Pharmacists, Mr B and Mr C

A Pharmacy

A Report by the

Health and Disability Commissioner

(Case 03HDC08821)

Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

Parties involved

Miss A	Consumer
Ms A	Complainant / Mother of consumer
A pharmacy	Provider
Mr B	Provider / Pharmacist
Mr C	Provider / Pharmacist
Dr D	Provider / General Practitioner

Complaint

On 16 June 2003 the Commissioner received a complaint from Ms A about a pharmacy. The complaint was summarised as follows:

The pharmacy
On 6 June 2003, a pharmacist at the pharmacy did not provide Miss A (aged five years at the time and accompanied by her mother, Ms A) with services of an appropriate standard. In particular, the pharmacist dispensed Tripress, a drug not normally prescribed for children, without first confirming the prescription with the prescribing doctor.

The pharmacists involved in dispensing the medication were Mr B and Mr C. The matters investigated were as follows:

Mr B
Whether on 6 June 2003 Mr B, pharmacist at the pharmacy, provided Miss A with services of an appropriate standard. In particular, whether Mr B prepared a label for the drug Tripress, a drug not normally prescribed for children, without satisfying himself as to the suitability of the prescription for Miss A.

Mr C
Whether on 6 June 2003 Mr C, pharmacist at the pharmacy, provided Miss A with services of an appropriate standard. In particular, whether Mr C dispensed the drug Tripress, a drug not normally prescribed for children, without satisfying himself as to the suitability of the prescription for Miss A.

An investigation was commenced on 29 July 2003.

Information reviewed

- Complaint material and information from Ms A
- Information from Mr B
- Information from Mr C
- Information from the pharmacy
- Independent expert advice obtained from Ms Andrea Shirtcliffe, a pharmacist.

Information gathered during investigation

Background
On 6 June 2003, Ms A took her five-year-old daughter, Miss A, to Dr D, at the pharmacy's clinic. Dr D intended to prescribe the antibiotic trimethoprim (Triprim) for a suspected urine infection. However, Dr D mistakenly provided Ms A with a prescription for Tripress, an antidepressant. Tripress is dispensed in the form of rigid gelatine capsules. Matters relating to the prescribing of this medication are the subject of a separate investigation and report.

Ms A presented the prescription to a shop assistant at the adjacent the pharmacy Pharmacy. The prescription was processed through the computer by pharmacist Mr B. The medication was selected, labelled and signed by pharmacist Mr C. Mr C also issued the prescription items to Ms A. Neither pharmacist noticed that the prescription was for a five-year-old child, or took steps to establish the suitability of the medication for Miss A.

Ms A returned home and attempted to administer the medication to her daughter. However, Miss A found the capsules hard to swallow. Ms A phoned the pharmacy to find out if the capsules could be dissolved. Mr B told Ms A that Tripress was, in fact, an antidepressant. Ms A recalled events as follows:

> "On returning home I opened the packet and took out three capsules as instructed on the packet and tried to encourage [Miss A] to take them. [Miss A] had a problem with swallowing the capsules so I decided to break them up and put them into a glass with some Orange Juice which I did. I then thought I better just check with the pharmacy to see if this was ok to do. When I rang the pharmacist he said he would check then came back and said this medication is not usually given to children. 'What's it for?' he asked. I told him a urine infection, that's when he told me it was an anti-depressant Tripress. The doctor had prescribed the wrong one.
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> …
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> I was so upset and feeling sick that I was trying to encourage my daughter to take this medication that could have had serious consequences."

Ms A returned to the pharmacy later that day and was given the correct medication. She returned the antidepressants to the pharmacy the next day.

Labelling of prescription
Mr B received the prescription from a shop assistant and processed it through the computer to prepare the label. He recalled:

> "As I recall [Ms A] presented to the pharmacy with two prescriptions; one for [Miss A], and one for another child. I typed the labels for both prescriptions as per Standard Operating Procedure # 2.2 'Dispensing Prescriptions'. Typing labels is normally the task of the dispensary technician.
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> It is my professional habit, when typing prescription labels, to focus on the transfer of information from the prescription to the label. I always perform a comprehensive prescription check (which would include checking for appropriateness of medicine etc) before releasing the medicine to the patient. On this occasion, I was not involved in the final check.
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> After I typed the label for the prescription for the first child, my natural assumption was that the second prescription was for [Ms A] herself (as she had only one child with her in the pharmacy at the time.) Regrettably I did not notice that the prescription was for a second child."

Dispensing of prescription
Mr C was responsible for completing the dispensing of Dr D's prescription. He stated:

> "I selected, labelled and signed off the prescription as written. In this dispensing process, I selected the medication from the shelf and checked against the prescription that it was the medication that was written. I counted the appropriate quantity and placed them in a skillet. I then checked that the label was correct and attached this to the skillet. I then signed the prescription as being correct. I missed the date of birth written on the prescription.
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> I then issued the prescription to [Ms A] (who was not accompanied by her daughter) assuming she was the patient. I gave instructions as to how to take it.
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> The label was generated by another pharmacist, when details of age etc. are entered.
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> As a consequence of this incident we now highlight the age of children under 12 to avert further incidences. Including information on the prescription regarding diagnosis would also help to avoid incidences of this nature."

Mr C recalled that Ms A responded, after he called out Miss A's name. Mr C read the instructions from each label out aloud, without further enquiry or discussion on Ms A's part. Ms A confirmed that she was provided with instructions on how to take the medicine.

Follow-up actions
Mr B confirmed that shortly after dispensing Miss A's prescription, he received a telephone call from Ms A seeking advice due to difficulty in administering the Tripress capsules to her daughter:

> "At this point I thought it unusual for a child to be receiving an antidepressant, but nothing at the time led me to believe it was inappropriate. The instructions were appropriate for Tripress, whereas the usual frequency for UTI antibiotics would be once or twice daily. It wasn't until I asked [Ms A] what the medicine was for, that I realised [Dr D] had intended trimethoprim (or something similar) rather than trimipramine.
>
> I informed [Ms A] that there had been a prescribing error, not to give any of the capsules to [Miss A], and the Dr should be contacted so that the error could be corrected. [Ms A] was upset at [Dr D's] mistake, and I tried my best to reassure her that things would be okay.
>
> …
>
> Realising the seriousness of the error, and the importance of the intervention I had made, I then filled out a Pharmacist's Intervention Form as per Organisational Quality Standard F8 'Incident Reporting'. I had also verbally told [Ms A] that I was sorry the error had occurred but it was clear that her complaint was being directed towards the prescriber, so I did not think it was appropriate to write a formal written apology at the time."

The Pharmacist Intervention Report states, in part:

> "Mother phoned pharmacy about 30 minutes later, asking if capsules could be halved as patient is only five can't take capsules. I ([Mr B]) suggested Tripress wasn't really appropriate for children, so I asked what the medicine was for. On learning it was supposed to be for a urine infection, I informed the mother that the wrong drug had been prescribed and not to give any to the patient."

Mr B commented that there was not enough information on the prescription to indicate that the wrong medicine had been prescribed. He added that if information about diagnosis was included with prescriptions this would assist with the identification of errors of this nature.

The pharmacy
The Manager of the pharmacy provided a copy of the original prescription written by Dr D, together with a copy of the pharmacy standard operating procedures and incident reporting form. He did not include a copy of the pharmacy label, which he advised was removed from the pharmacy database to ensure the accuracy of pharmacy electronic pricing claims. The Manager stated:

> "If a prescriber needs to be contacted concerning some aspect of a prescription this action is always performed before the prescription is released to the patient. The decision to contact the prescriber is a matter of professional judgement.

…

A typical day of dispensing involves a wide variety of drugs prescribed by an equally vast range of prescribers, including medical specialists to patients with diverse health problems. It is not always necessary to check 'unusual' prescriptions with prescribers.

The pharmacists involved in dispensing the prescription for [Miss A] regret that the age of the patient did not lead them to question [Ms A] further, in order to establish the appropriateness of the doctor's prescribing. It was unfortunate [Ms A] did not collect the prescription with [Miss A] present. The pharmacist issuing the prescription was not only unaware of the diagnosis but also the physical and intellectual status of [Miss A]."

The Manager advised that, as a result of this complaint, the pharmacy has amended its standard operating procedure. Pharmacy staff preparing labels are now required to use a felt pen to highlight the age of the patient on the label.

Independent advice to Commissioner

The following expert advice was obtained from Ms Andrea Shirtcliffe, an independent pharmacist:

"**Conclusion:**

Questions asked:

1 I am not aware of any use for trimipramine (Tripress®) in the pediatric population, niche or otherwise. I consider the prescription of trimipramine (Tripress®) to be inappropriate, and at the very least unusual for a child.

2 The prescription involved in this case included the patient code 'Y1' which indicates that the patient was a child under the age of six years. The date of birth was documented on the prescription which identified that the patient was under the age of six years. This prescription would not have incurred a prescription charge which would indicate that the patient is either a patient under the age of six years or a Prescription Subsidy Card Holder. I conclude that there were sufficient prompts for [Messers B and C] to enable them to ascertain that this prescription was intended for a child.

3 I do not consider that [Messers B and C] were disadvantaged by not having any information in relation to the diagnosis. The diagnosis is not routinely included on prescriptions. However, I feel inclusion of such information enables pharmacists to provide more targeted and appropriate medication counselling at the time of dispensing. It would be ideal if prescribers could be encouraged to include such details on prescriptions in the future.

4 When a pharmacist is presented with a prescription of trimipramine (Tripress®) for a child their actions should include checking the legality and eligibility of the prescription and the patient details. [Messers B and C] do not appear to have accurately assessed the patient details (in particular age and category) or appropriateness of the medication for the patient.

5 Dispensing standard 6.2b '*the pharmacist interprets and evaluates prescriptions for correctness and completeness, verifies their authenticity and appropriateness and determines their priority for dispensing'*

Code of Ethics

1.2 Medicines and therapies prescribed by another provider '*the pharmacist must ensure that the patient is provided with understandable information about … expected outcomes of therapy within the limitations of available information …*'

2.3 Patient focused care '*the pharmacist must in all matters endeavor to provide professional patient focused care*'

2.6 Dispensing '*… the pharmacist … assess its suitability [the prescription] for the patient within the limitations of available information …*'

3.10 Inappropriate or erroneous prescribing '*where a pharmacist has reasonable grounds to consider that a prescription contains any error, omission, irregularity or ambiguity or is not legitimate, or that a prescribed medicine could be detrimental to a patient's health, the pharmacist must confer with the prescriber and document the details and outcomes …*'

3.15 Inappropriate supply '*The pharmacist must exercise professional judgment to prevent the supply of any medicine complementary therapy, herbal remedy or other healthcare product likely to constitute a hazard to health …*'

It is my opinion that with respect to the above standards the pharmacy has not deviated from an acceptable standard of practice but that [Messers B and C] have deviated to a moderate degree.

6 [The pharmacy's] standard operating procedures (SOPs) describe an acceptable standard of practice. In my opinion the actions taken by [Messers B and C] did not comply with the pharmacy's SOPs.

7 There are no other matters with respect to pharmacist professional standards that I believe are relevant. However, the pharmacy have identified that prescribing errors of this nature have occurred in the past with this prescriber. This should make pharmacists more alert to potential problems with this prescriber's prescriptions and hence make them more diligent in their checking procedures. Having said this, if this is a recurring problem with this particular prescriber I would hope that this is being

investigated at the very least to enable this prescriber to review their own SOPs to minimize the chance of such errors recurring in the future.

1 *Do you consider the prescription of Tripress® to be generally inappropriate/ unusual for a child?*

The trimipramine (Tripress®) Datasheet and the British National Formulary (BNF) states that trimipramine (Tripress®) is not recommended for use in children.[1,2] Neither the Pediatric Dosage Handbook nor Pediatric Pharmacopoeia list trimipramine for use in pediatrics.[3,4]

Pubmed searches using the terms: Pediatrics [MeSH], pediatrics [text], pediatrics [text], Antidepressant Agents, Tricyclic [MeSH], tricyclic antidepressants [text] and tricyclics [text] identified no references specifically commenting on trimipramine use in pediatrics.

Tricyclic agents are used in pediatrics to treat enuresis. Imipramine, amitriptyline and less commonly nortriptyline are the more common agents (although the group as a whole would be regarded as second line).[2]

Tricyclic agents are also used as second line agents for treatment of Attention-Deficit/Hyperactivity Disorder. Imipramine and Desipramine are more commonly used (at a dose of 2-5mg/kg/day)[5] Imipramine and Trimipramine are equivalent in potency (mg for mg).[6]

I am not aware of any use for trimipramine in the pediatric population, niche or otherwise and cannot recollect ever having seen it prescribed in the sixteen years I have been practising pharmacy. Therefore I consider the prescription of trimipramine (Tripress®) to be inappropriate and at the very least unusual for a child.

2 *Were [Mr B] and [Mr C] provided with sufficient information to enable them to inform themselves that the prescription was for a child and may have been unsuitable?*

[Mr B] and [Mr C] were provided with the date of birth on the prescription. They were also provided with the prescription code 'Y1' which indicates that the prescription is for a child under the age of six years. This is sufficient information to enable a dispenser and/or checker to ascertain the age of the intended recipient.

The lack of a charge on a new prescription should alert the dispenser and/or checker to the fact that the patient is either a child under the age of six or is the holder of a prescription subsidy card. If the recipient was the holder of a prescription subsidy card then this information (according to the SOPs of [the pharmacy]) should have been annotated at the top of the prescription.

At the time of writing this report there is no premium charge on trimipramine (Tripress®). This medicine is a sole supply product (under the brand name Tripress®) so is fully funded i.e. does not attract any additional prescription charges over and above

the standard prescription co-payment.[7] There is no co-payment payable on prescriptions for children under the age of six.

Pharmac have not recorded an out of stock situation for this product during the 2003 year,[8] and as this is a sole supply product Pharmac are usually made aware of out of stock situations, as this usually incurs some additional charges or inconveniences for patients. Therefore it could be reasonably assumed that this prescription did not attract a prescription charge, so would be readily identifiable as either a prescription for a child (under the age of six years) or a Prescription Subsidy Card Holder.

I conclude that there were sufficient prompts for [Mr B] and [Mr C] to enable them to ascertain that this prescription was intended for a child.

3 Do you consider that [Mr B] and [Mr C] were disadvantaged by not having any information in relation to the diagnosis?

It is normal practice not to have information on diagnosis at the time of dispensing, so [Mr B] and [Mr C] were not disadvantaged any more or less than during the course of dispensing any other prescription.

[Mr B] suggests that inclusion of diagnosis information on prescriptions would be helpful. I agree with him … this could be a guideline that could be passed on to doctors when they are reconsidering how they write their prescriptions. Inclusion of diagnosis information on prescriptions enables pharmacists to provide more targeted and appropriate medication counselling at the time of dispensing.

4 What steps should a pharmacist undertake when presented with a prescription of Tripress for a child?

Dispensing Process according to the Pharmaceutical Society of New Zealand's Pharmacy Practice Handbook 2003[9]

Dispensing involves the following steps:

- Receiving the prescription or medicine order
- Checking legality and eligibility of the prescription:
  - is it legibly and indelibly printed
  - is it personally signed by the prescriber and dated
  - does it contain the name and address of the prescriber
  - does it contain the title, surname, initial and address of the patient
  - does it contain the date of birth if the patient is under 13 years
  - is the correct patient category marked
  - does it include the name, form and strength of the medicine
  - does it include the period or quantity of supply
  - does it include the dose and frequency the medicine is to be given or taken, or directions for use

- is the prescriber actually permitted to prescribe the medication and for the period prescribed
- does it meet the criteria of the Pharmaceutical Schedule for payment

- Checking patient details:
  - check patient details on the prescription are correct, i.e. name, address, age and patient category
  - check whether patient has had this medication before
  - check for interactions with any concomitant medication if a patient medication record is available
  - determine whether the prescription or medicine order is appropriate in light of the patient's past history

- Determining the priority of the prescription: …

In my opinion [Mr B] and [Mr C] do not appear to have accurately assessed
- the patient details, in particular the patient's age and patient category
- the appropriateness of the medication for the patient

5 What are the relevant standards relating to this complaint and did [Mr B] and [Mr C] and [the pharmacy] comply with those? If they deviated from those standards, do you consider the deviation to be minor, moderate or major?

Dispensing standard according to Pharmaceutical Society of New Zealand's Pharmacy Practice Handbook 2003[9]

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

6.2a Procedures for dispensing and supply of pharmaceuticals are developed, documented and approved by the pharmacist.
6.2b The pharmacist interprets and evaluates prescriptions for correctness and completeness, verifies their authenticity and appropriateness and determines their priority for dispensing.
6.2c 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.
6.2d The use of generic medicine substitution is controlled by documented policies developed by the pharmacist. Such policies are regularly reviewed.
6.2e Activities of medical sales representatives are governed by documented policies developed by the pharmacist and made available to sales representatives and pharmacy staff.

In my opinion [Mr B] and [Mr C] do not appear to have verified the appropriateness of the prescription for this patient with respect, in particular, to the patient's age. It is my opinion that [Messers B and C] have deviated from an acceptable standard of practice to a moderate degree. [The pharmacy's] SOPs quite clearly state that this should be verified (see Question 6) so it is my opinion that [the pharmacy] has not deviated from an acceptable standard of practice.

Standards expected according to the Pharmaceutical Society of New Zealand's Code of Ethics and Professional Standards 2001[10]

1.2 Medicines and therapies prescribed by another provider

Where the patient is receiving, from the pharmacist or from other personnel for whom he or she has responsibility, any medicine, complementary therapy, herbal remedy or other healthcare product prescribed by another healthcare provider, the pharmacist must ensure that the patient is provided with understandable information about its safe and effective use, expected outcomes of therapy within the limitations of available information, any significant risk of side effects, what to do if side effects occur, and storage and disposal requirements.

It does not appear that [Mr C] ensured that the patient's mother was provided with understandable information about the expected outcomes of therapy at the time of dispensing. This would have highlighted the fact that the pharmacy had dispensed an antidepressant instead of an antibiotic.

It is my opinion that with respect to this clause [the pharmacy] has not deviated from an acceptable standard of practice but that [Mr C] has deviated to a moderate degree.

2.3 Patient focused care

The pharmacist must in all matters endeavour to provide professional patient focused care

[Messers B and C] have not provided professional patient focused care in that they failed to identify who the prescription was for and therefore could or did not provide adequate counselling as to expected outcomes of therapy.

It is my opinion that with respect to this clause [the pharmacy] has not deviated from an acceptable standard of practice but that [Messers B and C] have deviated to a moderate degree.

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.

The suitability for the patient has not been verified within the limits of available information. The age of the patient is quite clearly documented on the prescription and it would be acceptable standard of practice to identify Tripress® as a medication that is not usually (if ever) indicated for use in a child under the age of six years.

It is my opinion that with respect to this clause the pharmacy has not deviated from an acceptable standard of practice but that [Messers B and C] have deviated to a moderate degree.

3.10 Inappropriate or erroneous prescribing

Where a pharmacist has reasonable grounds to consider that a prescription contains any error, omission, irregularity or ambiguity or is not legitimate, or that a prescribed medicine could be

detrimental to a patient's health, the pharmacist must confer with the prescriber and document the details and outcome. If the prescriber verifies the prescription but the pharmacist's concerns remain unresolved the pharmacist must consult with their Medicines Control Advisor or the Medical Officer of Health and document this action.

Had [Messers B and C] identified the unsuitability of trimipramine (Tripress®) for this patient it would have been acceptable standard of practice for them to contact the prescriber to verify the prescriber's intentions. As the age of the patient had not been ascertained and the patient counselling did not cover certain important areas – this step did not occur.

It is my opinion that with respect to this clause [the pharmacy] has not deviated from an acceptable standard of practice but that [Messers B and C] have deviated to a moderate degree.

3.15 Inappropriate supply

The pharmacist must exercise professional judgement to prevent the supply of any medicine, complementary therapy, herbal remedy or other healthcare product likely to constitute a hazard to health or the supply of unnecessary or excessive quantities of these, particularly those which the pharmacist knows or should reasonably be expected to realise are likely to cause or have a potential for misuse, abuse or dependency.

Failure to identify the unsuitability of this medication for this patient has meant that the [Messers B and C] have failed to identify the occurrence of provision of a medicine that is likely to constitute a hazard to the health of this patient. Essentially this hazard may occur by the provision of a medication for which there is no indication/diagnosis.

It is my opinion that with respect to this clause the pharmacy has not deviated from an acceptable standard of practice but that [Messers B and C] have deviated to a moderate degree.

6 *Do you consider pharmacy systems in place at the time were sufficient with regards to the suitability of prescriptions for pharmacy customers?*

The Standard Operating Procedures (SOP) provided by the pharmacy describe acceptable standard of practice with regards to the suitability of prescriptions for pharmacy customers.

[The pharmacy has] reviewed their Dispensing SOP to include an additional step requiring staff to highlight (to emphasize) the patient age, and also to preferably write the age in years beside this. It is acceptable standard of practice to regularly review SOPs and to review SOPs as a result of an 'incident' to identify any possible areas of the SOP that can be improved to minimize the chance of such an incident recurring in the future. [The pharmacy] has provided evidence that they at least review SOPs as a result of a dispensing incident.

[The pharmacy's] Dispensing SOP states the following:

'Read whole prescription. Make a mental assessment of the prescription, consider:

- Medicine(s)
- Dose
- Dosage form
- Nature of patient
  - Age
  - Weight
  - Physical ability
  - Pregnancy, other special conditions'

This step of the SOP has not been carried out to an acceptable standard of practice as the age of the patient has not been ascertained. The dosage form does not appear to have prompted any enquiry by [Messers B and C]. The dispensing of a tablet or capsule for a 'Y' coded patient (i.e. under six years of age) could be reasonably assumed to prompt some additional counselling for the parent/care giver to facilitate 'easy' administration to the patient as children of this age are not always able to swallow such dose forms. Finally the medicine itself has not been assessed to an acceptable standard regarding appropriateness for the patient.

[The pharmacy's] Handing out Prescriptions SOP also mentions (amongst other things) that 'the pharmacist must ensure the patient knows the answers to the following questions before they leave the pharmacy … why is the medicine being prescribed for me? ...' It would appear that this did not happen in this instance.

[The pharmacy's] SOPs describe an acceptable standard of practice. It would appear that the actions taken by [Messers B and C] did not comply with the pharmacy's SOPs.

7 Are there any other matters relating to professional standards which you believe to be relevant to this?

There are no other matters with respect to pharmacist professional standards that I believe are relevant. However, [the pharmacy has] identified that prescribing errors of this nature have occurred in the past with this prescriber. This should make pharmacists more alert to potential problems with this prescriber's prescriptions and hence make them more diligent in their checking procedures. Having said this, if this is a recurring problem with this particular prescriber I would hope that this is being investigated at the very least to enable this prescriber to review their own SOPs to minimize the chance of such errors recurring in the future.

Documents provided:

1 Letter from [Ms A] to the Commissioner dated 13 June 2003, marked 'A' (Pages 1-2)
2 Investigation Letters to [the pharmacy] (29 July 2003), [Mr B] and [Mr C] (24 October 2003), marked, 'B' (Pages 3-8)

3 Letter from [the Manager of] the pharmacy dated 10 August 2003, with attachments, marked, 'C' (Pages 9-34)
4 Letter from [Mr B] to the Commissioner dated 30 October and 21 November 2003, marked 'D' (Pages 35-39)
5 Letter from [Mr C] to the Commissioner dated 30 October 2003, marked 'E' (Pages 40-42)

References

1 Information for Health Professionals Tripress Data Sheet http://www.medsafe.govt.nz/profs/Datasheet/t/Tripresscap.htm <accessed 19 December 2003>
2 British Medical Association and the Royal Pharmaceutical Society of Great Britain. British National Formulary. London: British Medical Association and The Royal Pharmaceutical Society of Great Britain; Sept 2003
3 Taketomo CK, Hodding JH, Kraus DM. Pediatric Dosage Handbook 9th ed. Hudson, Ohio: Lexi-Comp, Inc 2002
4 Kemp CA, McDowell JM. Pediatric Pharmacopoeia 13th ed. Royal Children's Hospital, Melbourne; 2002
5 Behrman RE, Kleigman RM, Jenson HB. Nelson Textbook of Pediatrics 17th ed. Saunders, Philadelphia, Pennsylvania.
6 Therapeutic Guidelines. Therapeutic Guidelines Psychotropic 3rd ed. Victoria, Australia; 1997
7 Pharmaceutical Management Agency. New Zealand Pharmaceutical Schedule December 2003
8 e-mail correspondence with Pharmac staff 19 December 2003
9 Pharmaceutical Society of New Zealand. Pharmacy Practice Handbook 2003. Pharmaceutical Society of New Zealand 2003.
10 Pharmaceutical Society of New Zealand Code of Ethics 2001."

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.

Names have been removed to protect privacy. Identifying letters are assigned in alphabetical order and bear no relationship to the person's actual name.

Professional Standards

The Pharmaceutical Society of New Zealand *Code of Ethics* (2001) states:

"**1.2 Medicines and therapies prescribed by another provider**

Where the patient is receiving, from the pharmacist or from other personnel for whom he or she has responsibility, any medicine, complementary therapy, herbal remedy or other healthcare product prescribed by another healthcare provider, the pharmacist must ensure that the patient is provided with understandable information about its safe and effective use, expected outcomes of therapy within the limitations of available information, any significant risk of side effects, what to do if side effects occur, and storage and disposal requirements

2.3 Patient focused care

The pharmacist must in all matters endeavour to provide professional patient focused care

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.

3.10 Inappropriate or erroneous prescribing

Where a pharmacist has reasonable grounds to consider that a prescription contains any error, omission, irregularity or ambiguity or is not legitimate, or that a prescribed medicine could be detrimental to a patient's health, the pharmacist must confer with the prescriber and document the details and outcome. If the prescriber verifies the prescription but the pharmacist's concerns remain unresolved the pharmacist must consult with their Medicines Control Advisor or the Medical Officer of Health and document this action

3.15 Inappropriate supply

The pharmacist must exercise professional judgement to prevent the supply of any medicine, complementary therapy, herbal remedy or other healthcare product likely to constitute a hazard to health or the supply of unnecessary or excessive quantities of these, particularly those which the pharmacist knows or should reasonably be expected to realise are likely to cause or have a potential for misuse, abuse or dependency."

Other relevant standards

- Quality Standards for Pharmacy in New Zealand, Standard 6.2 Dispensing
- [The pharmacy's] Standard Operating Procedures

Opinion: Breach – Mr B and Mr C

Ms A complained that staff at the pharmacy dispensed a prescription for an antidepressant, Tripress, to her five-year-old daughter, Miss A. Although the medication was dispensed correctly, the complaint concerns whether the dispensing pharmacists should have realised the medication was unsuitable for a child.

Under Rights 4(1) and 4(2) of the Code every consumer has the right to have services provided with reasonable care and skill, and in accordance with legal, professional, ethical and other relevant standards. The standards relating to this complaint include the Pharmaceutical Society *Code of Ethics* (2001) and Quality Standards for Pharmacy. These professional standards are made operational through the pharmacy's Standard Operating Procedures.

These inter-linking professional standards emphasise that pharmacists must ensure that they are satisfied that any medications dispensed are appropriate for the patient and that they do not dispense unsafe medication. While ultimate responsibility for prescribing lies with the prescriber, professional standards stipulate that pharmacists have responsibility for assessing the safety and appropriateness of any medication to be dispensed, within the limits of available information.

The most relevant professional standard is Principle 2.6 of the *Code of Ethics* (2001) which states:

> "**Principle 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."

I note that both Mr B and Mr C participated in the preparation of Miss A's medication. Mr B received the prescription from the shop assistant and processed it through the computer while preparing the label. Mr C selected, labelled, and signed off the medication. Mr C also issued the medication to Ms A.

In 1995, the Pharmaceutical Society of New Zealand adopted the following definition of dispensing:

> "Dispensing includes all the processes which occur from receipt of the prescription, medicine order, or request at the pharmacy to the prescribed item or medicine being collected or delivered to the patient or their representative."

Clearly, both Mr C and Mr B "dispensed" the prescription under scrutiny. It is not disputed that neither of them considered whether the medication they dispensed was appropriate for a child. This lack of vigilance was the underlying cause of the error. My advisor commented:

> "The prescription involved in this case included the patient code 'Y1' which indicates that the patient was a child under the age of six years. The date of birth was documented on the prescription which identified that the patient was under the age of six years. This prescription would not have incurred a prescription charge which would indicate that the patient is either a patient under the age of six years or a Prescription Subsidy Card Holder. I conclude that there were sufficient prompts for [Messers B and C] to enable them to ascertain that this prescription was intended for a child."

My advisor noted that the prescription of Tripress for a child patient was "inappropriate, and at the very least unusual for a child". The provision of Tripress to a young child constituted "inappropriate supply" under 3.15 of the *Code of Ethics*:

> "Failure to identify the unsuitability of this medication for this patient has meant that the [Messers B and C] have failed to identify the occurrence of provision of a medicine that is likely to constitute a hazard to the health of this patient."

I accept my advisor's comments. In my view, Mr B and Mr C were provided with sufficient information to alert them to the fact that the prescription was for a child. They should not have dispensed the medication without clarifying the medication with Ms A or the prescriber. Failure to realise that the recipient of the medication was a child meant that none of the appropriate measures was followed.

In a previous investigation by my Office (case 99HDC01986, 31 October 2000) a pharmacist was presented with a codeine linctus prescription for a seven-week-old baby. The baby's date of birth was clearly stated but the strength of the solution was not specified. The pharmacist dispensed an adult dosage and the baby suffered an overdose.

I formed the view that the pharmacist breached the Code of Health and Disability Services Consumers' Rights by not considering whether the medication prescribed was appropriate for a baby. The pharmacist should have consulted with the general practitioner to verify the prescription. The matter was referred to the Director of Proceedings, who filed charges before the Disciplinary Committee of the Pharmaceutical Society of New Zealand. The Disciplinary Committee concluded that the pharmacist breached his duty of care to his patient, although in all the circumstances his conduct did not justify a finding of professional misconduct (Re *Sandlant*, 13 September 2001). This case was also one in which an error

made by the prescribing doctor was compounded by the failure of the pharmacist to exercise due vigilance.

Mr B
Mr B recalled that Ms A presented to the pharmacy with two prescriptions, one for Miss A, and one for another child. He typed the labels in accordance with standard operating procedure:

> "After I typed the label for the prescription for the first child, my natural assumption was that the second prescription was for [Ms A] herself (as she had only one child with her in the pharmacy at the time). Regrettably I did not notice that the prescription was for a second child."

The pharmacy's Standard Operating Procedure 2.2 deals with the dispensing process. It stipulates that before entering the prescription details into the computer the pharmacist must read the whole prescription and make an assessment of its appropriateness for the individual patient, in compliance with the *Code of Ethics* Principle 2.6, "Dispensing". The operating procedure also indicates that if a pharmacist observes any discrepancies, these should be followed up with the customer, or the prescriber, prior to proceeding further with that dispensing, in compliance with the *Code of Ethics* Principle 3.10, "Inappropriate or erroneous prescribing".

Mr B submitted that there was not enough information on the prescription to indicate that the wrong medicine had been prescribed. However, as discussed above, I consider that a pharmacist undertaking a correct assessment of the information provided, in particular the birth date of Miss A, would have concluded that the prescription might contain an error and taken steps to clarify the situation with Ms A or the prescriber.

Mr B stated that he normally performed a comprehensive prescription check before releasing the medication to the patient. However, standard operating procedures indicate that the assessment of prescription information prior to the preparation of the label is a crucial step in the dispensing process. Comprehensive checks are required at this stage.

Mr B commented that if information about diagnosis was included with prescriptions, this would assist with the identification of errors of this nature. My advisor agreed that it would be helpful for doctors to include diagnosis information. However, it is not standard practice.

I consider that Mr B undertook an appropriate course of action after Ms A phoned him. In particular, he observed that the prescription of Tripress was unusual for a child, and took steps to clarify the matter with Ms A. Mr B informed Ms A that there had been a prescribing error and not to administer the medication, but to contact Dr D. Additionally, Mr B apologised and completed a Pharmacist Intervention Report describing the error. He informed Ms A of the role of the Health and Disability Commissioner.

Nevertheless, by not satisfying himself as to the suitability of the prescription for Miss A at the time he was processing it through the computer, Mr B breached Rights 4(1) and 4(2) of the Code.

Mr C
Mr C recalled that he dispensed and checked the medication in accordance with normal procedure:

> "I then signed the prescription as being correct. I missed the date of birth written on the prescription.
>
> I then issued the prescription to [Ms A] (who was not accompanied by her daughter) assuming she was the patient. I gave instructions as to how to take it."

The Manage of the pharmacy commented that it was unfortunate that Miss A was not present when the prescription was collected and that, as a result, the pharmacist was unaware of "the intellectual and physical status of [Miss A]".

It is clear that Miss A was with Ms A at the pharmacy, although Mr C may not have seen her. I note that medication is often collected by a patient's representative, and indeed that is to be expected when dispensing to a small child. While it may occasionally be appropriate, it would be unwise for a pharmacist routinely to determine the suitability of medication by relying solely on the customer's physical appearance.

The pharmacy's Standard Operating Procedures require the pharmacist responsible for completing the dispensing to perform a final prescription check. This involves checking the accuracy of the dispensing in relation to the label and prescription. The checking pharmacist, as the pharmacist with final responsibility for the dispensing, must undertake an assessment of the suitability of the medication for the patient as described in the *Code of Ethics*, Principle 2.6 "Dispensing". This is particularly so in circumstances where the label, and initial assessment of suitability, may often be undertaken by a pharmacy technician.

Mr B did not express any concern to Mr C regarding this prescription. Although the initial data preparation was undertaken by a pharmacist, rather than a technician, this does not derogate from Mr C's responsibility to make his own assessment of the prescription. As discussed above, Mr C was provided with sufficient information to be alerted to the fact that he was dispensing to a small child, and the nature of the medication should have prompted him to clarify the prescription.

Furthermore, as the pharmacist handing out the medication, Mr C had an obligation, under the pharmacy's Standard Operating Procedure # 2.7, to explain how to use the medication. It is not disputed that Ms A received instructions on taking the medication, but they appear to have been somewhat cursory.

My advisor commented that if Ms A had been provided with understandable information about the expected outcomes of therapy at the time of dispensing, this would have highlighted the fact that an antidepressant had been dispensed. I agree with my advisor's

comments and note that if Mr C had adequately explained the medication dispensed, it appears likely that Ms A would have noticed the error at that point.

Accordingly, in my view Mr C breached Rights 4(1) and 4(2) of the Code by not satisfying himself as to the suitability of the prescription for Miss A.

Opinion: No breach – The Pharmacy

Employers are vicariously liable under section 72(2) of the Health and Disability Commissioner Act for ensuring that employees comply with the Code of Health and Disability Services Consumers' Rights. Under section 72(5) it is a defence for an employing authority to prove that it took such steps as were reasonably practicable to prevent the employee from breaching the Code.

As noted above, Mr C and Mr B breached Rights 4(1) and 4(2) of the Code in not satisfying themselves as to the suitability of the prescription for Miss A.

My advisor commented:

> "The Standard Operating Procedures (SOP) provided by the pharmacy describe acceptable standard of practice with regards to the suitability of prescriptions for pharmacy customers.
>
> [The pharmacy has] reviewed their Dispensing SOP to include an additional step requiring staff to highlight (to emphasize) the patient age, and also to preferably write the age in years beside this. It is acceptable standard of practice to regularly review SOPs and to review SOPs as a result of an 'incident' to identify any possible areas of the SOP that can be improved to minimize the chance of such an incident recurring in the future."

I accept my advisor's comments. I am satisfied that the pharmacy had appropriate systems in place at the time, and has taken reasonable steps to prevent further dispensing errors of this nature.

Accordingly, the pharmacy is not vicariously liable for its employees' breaches of the Code.

Actions taken

In response to my provisional opinion, Mr B and Mr C:

- provided written apologies to Ms A for breaching the Code; and
- confirmed that they have reviewed their practice in light of this report.

Follow-up actions

- A copy of this report will be sent to the Pharmaceutical Society of New Zealand.
- A copy of this report, with details identifying the parties removed, will be sent to the Pharmaceutical Society of New Zealand, and placed on the Health and Disability Commissioner website, www.hdc.org.nz, for educational purposes.

Names have been removed to protect privacy. Identifying letters are assigned in alphabetical order and bear no relationship to the person's actual name.