disciplined procedure.

Pharmacy Practice Handbook 2003

Many elements of the Pharmacy Practice Handbook 2003 have been superseded or supplemented by the updated Code of Ethics 2004 and Professional Competence Standards 2004. Nevertheless (and at the risk of being repetitious), the following standard, expressed in the handbook, is worth outlining:

Part 2, Section 2.2, Standard 6 (Pharmaceutical Services)

6.2 The pharmacist maintains a disciplined dispensing procedure which ensures the appropriate product is selected and dispensed correctly and efficiently …

…

6.2(b) The pharmacist interprets and evaluates prescriptions for correctness and completeness, verifies their authenticity and appropriateness and determines their priority for dispensing.

6.2(c) The pharmacist ensures that the dispensed medicine is selected correctly, packaged and stored appropriately and that sufficient information is given to ensure its appropriate use.'

This standard was not met, for obvious reasons which have already been outlined in detail.

3.4. Please comment on the relative responsibility of the pharmacist and the pharmacy technician in the dispensing process.

In New Zealand, the relative levels of responsibility of pharmacists and pharmacy technicians are clearly spelled out under the Medicines Regulations 1984 (which exist pursuant to section 105 of the Medicines Act 1981); the Pharmacy Code of Ethics 2004 (especially obligations 6.4 and 6.5); the Pharmacy Competence Standards (especially sub-elements 4.1.1, 4.1.2 and 4.1.3); and the Pharmacy Practice Handbook 2003 (especially Part 3, Section 3.1.5; Part 4, Section 4.1 and Part 6, Section 6.1).

Medicines Regulations 1984

Part 7 r 42 — Dispensing of prescription medicines

(1) Except as provided in subclause (2), no person other than an authorised prescriber, veterinary surgeon, pharmacist, pharmacy graduate, a pharmacy technician, a student, or dispensary technician may dispense a prescription medicine.

(1A) The following persons may not dispense prescription medicines unless under the direct personal supervision of a pharmacist:

(a) dispensary technicians;

(b) pharmacy graduates;

(c) pharmacy technicians;

(d) students.

Part 7 r 63 — Restriction on, and supervision of, compounding medicine

(1) A dispensary technician must not undertake any process of compounding a medicine.

(2) The following persons may compound a medicine, but only if under the direct personal supervision of a pharmacist:

(a) pharmacy graduates;

(b) pharmacy technicians;

(c) students;

(d) despite subclause (1), dispensary technicians who have served an apprenticeship in pharmacy under the Pharmacy Act 1939.

Pharmacy Council of New Zealand Code of Ethics 2004

Obligation 6.4 — Supervision

'The pharmacist must provide appropriate direct supervision for other personnel for whom they have responsibility.'

Obligation 6.5 — Responsibility for professional activities

'The pharmacist must accept responsibility for their own professional activities and for all activities undertaken under their direct supervision.'

Pharmacy Council of New Zealand Competence Standards 2004

Sub-element 4.1.1 — Organises own work

'Examples of evidence: explains own work and responsibilities in work place; meets deadlines; prioritises work; decides what to do, plans to get it done and does it.'

Sub-element 4.1.2 — Takes responsibility for the work of non-pharmacist staff

'Examples of evidence: describes roles and responsibilities of non-pharmacist staff; supervises work of non-pharmacist staff e.g. technicians and assistants; works with others to prioritise and organise workflow.'

Sub-element 4.1.3 — Supports the work of colleagues in the work place

'Examples of evidence: describes pharmacist's role and responsibilities in workplace; works in partnership with colleagues in work place, if applicable, to ensure safe practice.'

Pharmacy Practice Handbook 2003

Part 3, Section 3.1.5 (Supervision in Pharmacies)

'Section 41 of the Pharmacy Act 1970 requires that a registered pharmacist must always be present to supervise the activities going on in a pharmacy during opening hours.'

The issue of supervision in pharmacies is a recurring one. Pharmacies are places where members of the public can go to receive informed, unbiased professional health advice and information. In order to maintain a professional image and retain the range of medicines able to be sold in a pharmacy it is essential that pharmacists continue to ensure appropriate supervision of all transactions occurring in a pharmacy. This is implicit in the act. Section 41 states 'no person shall keep, or permit to be kept, or manage, any pharmacy which is not for the time-being under the immediate supervision and control of a pharmacist.' Supervision is not defined in the act but it has been defined in the courts as existing only when the person supervising is in touch with transactions by sight and sound and is in a position to intervene if this is necessary. Clearly, supervision cannot operate without the physical presence of a pharmacist. Members of staff should be made aware of the effect of section 41 of the act.

The Council of the Pharmaceutical Society is convinced that it is in the interest not only of members of the public but of all pharmacists that there should be strict compliance with section 41. In the absence of a pharmacist, there is no apparent difference between a pharmacy and any other retail outlet.

…

Council expects close compliance with the provisions of section 41 and will continue to take a serious view of any contraventions.'

Part 4, Section 4.1, 4.1.1 (Dispensing)

'Pharmacy graduates, dispensary technicians, pharmacy technicians, pharmacy students and pharmacy technician students may only dispense under the direct personal supervision of a pharmacist …'

Part 6, Section 6.1 (Dispensary and Pharmacy Technicians)

'Dispensary and pharmacy technicians assist pharmacists with the dispensing of prescription medicines. They must always work under the direct personal supervision of a pharmacist (reg 63 of the Medicines Regulations 1984). Regulation 2 of the Medicines Regulations defines a Dispensary Technician and a Pharmacy Technician.

A Dispensary Technician (previously termed a Dispensary Assistant) has a Dispensary Assistant's Certificate issued by the Pharmaceutical Society following completion of a course of training prior to 1998.

A Pharmacy Technician has a National Certificate in Pharmacy (Technician) issued by the New Zealand Qualifications Authority, or has an overseas qualification recognised by the Pharmaceutical Society as equivalent.

In pharmacy, only pharmacists, pharmacy graduates actively taking steps towards registration as a pharmacist, pharmacy students, dispensary technicians, pharmacy technicians, pharmacy technician students and persons who served an apprenticeship under the Pharmacy Act 1939 are permitted to dispense prescription medicines (reg 42 Medicine Regs). All, except pharmacists, must work under the direct personal supervision of a pharmacist. Dispensary technicians are not permitted to compound medicines.'

Part 6, Section 6.1.1 — Roles of Dispensary and Pharmacy Technicians

Guidelines for the Pharmacist

'The functions performed by a pharmacist can be categorised as either non-judgemental product orientated or patient orientated. In developing the concept of comprehensive pharmaceutical care, it is essential that the pharmacist devolve responsibility for as many product orientated functions as possible so allowing time for patient orientated activities. However, technicians must be supervised by a pharmacist at all times when involved with the dispensing and supply of medicines.

Limitations of Role

… Under no circumstances will a technician give a prescription to a patient unless it has been checked and initialled by a pharmacist …'

The above standards are unanimous and very clear. They are repeatedly emphasised to pharmacists and pharmacy technicians throughout their training. There should be no ambiguity in the understanding of their respective roles. Pharmacy technicians must always work under the care of a pharmacist, who supervises their work and normally assumes full responsibility for each dispensing under their care.

Technicians have a greatly reduced degree of responsibility for their role in the dispensing process.[11] There is a very strong suggestion that whenever a pharmacy error occurs, it must be the responsibility of a pharmacist; as such I am generally very hesitant to ever suggest that a technician has departed from an 'acceptable standard of care.'

However, despite the clear understanding that pharmacists are fully responsible for everything that occurs under their supervision, I am of the opinion that there are rare occasions when to apply this rule inflexibly and 'to the letter of the law' would violate common sense and natural justice. In those rare cases, it may be reasonable to hold a pharmacy technician directly responsible for an error, while *not* holding the supervising pharmacist responsible. Such determinations should not be made lightly, but only after an extremely thorough examination of all salient facts of the matter.

Examples of such situations might include:

1. Instances where a technician acts in bad faith or otherwise deliberately acts to harm patients;
2. Instances where a technician deceives a pharmacist or other authority about their actions;
3. Instances where a technician commits a serious error in dispensing, where the nature of the error is such that it would be unreasonable to expect even the most diligent supervising pharmacist to detect and amend the error prior to dispensing, and where there are no other relevant ameliorating or extenuating circumstances.

It should be emphasised that these three examples are merely hypothetical cases that I raise to illustrate my point; they should not be interpreted as necessarily applying to this nor any other case before the Commissioner.

In the current case, although the error was committed by one technician and not detected by another technician, there are no exceptional circumstances extant. It is entirely reasonable to expect the supervising pharmacist, [Ms B],

[11] While there are some calls to expand the role and responsibility of technicians, these proposals are only at the stage of informal discussions, and any changes in this area will be years away — if they happen at all.

to have detected the error. Thus, it is my opinion that in the current case, the full responsibility for the error rests with supervising pharmacist [Ms B].

As I already stated in section 3.2., 'In my opinion, [Ms B] clearly did not provide [Baby A] — a vulnerable infant — with an adequate standard of care. I believe pharmacy peers would regard the departure from care with mild disapproval.'

3.5. Please comment on the actions taken by the Pharmacy and the pharmacy staff following the discovery of the dispensing error.

The Pharmacy Defence Association spells out the appropriate steps to take in response to a medication error[12,13]:

- if a patient notifies an error, the appropriate response is to express immediate concern;
- if the error is obvious, then the pharmacist should acknowledge the error and apologise;
- if the error is not obvious, the pharmacist should inform the patient they will investigate the situation and report back to the patient as quickly as possible;
- the pharmacist should ask questions of the patient to find out whether he or she has taken any of the incorrect medication and, if so, what symptoms have been experienced;
- the pharmacist should inform the patient about what the incorrectly dispensed medication is normally used for and its possible side effects;
- if appropriate, the patient should be reassured that the symptoms experienced are side effects of the medication and advised when they are likely to abate;
- if necessary, the patient should be referred to the prescriber, and the pharmacy should offer to pay for the visit;
- the pharmacist should notify the prescriber of the situation, how the patient is, and what actions have been taken to date; and
- all aspects of the incident should be documented.

It appears that in this case most of these guidelines have been followed, as far as is reasonable to expect.

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[12] Pharmaceutical Society of New Zealand (2002). Pharmacy Defence Association: How to respond when a dispensing error occurs. *Interactions.* Vol 60, p.2.

[13] Pharmacy Defence Association of New Zealand (2005). How to respond when a dispensing error occurs. The Pharmacist's Guide to Member Benefits, p.10; available on the World Wide Web at: http://www.pharmacydefence.co.nz/errors.cfm

The response taken by the pharmacy management on discovery of the error has been outlined in documents provided by the pharmacy — including an incident reporting form and various letters of explanation.

- When the error was discovered, all staff were immediately informed, and the pharmacy started conducting its own investigation into the error. The error was also further discussed at staff meetings.
- [Ms B] acknowledged the error and expressed genuine concern in a letter of apology to [Baby A's] family, dated 21 July 2006.
- Pharmacy staff liaised with [Baby A's] general practitioner, [Dr E], to discuss the error and ensure any ongoing medication issues would be managed appropriately.
- Appropriate actions were taken to prevent further dispensing errors. The pharmacy SOPs were reviewed and updated within a few days of the incident.
- All salient aspects of the error (and the response to it) were thoroughly documented.

In short, all parties involved seem to have responded appropriately to a significant and regrettable error. The only problem I note is the delay in [Ms B] writing a letter of apology to [Baby A's] family. [Ms B] agrees that this could have been done earlier. It also would have been an appropriate gesture to have made immediate face-to-face contact with the family when informed of the error. While this delay in acting is a lapse of good practice, in my opinion (based on the documents I have reviewed), it is not quite as serious as another pharmacist's failure to follow up a subsequent error at the same pharmacy (refer to HDC 06-12613).

3.6. Please comment on the appropriateness of the standard operating procedure in place at the time of the dispensing error.

I have reviewed all relevant aspects of the standard operating procedures (SOPs) at [the Pharmacy] at the time of the error, and in my opinion they were all adequate and appropriate.

I note that the pharmacy's SOPs had been very thoroughly reviewed and approved shortly before this error occurred (in response to a previous serious error).

I also note that the pharmacy procedures had passed MedSafe Quality Audits before the error occurred. I understand that the audits undertaken were extremely thorough.

In my opinion, the error that affected [Baby A] was *not* due to inadequate or inappropriate operating procedures at [the Pharmacy]. It resulted from a single

error which was not detected during the normal dispensing process, resulting in an unintentional breach of those procedures.

3.7. Please comment on the changes made to the standard operating procedures following this dispensing error.

While the old SOP was adequate and appropriate, the updated SOP has improved procedures. In particular, the updated SOP outlines more explicit and pro-active procedures for dispensing liquids and paediatric preparations. These improvements would help to further reduce the risk for dispensing errors.

I must again emphasise my answer to question 3.6 — that the old SOP was perfectly adequate. While every pharmacy's SOPs could probably be continuously improved and expanded, there comes a point where the procedures simply become too unwieldy for day-to-day operation of a pharmacy. (A 'bloated' SOP may even be counterproductive, causing staff frustration and anxiety, and actually work against the basic goals of safety and efficiency.)

The real discipline is developing a good SOP and *religiously following it for each and every dispensing.*

(As an expert advisor, I can only make comments on the documents I am supplied with. I can certainly say that all SOPs for [the Pharmacy] which I have reviewed are acceptable. However, I cannot make any comments on potentially relevant issues such as the professional culture at [the Pharmacy]; nor can I consider how rigorously the pharmacy staff follow the SOPs in day-to-day practice. I can only assume, in good faith, that the entire team at [the Pharmacy] are professional and diligent. I have absolutely no reason to believe otherwise.)

3.8. Any other comment you wish to make.

Doctor's Prescription

I have reviewed the doctor's prescription, and in my opinion there are no factors associated with its style or legibility that have any relevance to the current case.

Manufacturer's Packaging

I have reviewed the manufacturer's bottle of Zantac (a brand name of ranitidine hydrochloride), and in my opinion there are no factors relating to the manufacturer's labelling that have any relevance to the current case.

Retrospective Checking

It is lamentable that 15 days passed between the occurrence of the error and its discovery — but it is not really practical to expect the pharmacy to have somehow detected the mistake after the dispensing was signed off, the medicine picked up, and the original prescription filed away.

However, one possible technique that *could* have caught the error, and possibly minimised the impact of the mistake on [Baby A], is 'retrospective checking.' In my pharmacy, my staff or I go through a day's prescriptions (usually during a quiet time on the next working day) and perform some quick checks to ensure the prescriptions are accurate before being sent away for processing and filing in Wanganui.

These retrospective checks are an important part of my safety routine. While they cannot prevent errors, these checks can detect them and thus minimise their impact. They are particularly important if the previous day's dispensing had been busy or stressful.

Among the items checked:

- Telephone and fax prescriptions are matched up
- The prescriptions meet all legal requirements, such as being properly signed and stamped
- Chem numbers, specialist approvals, certified conditions, etc. are all correct
- Any important calculations are re-checked

Although this sounds quite laborious, I find these checks are actually quite quick and not inconvenient.

Since the pharmacy annotation on [Baby A's] prescription was incorrect, there is a *chance* that such a check might have caught the error.

I would suggest that [the Pharmacy] consider instituting retrospective checks if they don't already. However, I would like to reiterate my concerns about 'bloating' of procedures; I think that such checks should be instituted only at the manager's discretion, and fine-tuned to the specific needs of the pharmacy.

4. Conclusion

It is obvious that [Baby A's] family, and the team at [the Pharmacy], were deeply upset by this incident. I am sure that everyone involved was shocked and upset as the nature of the error affecting young [Baby A] became apparent.

It is also obvious that [the Pharmacy] have a commitment to provide optimum care for their patients — a goal that can be difficult in the overworked and often hectic environment of modern pharmacies.

I wish to commend [the Pharmacy] team for the way they have positively and constructively responded to this unfortunate chain of events. This incident has clearly resulted in a renewed emphasis on following proper procedures at [the Pharmacy].

My wish is that this incident should be seen as a learning experience for all parties and that a stronger pharmaceutical profession will emerge from the lessons of these unfortunate mistakes."

Code of Health and Disability Services Consumers' Rights

The following Rights in the Code of Health and Disability Services Consumers' Rights are applicable to this complaint:

RIGHT 4

Right to Services of an Appropriate Standard

(1) Every consumer has the right to have services provided with reasonable care and skill.
(2) Every consumer has the right to have services provided that comply with legal, professional, ethical, and other relevant standards.

Other relevant standards

Pharmacy Council of New Zealand Code of Ethics (2004)

Obligation 2.6 — Dispensing

"The pharmacist who is responsible for the dispensing of a prescription must verify its authenticity, interpret and evaluate the prescription, ensure that it is correct and complete, assess its suitability for the patient within the limitations of available information, and dispense it correctly."

Opinion

This report is the opinion of Rae Lamb, Deputy Commissioner, and is made in accordance with the power delegated to her by the Commissioner.

Opinion: Breach — Ms B

Introduction
Under Rights 4(1) and 4(2) of the Code, Baby A had the right to pharmacy services provided with reasonable care and skill, and in compliance with professional standards. The standards that apply in this case are determined by the Pharmacy Council of New Zealand (the Council), and have been set out in detail by my independent expert, Mr John Fraser, in his report.

I concur with Mr Fraser's advice that, although two pharmacy technicians were involved in the dispensing error, "the full responsibility for the error rests with supervising pharmacist [Ms B]".

In my opinion, the prescription was clear and unambiguous. Mr Fraser advised: "there are no factors associated with [the prescription's] style or legibility that have any relevance to the … case".

Dispensing error
Although the original error was made by a pharmacy technician, and not picked up by a subsequent technician, Ms B, as the charge pharmacist, has correctly accepted responsibility for the dispensing error. She explained that she made a mistake, during a busy phase of the day, confusing 5ml with 5mg (the latter being the prescribed — and correct — dose).

Mr Fraser advised that although this may seem like an easy mistake to make, "it is a basic and important distinction that all pharmacy staff should make without difficulty". Mr Fraser has pointed out that very young children require "specially calculated doses", and particular care must be taken in dispensing for them. However, in this case Ms B failed to perform an adequate check. As Mr Fraser stated, Ms B "did not seem to link the patient's age with the need for extra care".

It is fortunate that the drug dispensed appears to have had no ill-effect on Baby A, and no doubt all involved in this case have pondered what may have occurred had she received a dose of another drug at over five times the prescribed dose for such an extended period.

I note that although Ms B responded appropriately to the error when it became apparent, there was some delay before she wrote a letter of apology. Ms B has conceded that she could have written an apology earlier and I would reinforce this.

When a mistake such as this has occurred, an early apology is paramount. Like Mr Fraser, I also believe Ms B should have endeavoured to meet with Mr and Mrs A.

In relation to the dispensing process, Mr Fraser identified a number of professional standards that Ms B breached. In particular, she failed to comply with Obligation 2.6 of the Council's Code of Ethics, which states:

> "The pharmacist who is responsible for the dispensing of a prescription must verify its authenticity, interpret and evaluate the prescription, ensure that it is correct and complete, assess its suitability for the patient within the limitations of available information, and dispense it correctly."

By failing to provide pharmacy services with reasonable care and skill, and in compliance with professional standards, Ms B breached Rights 4(1) and 4(2) of the Code.

Opinion: No breach — The pharmacy

Mr Fraser has advised that the SOPs in place at the pharmacy are of an appropriate standard. I am satisfied that the pharmacy had appropriate processes in place to enable the provision of services of an appropriate standard, as long as those processes were followed.

Having reviewed the available information, I am satisfied that no act or omission by the pharmacy could, in this case, be considered a breach of the Code.

Vicarious liability
In addition to any direct liability for a breach of the Code, an employing authority may be vicariously liable under section 72(2) of the Health and Disability Commissioner Act 1994 for any breach of the Code by an employee. Section 72(5) affords a defence for an employing authority if it took such steps as reasonably practicable to prevent the act or omission in question. Ms B was an employee of the pharmacy. The pharmacy had clear policies and guidelines, set out in the SOPs, which Ms B was aware of.

In my opinion, the pharmacy took reasonable steps to prevent the act in question and is therefore not vicariously liable for Ms B's breach of the Code.

Other matter

I note that this is the second dispensing error from this pharmacy in 2006 investigated by this Office.[14] A third case (06/12613) is still under investigation. Although all three cases involve the same pharmacy, different pharmacists were involved. In relation to the third case, I have asked my expert advisor, Mr Fraser, to consider the number of errors, the pharmacy's systems, and the role of pharmacy technicians. I will address this matter in my report of that case.

Action taken

Ms B has apologised to Mr and Mrs A for her error, and the pharmacy has amended the SOP to ensure that prescriptions for children are more closely monitored, and that drug calculations are to be recorded and checked by a second person. Accordingly, I do not feel that further recommendations are required.

Follow-up action

- A copy of this report will be sent to the Pharmacy Council of New Zealand.
- A copy of this report with details identifying the parties removed, but naming the pharmacy, will be sent to Medsafe and the relevant District Health Board.
- A copy of this report, with details identifying the parties removed, will be sent to the Pharmaceutical Society, the Pharmacy Industry Training Organisation, and the Quality Use of Medicines Group, and placed on the Health and Disability Commissioner website, www.hdc.org.nz, for educational purposes.

[14] The first case investigated was 06HDC01037.