# Locum in general practice, Dr C

# A Medical Centre

# Pharmacist, Mrs D

# A Pharmacy

## A Report by the

## Health and Disability Commissioner

## (Case 05HDC07953)

Health and Disability Commissioner
*Te Toihau Hauora, Hauātanga*

## Parties involved

| | |
|---|---|
| Baby A | Consumer |
| Mr and Mrs A | Parents |
| Dr B | Complainant/Paediatric registrar |
| Dr C | Provider/Locum in general practice |
| Medical Centre | Provider/Medical Centre |
| Mrs D | Provider/Pharmacist |
| The Pharmacy | Provider/Pharmacy |
| Dr E | General practitioner |
| Dr F | General practitioner |
| Mr G | Practice manager/The Medical Centre |
| Mr H | Joint manager/the Pharmacy |
| Mrs I | Joint manager/the Pharmacy |
| Dr J | General practitioner |
| Dr K | Medical officer in general practice |

## Complaint

On 1 June 2005 the Commissioner received a complaint from Dr B about the services provided by Dr C. The following issues were identified for investigation:

***Dr C***
*The appropriateness of the care provided to Baby A by Dr C at a Medical Centre on 29 May 2005, including:*

- *the information given to Baby A's parents; and*
- *the adequacy of any communication with the pharmacy dispensing the medication prescribed.*

***The Pharmacy***
*The appropriateness of the care provided to Baby A by staff at a Pharmacy on 29 May 2005, including:*

- *the medication dispensed;*
- *whether the information on the label of the medication bottle was adequate and accurate; and*
- *the information given to Baby A's parents.*

An investigation was commenced on 13 September 2005. On 17 November 2005 the investigation was extended to include pharmacist Mrs D, as follows:

***Mrs D***
*The adequacy and appropriateness of the care pharmacist Mrs D provided to Baby A on 29 May 2005, including:*

- *the medication dispensed;*
- *whether the label on the medication bottle was adequate and accurate; and*
- *the information given to Baby A's parents.*

The investigation has taken over a year to complete owing to the complexity of the matter and internal delays. Expert advice was received in April and May 2006.

## Information reviewed

Information was obtained from:

- Mr and Mrs A
- Dr C
- The Medical Centre
- Mrs D
- The Pharmacy
- The District Health Board.

Independent expert advice was obtained from pharmacist Mr John Fraser and general practitioner Dr Jim Vause.

## Information gathered during investigation

*Overview*
On 29 May 2005, six-month-old Baby A was taken to a Medical Centre by her parents. Dr C, a locum in general practice, diagnosed a urinary tract infection, impetigo, oral thrush and gastroenteritis. She prescribed various medications, including 3mg Maxolon solution, three times daily, to relieve Baby A's nausea and vomiting associated with her gastroenteritis.

Owing to the absence of Maxolon solution in stock, pharmacist Mrs D dispensed Baby A the Maxolon in tablet form (to be taken in half-tablet dosages). Mrs D retyped the label but did not include the frequency of dosage on the retyped label. She also dispensed 5mg instead of 3mg. Baby A vomited after her parents gave her the first dose of Maxolon. She was given another dose approximately two hours later. Baby A

suffered an acute dystonic reaction (involving muscle spasms of the shoulders, neck, trunk and limbs) and was admitted to hospital, but subsequently recovered.

*Dr C — background*
Dr C qualified as a doctor in another country in 1991, and then worked as a hospital house officer for several years. Dr C subsequently spent eight years employed in medical publications. She returned to medicine in 2001 (as a house officer) but was unable to obtain entrance into general practitioner training schemes in her own country, and investigated opportunities elsewhere.

In June 2004, Dr C spent six months as a cardiology registrar at a public hospital in New Zealand. In mid-February 2005, Dr C commenced work at the Medical Centre (the Centre). Dr C worked Tuesdays and Thursdays at the Centre. Under the terms of her registration within a provisional general scope of practice with the Medical Council of New Zealand, Dr C was required to be supervised. This was undertaken by an experienced general practitioner, Dr E. (Dr C also worked under supervision two days a week at another medical centre.) Dr C also enrolled in a weekly "Seminar Attenders Course" organised by the Royal New Zealand College of General Practitioners.

The Centre practice manager, Mr G, informed me that Dr C had "prime service responsibility" and was contracted as a doctor in "her own right". She was an independent contractor, contracted to the Medical Centre (a limited company). Dr C's contract stated that Dr C "is not an employee of the Medical Centre".

*Dr C's orientation to the practice*
Dr C stated that she was not given a proper orientation to the Centre. She informed me:

> "My first introduction to the Medical Centre was a quick hello from the practice manager [Mr G], then I was escorted to my room where I was presented with the computer software MedTech 32. I asked how to use this and was given very basic instructions which I later tried to develop. I asked for further instruction in the use of MedTech 32 later on several occasions of [Dr F] and [Dr E] as I began to understand how useful a tool it is. This request was noted but never happened."

Mr G explained that Dr C underwent a comprehensive 36-point orientation programme when she came to the practice, including Medtech 32 training. The Centre's "most competent" nurse was assigned to Dr C. The nurse regularly approached Dr C during the first fortnight and was assured that "all was well". Dr C was also reminded of standard prescription guidelines.

Dr F disputed that she did not provide Dr C with assistance in relation to her queries about MedTech 32.

*Dr C's supervision*
Dr C was scheduled to meet with Dr E on a weekly basis. Dr E commented:

> "Following an orientation programme into the physical facilities, procedures and computer programmes of [the Medical Centre] I planned to see her regularly; this contact was shared with the other doctors in the practice."

Dr C said that during the initial week Dr E would "come in briefly" and check on her. However, Dr C felt Dr E often gave brief replies and appeared disinterested, taking little interest in how her skills were developing. In addition, Dr E was often unwell and absent from the practice. Dr C stated:

> "On the whole I have worked on my own in [the Medical Centre], seeking advice from experienced GPs as I saw necessary. It is impractical in a busy surgery to ask about every case that presents. My patients are not screened for me and I see every kind of presentation."

Dr E explained that contact was not as regular as was planned, partly owing to his absence for some weeks due to illness. Overall, 18 meetings were documented over a period of 27 weeks. Dr E stated:

> "I and the other doctors in the practice made it clear that we were available for discussion and consultation at any time. This did not happen as often as we would have expected."

General practitioner Dr F took over responsibility for Dr C's supervision in April 2005, until Dr E became well again. Dr F undertook weekly meetings with Dr C. Dr F commented that she had "only a few concerns" about Dr C's practice. These related to a missed fracture, and the follow-up of test results using MedTech 32. Dr F stated:

> "3) The other [concern] was that Dr C did not participate in mixing with any members of [the Medical Centre], even though every nurse and every doctor personally asked her to do so.
>
> 4) On discussion with our nurses they felt Dr C was reluctant to ask for assistance from colleagues."

Dr C acknowledged that the sessions with Dr F were "more structured" but emphasised that her prescribing practice was not raised as an issue.

Dr C also stated that she "frequently" asked other doctors to sit in on her consultations but "they refused as they told me they would be working without pay". Mr G disputed this and Dr E noted that "she did not ask me to sit in on her consultations". Other doctors cited examples to Mr G of cases which they actively followed up with Dr C.

*Concerns about Dr C's prescribing*

The Pharmacy joint owner/manager Mrs I explained that she became concerned about the level of Dr C's prescribing. In particular, Dr C was known to prescribe large amounts of antibiotics, codeine and Maxolon. Dr C was also regarded as a "soft touch" with patients who requested unnecessary medication. Mrs I commented that the Pharmacy contacted Dr C directly as concerns about individual prescriptions arose, but did not broach concerns about Dr C's prescribing with the Medical Centre until June. Mrs I noted that "we had no idea of the [Baby A] incident [in May — see discussion below] when "we raised the issue with Dr C's mentors" [in June] … We were working in parallel at that time."

The Pharmacy intervention report records that staff contacted Dr C regarding prescriptions on seven occasions during 2005, including about an inappropriately high dosage of Maxolon prescribed to a child on 5 May 2005 (prior to the prescribing of Maxolon to Baby A). On this occasion, Dr C prescribed 5mg Maxolon three times daily for a two-year-old. The Pharmacy intervention report records that the pharmacist undertook a literature search and contacted Dr C. Dr C does not recall this incident but accepts that it happened, and that a discussion took place regarding the appropriate dose of Maxolon. The prescription was then amended to 1mg three times daily.

The Pharmacy also provided a prescription issued by Dr C on 10 May 2005 for 2mg Maxolon three times daily for a two-month-old baby (Dr C was not contacted on this occasion).

In addition to the incidents mentioned above, the Pharmacy provided a record of three occasions where 5mg Maxolon (three times daily) was prescribed to children by Dr C from eight prescriptions for Maxolon between 17 March and 5 May 2005. Mrs I noted that none of the other doctors from the Centre prescribed Maxolon to a child over the same period.

Mrs I stated that whenever the Pharmacy contacted Dr C about a possible error "she was always positive about our input, and was willing to make alterations". Mrs I also stated:

> "It should be mentioned that both [Mr H] and myself, each with thirty years experience, have never before had call to query an individual doctor's prescribing to this degree."

Mrs I alerted staff to be vigilant for any anomalies with Dr C's prescribing, and asked that staff remedy any concerns using their professional discretion. She stated:

> "We had discussed [Dr C's] prescribing. I raised my concerns in the first instance and asked all pharmacists to keep copies of scripts where they had intervened. I asked that this be an off the record request at this stage … At this time of the incident [concerning Baby A] we were building the portfolio."

*Consultation with Baby A*
On Sunday 29 May 2005, six-month-old Baby A was taken to the Medical Centre (at around midday) by her parents, Mr and Mrs A. Mr A informed me that Baby A had a cough, temperature, vomiting and diarrhoea. Baby A was seen by Dr C.

Dr C informed me that Mr and Mrs A also raised concerns about irritability, eczema and an itchy rash. Dr C stated:

> "I examined her [Baby A] and noted that she had good tone and a flat fontanelle. She had mild eczema on her extensor surfaces and a diffuse golden-crusted rash on her face. Her ears were clear, her throat was clear, but she had white papules in her mouth consistent with oral thrush, her chest was clear and she had suprapubic tenderness."

Dr C noted in her medical records:

> "She [Baby A] had had a fever 2 days ago and seems very irritable today and she was vomiting with diarrhoea today and had come up in an itchy rash — has eczema. Developed a UTI a week ago and never took Abs [antibiotics]. O/E ears clear, child has a diffuse rash over the face, looks like impetigo, throat clear, oral thrush, chest clear, abdo tender suprapubically: Impression — UTI impetigo and oral thrush — for Abs and symptomatic relief."

Dr C concluded that Baby A had a urinary tract infection that was probably responsible for her symptoms. Dr C stated:

> "The parents were asked to go to [a medical laboratory][1] to collect the urine collection bag for female infants … I would have issued a form for the specimen on its return. In hindsight, it would have been better if I had issued the form for the specimen first and this is the procedure I now follow."

Dr C prescribed amoxycillin (an antibiotic) for the urinary tract infection, flucloxacillin (an antibiotic) and Fucidin (antibiotic) cream for impetigo, nystatin (an antifungal) for oral thrush and ibuprofen for pain and fever. She also prescribed 3ml of 5mg/5ml oral solution of Maxolon, three times daily to stop the vomiting associated with gastroenteritis. Dr C stated:

> "My recollection of that time was the standard recommended dose was 2.5ml three times daily (in the liquid form I prescribed 3ml as I accounted for an estimated 0.5ml wastage). In retrospect I realise that this dose was too high for a child of [Baby A's] age. I acknowledge that my experience in paediatrics was largely with

[1] Mr G informed me that medical laboratory services were unavailable on Sunday.

> slightly older children, and as such the standard dosage was higher. I do accept that I prescribed an inappropriate dose to [Baby A] and I very much regret this, and the distress that was caused."

Dr C's Maxolon prescription stated:

> "Maxolon 5mg/5mls Oral Soln [solution]
>
> Sig: 3mls Three Times Daily
>
> Mitte: 63mls."

Dr C said that she instructed Mr and Mrs A that the medicine should be used with caution and there were risks of "writhing and restlessness". However, the medicine could stop the vomiting. Dr C stated:

> "At the end of the consultation I was satisfied that [Baby A's] parents understood how to use the medications I had prescribed."

Dr C stated that she gave Baby A's parents instructions to take the child to hospital "should her general condition appear worse, if she had dark urine, if she stopped urinating or if she fitted". These instructions were not documented. Dr C stated that she has since reviewed her practice and now records follow-up instructions in her medical record.

Mr A said that "the doctor" advised them to give Baby A half a tablet of medicine, and a further half tablet after six hours. Baby A would "get better" after taking the medicine.

*Presentation of prescription — actions of pharmacy staff*

Mrs D was the pharmacist on duty when Mr A presented the prescription at the Pharmacy at approximately 12.20pm. Mrs D had already closed the doors (at the usual time, on a Sunday, of midday) but had been requested by the medical centre receptionist to stay open for one more patient. Mrs D was working alone. The prescription was for six items, including Maxolon. Mrs D commented that normally she would consider "the combination of medications extreme" — but it was not particularly unusual for Dr C. Mrs D stated:

> "It was common practice for her [Dr C] to prescribe Maxolon for young children compared to her peers who never used it under 12 years."

Mrs D explained that she typed the full prescription, as presented. The pharmacy stock records indicated that 800ml of Maxolon syrup was in stock. However, on preparing the medications, Mrs D discovered that there was no Maxolon syrup in stock. (Mrs I commented that the integrity of the stock data is normally very accurate and considerable time was taken by Mrs D to ascertain where the stock might be.)

Mrs D contacted Dr C (by cell phone) to clarify whether the Maxolon could wait until the following day. Dr C confirmed that Maxolon was needed that day to stop Baby A from vomiting. Dr C stated:

> "She [Mrs D] advised me that [the Pharmacy] had no Maxolon liquid available, and asked whether she could instead issue the medication in tablet form. I agreed. There was no discussion of the appropriateness of the drug or the administration regime."

Mrs D commented:

> "As I have mentioned (from any other practitioner) I would have been concerned about the number of items prescribed for any one patient but we had got used to, but still commented on [Dr C's] large prescriptions. I was fully aware of our pharmacy dispensary staff's concerns about her prescribing practice and I, amongst others, had brought prescriptions I was concerned about to the notice of my employers."

Mrs D decided to prepare the medication in tablet form and instruct Baby A's parents to crush the tablet before giving it to her. Mrs D stated:

> "All I can think is that I calculated the dose on the liquid being 5mg/5ml, and then transposed the 10mg to a 5mg tablet in my mind this would have made 2 and a half mg — so half a tablet was the closest I could get to the prescribed dose. This obviously was not accurate or adequate in hindsight, particular due to there already being an overdose prescribed. As I was working on my own and because of all the other extenuating factors, to complete this dispensing, I did not pick this up at the time of dispensing. This is definitely not my normal dispensing practice, a statement supported by my peers."

Mrs D explained that she retyped the label, to replace the label she had already prepared for the Maxolon liquid, but "in the confusion" omitted to include the frequency on the retyped label. The label stated:[2]

> "10 Metamide [metoclopramide hydrochloride] Tablets 10mg. Give half a tablet crushed in some food or liquid."

The Pharmacy standard operating procedures (SOPs) for dispensing required the label to be checked for label accuracy, to be checked at every step of the dispensing process, and to be signed by the dispenser and checker.[3] In this case, Mrs D was the only pharmacist involved in dispensing the medication. Mrs D initialled every medication

[2] The medication and label are held by this Office.
[3] See Appendix 1.

she dispensed for Baby A on 29 May 2005 as checked against the prescription, with the exception of Maxolon.[4]

Mrs I stated:

> "The pharmacist was rattled by the end of this script and did not notice at the time of dispensing that she had no frequency on the label.
>
> …
>
> We record interventions on our computer system, and documentation is written on the relevant prescription.[5] This was not fully followed in this instance … as she [Mrs D] was very busy on her own and after closing time."

Mrs D stated that she handed out all the medications to Mr A and explained how to take, use and store them:

> "I then gave him the Metamide [Maxolon] tablets, and explained to him that they were the reason for the delay, which by now had been at least 25 minutes since he presented the prescription … I showed him how to halve the tablets and suggested crushing it between two spoons and mix with soft food or liquid to give it to the child. I think I told him only to give a few doses but the discussion is now five months ago and I can't remember all of what was a very stressful prescription even before the child experienced the adverse reaction. [Mr A] seemed to understand what I was saying but I had never seen him before, or since the incident, I had no reason to suspect he had trouble comprehending my directions."

Mrs D did not provide any instructions on what to do if the patient deteriorated, and commented that this advice is more appropriately given by the prescribing doctor. Mr A does not remember the "exact instructions" he was given by Mrs D for preparing the medicine but recalled that the information was written on the bottle.

Mrs I wrote to Mr and Mrs A, stating:

> "The pharmacist involved with this incident is most distressed with this situation and she is also working closely with us to prevent a similar incident from occurring in the future."

[4] See Appendix 2.
[5] The Pharmacy SOPs state at 98.8: "Intervention is recorded under the patient's name or on the notes for the script item, as well as annotated on the script or stapled to the original."

*Baby A's hospital admission*
Baby A was taken home by her parents and given the medications. Mr A recalled breaking a tablet in half, making a powder and mixing it with either milk or water. Baby A vomited and cried, but after being fed, went to sleep for approximately two hours. On waking, Mr and Mrs A administered further Maxolon to Baby A, because she had vomited the first dosage. Baby A's condition deteriorated and she became very quiet and unresponsive. Baby A then developed a fixed upward gaze with hyperextension of the neck and shaking of her entire body for approximately one hour. She was taken to hospital by ambulance and diagnosed with an acute dystonic reaction. Baby A was admitted to hospital overnight for observation and given benztropine mesylate [remedy for acute dystonic reaction]. Baby A was discharged the following day, and does not appear to have suffered any long-term harm.

Paediatric registrar Dr B, at the hospital, was concerned that Baby A had been prescribed five times the recommended paediatric dosage of Maxolon, which is not usually recommended for viral gastroenteritis in children. In addition, Mr and Mrs A had been given insufficient instructions about the administration and side effects of Maxolon. Dr B also commented that she had some difficulty in communicating with Mr and Mrs A owing to their "poor English". Dr B reported her concerns to this Office on 29 May 2005. She is to be commended for taking such prompt action.

*Comments from Dr C*
Dr C informed me that she was not aware at the time of prescribing that the antibiotics she prescribed could cause diarrhoea, to the extent that this would outweigh the benefits of treatment. Dr C stated that she is now aware of different prescribing practices between New Zealand and the country she was trained in, and is now diligent to ensure that her prescribing is in accordance with New Zealand protocol. She stated:

> "I understand that I have made an error in prescribing Maxolon to [Baby A] and would like to extend my sincere apologies to [Baby A's] parents and deeply regret any distress the family suffered from her misadventure."

*Comments from the Pharmacy*
Mrs D explained that as a result of these events the checking pharmacist now circles the date of birth of the child, to alert the pharmacist to the risk of any overdose prescribing. In addition, the pharmacy computer system now allows them to fully record any pharmacist interventions. Mrs I stated:

> "[Dr B] alluded to the fact that the medicine was dispensed and not needed. This is impossible to tell from the dispensing perspective, especially when the Doctor had re-assured the pharmacist that it was needed."

Mrs I also commented:

> "If every slight concern were to be related to prescriber we would be 'pharmacops' not fellow professionals. Obviously it is a responsibility of a pharmacist to check that a drug and dose are in the safe range for the particular patient, however the prescriber too must be accorded some leeway in their professional decision-making. Many factors may influence their prescribing of an individual drug and required dose which will not be evidenced by the pharmacist as they read a prescription."

*Subsequent events*

Mrs I stated that the prescribing of Maxolon (and other drugs) to children by Dr C was discussed directly with Dr F on 26 June, and with Dr E the next week. (Baby A's case was not specifically discussed at that time, as the Pharmacy was not aware of the error until several months later when contacted by this Office.) Mrs I stated:

> "We built up a record of our interventions, and then when we felt there was sufficient concern went to her preceptors in June 05 at [the Medical Centre] practice. They were the people who were best able to judge her competency where all the clinical data was available to them."

Dr F recalled:

> "This [the discussion with Mrs I] included inappropriate prescribing of Maxolon especially in children, multiple antibiotics for infection and prolonged courses of codeine based medications. [The Medical Centre] were very grateful for this as we had no idea that this had been happening.
>
> I intended to speak to [Dr C] the next day but unfortunately I was unwell and was not able to speak to her until the following Thursday 7/07/05.
>
> …
>
> I advised her that especially as she was under supervision it would be wise to prescribe what is considered to be best practice in New Zealand. That was for single antibiotics unless there are exceptional circumstances, short prescriptions for codeine based medications and no Maxolon prescribing for children and generally not in an adult for simple gastroenteritis.
>
> I liaised with Dr E prior to this and I believe he spoke to Dr C on that day as well."

Dr E confirmed that he separately spoke to Dr C about her prescribing practice. Dr E stated that this discussion included reference to the prescribing of inappropriate dosages of Maxolon, and incorporated the inappropriateness of prescribing Stemetil (for the treatment of nausea associated with migraine) to an infant. Dr E stated:

> "She [Dr C] was given a copy of the [local] IPA prescribing guidelines and advised to make use of the MIMS prescribing information which was available through the

> computer on her desk and also shown how to access the British National Formulary on the internet.
>
> …
>
> In this practice we have had a long experience of providing supervision and support for junior doctors … we have found them keen to learn and identify their learning needs: we have not found this to the expected extent in Dr C."

Mrs I provided a prescription written by Dr C dated 7 July 2005 for what she described as "high amounts of drugs of abuse", including 100 tablets of 5mg diazepam and 360 tablets of 60mg codeine phosphate. Dr C was not available to discuss the prescription, but the dispensing pharmacist gave only limited amounts of the prescription to the customer. Mrs I noted:

> "Interestingly, when brought to the mentor's [Dr E] attention the next day he had spoken to Dr C only hours before about this sort of prescribing."

Dr C stated that, in mid-July, she was asked to attend a supervision session with Dr F to discuss concerns about the level and combination of her prescribing. Dr F explained "politely" that Dr C had been over-prescribing paracetamol, ibuprofen, codeine, diazepam (for relaxation) and combination antibiotics. Dr C stated that the issue of prescribing Maxolon or Stemetil was not mentioned. Dr C said that she immediately changed her practice to avoid the use of combination antibiotics and decreased the amount of medicines she issued to no more than a week's worth at a maximum. Dr C stated:

> "In or around mid July, I was presented with the MIMS magazine by [Dr E], a vital tool in cross referencing prescriptions and only later than this discovered that this tool was available from the options on the computer."

Dr F explained that the Centre had hoped to employ Dr C as a full-time locum from early August 2005 for about three months. However, in mid-July it was decided that Dr C's general practice skills were not at a sufficient level to allow this. In particular, she continued to prescribe medications contrary to the advice given by her supervisors. (As noted above, according to the information provided by Mrs I, Dr C had prescribed "high amounts of drugs of abuse" on 8 July 2005 shortly after Dr E had cautioned her about this type of prescribing.) Dr F stated:

> "Our plan was to cancel the locum contract and to continue with her two days per week with additional supervision provided by [Dr J] and [Dr K]."

Dr C stated that Dr F went on holiday in July, and thereafter she was required to have supervision twice weekly, with Drs J and K. The sessions were useful and constructive, although they soon ceased, and there was never any adverse issue raised in relation to her prescribing. Accordingly, Dr C considered her clinical performance was satisfactory. Dr C said that she learnt in August 2005, when she attended a seminar

course, that Maxolon was never to be given to a baby with diarrhoea and vomiting. (Dr C provided a letter from her course supervisor confirming that she worked to a "high standard" and "contributed well to the group" during the seminars.)

Dr E and Dr F advised me that they had further discussions with Dr C about her prescribing after being informed by the Pharmacy of a telephone enquiry from the Health and Disability Commissioner in late July. (This Office telephoned joint owner/manager pharmacist Mr H on 8 August 2005, following the complaint by Dr B, to obtain a copy of the relevant prescription and ascertain the identity of the prescribing doctor. The prescription was formally requested on 18 August 2005.)

On 23 August 2005, Dr E documented a discussion with Dr C about the prescribing of Maxolon to Baby A, and the prescribing of Stemetil suppositories to an infant on 16 August 2005 (the prescription was not issued to the patient concerned after Mrs I contacted Dr C). Dr C was reminded to utilise prescribing guidelines and to consult other doctors when questions arose. It was also agreed that the pharmacist would contact her and the Centre if there were any further concerns about her prescribing.

Dr C believes that this discussion (on 23 August 2005) was the first time that her medical colleagues advised against the prescribing of Maxolon in young children (contrary to Dr F's recollection of an earlier discussion on 7 July).

Dr C recalls that Baby A's care was discussed with her supervisor, Dr E, after being shown the "letter from the Health and Disability Commissioner". Dr C accepted that this was her prescription, and told Dr E that she had now learnt that this was not the correct way of managing vomiting in an infant. Dr E provided her with further instructions on the management of babies with diarrhoea and vomiting.

Dr C resigned from the Centre, effective from 23 September 2005.

*Further comments from Dr C*

Dr C acknowledges that she should have made greater effort to consult prescribing references. However, she stated that the errors in her prescribing should have been rectified earlier through the supervisory process. She understood that the Centre was aware of concerns about her prescribing sometime before the subject was broached with her. In addition, she was not made aware that the Pharmacy had any concerns about her prescribing until after she left the Centre. Dr C stated:

> "I am very surprised that with such apparently serious and repeated concerns, no effort was made to broach this with me directly. Had this occurred, I would immediately have sought advice and changed my practice.
>
> …
>
> I am horrified that this situation was left until the stage where I have prescribed Maxolon to babies on a number of occasions."

Dr C's lawyer stated that it was a reasonable expectation that prescribing errors would be raised with Dr C directly, either by the pharmacists or the medical practice. Dr C's lawyer stated:

> "While that is not a complete explanation for the concerns raised (and [Dr C] has acknowledged her error), early detection and instruction would have gone a long way to alleviate the seriousness of this matter.
>
> …
>
> [Dr C] instructs me that she is clear that other than the discussion that she had with [Dr F] in or about mid July … none of the practice partners approached her with [the Pharmacy's] concerns. This is plainly inappropriate and some responsibility for ongoing prescribing of concern must rest with the pharmacist(s) and [Dr C's] former supervisor and/or practice partners."

*Dr C's competence*
On 31 October 2005, the Commissioner referred Dr C to the Medical Council of New Zealand (the Council) for consideration of a competence review owing to serious concerns about Dr C's prescribing practice, which arose from the complaint concerning Baby A and from additional information received about Dr C's prescribing practice.

## Independent advice to Commissioner

*General practitioner advice*
The following expert advice was obtained from general practitioner Dr Jim Vause:

> "Thank you for your request for independent advice on the care provided by [Dr C] for [Baby A].
>
> I am a vocational registered general practitioner, having graduated MBChB from Otago University in 1976. I have practised as a general practitioner since 1979 and gained Membership of the Royal New Zealand College of General Practitioners in 1989 which was converted to Fellowship in 1998. In 2001 I gained a Diploma of General Practice from Otago University. For my first five years I practised as a rural general practitioner and have spent my subsequent years in provincial practice firstly solo before slowly expanding into its current 5 doctor practice. I have been extensively involved in matters of professional standards in general practice and am currently a practice assessor for the RNZCGP Cornerstone practice accreditation program.
>
> With respect to any conflict of interest, I do not know any of the persons mentioned in the documentation.

I have read and agree to follow the Health and Disability Commissioner Appendix H: Guidelines for Independent Advisors.

I have perused the following supporting information supplied by you in relation to this enquiry:

1. Letter dated 29 May 2005 from [Dr B], marked 'A' (numbered).
2. Letter dated 29 July 2005 from [Dr B], marked 'B' (numbered 2).
3. Letter dated 23 August 2005 and enclosures from [Mrs I] of [the Pharmacy], marked 'C' (numbered 3–4).
4. Notes of telephone conversation with [Mr and Mrs A] on 26 August 2005, marked 'D' (numbered 5).

5. Medical notes received from [the] District Health Board on September 2005, marked 'E' (numbered 6–28).
6. Letter dated 6 September 2005 from [the] Clinical Director at [the] District Health Board, marked 'F' (numbered 29–30).
7. Letter dated 27 September 2005 from [Dr C] and enclosure, marked 'G' (numbered 31–35).
8. Letter dated 28 September 2005 and enclosure from [Mrs I] of [the Pharmacy], marked 'H' (numbered 36–39).
9. Letter dated 7 October 2005 and enclosures from [Mr G] of [the Medical Centre], marked 'I' (numbered 40–52).
10. Letter dated 7 November 2005 from [Mrs I], marked 'J' (numbered 53–54).
11. Letter dated 8 November 2005 and enclosures from [Dr E], marked 'K' (numbered 55–66).
11. Letter dated 29 November 2005 from [Mrs D], marked 'L' (numbered 67–68).
12. Letter dated 7 December 2005 from [Dr C], marked 'M' (numbered 69–74).
13. Letter dated 9 December 2005 from [Dr …], marked 'N' (numbered 75).
15. Letter dated 12 December 2005 from [Mrs I], marked 'O' (numbered 76–77).
16. Facsimile dated 14 December 2005 from [Dr C's lawyer], marked 'P' (numbered 78–80).
17. Action note of conversation with [Mr H] on 2 March 2006, marked 'Q' (numbered 81).
18. Facsimile dated 2 March 2006 from [Mr H], marked 'R' (numbered 82–83).

…

**Standards of care**

The adverse outcome in [Baby A's] case centres around [Dr C's] prescribing of metoclopramide and the resultant overdosing of this medication leading to the well recognised side effect of a dystonic reaction (oculogyric crisis) and [Baby A's] admission to [hospital].

In assessing [Dr C's] care for [Baby A] there are a number of areas of diagnosis and management which demonstrate deficits in care which were contributory to this adverse outcome.

**Multiple Diagnosis**

[Dr C's] working diagnoses were urinary tract infection, impetigo, oral thrush and gastroenteritis.

From the letter dated … (page 031–032) and her clinical notes 043

*'Subjective: presentation with a number of complaints: irritability, vomiting and diarrhoea, eczema and an itchy rash.*

*Examination: good tone, mild eczema, oral thrush, suprapubic tenderness*

*Diagnosis: urinary tract infection, impetigo, gastroenteritis,*

*Rx Amoxil for urinary tract infection (UTI), fluclox (for impetigo), fucidin (far too much 50gm rather than 15) in case she vomited (oral instructions and written instruction were simply amount and frequency), Maxolon for gastroenteritis, ibuprofen for symptomatic relief and nystatin oral drops'.*

[Dr C] made a number of diagnoses (of infectious diseases) in a situation where a reasonable general practitioner would only make one or two. I will consider each diagnosis in isolation below, but it is also important to take an over view of [Baby A's] presentation in order to appreciate the difficulties [Dr C] created for herself in making multiple diagnoses. The most obvious diagnosis was gastroenteritis, a diagnosis also made by the paediatric department at [the hospital]. [Dr C's] other diagnoses were not made by the hospital doctors.

Further consideration should be made of the manner in which [Dr C] related these separate diagnoses (the second to last paragraph on page 032 of her account).

'*I told them that the baby probably had a urinary tract infection that was probably partly responsible for her vomiting, impetigo, oral thrush and gastroenteritis'.*

While a urinary tract infection may well cause vomiting, as a disease it does not 'partially account' for gastroenteritis, impetigo or oral thrush. Doctor [C's] connection between these different infections is a concern, for each is normally caused, in a general practice setting, by different organisms and are not related,

except possibly in a person with suppressed immunity which clearly [Baby A] did not have.

**Considering the first diagnosis: urinary tract infection**

There is only one clinical sign [Dr C] elicited which might possibly be specific enough to support this diagnosis, namely 'suprapubic tenderness'. The clinical features of a urinary tract infection are frequency of urine and pain on passing urine (dysuria) which are difficult to elicit in a child of 6 months. Generalised signs and symptoms of a 'sick looking kid' such as fever, off colour, and vomiting would be typical. Unfortunately such features are also typical of a myriad of common childhood viral and bacterial infections, and while a general practitioner must consider a urinary tract infection, the reality is that gastroenteritis and other viral infections are a lot more common in a general practice setting. Common things happen commonly.

In this case a general practitioner would normally seek some objective signs before making a diagnosis of a urinary tract infection. This would require the obtaining of a urine sample for testing in the surgery with a dipstick and visual urine signs such as cloudy urine in a fresh specimen. In addition it would be normal to send any sample to a laboratory for microscopic examination and a culture.

Obtaining a urine sample from a female child of 6 months is difficult to say the least. The ideal method is to obtain a suprapubic (a needle inserted through the lower abdomen into the child's bladder) or a catheter specimen (a tube inserted via the urethra into the child's bladder), both procedures not normally the realm of a general practitioner. More commonly an adhesive 'catch bag' is applied to the child's genital region and any urine passed is then analysed. The results in a 'catch bag' situation are often less than ideal.

Nevertheless because of the potential significance of a urinary tract infection in a child of this age, namely the possibility of structural abnormality of the child's urinary system, it is normal practice for a general practitioner to try and confirm a urine infection by one of the above methodologies prior to commencing antibiotic therapy.

While [Dr C] indicates in her letter (page 073) that:

*'The parents were asked to go to [a medical laboratory] to collect the urine collection bag for female infants'.*

There is alas no record of her ordering or considering a urine specimen collection in her clinical notes. I cannot ascertain whether [Mr and Mrs A] were given a urine collection bag.

In summary [Dr C's] actions in diagnosing a UTI in [Baby A] is possibly acceptable, however her prescribing of an oral antibiotic without further effort to obtain a urine sample is unacceptable for a general practitioner.

**Second diagnosis: Impetigo**

[Dr C] records in her notes (page 043) as follows:

*'… and has come up in an itchy rash — has eczema.*

…

*O/E (on examination) … child has a diffuse rash over the face, looks like impetigo'.*

In her letter written on 19 September 2005, on page 032, [Dr C] writes:

*'She had a mild eczema on her extensor surfaces and a diffuse golden-crusted rash on her face'.*

Impetigo is a bacterial skin infection due to staph aureus, a bacteria and is also known as school sores. It usually has an appearance of discrete large crusty sores, not a diffuse rash. 'Itchiness' is not a common feature although eczema is itchy and impetigo is a common complication of eczema. [Dr C's] description of diffuse rash and itch goes against impetigo as a diagnosis.

[Dr C's] diagnosis is countered by the paediatric house surgeon at [the hospital] making the following entry among a comprehensive recording of examination findings on admission (013):

*'No significant rash'.*

If [Baby A's] diffuse rash had been due to her fever it is possible for this to have settled by the time of her admission to [the hospital]. Impetigo would not settle in that time. The paediatric registrar wrote on [Baby A's] discharge the next day from [the hospital]:

'*No meds on discharge*'.

Which further supports that this rash was not impetigo.

There is one hard to read nursing entry (015) which states

*'Some … over baby's face … itchy as she's been rubbing with hands'.*

However I can find no other references in the hospital records to a rash such as impetigo.

Thus on the balance of the evidence I favour that [Dr C's] diagnosis of impetigo was incorrect.

**Third diagnosis: gastroenteritis**

[Baby A] was presenting with diarrhoea and vomiting. Probable causes for this in general practice are primarily gastroenteritis, a bowel infection most commonly caused by viral infections with bacterial infection being less common but a definite possibility. Other non bowel infections such as urinary tract infection can commonly be associated with vomiting, although diarrhoea is less so. The combination of vomiting and diarrhoea is a strong pointer towards gastroenteritis and this seems the most likely diagnosis.

[Dr C's] diagnosis of this condition was correct however she failed to record either clinical signs relating to this, or of a formal diagnosis or exclusion in the notes thus it appears she overlooked this important component of assessment in this type of presentation.

**Fourth diagnosis: oral thrush**

This diagnosis seems reasonable at first glance as is [Dr C's] management of it. However [Dr C] did not document in her clinical notes the objective features upon which she made this diagnosis. The paediatric house surgeon's admission note (011) state the parents had noted:

*'2 white spots seen on lower gum'.*

However the house surgeon did not record any signs of thrush in his clinical records although he/she clearly examined, judging from the hospital notes (page 013) [Baby A's] mouth, noting:

*'mildly inflamed pharynx (back of throat) no tonsillitis. First sign of dentition lower incisors, mucous membranes nicely moist'.*

One would normally expect signs of oral thrush to still be present 8 hours after [Dr C] had made the diagnosis of oral thrush. Furthermore the hospital did not give any medications for this (page 024).

**In summary on diagnosis**

Thus three out of [Dr C's] four diagnoses are doubtful. I conclude her diagnostic skill was poor. Whether this was due to her lack of general practice experience or poor judgement is difficult to ascertain from this one case, although given her hospital experience I would expect her to be able to exercise the required judgement to understand the hazards of multiple diagnosis. In addition I cannot ascertain whether there were factors at [the medical centre] on the Sunday in

question, such as workload when on call which might adversely impact upon a trainee general practitioner's skills.[6]

**Management**

[Dr C's] management centred around prescribing pharmaceuticals and some advice on their usage.

**Multiple prescribing**

While in hospital situations, particularly when patients have potentially life threatening infections, doctors sometimes prescribe multiple antibiotics, in general practice the use of multiple antibiotics is rare and generally frowned upon, unless there is a clearly established bacterial infection which indicates that two antibiotics may be necessary. Considering the antibiotics [Dr C] chose to prescribe, she used amoxycillin for [Baby A's] urinary tract infection, flucloxacillin and fusidic acid cream for her impetigo.

The most common organism causing urinary tract infections is E Coli. As a rule most general practitioners will not use amoxycilllin to treat a urinary tract infection as:

'Approximately 50% of E. coli are resistant to amoxicillin'[i]

Normally, if amoxycillin was to be used, it would be combined with clavulanamic acid which greatly increases the effectiveness against E coli. This combination is readily available in this country and is commonly used in general practice. The prescribing of amoxycillin in isolation for a urinary tract infection would be regarded as inappropriate but appears from my observation of other colleagues' prescribing and discussion in education sessions to still occur.

The use of flucloxacillin for impetigo is entirely appropriate.

Fusidic acid, a topical antibiotic for use on skin infections was also prescribed.

The use of a topical and an oral antibiotic for treatment of impetigo seems a needless duplication, particularly as the diagnosis of [Baby A's] impetigo is debatable, but it cannot be regarded as wrong.

In addition to the antibiotics, [Dr C] prescribed three other medications namely ibuprofen suspension, nystatin drops and maxolon oral solution, giving a total of five to be administered by mouth to a child who was vomiting.

[6] [Mr G] informed me that the Centre was not particularly busy that day.

The fact that [Baby A's] parents administered a second dose of metoclopramide following their observation that their daughter had vomited back the first dose of this drug exemplifies the problem of administering any oral medications in such circumstance. The only oral medication that would be recommended in a vomiting child would be oral rehydration fluid should dehydration be a concern.

In addition the potential of the medications prescribed to aggravate this child's condition would be high both individually and more so in combination. Ibuprofen for instance, has a well established significant incidence of gastric side effects and oral antibiotics (amoxycillin and flucloxacillin) have a significant incidence of causing diarrhoea[ii] (1 in 17 reference) oral thrush and to a lesser extent, vomiting.

Of these medications only the nystatin oral drops and the fucidin cream could be regarded as relatively free of gastric side effects, for oral antibiotics have a significant incidence of causing diarrhoea and oral thrush.

**Prescribing of metoclopramide**

This was prescribed for the management of [Baby A's] vomiting, either from a urinary tract infection or from gastroenteritis. As far as the latter diagnosis more appropriate management of gastroenteritis is the use of oral rehydration fluids in a child who was dehydrated. As already identified it appears from the notes that [Dr C] did not establish [Baby A's] state of hydration, an essential step in decision making in a child with vomiting or gastroenteritis.

Central to the adverse outcome in this case was the dystonic reaction resultant from the prescribing of metoclopramide. The issue is firstly the appropriateness of prescribing this medication in a child of this age; secondly, the dose prescribed and thirdly the dose administered.

On the first:

Metoclopramide is an antiemetic used to reduce vomiting. The prescribing of metoclopramide for children is acceptable in some specific situations in the country, as per the Medsafe data sheet for metoclopramide oral solution:[iii]

*'YOUNG ADULTS AND CHILDREN*

*The use of MAXOLON in patients under 20 years should be restricted to the following:*

*Severe intractable vomiting of known cause*

*Vomiting associated with radiotherapy and intolerance to cytotoxic medicines*

*As an aid to gastrointestinal intubation*

*As part of the premedication before surgical procedures.'*

This information from Medsafe is available as part of the Medtech 32 Practice Management System software as used by the [practice]. [Dr C] states that she was not aware of this resource at the time of prescribing however it does appear that she was aware of the potential for metoclopramide to cause adverse muscular reactions as evidenced by her statement on page 033

*'I also said that there were risks of writhing and restlessness with the medication'.*

Guidelines for the management of gastroenteritis in children have been produced by [the] District Health Board. These are largely consensus based and have the following recommendation on the use of antiemetics.[iv]

> • *Is there a place for anti-emetic agents in childhood gastroenteritis?*
>
> Standard practice guidelines discourage the use of anti-emetics in childhood gastroenteritis on the basis of potential harm (direct side-effects, masking other conditions) and lack of proven benefit. There is little published data.

In New Zealand prescribing metoclopramide for a child with gastroenteritis would be rare in general practice. In 1993 I surveyed 125 general practitioners from the Central RHA [Regional Health Authority] area on their management of a two year old child presenting with the symptom of gastroenteritis. Only two doctors would have used metoclopramide.

It is also sometimes used overseas in the treatment of gastro-oesophageal reflux. This information is consistent with accepted practice in [the country Dr C trained in], as exemplified by the Clinical Evidence advice on the use of metoclopramide.[v] However its use in children in the country Dr C trained in is generally frowned upon.

[An online database in this country] gives the following evidence summary on the use of antiemetics in children:

*'There is a lack of evidence to support the use of anti-emetics in primary care. Consensus opinion appears to be that they are of little value and may cause significant adverse effects, particularly in children. Nausea and vomiting often improve after adequate rehydration with oral rehydration therapy.'*[vi]

Consideration must however be made of the research evidence on antiemetics in children with gastroenteritis.

The following comment from Dynamic Medical, a high quality up-to-date summary of research website states:[vii]

 *antiemetics not recommended in children but appear safe; retrospective study of >20,000 children with acute gastroenteritis, 9% filled prescriptions for*

*antiemetics (usually promethazine) within 3 days of index visit, seven children treated with antiemetics had adverse reactions, only 1 had extrapyramidal reaction (Arch Pediatr Adolesc Med 2003 May;157(5):475 in J Watch Online 2003 May 23)*

It is important to note that this reference is to antiemetics as a class, as opposed to metoclopramide. There are some newer antiemetics (ondansetron for instance) which have been shown to be safe and effective in children with gastroenteritis, however metoclopramide is not the same for its risk of oculogyric crisis/dystonia in children is well documented in the medical literature.

Thus we have a situation where current practice in this country is very much against the use of metoclopramide. It is difficult to defend [Dr C's] prescribing, especially as there are other references in the documentation of [Dr C's] prescribing of anti-emetics. On page 057 [Dr E] states:

'*There were some instances of inappropriate prescribing after this, the most important being the prescription of Stemitil suppositories to an infant.'*

Stemitil, another anti-emetic is commonly used in adults, however its use in children is more restricted than metoclopramide as per the Medsafe data sheet:

*'Children:*
*STEMETIL is not recommended for children weighing less than 10 kg. Intramuscular or rectal STEMETIL should not be given to children. When treating children it is recommended that the 5 mg tablets are used.'*

Page 077 contains reference to the pharmacist's concern over prescribing including Maxolon (metoclopramide).

**On the second:**

The dose of maxolon prescribed was 3mg three times a day.

[Dr C] indicates that she believes the standard recommended dose was 2.5 mg three times daily, but acknowledges that this dose was too high as her paediatric experience was:

*'with slightly older children'*.

She acknowledges her error in the letter.

Indeed the dose should have been in the realm of 1mg twice a day maximum[viii] based on [Baby A's] age.

Should metoclopramide be used in a child, it is critical to use a dose calculated according to body weight. Unfortunately [Dr C] does not appear to have prescribed

in this manner. There is no record of [Baby A's] body weight in the notes as presented to me. It is possible that this information is elsewhere in the PMS system at [the Medical Centre] as the printout of computer records does not cover all the demographic and other information that could be expected in a general practice.

Assuming that the weight has not been taken or recorded, this is a significant oversight on [Dr C's] part, particularly given her paediatric SHO experience and is a significant contributor to the subsequent adverse outcome.

**On the third:**

[Dr C] cannot be held responsible for the dispensing error where the label on the bottle did not reflect her prescribing directions, particularly as the total dose of metoclopramide given was 7mg more (over two hours) than she prescribed.

She was however responsible to assure that [Baby A's] parents understood the potential for this medication to induce a reaction such as an oculogyric crisis, and thus to assure they did not overdose their child. This would be part of the normal provision of information on the harms and benefits of this medication, an important issue given this well known potential of metoclopramide to produce dystonia and the general disapproval of its prescribing in children.

[Dr C] states on page 033:

*'The instructions I gave to the parents was that this medication was to be used with caution but could stop their daughter from vomiting. I also said that there were risks of writhing and restlessness with the medication'.*

The issue of parental comprehension is important. [Dr C] states following the above sentence:

*'I was satisfied that [Baby A's] parents understood how to use the medications I had prescribed.'*

There is no record in the computer note printout of [Dr C] providing this information to [Baby A's] parents. While such information should be recorded, reality is that in many situations it is common for a general practitioner not to record this.

Note however the letter from [Dr B], Paediatric Registrar at [the hospital] to yourself (002) states under paragraph labelled 4:

*'There was a language difficulty present with parents having poor English'.*

According to the registrar her parents, two hours after [Baby A] vomited the first tablet

*'[G]ave another half tablet'*

[w]hich indicated that the importance of not overdosing metoclopramide was either never given to [Baby A's] parents or that they did not understand this. It is difficult to evaluate a communication issue such as this but on the balance I would suspect parental understanding based on language and cultural difference was the main source of the problem. Given [Dr C's] short experience of the NZ medical care system and general practice, I would not expect her to be able to readily prevent miscommunication in what can frequently prove to be a very difficult area of general practice.

**Other issues**

**[Dr C's] experience**

A likely explanation of [Dr C's] actions is a lack of experience. Her work history in hospital based medicine, as summarised on pages 58–61 (her curriculum vitae), was comprehensive. Prior to her time off (8 years) for having her daughter (x1), her hospital medical officer work included 7 months as a senior house officer [in 1993]. This should have involved common conditions as gastroenteritis and the use, or non use, of metoclopramide. After re-entering the medical workforce in June 2002 her hospital medical officer work was diverse. Considering all her hospital work, her experience is greater than many New Zealand trained entrants into general practitioner training.

By contrast her experience of the New Zealand health care system was limited to 6 months in New Zealand as a cardiology registrar. However analysis of this case shows that there were no situations which created problems for [Dr C] that would have been unique to the NZ situation. While there are a number of differences in the naming and availability of prescription pharmaceuticals between NZ and [Dr C's home country], as per [Dr C's] letter (page 032) the medications she prescribed for [Baby A] are available both [there] and in NZ and available here without restriction.

[Dr C's] experience of general practice prior to seeing [Baby A] was limited to three months. It is likely that some of her mistakes, namely some of her diagnostic difficulties and polypharmacy at least could be attributed to this inexperience although I would favour some more basic judgement problems as being the source of her difficulties.

I have attempted to identify any significant differences between the [two] health systems on metoclopramide prescribing. The reference to [the online database] and Clinical Evidence above are sourced from [Dr C's home country]. I have also verified with [a] general practitioner in [that country] on the current practice of antiemetics in gastroenteritis. He has confirmed that metoclopramide would not be used and that the [the online database] would be an acceptable standards setter.

**Clinical notes**

From [Dr C's] computer notes (043) the following appears:

*'[D]eveloped a UTI a week ago and never took Abs'.*

This suggested that [Baby A] has a recent presentation to a doctor for which she had been prescribed antibiotics. There is also a record of this in the hospital admission interview by the house surgeon (page 012). There is no documentation of previous consults in the clinical records (page 043) from [the Medical Centre]:

*'UTI 3/52 ago suspected by GP'*

Explanation of this might be that

- She had been seen elsewhere
- That the clinical records from [the Medical Centre] as forwarded to the HDC were incomplete[7]
- That the records as above were incorrect for some reason, possibly communication.

According to the documentation (062) the [practice] used the Medtech practice management system PMS (software). Looking at the clinical records sourced from the practice computer (043) these do not contain other information, especially demographic data at least that would normally be expected and I would suggest that the practice be requested to send any other clinical or transaction information they have for [Baby A]. This information is generated by a report function from Medtech and can be easily filtered to produce only certain data. For instance there is no copy of [Baby A's] discharge letter from [the hospital].

I trust the above answers your questions 1–7. Below are my replies to your questions on [Dr C's] supervision and support at the Medical Centre.

**7. Was [Dr C's] induction to [the Medical Centre] appropriate?**

*Orientation/induction into [the Medical Centre]*

Guidance for orientation into New Zealand general practice is provided in the RNZCGP booklet 'Your guide to general practice' which covers various legal and business aspects, some cultural realms and also an outline practice orientation. As [Dr C] had been practising in NZ for 6 months, the [practice] would be correct in

[7] [Baby A] was not enrolled as a patient at [the Medical Centre] and did not attend at any other time.

presuming she had been orientated to the NZ health system and their duty would be to provide orientation into general practice.

Practice orientation as such provides information on the environment in which a doctor will practise, including how the practice operates, local resources and national systems. Such information cannot be provided at the very moment a doctor commences clinical work but will be spread out over some time. Orientation has to be tailored to each doctor's circumstance.

Judging the induction [Dr C] received is very difficult, for she states in her letter of 7 December 2005 (063):

*'I was escorted into my room where I was presented with the computer software Medtech 32 … I was given very basic instruction which I later tried to develop'.*

By contrast [Dr E] states in his letter of November 8 2005:

*'Following an orientation programme into the physical facilities, procedures and computer programs of [the Medical Centre] ...'*

[Dr C's] account identifies inadequate orientation while [Dr E's] would be an appropriate practice orientation.

In answer to your question, to adequately assess [Dr C's] orientation would require documentation that is not available and interviewing both [Dr C] and the practice management, plus judging the practice process against the RNZCGP Guide on Orientation which itself does not define a minimal standard but rather good practice.

**8. Was [Dr C] given appropriate support and supervision at [the Medical Centre]?**

*Support and supervision*

[Dr C] was working under the Medical Council's Provisional General registration. The requirements for supervision are defined in the Medical Council's 'Guidance for Doctors working in supervised practice and their supervisors'.

These call for regular meetings between the general practitioner and their supervisor.

Clearly from the documentation supplied by [the Medical Centre] the number of documented meetings did not fulfil the MCNZ requirements for supervision (page 054). The apprenticeship model of training as used in general practitioner training is one where the teacher provides facilitation and resource for the trainee in an experiential learning manner. This requires that the trainee has available a resource person in the practice to address their self determined needs. In this circumstance

there will normally be a number of meetings between trainee and trainer (in this case the MCNZ determined 'supervisor' or substitute) that occur as needed usually in the form of just in time 'corridor' consultations. It is difficult to document such spur of the moment meetings.

I note that [Dr E] states in his November 8 letter (057):

*'[I]n this practice we have a long experience of providing supervision and support for junior doctors-trainee interns, FMTP registrars, locums with or without previous general practitioner experience, surveillance of experienced overseas doctors'.*

I cannot verify this information, however if this is the case the practice clearly had past experience of doctors in [Dr C's] situation, namely FMTP registrars (Family Medicine Training Program, the forerunner to the RNZCGP GVTVP). This would at least suggest the practice has some experience of the requirements of this role, especially the requirements of the apprenticeship model. In addition they were aware of [Dr C's] previous experience for she could hardly be regarded, given her [overseas] hospital experience, as a raw recruit in the same vein as are many NZ graduate general practice training entrants.

Consideration must be made of the responsibilities in the apprenticeship model as applied to adult learners. The principles of androgogy focus on self identified learning needs in mature students who are to be regarded as being capable of proactively seeking out help. The Medical Council document referred to above defines requirements on both sides of the learning platform in line with androgogy.

Of import is the comment by [Dr E], following on from that above (page 057)

*'We have found them (junior doctors) keen to learn and to identify their learning needs: we have not found this to the expected extent in [Dr C].'*

[Dr F] who took over [Dr C's] supervision from [Dr E] records on page 062 of the documentation:

*'3) The other is that [Dr C] did not participate in mixing with any members of [the Medical Centre], even though every nurse and every doctor personally asked her to do so.*

*4) On discussion with our nurses they felt [Dr C] was reluctant to ask for assistance from colleagues.'*

[Dr C] writes on page 063:

*'I now appreciate that I should have been more persistent with my requests for assistance and advice, in particular with respect to queries I had regarding prescribing of medication.'*

There is some dissonance in the accounts of the learner trainer interactions between [Dr C] and [the Medical Centre]. However it does appear that [Dr C] did not have a close learning relationship with her supervisors and there is some admission on her part that this may have been sourced with herself. Equally her supervisor [Dr E] had to transfer this supervision to [Dr F] because of his ill health with his admission that:

*'Contact was not as regular as was planned'. (page 056)*

In answer to your question, it is difficult to identify with accuracy the interactions between [Dr C] and her supervisors. [Dr C's] subsequent performance in other general practice learning environments may help establish the cause of this failing of the learning relationship for I note that she subsequently moved on to [another medical centre] under the supervision of [another doctor].

**In summary**

[Dr C's] treatment and care for [Baby A] has several areas of concern, namely multiple and largely incorrect diagnosis along with inappropriate and multiple prescribing. Communication problems between [Dr C] and [Baby A's] parents were contributory but it is difficult to lay blame for this upon [Dr C] given the circumstances.

[Dr C] was a relatively experienced hospital doctor from [overseas] who entered NZ general practice at [the Medical Centre] working under 'supervision', necessary because of her lack of general practice experience or training. Her learning relationship with the practice was less than desirable for a variety of reasons and her prescribing caused some concern for the local pharmacist.

[Dr C] saw [Baby A] on a Sunday, made multiple diagnoses and prescribed multiple pharmaceuticals, one of which was metoclopramide at a higher than indicated dosage. This medication is not recommended for use in children in these circumstances. A mistake in the dispensing saw a higher than prescribed dose dispensed, further aggravating the situation which resulted in [Baby A] suffering a predictable dystonic reaction.

I find that [Dr C] failed to provide an adequate standard of care to [Baby A], the use of metoclopramide in a child of this age being regarded with moderate disapproval in general practice after due consideration of [Dr C's] lack of general practice experience.

**References:**


i. Guide to Pathogens and Antibiotic Treatment. Chapter 21. Diagnostic Medlab. Available online at http://www.dml.co.nz/clin_aguide.asp

ii. Medsafe. Available online at http://www.medsafe.govt.nz/profs.htm

iii. Available online at http://www.medsafe.govt.nz/DatasheetPage.htm

[iv] [The] DHB Primary care management guidelines.
[v] Clinical Evidence, BMJ. Available on line at http://www.clinicalevidence.org/ceweb/conditions/chd/0310/0310_I9.jsp
[vi] [An online database]
[vii] http://www.dynamicmedical.com/
[viii] Medsafe. Available online at ttp://www.medsafe.govt.nz/DatasheetPage.htm."

*Pharmacist advice*
The following expert advice was obtained from pharmacist Mr John Fraser:

"**1 Introductory comments**

**1.1 Introduction**
I would like to thank the Commissioner for allowing me to review this case, number 05/07953/WS. This matter was referred to me for my opinion on 3rd March 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 apprentice to owner/manager.

I am a past President of 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 professional nor financial interests in this area.

**1.3 Declarations**
I have read and agree to follow the HDC Guidelines for Independent advisors. I have also previously entered into a confidentiality agreement with the HDC.

I have compiled this report in good faith based on the information available to me.

I have no relationship with [the Pharmacy] or its staff, and believe I have no conflicts of interest in compiling this report. However in the spirit of full disclosure, I note that one of my previous interns subsequently worked at [the Pharmacy] for a time, and I believe I briefly met pharmacy proprietor Mrs I at a conference in 2004.

Such coincidences are almost inevitable in a country as small as New Zealand, and I do not consider that these factors will influence my opinion in any way.

### 1.4 Directions from the Commissioner

I have been directed by the Commissioner to consider the following questions:

1. In your professional opinion, was the service [Mrs D] and/or [the Pharmacy] provided to [Baby A] on 29 May 2005 appropriate? Please give reasons for your opinion, with reference to the individual staff members involved.

2. If the care provided was not appropriate, please explain why.

3. What standards apply in this case? Were these standards satisfactorily applied by [Mrs D] and/or [the Pharmacy]?

If not covered above, please answer the following, giving reasons for your opinion:

4. Should [Mrs D] have queried the dosage of the Maxolon with Dr C?

5. Was [Mrs D's] decision to use tablets instead of liquid appropriate under the circumstances?

6. What other options were available to [Mrs D] in relation to preparing the Maxolon for [Baby A]?

7. Was the label on the Maxolon container appropriate?

8. Were the instructions and information given to [Mr A] appropriate?

9. What policies should a pharmacy have in place for recording concerns about prescriptions?

10. At what point should a prescriber raise concerns directly with the prescriber?

11. At what point should a pharmacy raise concerns with a third party such as a supervisor, a practice manager or the Medical Council?

If, in answering any of the above questions, you believe that [Mrs D] and/or [the Pharmacy] did not provide an appropriate standard of care, please indicate the severity of the departure from that standard.

To assist you on this last point, I note that some experts approach the question by considering whether the providers' peers would view the conduct with mild, moderate, or severe disapproval.

Are there any aspects of the care provided by [Mrs D] and/or [the Pharmacy] that you consider warrant additional comment?

### 1.5 Material examined

In providing my opinion, I have examined the following material:

1. Letter dated 29 May 2005 from [Dr B], marked 'A' (numbered 1).
2. Letter dated 29 July 2005 from [Dr B], marked 'B' (numbered 2).
3. Letter dated 23 August 2005 and enclosures from [Mrs I] of [the Pharmacy], marked 'C' (numbered 3–4).
4. Notes of telephone conversation with [Mr and Mrs A] on 26 August 2005, marked 'D' (numbered 5).
5. Medical notes received from [the] District Health Board on September 2005, marked 'E' (numbered 6–28).
6. Letter dated 6 September 2005 from [the] Clinical Director at [the] District Health Board, marked 'F' (numbered 29–30).
7. Letter dated 27 September 2005 from [Dr C] and enclosure, marked 'G' (numbered 31).
8. Letter and enclosure received from [Mrs I] of [the Pharmacy], marked 'H' (numbered 32–43).
9. Letter dated 7 November 2005 from [Mrs I], marked 'I' (numbered 44–50).
10. Letter dated 29 November 2005 from [Mrs D], marked 'J' (numbered 51–53).
11. Letter dated 7 December 2005 from [Dr C], marked 'K' (numbered 54).
12. Letter dated 12 December 2005 from [Mrs I], marked 'L' (numbered 55–57).
13. Facsimile dated 14 December 2005 from [Dr C's lawyer], marked 'M' (numbered 58).
14. Action note of conversation with [Mr H] on 2 March 2006, marked 'N' (numbered 59).
15. Facsimile dated 2 March 2006 from [Mr H], marked 'O' (numbered 60–61).

## 2 Summary of Facts

…

## 3. Commissioner's questions

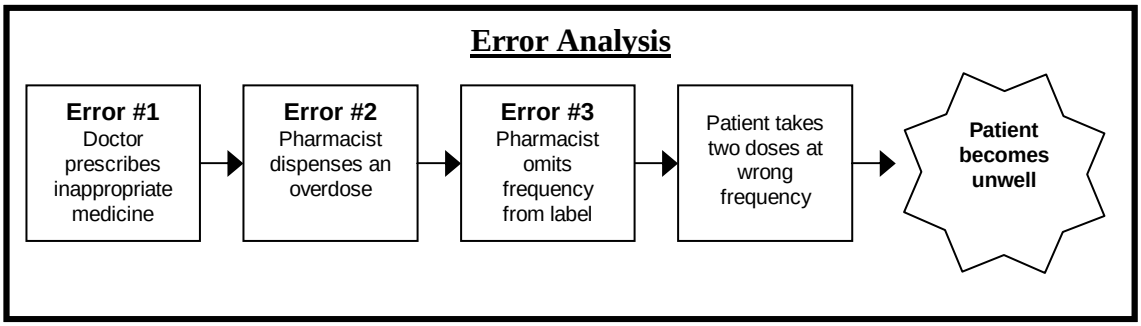
### 3.1. In your professional opinion, was the service [Mrs D] and/or the Pharmacy provided to [Baby A] on 29 May 2005 appropriate? Please give reasons for your opinion, with reference to the individual staff members involved.

Three separate errors occurred in the prescribing and dispensing of [Baby A's] prescription on 29 May 2005:

1. She was prescribed and dispensed an inappropriate drug that is rarely indicated for such a young person.

2. She was dispensed 5mg of Maxolon per dose instead of the prescribed amount of 3mg per dose.
3. The label on her medication bottle did not mention frequency of dosage, which is an important requirement to ensure the patient takes the right amount of medicine at the right time.

The three errors led to the patient, [Baby A], receiving an overdose of Maxolon which required hospitalisation.




### *3.1.1 Inappropriate supply of Maxolon*

After very careful consideration, I believe that the Pharmacy and the pharmacist, [Mrs D], *did* provide an appropriate standard of care in relation to the first error (providing the Maxolon). I arrived at this conclusion for the following reasons:

- Experienced pharmacists are expected to be highly familiar with around 2000 drugs — but it is not reasonable to expect pharmacists to be familiar with the *paediatric* doses of most of these.
- Pharmacists are expected to fill hundreds of prescriptions per day. It is unreasonable to expect pharmacists to question every slightly unusual prescription that they see, especially when the pharmacy has a history of dispensing the same drug to other young people without apparent problems (here I am referring to the Prescription Details Report on page 46 of my case notes).
- Pharmacists are rarely privy to any clinical details about patients. Therefore, a prescription that seems unusual to the casual observer might actually be perfectly normal when viewed in context of the clinical history.
- [Mrs D] did telephone the prescriber, [Dr C], to question whether the medicine was urgent. Although the prescription itself was not explicitly questioned, I believe that by making contact and verbally confirming the prescription was needed, [Mrs D] did everything that would be reasonably expected of her.
- Although it may sound trite or flippant to say it, it is not the job of pharmacists to 'baby-sit' doctors. [Baby A's] prescription was

> complete, legal and authentic; and the pharmacist involved discussed the prescription with the prescriber. There is little more I would expect from any pharmacist in the same situation.

Clearly, a serious mistake was made, and [Baby A] received an overdose of an inappropriate drug. However, I cannot say that the pharmacy departed from an appropriate standard of care in supplying the Maxolon.

### *3.1.2 Supplying 5mg Maxolon per dose instead of 3mg Maxolon per dose*

While [Baby A] was prescribed 3mg Maxolon, three times daily, she was actually dispensed 5mg Maxolon, three times daily. It does not appear that [Dr C] confirmed and approved the increase in dose. However, I note that half a 10mg tablet (5mg per dose) is probably the closest reasonable dose for dividing a tablet. A better alternative would be to dispense a quarter tablet (2.5mg per dose) — but this might be too difficult to divide without crumbling.

Nevertheless, on balance it does seem that [Mrs D] made a mistake, and she admits that this was 'not accurate or adequate' (page 052 of my case notes). This error exacerbated an already erroneous prescription by giving too high a dosage.

On balance, I feel this error, while very serious, has some 'mitigating' factors and as such would be viewed with slight disapproval by pharmacy peers.

### *3.1.3 Inappropriate labelling of medication*

[Mrs D] also departed from an appropriate standard of care in failing to note the frequency of dosage on the Maxolon label; although this is offset somewhat by the fact that [Mrs D] discussed the use of the medicine with [Baby A's] father.

However, lack of frequency information may have contributed to the fact that [Baby A] was given another dose of Maxolon only a couple of hours after the first dose, as her parents believed she vomited the first dose back up. This was probably too soon for a second dose; the original prescription was to take a dose 'three times daily' or about once every six to eight hours.

On balance, I believe that this error was also very serious; but again it is mitigated somewhat by [Mrs D's] verbal explanation to [Mr A]. Nevertheless, I believe that this departure from standard in labelling would be regarded by [Mrs D's] pharmacist peers with slight disapproval.

**3.2. If the care provided was not appropriate, please explain why.**

I believe this question has already been covered above.

**3.3. What standards apply in this case? Were these standards satisfactorily applied by [Mrs D] and/or [the Pharmacy]?**

The standards that apply in this case are the standards that would apply to all pharmacists practising in community pharmacy in New Zealand on Sunday 29 May, 2005. There are a number of rules and regulations affecting pharmacy, but the following are particularly relevant to this case:

- Pharmacy Council of New Zealand Code of Ethics 2004
- Pharmacy Council of New Zealand Competence Standards
- Pharmacy Practice Handbook 2003
- Medicines Regulations 1984
- The Pharmacy's Standard Operating Procedure

**The following selected standards are particularly relevant:**

**Code of Ethics 1.7: Consult with patient**
*'The pharmacist must consult with the patient to achieve a mutually acceptable arrangement when it is not possible to dispense a medicine as prescribed.'*

I believe this standard was complied with. It appears that [Mr A], as [Baby A's] caregiver, found crushed Maxolon tablets an acceptable alternative to Maxolon liquid.

**Code of Ethics 2.1: Medicines related health outcomes**
*'The pharmacist must endeavour to optimise medicines related health outcomes for the patient as a fundamental tenet of pharmacy practice.'*

This standard is accompanied by the following commentary:
*'Achievement of this goal depends not only on the pharmacist but also on the collaborative efforts of other members of the healthcare team. Therefore, it is to be noted that this provision is phrased 'The pharmacist must endeavour to …' rather than as 'The pharmacist must …' This is recognising that the pharmacist cannot be solely responsible for achieving this goal.'*

I believe this standard was only partially complied with. While most aspects of [Mrs D's] care of [Baby A] were adequate, she made two errors: an overdose above the prescribed amount, and an omission of details from the label. However, this code also emphasises that a pharmacist is only one part of the healthcare team, and other parties are also responsible for ensuring optimal health outcomes.

**Code of Ethics 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 believe this standard was only partially complied with. The pharmacist, [Mrs D], did implicitly verify the authenticity and suitability of the Maxolon prescription by telephoning the prescriber to query whether the drug was needed. However, [Mrs D] failed to dispense the prescription correctly, in that 5mg per dose was dispensed instead of 3mg per dose. Further, she failed to adequately label the medicine, by omitting frequency of dose.

**Code of Ethics 3.4: Safe use of medicines and other therapies**
*'The pharmacist must only supply a medicine, complementary therapy, herbal remedy or other healthcare product, to a patient when the pharmacist has reason to be satisfied that the patient understands how to use it safely.'*

Although there is some reason to believe [Mr A] did not know how to use the medicine safely — as he gave [Baby A] a second dose too soon — it seems [Mrs D] had little reason to doubt [Mr A's] understanding of the instructions for use of the Maxolon at the time of dispensing. Therefore I feel this standard was complied with.

**Code of Ethics 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.'*

I believe, on balance, that this standard was complied with for reasons already discussed in section 3.1.1 above. (See also my answers to Questions 3.9 and 3.10.)

**Code of Ethics 5.2: Pharmaceutical knowledge**
*'The pharmacist must keep abreast of pharmaceutical knowledge applicable to the area in which they practise.'*
I have no reason to doubt this standard was complied with. I am quite sure that [Mrs D] has comprehensive pharmaceutical knowledge, and I am sure she was familiar with the drug Maxolon. However it is unreasonable to expect her to be familiar with the specific paediatric doses of a drug such as Maxolon.

**Competence Standard 1.1.5: Works accurately**
It is questionable whether dispensing 5mg per dose when the prescription called for 3mg per dose is an accurate standard of work. In this sense it seems [Mrs D] made a mistake and thus fell short of the accuracy standards expected. Furthermore, the label was not complete, and this is a lapse in accuracy by omission.

**Competence Standard 2.2.2: Evaluates the available medicines, dose forms and methods of administration**
I have no reason to doubt that this standard was complied with. As already mentioned, [Mrs D] discussed the Maxolon prescription with [Dr C] who said it was urgent. Furthermore the script was properly formatted, legal and authentic.

**Competence Standard 2.3.2: For each medicine, checks the dosages and methods of administration are optimal**
I have no reason to doubt that this standard was complied with. As already mentioned, [Mrs D] discussed the Maxolon prescription with [Dr C] who said it was urgent. Furthermore the script was properly formatted, legal and authentic.

**Competence Standard 2.6.2: Communicates effectively with prescriber and other health professionals**
I have no reason to doubt that this standard was complied with. [Mrs D] made a concerted effort to telephone [Dr C] to see if the prescription was urgent.

**Competence Standard 6.2.1: Determines whether individual prescriptions should be dispensed**
I have no reason to doubt that this standard was complied with. [Mrs D] telephoned [Dr C], who confirmed the prescription was urgent.

**Competence Standard 6.2.4: Determines the stock availability of prescribed medicines**
This standard was clearly complied with. Although the computer stock system was in error (which is not that uncommon), [Mrs D] determined that no Maxolon liquid was readily available and offered an alternative.

**Competence Standard 6.5.1: Confirms that each selected medicine is suitable for the patient**
On balance, I think this standard was complied with. I say this because [Mrs D] phoned [Dr C], who said the prescription was urgent and needed to be dispensed immediately. Any reasonable pharmacist would conclude, based on this conversation, that the doctor had confirmed the dispensing.

**Competence Standard 6.5.2: Addresses factors likely to affect patient compliance**
[Mrs D] identified that giving whole tablets to a young child was not appropriate; hence she gave directions to crush the tablets. This was appropriate and thus this standard was complied with.

**Competence Standard 6.7.2: Produces comprehensible and complete labels for medicines**
This standard was not achieved, in the sole sense that the label did not refer to frequency of dose.

**Medicines Regulations 1984/143, Part IV, clause 23**

[This section of the regulation sets out the minimum requirements for a pharmacy label]:

*(a) (i) a statement of the general nature of the medicine, and a recognised code indicating the precise nature of the contents or being a reference to a prescription book or similar entry; or*
*(ii) the name of, or a description of the nature of, the contents; and*
*(b) the name of the patient*
*(c) the name and address of the seller; and*
*(d) in the case of a medicine for internal use, the dose and frequency of the dose; and*
*(e) in the case of a medicine for external use, a statement of the directions for use and frequency of use, and 1 or other of the following statements, or words of similar meaning: 'Caution Not To Be Taken', or 'For External Use Only'*

This regulation was not met, in the sole sense that the label did not refer to frequency of dose.

**3.4. Should [Mrs D] have queried the dosage of the Maxolon with [Dr C]?**
First, I should point out that [Mrs D] did *indirectly* query the validity of the prescription by asking whether the drug was urgent.
However, the obvious question is whether [Mrs D] should have directly and explicitly questioned whether the Maxolon should have been prescribed at all.

After careful consideration of this matter, I feel that [Mrs D's] actions were appropriate under the circumstances. While it would have been much better if [Mrs D] did directly raise the issue of the prescription, it was not something she was obligated to do. We must separate what she *should have* done from what she *ideally would have* done. The former implies a duty or obligation; the latter a possibly important but not mandatory intervention.

**3.5. Was [Mrs D's] decision to use tablets instead of liquid appropriate under the circumstances?**

Yes. It is reasonable and routine for pharmacists to crush tablets, or to give instructions to crush tablets, especially for administration to children. Unfortunately the administration of the crushed tablet was complicated by the fact that there was an overdose that apparently was not approved by [Dr C].

**3.6. What other options were available to [Mrs D] in relation to preparing the Maxolon for [Baby A]?**

Options for [Mrs D] would have included the following:

- To tell [Mr A] to go to another pharmacy for the Maxolon liquid (possibly a significant distance away)
- To place an urgent order for the Maxolon liquid and ask [Mr A] to come back when it arrived (probably 24 hours wait or more)
- To try to contact another pharmacy to arrange an urgent loan of Maxolon liquid (unfeasible given it was Sunday afternoon in a semi-isolated area)
- To powder the tablets herself and create a suspension (a time-consuming task)
- To contact the prescriber and see if the drug was really necessary
- To give divided Maxolon tablets in an approximately equivalent dosage to the Maxolon liquid prescribed.

Of all the options I have listed, [Mrs D] selected the last two.

It is my opinion that [Mrs D's] choice to give crushed tablets was reasonable under the circumstances, and she had few if any reasonable alternative options. However I believe that giving a pre-cut quarter tablet (a slight under-dose) would have been a more appropriate action than giving half a tablet (a larger over-dose).

**3.7. Was the label on the Maxolon container appropriate?**

Various pharmacy rules and regulations, as they apply to this case, say the label must legibly state:

- An accurate description of the contents of the container
- Name of patient
- Name and address of seller
- The dose, and frequency of dose.

The label was inappropriate in the sole aspect that it omitted frequency of dose. This omission is offset by the fact that both the prescriber ([Dr C]) and dispenser ([Mrs D]) verbally discussed the frequency with [Mr A]; nevertheless the label falls short of what would be expected.

**3.8. Were the instructions and information given to [Mr A] appropriate?**
It seems that all of the information given to [Mr A] was appropriate with the exception of the omission of frequency of dose on the label, already mentioned above.

It is possible that language and/or comprehension difficulties may have affected verbal communications with [Mr A], but I cannot speculate on what role (if any) this may have played in this case.

**3.9. What policies should a pharmacy have in place for recording concerns about prescriptions?**
It is unreasonable to expect a pharmacy to have a written policy for every possible eventuality — if this were the case, the procedures manual would be three feet thick and entirely unmanageable. *However*, all pharmacies should be willing and able to rapidly react and develop an appropriate policy as soon as a 'concerning' situation presents itself. The Standard Operating Procedure is a 'living' document which should be updated as necessary.

I suggest that if the situation of concern arises, pharmacy staff should hold an urgent meeting, develop a policy of thorough documentation of all concerns, and make preparations to contact outside organisations if the situation persists.

Indeed, it seems that the staff at [the Pharmacy] were in the process of formulating a response when the error occurred in [Baby A's] Maxolon dispensing. I think [the Pharmacy] did everything reasonable under the circumstances and I do not believe any level-headed pharmacist could fault their actions.

**3.10. At what point should a pharmacy raise concerns directly with the prescriber?**
This is an extremely difficult question as there is no 'clear cut' point at which action must be taken. Ultimately, such a decision must be made on a case-by-case basis, by a pharmacist exercising his or her professional judgement.

I do note that the Pharmacy Council Code of Ethics includes the following statement:

*Code of Ethics 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.'*

On one hand, pharmacists must avoid raising concerns which are perceived as 'frivolous' or 'nuisance' in nature. On the other hand, pharmacists must not hesitate to question unusual or dubious prescribing practices.

A pharmacist should not hesitate to contact a prescriber if they have any query about a specific prescription. This is entirely normal practice.

However, a pharmacist raising more serious concerns — perhaps suggesting a systematic defect in a doctor's prescribing practice — should be very careful before acting.

They should:

- Exercise professional judgement at all times
- Discuss the issue (confidentially) with colleagues and professional associates
- Discuss the case with the Pharmacy Defence Association
- Gather concrete, documented evidence of a problem (eg, copies of prescriptions, letters of complaint, etc).

I must point out a serious psychological impediment — some doctors see themselves as 'above it all' and even tactful questioning of their prescribing habits can be met with overt hostility. I personally recall once questioning an unusual prescription by a specialist. His response was to berate me very unprofessionally and criticise me for wasting his time. I am not at all suggesting that [Dr C] was like this, but point out that this is the environment that pharmacists sometimes work under, and at times it is very much like being 'between a rock and a hard place'.

Conversely, doctors can be very grateful for help in avoiding major departures from good practice.

**3.11. At what point should a pharmacy raise concerns with a third party such as a supervisor, a practice manager or the Medical Council?**
Once again, this is an extremely difficult question to answer, and once again, it is a question of one's professional judgement.

Normally one would raise the issue with the prescriber first; and if that fails, then contact 'higher authorities'. However, in certain rare circumstances one might want to contact a third party in the first instance.

As a pharmacist, the first party I would contact would be the Pharmacy Defence Association (PDA), simply to get their opinion. The PDA is an expert body who provide advice to pharmacists in such situations.

Because even an 'informal concern' shared with such parties will almost certainly elicit a formal, and dare I say very 'heavy' response, a pharmacist must be very certain about their concerns before acting. The statement by [Mrs I] that she 'didn't want to be damning a doctor's career before we had evidence' (page 56 of my notes) is very apt.

**3.12. Are there any aspects of the care provided by [Mrs D] and/or [the Pharmacy] that you consider warrant additional comment?**

I believe my above answers cover all of the salient points raised at this time. Feel free to contact me if you want clarification on anything I have discussed.

**4. Conclusion**

I am very sorry that this error occurred — and I am sure that [the family], [Mrs D] and [Dr C] share my sentiments. I hope that this incident should be seen as a learning experience for all parties, and that constructive measures will be taken to prevent such an error recurring."

## Responses to provisional opinion

*Dr C*

In response to the provisional opinion, Dr C acknowledged her error in prescribing Maxolon to Baby A. However, Dr C reiterated that the expectations placed upon her by the Centre were greater than her experience warranted. Dr C's lawyer, Dr C's lawyer, stated:

> "She [Dr C] did require supervision and assistance, which it is clearly apparent, was not provided at an appropriate level."

Dr C's lawyer reiterated that Dr C was not made aware of any concerns about her practice, other than the discussion about her prescribing (in mid-July 2005). Dr C commented that the Royal New Zealand College of General Practitioners seminar programme provided her with advice and support that was lacking at the Centre.

Dr C's lawyer commented that there was no suggestion that Dr C was not receptive to input from Pharmacy staff about her prescribing, and drew attention to Mrs I's comments on this point (see page 5). Ms L stated:

> "There is also no adequate explanation as to why the pharmacy staff approached [Dr C's] colleagues, rather than [Dr C] directly — particularly where there was no employment relationship."

Dr C's lawyer informed me that Dr C is not currently working and any return to work will be in close consultation with the Medical Council. In addition, the medical assessor appointed by the Health Committee has confirmed that Dr C was suffering from health issues at the time which affected her judgement. Dr C's lawyer reported that Dr C is now well.

*The Medical Centre*

In response to the provisional opinion, practice manager Mr G submitted that criticisms of the supervision provided to Dr C were unjustified. He informed me that the Centre has been involved with medical training for over 25 years, and has a good record. Mr G acknowledged that the quality of the supervision provided may not have been subject to dispute, had it been fully documented. He stated:

> "Please be assured that [the Medical Centre] takes the advice to review its supervision seriously. This is not only to avert a recurrence when we were not able to provide documentary evidence of compliance, but also to match the high standard of external validation of the College's cornerstone accreditation."

Mr G considered the comments by Dr C about Dr E's supervision being interrupted by ill-health to be exaggerated and noted that Dr C did not always attend pre-arranged supervision sessions. He commented:

> "[Dr E] was available for the planned supervision sessions more often than those for which [Dr C] turned up. Alternative supervision was offered and not accepted by [Dr C]. [Dr E] is an effective supervisor and keenly interested in assisting those willing to take up his offers to assist."

Dr K explained that there was a standard protocol for orientation at the Centre, which takes two days. He underwent the orientation in August 2002 (having similarly arrived after only recently living and working in New Zealand) and it was "made clear" to him that it must be completed before any clinical work was commenced.

Dr K expressed disappointment that Dr C did not take steps "to become well acquainted with local practice conditions and best practice guidelines". He said there was "widespread dissatisfaction" with Dr C's attitude of non-participation in staff social functions. Dr K was disappointed that Dr C did not avail herself of the offer of his collegial support, particularly as he was in a similar stage in his career. Dr K also commented that he had found Dr E to be an effective mentor, describing him as intelligent and experienced. Dr K stated:

> "It is highly plausible that my relatively lower needs may have caused our practice team to underestimate the level of need [Dr C] required.
>
> …

As a unit we became well aware of [Dr C's] isolation but it is difficult to talk to someone who won't take her tea and lunch breaks with the staff.

…

[The Medical Centre] … has learnt several painful lessons regarding the closeness of supervision and the importance of engagement with its contractors.

….

I believe with better communication and a more rigidly enforced supervisory process [Dr C] could have succeeded in [the Medical Centre] …"

## 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.*

*RIGHT 5*
*Right to Effective Communication*

*(1) Every consumer has the right to effective communication in a form, language, and manner that enables the consumer to understand the information provided. Where necessary and reasonably practicable, this includes the right to a competent interpreter.*

*RIGHT 6*
*Right to be Fully Informed*

*(1) Every consumer has the right to the information that a reasonable consumer, in that consumer's circumstances, would expect to receive, including —*
*…*

*(b) An explanation of the options available, including an assessment of the expected risks, side effects, benefits, and costs of each option;*

## Other relevant standards

The Pharmacy Council of New Zealand's *Code of Ethics* (2004)

The Pharmacy Council of New Zealand's *Competence Standards* (August 2006)

The Pharmacy Standard Operating Procedures

The Medicines Regulations 1984/143, section 23

## Opinion: Breach — Dr C

*Prescribing of Maxolon*
Under Right 4(1) of the Code of Health and Disability Services Consumers' Rights (the Code) Baby A had the right to receive medical services of an appropriate standard. In my opinion, Dr C breached Right 4(1) by inappropriately prescribing Maxolon (generically known as metoclopramide) for Baby A. The reasons for my decision are set out below.

It is not disputed that Dr C prescribed Baby A 3mls of 5mg/5ml oral solution of Maxolon, three times daily. The prescribing of Maxolon to prevent nausea and vomiting associated with gastroenteritis is not in accordance with Medsafe guidelines and [the] District Health Board guidelines, nor is it accepted practice in New Zealand or the country Dr C trained in. There is also no doubt that the dosage prescribed was more than the level recommended by Medsafe to avoid the well-known risk of acute dystonic reaction.

My expert medical advisor, Dr Jim Vause, explained that any prescribing of metoclopramide to children should be undertaken very carefully, because of the risk of dystonic reaction, and should be limited to circumstances outlined in the Medsafe prescribing datasheet (which is available on Medtech). The datasheet states that Maxolon prescribed to patients under 20 years should be restricted to "severe intractable vomiting of known cause" and vomiting associated with radiotherapy and intolerance to cytotoxic medicines.

Dr Vause noted that the use of anti-emetics (drugs to reduce vomiting) is discouraged under the [the] District Health Board guidelines because of the lack of proven benefits and potential harm. He commented that the approach taken in New Zealand is consistent with accepted practice in the country Dr C was trained in. Overall, Dr Vause considered that there was no reason to prescribe metoclopramide to Baby A.

Dr Vause explained that the dosage of metoclopramide prescribed by Dr C (3mg three times a day) was too high, although the error was subsequently compounded by the dispensing pharmacist by omitting the label instructions. Dr Vause considered that any

prescribing of metoclopramide by Dr C should have been in the realm of 1mg twice a day and it was a "significant oversight" on the part of Dr C not to calculate the dosage to be given to Baby A on the basis of weight, particularly given her paediatric house officer experience. He stated:

> "Should metoclopramide be used in a child, it is critical to use a dose calculated according to body weight. Unfortunately [Dr C] does not appear to have prescribed in this manner. There is no record of [Baby A's] body weight in the notes as presented to me."

Dr C stated that she was not aware that prescribing Maxolon to children was not appropriate at the time she saw Baby A. This is not consistent with the clear evidence that the Pharmacy had brought a previous incident of inappropriate prescribing of Maxolon for a two-year-old child to her attention. It is documented that this was discussed with Dr C by Pharmacy staff on 5 May 2005. Dr C concedes that this discussion occurred, but claims that it was confined to the appropriate dosage.

Dr C stated that the Pharmacy, and the Centre, must bear some responsibility for what occurred by not identifying concern about her prescribing (including the prescribing of Maxolon to children) at an earlier date. If she had been advised of these concerns, she would have immediately changed her practice and Baby A would not have been prescribed Maxolon. Dr C submitted that the Centre had unreasonably high expectations of her, in light of her experience, and did not provide her with appropriate supervision or assistance.

However, as a qualified medical practitioner, Dr C is individually responsible and accountable for her prescribing. Mrs I provided me with information about three previous incidents when inappropriately high dosages of Maxolon had been prescribed for children by Dr C. Dr C prescribed a further high dosage of Maxolon (2mg) for a baby aged two months on 10 May 2005, shortly prior to the prescribing of 3mg Maxolon to Baby A on 29 May 2005.

Dr C failed to become more cautious when prescribing Maxolon to young children despite an inappropriately high prescription of it being specifically discussed with her by Pharmacy staff on 5 May 2005. The fact that she did not know how to access the relevant reference material is certainly no excuse. It is remarkable that it is only since these events that Dr C appreciates the need for greater effort to consult prescribing references. Dr C should have immediately sought advice from her supervisors, or any of her colleagues at the Centre, on how to access the relevant reference material if she did not know how to do so.

Dr C's response that she is now aware of the different prescribing practices between New Zealand and the country she was trained in does not wash in relation to prescribing Maxolon to a young child, since there is no evidence that practice in the country she was trained in is different.

Dr Vause acknowledged that Dr C was relatively inexperienced and considered that her learning relationship with the practice appears to have been "less than desirable" for a variety of reasons. I agree that Dr C did not have an optimal relationship with her supervisors or her colleagues, although the evidence indicates that she did not fully avail herself of the learning opportunities open to her.

In any event, I share Dr Vause's view that "basic judgement problems" rather than inexperience were the source of her difficulties. Dr Vause concluded:

> "I find that [Dr C] failed to provide an adequate standard of care to [Baby A], the use of metoclopramide in a child of this age being regarded with moderate disapproval in general practice after due consideration of [Dr C's] lack of general practice experience."

I also note the following statement of the Medical Practitioners Disciplinary Tribunal in *Director of Proceedings v Walford* (Decision Med/01/76D, www.mpdt.org.nz):[8]

> "It is a medical practitioner's responsibility to determine that a prescription is safe."

In my view, notwithstanding any deficiencies in her orientation and supervision at the Centre (discussed below), Dr C should have known that it was not appropriate to prescribe Maxolon to Baby A. Overall, I consider that Dr C made a serious error in judgement in prescribing 3ml of 5mg/5ml Maxolon solution to a six-month-old baby. Dr C compounded her mistake by failing to calculate the dosage carefully with reference to Baby A's bodyweight. While this error was subsequently further compounded by the lack of instructions on the pharmacy label, there is no doubt that Dr C prescribed an inappropriate dosage of Maxolon to Baby A.

Dr C's error must also be viewed in light of her paediatric experience in her own country. Although she was inexperienced in general practice, she had previous experience as a senior house officer at a children's hospital in that country. I accept Dr Vause's advice that this experience should have involved common conditions such as gastroenteritis and the use, or non-use, of metoclopramide. The evidence indicates that Dr C consistently failed to learn from her prescribing errors.

Dr C had a commensurate responsibility to participate and engage in the supervisory process, and to be honest and up-front with her supervisors about any concerns that had been raised with her about her practice. The prescribing of Maxolon to a young child had been discussed with her previously by Pharmacy staff, and other concerns

[8] Dr Walford was found guilty of professional misconduct for prescribing adult strength codeine to a baby (see also 99HDC01986, www.hdc.org.nz).

about her prescribing had been drawn to her attention. Dr C also had a personal responsibility to ensure she could access the relevant information to check the safety of her prescribing, and to endeavour to address concerns about her prescribing through the supervisory process. In omitting to take these basic steps, Dr C failed to fulfil her responsibilities as a medical practitioner and placed her patient's safety at risk.

In these circumstances, Dr C breached Right 4(1) of the Code.

*Diagnoses and prescribing*
Dr C assessed Baby A on 29 May 2005. She elicited a history of vomiting and diarrhoea, with fever and irritability. Dr C explained that Baby A had mild eczema with a facial rash, white papules in her mouth, and supra-pubic tenderness. Dr C diagnosed a urinary tract infection, impetigo, oral thrush and gastroenteritis and considered that the urinary tract infection was "probably responsible" for Baby A's symptoms.

Dr Vause noted that the only indication of a possible urinary tract infection in Baby A was supra-pubic tenderness. The other clinical features (frequency of urine and pain on passing urine) are difficult to ascertain in a baby. However, obtaining a urine sample is an essential step in confirming a diagnosis (although obtaining a sample from a baby can be difficult), and there is no record in the clinical notes that Dr C gave consideration to a urine specimen collection.

Dr C informed me that she told Mr and Mrs A to obtain a collection bag from a medical laboratory, but there is no documentation to show this occurred, and the laboratory was not open that day. Dr Vause stated:

> "In summary [Dr C's] actions in diagnosing a UTI in [Baby A] is possibly acceptable, however her prescribing of an oral antibiotic without further effort to obtain a urine sample is unacceptable for a general practitioner."

Dr Vause considered that Dr C's diagnosis of impetigo was incorrect. Her description was at variance with the symptoms of impetigo, and there was no suggestion of impetigo in the [the hospital] medical records. He stated:

> "[Dr C's] description of diffuse rash and itch goes against impetigo as a diagnosis.
>
> …
>
> If [Baby A's] diffuse rash had been due to her fever it is possible for this to have settled by the time of her admission to [hospital]. Impetigo would not settle in that time."

Dr Vause noted that Dr C did not document the objective features in relation to her diagnosis of oral thrush. In addition, no signs of oral thrush were detected by the hospital house surgeon, despite an apparently thorough mouth examination. Overall, Dr Vause doubted that Dr C's diagnosis of oral thrush was correct. He stated:

> "One would normally expect signs of oral thrush to still be present 8 hours after [Dr C] had made the diagnosis of oral thrush. Furthermore the hospital did not give any medications for this."

Dr Vause considered that Dr C's diagnosis of gastroenteritis was correct but noted that she omitted to record any objective clinical signs or establish Baby A's state of hydration — which are important components of assessment in this type of presentation. In addition, there is no record of her making a formal diagnosis.

Dr Vause was also concerned that Dr C formulated four different diagnoses in circumstances where she should have "only made one or two diagnoses". He stated:

> "The most obvious diagnosis was gastroenteritis, a diagnosis also made by the paediatric department at [the hospital]. [Dr C's] other diagnoses were not made by the hospital doctors.
>
> …
>
> While a urinary tract infection may well cause vomiting, as a disease it does not 'partially account' for gastroenteritis, impetigo or oral thrush. [Dr C's] connection between these different infections is a concern, for each is normally caused in a general practice setting, by different organisms and are not related, except possibly in a person with suppressed immunity which clearly [Baby A] did not have."

Dr Vause noted that Dr C prescribed three different antibiotics for Baby A (amoxycillin for her urinary tract infection, and flucloxacillin with Fusidin cream for impetigo). He commented that the prescribing of multiple antibiotics is "rare and generally frowned on", unless there is a clear indication that two antibiotics may be necessary. In addition, the prescribing of amoxycillin in isolation for a urinary tract infection is inappropriate because the organisms usually responsible for UTI are often resistant to amoxycillin. Dr Vause considered the prescribing of flucloxacillin for impetigo appropriate (although the diagnosis was apparently wrong), but Fusidin (although not wrong for impetigo) was a needless duplication. The high number of medications prescribed increased the risk of side effects, both individually and in combination. Dr Vause stated:

> "In addition to the antibiotics, [Dr C] prescribed three other medications namely ibuprofen suspension, nystatin drops and Maxolon oral solution, giving a total of five to be administered by mouth to a child who was vomiting.
>
> The fact that [Baby A's] parents administered a second dose of metoclopramide following their observation that their daughter had vomited back the first dose of this drug exemplifies the problem of administering any oral medications in such circumstance. The only oral medication that would be recommended in a vomiting child would be oral rehydration fluid should dehydration be a concern."

*Conclusion*
Dr Vause has identified a number of concerns in relation to Dr C's care of Baby A — quite apart from the prescribing of Maxolon. These include omitting to ensure a urine test was undertaken to confirm the presence of a urinary tract infection, incorrectly diagnosing impetigo and oral thrush, and erring in making a connection between these different infections. Dr C's documentation of objective clinical signs (or formal diagnosis) was also lacking. While the diagnosis of gastroenteritis was correct, there is no indication that Dr C undertook any steps to establish the level of Baby A's hydration. Furthermore, Dr Vause was critical of Dr C's combination of prescribing for Baby A (including three different antibiotics). Dr C prescribed a total of five oral medications for a baby, in circumstances where the only oral medication recommended would be rehydration fluid to counter dehydration.

I consider that the errors made by Dr C are mitigated only to a minor degree by her relative inexperience. Her medical care for Baby A was woeful. Although Dr C expressed deep regret for any distress the family suffered from her misadventure, her responses to my investigation suggest a lack of insight into the problems of her practice and her responsibilities as a health practitioner. Clearly, Dr C breached Right 4(1) of the Code in not providing medical services with reasonable skill and care to Baby A.

*Information about Maxolon*
Right 6(1)(b) of the Code stipulates that a patient has the right to information about any expected risks or side effects. Right 5(1) of the Code states that a patient has the right to effective communication — in a form, language, and manner that enables the patient to understand the information provided. Therefore, Dr C was responsible for ensuring that Mr and Mrs A understood the risk of the side effects associated with Maxolon, such as a dystonic reaction. As noted by Dr Vause:

> "This would be part of the normal provision of information on the harms and benefits of this medication, an important issue given this well known potential of metoclopramide to produce dystonia and the general disapproval of its prescribing in children."

There is no documentation of any such discussion, although Dr C stated that she gave information about the risk of "writhing and restlessness" and was satisfied that Baby A's parents understood her instructions. Mr A does not recall any discussion in relation to any risks associated with Maxolon.

Dr Vause acknowledged the potential for misunderstanding due to language and cultural differences:

> "It is difficult to evaluate a communication issue such as this but on the balance I would suspect parental understanding based on language and cultural difference was the main source of the problem. Given [Dr C's] short experience of the NZ medical care system and general practice, I would not expect her to be able to

> readily prevent miscommunication in what can frequently prove to be a very difficult area of general practice."

Mr and Mrs A's actions in providing Baby A with additional Maxolon clearly demonstrate that they did not understand the risk of serious side effects. I acknowledge that there may have been some communication difficulties between Dr C and Mr and Mrs A. However, Dr C had a responsibility to clearly communicate to Mr and Mrs A the importance of not providing any additional Maxolon.

I doubt that Dr C was in a position to properly inform Mr and Mrs A of the associated risks, when she herself was unaware that it was not appropriate to prescribe Maxolon in these circumstances and had prescribed well above the recommended dosage. However, her apparent lack of knowledge is no excuse. In all the circumstances, I can see no evidence to suggest that Mr and Mrs A were adequately warned of the risks associated with Maxolon.

By her communication failures, Dr C also breached Rights 5(1) and 6(1)(b) of the Code.

## No Breach — The Medical Centre

*Vicarious liability*
Under section 72 of the Health and Disability Commissioner Act 1994 (the Act), an employing authority may be vicariously liable for acts or omissions by an employee.

Dr C breached Right 4(1) of the Code in relation to her care of Baby A, and Rights 5(1) and 6(1) in relation to her communication and information disclosure. Her contract with the Medical Centre (the Centre) clearly states that she is an independent contractor, rather than an employee. Vicarious liability arises under section 72(3) if the acts or omissions of an agent took place with the express or implied authority of the employing authority. Having considered the outward appearance of Dr C's relationship with the Centre to her patients, I am satisfied that the Centre allowed her to appear as their agent. Consequently, I consider that Dr C was an agent of the Centre for the purposes of section 72(3) of the Act and was clearly acting within the scope of her authority when she provided medical services to Baby A. As noted by the Court of Appeal:[9]

[9] *Savage v Taylor* (CA 103/95, 19 March 1996, Richardson P)

> "The legal principles relating to ostensible or apparent agency are well settled. A person who by words or conduct has allowed another to appear to a third party to be his or her agent cannot afterwards repudiate that agency."

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 acts or omissions leading to an employee's breach of the Code. The defence in section 72(5) is also available in relation to the acts or omissions of agents.

Clearly, the Centre had an obligation to orientate and supervise Dr C, and to take appropriate action after the concerns about Dr C's prescribing became evident.

Dr C was an inexperienced locum in general practice and believes that she was not adequately supervised (or oriented) by the Centre. She initially received supervision from Dr E. Dr C considered that Dr E was generally disinterested, and often unwell and absent.

The responsibility for supervision of Dr C was passed to Dr F in April, and shared with Drs J and K. Dr C acknowledged that Dr F provided more structured supervision, but stated that her prescribing practice was not raised as an issue before the incident with Baby A on 29 May 2005 — despite there apparently being concerns about her prescribing, including the prescribing of Maxolon to children. (The Pharmacy intervention report shows that Pharmacy staff contacted Dr C earlier in May to discuss a 5mg Maxolon prescription for a two-year-old, prior to the prescribing of Maxolon to Baby A. However, there is no information to suggest that the Centre knew of these concerns.)

Dr C's criticisms of her supervision are strongly disputed by the Centre. The practice manager, Mr G, advised that Dr C underwent a comprehensive orientation. He commented that Dr E was an effective and experienced supervisor. Mr G noted that Dr C, on occasion, did not attend pre-arranged supervision sessions. Her comments about Dr E's ill-health were exaggerated.

Dr E himself acknowledged that contact was not as regular as planned, but stated that he was not approached by Dr C as often as he would have expected. Dr E stated:

> "In this practice we have had a long experience of providing supervision and support for junior doctors … we have found them keen to learn and identify their learning needs: we have not found this to the expected extent in [Dr C]."

Dr F and Dr K both considered that Dr C was personally and professionally isolated at the Centre. Dr F received feedback from nursing staff that Dr C was "reluctant to ask for assistance" from colleagues.

Dr C confirmed that she attended a supervision session in mid-July to discuss concerns about the level of her prescribing, but stated that the issue of prescribing of Maxolon to children was not specifically discussed. In contrast, both Dr F and Dr E stated (after

Mrs I approached the Centre with concerns about Dr C's prescribing on 26 June) that the prescribing of Maxolon was discussed with Dr C at the next available opportunity (in July), although the discussion was not documented.

The information provided by Mrs I confirms that Dr E spoke to Dr C on 8 July 2005 about her prescribing practice (with particular reference to the prescribing of high quantities of diazepam and codeine phosphate). I also note that Dr C's prescribing of Maxolon to children was clearly a concern of Pharmacy staff. I am not able to determine whether concerns about the prescribing of Maxolon were specifically discussed with Dr C by Drs F and E in early July (although I am inclined to the view that it was).

Dr C claims that she did not learn that the prescribing of Maxolon to children with vomiting and nausea was inappropriate until mid-August, when she attended a seminar course. She claims that the prescribing of Maxolon (and Stemetil) to Baby A was not discussed with Dr E (or Dr F) until August 2005. (This discussion is documented as occurring on 23 August 2005.) Dr C stated:

> "I am horrified that this situation was left until the stage where I have prescribed Maxolon to babies on a number of occasions."

Dr Vause advised that the documentation provided by the Centre in relation to Dr C's supervision does not meet the Medical Council of New Zealand guidelines for supervision. (Mr G acknowledges that the quality of supervision would not be under such dispute, had it been fully documented.) However, Dr Vause also noted that there may also have been non-scheduled meetings that were not documented. In addition, Dr C would not have had the same requirements as a "raw recruit" and also had some shared responsibility to identify her own learning needs. The Centre had previous experience in providing supervision to trainee general practitioners. As noted by Dr Vause:

> "As [Dr C] had been practising in NZ for 6 months, the [practice] would be correct in presuming she had been orientated to the NZ health system and their duty would be to provide orientation into general practice.
>
> …
>
> [Dr C's] account identifies inadequate orientation while [Dr E's] would be an appropriate practice orientation.
>
> …
>
> There is some dissonance in the accounts of the learner trainer interactions between [Dr C] and [the Medical Centre]. However it does appear that [Dr C] did not have a close learning relationship with her supervisors and there is some admission on her part that this may have been sourced with herself. Equally her supervisor [Dr E]

had to transfer this supervision to [Dr F] because of his ill health with his admission that the 'contact was not as regular as was planned'."

It is difficult to determine whether Dr C's supervision was adequate. There was a shared responsibility on Dr C's part to identify her own learning needs, and to participate and engage in the supervisory process. It certainly appears that Dr C was relatively isolated, both professionally and personally, from her colleagues at the Centre. Both parties ultimately bear a degree of responsibility for this. However, I have been left with the distinct impression that Dr C was reluctant to approach her supervisors and colleagues with concerns as they arose.

It would have been prudent for the Centre to have placed more emphasis on ensuring there were appropriate mechanisms in place to support Dr C as a locum in general practice, particularly after it became apparent that she was becoming professionally isolated, and concerns about her prescribing arose. The concerns about the level of Dr C's prescribing were not detected through the supervisory process, but were made known through the actions of the Pharmacy in contacting the Centre. Clearly, with the benefit of hindsight, Dr C required a closer level of supervision.

Dr K acknowledges that the Centre may have underestimated Dr C's training needs. He stated that the Centre has learnt "painful lessons regarding the closeness of supervision and the importance of engagement with its contractors".

However, I consider that the Centre took appropriate action when concerns about Dr C's prescribing became known to it via the local Pharmacy. Dr C already had a significant base level of medical experience (including in paediatrics) and had been practising in New Zealand for six months. She omitted to draw the individual concerns about her prescribing on the part of the Pharmacy to the attention of her supervisors. In these circumstances, I consider that the Centre acted reasonably in relying on Dr C's ability to prescribe responsibly and safely. I do not consider that the failure to identify concerns about Dr C's prescribing prior to 29 May 2005 represents a failure of the Centre's supervisory process.

In conclusion, I consider that Dr C's errors were primarily failures in her individual clinical practice and the Centre is not vicariously liable for Dr C's breaches of the Code.

I am advised that the Centre has consistently performed in the top group of practices within a professional network in the region, and am confident that salutary lessons will be learnt from this case. I recommend that the Centre review its procedures in relation to orientation and supervision of trainee general practitioners, to ensure the requirements of the Medical Council are met, and to avoid a recurrence.

## Breach — [Mrs D]

Under Right 4(2) of the Code of Health and Disability Services Consumers' Rights (the Code), Baby A had the right to have pharmacy services provided in compliance with legal, professional and ethical standards. The standards that apply in this case are the Pharmacy Council of New Zealand's *Code of Ethics* (2004) and *Competence Standards* (August 2006).

Under principle 2.6 of the *Code of Ethics*, and as a matter of good practice, prescriptions must be dispensed correctly. Principle 2.6 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."

Three errors occurred in relation to Baby A's prescription on 29 May 2005. First, Maxolon was incorrectly prescribed by Dr C. Secondly, Baby A was dispensed 5mg of Maxolon per dose by Mrs D instead of the prescribed amount of 3mg per dose. Thirdly, the label prepared by Mrs D for Maxolon did not mention the frequency of dosage.

It is not disputed that, on receipt of the Maxolon prescription, Mrs D contacted Dr C to clarify whether the Maxolon was required that day — as there was no Maxolon syrup in stock. Mrs D was advised by Dr C that the Maxolon was required that day, and could be issued in tablet form. There was no discussion of the suitability of giving Maxolon to a baby.

My expert pharmacy advisor, Mr John Fraser, considered that it was reasonable in the circumstances for Mrs D to dispense Maxolon following her discussion with Dr C, although the appropriateness of Maxolon was not specifically discussed. He stated:

> "[Mrs D] did telephone the prescriber, [Dr C], to question whether the medicine was urgent. Although the prescription itself was not explicitly questioned, I believe that by making contact and verbally confirming the prescription was needed, [Mrs D] did everything that would be reasonably expected of her.
>
> …
>
> [Baby A's] prescription was complete, legal and authentic; and the pharmacist involved discussed the prescription with the prescriber. There is little more I would expect from any pharmacist in the same situation."

Mr Fraser considered that Mrs D fulfilled her obligations to ascertain the suitability of the medication for Baby A (in accordance with principle 2.6 of the *Code of Ethics*) by contacting Dr C — although she did not document this discussion.

Mr Fraser also considered that it was reasonable for Mrs D to elect to dispense the medication in tablet form, to be crushed by Mr A prior to administration.

Mrs D was presented with a prescription for 3ml of 5mg/5ml oral Maxolon solution. Accordingly, Baby A had been prescribed a dosage of 3mg of Maxolon (because there is 1mg of Maxolon per 1m of solution). Mrs D explained:

> "All I can think is that I calculated the dose on the liquid being 5mg/5ml, and then transposed the 10mg to a 5mg tablet in my mind this would have made 2 and a half mg — so half a tablet was the closest I could get to the prescribed dose."

Mr Fraser stated:

> "While [Baby A] was prescribed 3mg Maxolon, three times daily, she was actually dispensed 5mg Maxolon, three times daily. It does not appear that [Dr C] confirmed and approved the increase in dose. However, I note that half a 10mg tablet (5mg per dose) is probably the closest reasonable dose for dividing a tablet. A better alternative would be to dispense a quarter tablet (2.5mg per dose) — but this might be too difficult to divide without crumbling.
>
> Nevertheless, on balance it does seem that [Mrs D] made a mistake, and she admits that this was 'not accurate or adequate' … This error exacerbated an already erroneous prescription by giving too high a dosage.
>
> On balance, I feel this error, while very serious, has some 'mitigating' factors and as such would be viewed with slight disapproval by pharmacy peers."

Mrs D explained that she had to replace the label she had prepared for the Maxolon solution. However, she omitted to include the frequency (three times daily) on the new label — and did not notice her error. Mrs D made no record of having checked the Maxolon dispensing on the prescription.

Mrs D stated that she instructed Mr A on how to use the medications and "thinks" that she told him "only to give a few doses" of Maxolon.

Mr Fraser advised:

> "[Mrs D] also departed from an appropriate standard of care in failing to note the frequency of dosage on the Maxolon label; although this is offset somewhat by the fact that [Mrs D] discussed the use of the medicine with [Baby A's] father.
>
> However, lack of frequency information may have contributed to the fact that [Baby A] was given another dose of Maxolon only a couple of hours after the first dose, as her parents believed she vomited the first dose back up. This was probably too soon for a second dose; the original prescription was to take a dose 'three times daily' or about once every six to eight hours.

> On balance, I believe that this error was also very serious; but again it is mitigated somewhat by [Mrs D's] verbal explanation to [Mr A]. Nevertheless, I believe that this departure from standard in labelling would be regarded by [Mrs D's] pharmacist peers with slight disapproval."

Element 6.7.2 of the Council's *Competence Standards* places a duty on a pharmacist to produce comprehensible and complete labels for medicines. Mr Fraser noted that this standard was not achieved. Mr Fraser also noted that labelling of medications for frequency of use is required under the Medicines Regulations 1984, clause 23.

Mrs D confirmed that she provided Mr A with instructions for the medications, and she had no reason to suspect that Mr A did not comprehend her instructions. Mr Fraser commented that Mrs D's instructions appeared to be appropriate.

Overall, Mr Fraser stated:

> "I believe this standard [principle 2.6] was only partially complied with. The pharmacist, [Mrs D], did implicitly verify the authenticity and suitability of the Maxolon prescription by telephoning the prescriber to query whether the drug was needed. However, [Mrs D] failed to dispense the prescription correctly, in that 5mg per dose was dispensed instead of 3mg per dose. Further, she failed to adequately label the medicine, by omitting frequency of dose."

Mr Fraser also noted that Mrs D did not comply with Element 1.1.5 of the *Competency Standards*, which requires a pharmacist to work accurately.

*Conclusion*

Ultimate responsibility for the prescribing of Maxolon lay with Dr C, who was unaware that prescribing Maxolon to a baby was inappropriate. I consider it likely that, even if her prescribing had been specifically queried by Mrs D, Dr C would have confirmed the prescription.

I am not convinced, however, that Mrs D complied with her professional responsibility to assess the suitability of Maxolon for a six-month-old baby. Pharmacists are independent health professionals, and are well placed to consider the suitability of prescribing common, powerful medications to children.

The Disciplinary Committee of the Pharmaceutical Society in *Director of Proceedings v Sandlant* (13 September 2001) considered that a pharmacist breached the duty of

care he owed to his patient by dispensing an adult dosage of codeine to a baby (dispensed according to the prescription).[10]

Commentators have remarked on the level of responsibility pharmacists have for the medicines they dispense. Professor John Shaw, Head of the School of Pharmacy, Auckland University, has stated:[11]

> "[P]harmacists of the future will be more than 'dispensors' of medicine, rather they would fulfil a societal role 'managers' of medicine in ensuring optimum outcomes for individual patients."

Dr Fiona McCrimmon, formerly senior lecturer in healthcare law and ethics, Otago University, has stated:[12]

> "[P]harmacists increasingly act in the role of guardians and not mere vendors of medicines, providing products and services on the basis of the knowledge they have and the advice they can provide … If pharmacy stands on a platform of being medicine experts they also have to take responsibility for the obligations of that claimed position."

Mrs D realised that Dr C has prescribed an "extreme" combination of medications. The fact that Mrs D knew it was "common practice" for Dr C to prescribe Maxolon for young children does not excuse her failure to specifically query the prescription for Baby A. I accept Mr Fraser's view that pharmacists cannot be expected to "baby-sit" doctors, and I appreciate Mrs I's point that they cannot be expected to be "pharmacops" for "every slight concern" about a prescription. Nonetheless, pharmacists can be expected to specifically query unusual prescriptions of common medications known to have serious side effects. It is not sufficient simply to query the dosage. In my view this is responsible, rather than simply "ideal" pharmacy practice.

Mrs D was aware that Baby A required a 3mg dosage, but apparently calculated this with reference to a 5mg tablet — which would have provided a dosage of 2.5mg (slightly lower then the dosage prescribed). Unfortunately, she dispensed a 10mg tablet — which provided a 5mg dosage (2mg more than the dosage prescribed). The recommended dosage of Maxolon for a child under one (1mg twice daily) had already been exceeded by the prescribing of a 3mg dosage. Dr C's error was further compounded by Mrs D's mistake. Mrs D then omitted to include the frequency on the

[10] The Disciplinary Committee noted that the date of the patient's birth was clearly recorded on the prescription and concluded that the pharmacist should not have dispensed the medication at a strength normally reserved for adults (see also 99HDC01986, www.hdc.org.nz).
[11] *Pharmacy Today*, December 2000, 24.
[12] Medico-Legal Conference, Wellington, February 2001.

typed label, which is clearly an important requirement of correct dispensing and contributed to Baby A's overdose.

Mrs D's explanation that she was "confused" (apparently due to having to convert the prescription from a solution form into a tablet form) and was working by herself (although without any pressure from other dispensing requirements) is an inadequate excuse. Mrs D did not sign the Maxolon dispensing as checked — as required under the Pharmacy's Standard Operating Procedures. Mrs D should have checked the label against the prescription to ensure that it correctly stated the name of the medication, the name of the patient, and the quantity and directions for use of the medication.

I also am not convinced that Mrs D gave Mr A adequate instructions — he certainly did not understand the need for caution when administering additional Maxolon.

Mrs D failed to comply with Principle 2.6 of the *Code of Ethics*, elements 1.1.5 and 6.7.2 of the *Competency Standards*, and the Pharmacy's Standard Operating Procedures (SOPs), all of which required her to ensure that Baby A's prescription was correctly dispensed. Mrs D also failed to record her discussion with Dr C (which was particularly important given the known concerns about Dr C), as required by the SOPs. I also note that omitting to record the frequency on the label was in contravention of the 1984 Medicines Regulations.

In summary, notwithstanding some extenuating circumstances, Mrs D failed to comply with legal, professional and ethical standards, and therefore breached Right 4(2) of the Code.

## No Breach — the Pharmacy

*Vicarious liability*
Under section 72 of the Health and Disability Commissioner Act 1994 (the Act), an employing authority may be vicariously liable for acts or omissions by an employee.

Mrs D breached Right 4(2) of the Code in relation to her dispensing of Maxolon to Baby A. Mrs D is an employee of the Pharmacy. 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 acts or omissions leading to an employee's breach of the Code.

I am satisfied that the Pharmacy had taken reasonable steps to discharge its liability. The Pharmacy SOPs were perfectly satisfactory. The relevant procedures have been appropriately reviewed. The dispensing error in this case primarily resulted from Mrs D's error and her failure to follow the correct procedure. In these circumstances, the Pharmacy is not vicariously liable for Mrs D's breaches of the Code.

## Other comments

*Pharmacists raising concerns about prescribing*
Dr C has expressed concern that the Pharmacy did not contact her, or her employer, at an earlier date with concerns about her dispensing. The Pharmacy contacted Dr C directly to discuss individual prescriptions as concerns arose, and has provided a record of those interventions. Mrs I advised that the Pharmacy had become concerned about Dr C's prescribing and was "building the portfolio".

My pharmacist advisor, Mr John Fraser, commented that it is a difficult professional judgement for a pharmacist to decide when to draw attention to concerns about a doctor's prescribing. A pharmacist must be "very certain" of his or her concerns before acting — particularly when involving a third party. He stated:

> "Indeed, it seems that the staff at [the Pharmacy] were in the process of formulating a response [to their growing concerns about Dr C's prescribing] when the error occurred in [Baby A's] Maxolon dispensing. I think [the Pharmacy] did everything reasonable under the circumstances and I do not believe any level-headed pharmacist could fault their actions."

I essentially agree with Mr Fraser's comments — although I think that being "very certain" is an unduly high standard of the concern needed before a pharmacist has an ethical duty to act — and do not consider it is appropriate to apportion any blame for Dr C's prescribing error to the pharmacy. In my time as Commissioner, I have seen all too many instances of doctors (and their lawyers) condemning other clinicians for raising concerns about the doctor's practice. It is not surprising that a pharmacist would hesitate before approaching a local general practitioner's supervisor with concerns about the doctor's prescribing practices.

Dr C's lawyer expressed concern that the Pharmacy approached the Centre rather than Dr C directly, particularly when "there was no employment relationship", and given Mrs I's comment that Dr C was receptive to input from the Pharmacy as individual queries arose. However, Dr C was a relatively inexperienced general practitioner, working under supervision at the Centre. In the circumstances, I consider it was entirely appropriate for the Pharmacy to discuss their broader concerns with Dr C's supervisors.

## Actions taken

*Dr C*
The Medical Council of New Zealand (the Council) concluded that there were sufficient concerns about Dr C's practice to undertake a review of her competence to practise medicine. Subsequently, Dr C returned to her home country and the Council

decided to take no further action in relation to Dr C. The Council has advised that if Dr C returns to practice in New Zealand her competence will be reviewed. This report indicates that significant retraining and support is needed before she returns to practice.

Dr C has provided a letter of apology addressed to Mr and Mrs A. She has also reviewed her practice and "thought long and hard" about these events.

Dr C advised me that the personal health issues that affected her judgement at the time have resolved. Dr C is now living in New Zealand but is not currently working. She accepts that any return to work will need to be undertaken in close consultation with the Medical Council, and that the nature and location of her practice will inevitably be discussed.

*The Pharmacy*
Mrs I, joint owner/manager of the Pharmacy, reviewed pharmacy procedures following this incident. An additional step has been introduced whereby the checking pharmacist circles the date of birth of a child under 12, to alert the pharmacist to any possible overdose prescribing. In addition, the updated computer system now allows staff to fully record interventions.

*Mrs D*
Mrs D has reviewed and adapted her dispensing practice, undertaken further education in prevention of dispensing errors, and provided Mr and Mrs A with a written apology for her breach of the Code.

## Recommendations

*Dr C*
I recommend that Dr C provide a copy of this report to any future employer or any medical centre or agency with whom she contracts, if she returns to medical practice.

*The Medical Centre*
I recommend that the Medical Centre review its procedures in relation to orientation and supervision of trainee medical practitioners to ensure the requirements of the Medical Council are met.

## Follow-up actions

- A copy of my report will be sent to the Medical Council of New Zealand, the Medical Council in Dr C's home country, and the Pharmacy Council of New Zealand.

- A copy of my report with details identifying the parties removed, except the name of Dr C, will be sent to the Royal New Zealand College of General Practitioners.

- A copy of my report with details identifying the parties removed, except the name of Mrs D, will be sent to the Pharmaceutical Society of New Zealand.

- A copy of my report, with details identifying the parties removed, will be forwarded to the Quality Use of Medicines Group of District Health Boards New Zealand and placed on the Health and Disability Commissioner website, www.hdc.org.nz, for educational purposes.

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## Non-referral to Director of Proceedings

When a general practitioner breaches the Code of Health and Disability Services Consumers' Rights, and in doing so has provided "woeful" care, a referral to the Director of Proceedings may well be indicated. Accordingly, I specifically invited further comment on the matter.

Dr C's lawyer submitted:

> "A referral to the Director of Proceedings for consideration of disciplinary proceedings is in all the circumstances unduly punitive. It cannot be in the public interest to expend further resources on this matter, where [Dr C] has learned as much as can be taken from it. The public interest is also clearly protected by the ongoing involvement of the Medical Council. I note your concerns that [Dr C's] response to the investigation illustrates a lack of insight to her practice and responsibilities as a health practitioner. There can be no question but that [Dr C] has learned from this experience, and is acutely aware of the need to ensure a working knowledge of available resources and to refer to the same, and the need to actively engage with colleagues on a professional level (the comments about a failure to socialise are irrelevant in my view).
>
> In my view it is appropriate to take into account the length of time this investigation has taken and the ramifications it has already had for [Dr C]. It is no small matter that she has been unable to practice from over one year, and in reality, her return to practice (should she go down that path) will be anything but simple. It cannot be in the public interest to destroy the career of a doctor

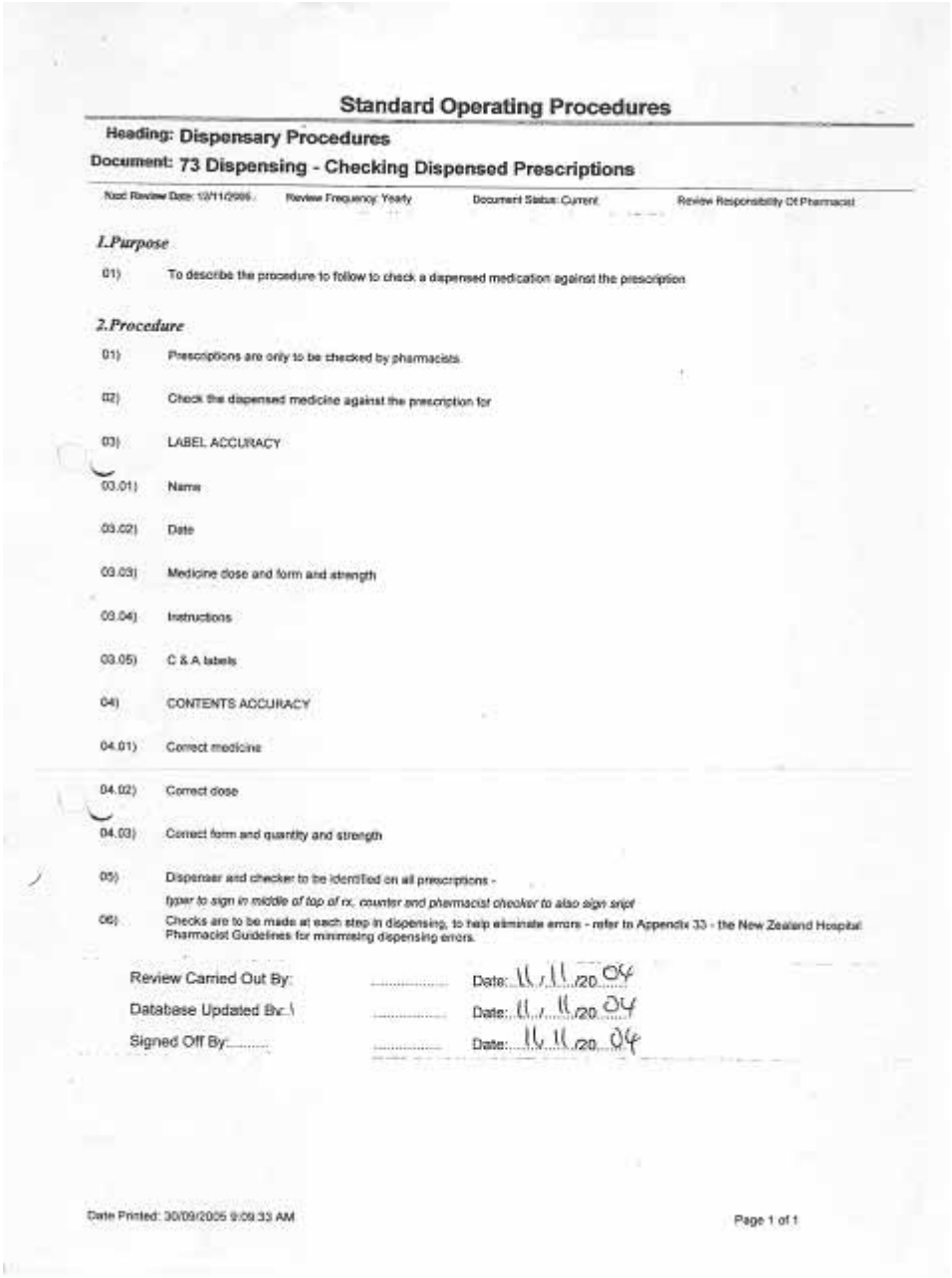
> and I do not hesitate to state that in this particular case, this is what any disciplinary proceedings will likely achieve regardless of the outcome.
>
> The fairly extensive publication that is intended for the final opinion also provides protection for the public.
>
> A further mitigating factor against referral for disciplinary proceedings is the role played by [Dr C's] health. She has not made much of this, having from the outset accepted responsibility for acting in error in relation to [Baby A]. For obvious reasons — not least that the report exposes [Dr C] to much criticism as it is in the public arena — it is not my intention that [Dr C's] medical records be made available. However, it is important to note that independent medical advice from the physician appointed by the Health Committee of the Medical Council to treat [Dr C's] [health problem] confirms that health issues played a significant part in her performance as a general practitioner."[13]

I also sought Mr A's view as I am obliged to consider the wishes of the complainant when considering whether to refer a matter to the Director of Proceedings. Mr A advised me that he does not support a referral to the Director of Proceedings. He stated that Dr C has apologised and has been "great" to his family. In addition, Baby A has not suffered any long-term consequences as a result of the Maxolon overdose.

In light of Mr A's view, Dr C's lawyer submission, and the requirement for Dr C to undergo a competence review if she decides to return to practice, I have concluded that the public interest (including the interest in accountability of health practitioners via disciplinary proceedings) does not require a referral of Dr C to the Director of Proceedings.

[13] At the time of these events, [Dr C] apparently suffered from an undiagnosed illness, which has now been successfully treated by surgery.

# Appendix 1



**Standard Operating Procedures**

**Heading: Dispensary Procedures**

**Document: 73 Dispensing - Checking Dispensed Prescriptions**

Next Review Date: 13/11/2006 Review Frequency: Yearly Document Status: Current Review Responsibility: Pharmacist

*1.Purpose*

01) To describe the procedure to follow to check a dispensed medication against the prescription

*2.Procedure*

01) Prescriptions are only to be checked by pharmacists

02) Check the dispensed medicine against the prescription for

03) LABEL ACCURACY

03.01) Name

03.02) Date

03.03) Medicine dose and form and strength

03.04) Instructions

03.05) C & A labels

04) CONTENTS ACCURACY

04.01) Correct medicine

04.02) Correct dose

04.03) Correct form and quantity and strength

05) Dispenser and checker to be identified on all prescriptions -
*typer to sign in middle of top of rx, counter and pharmacist checker to also sign slip*

06) Checks are to be made at each step in dispensing, to help eliminate errors - refer to Appendix 33 - the New Zealand Hospital Pharmacist Guidelines for minimising dispensing errors.

Review Carried Out By: ..... Date: 11/11/2004

Database Updated By: ..... Date: 11/11/2004

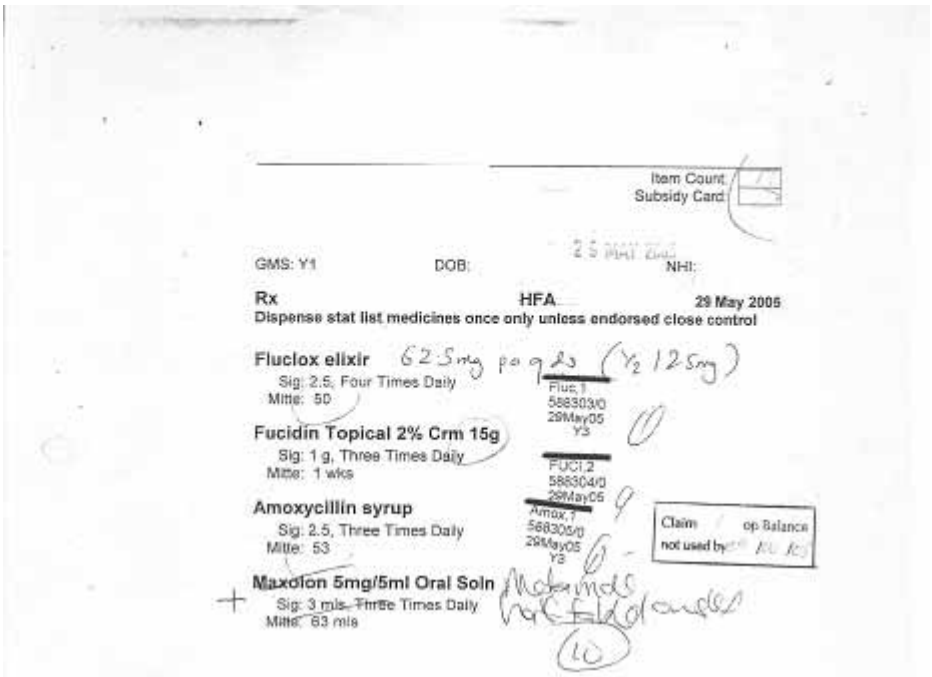
Signed Off By: ..... Date: 11/11/2004

Date Printed: 30/09/2005 9:09:33 AM Page 1 of 1



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

# Appendix 2



Item Count
Subsidy Card

GMS: Y1 DOB: NHI:

**Rx** **HFA** **29 May 2005**

**Dispense stat list medicines once only unless endorsed close control**

**Fluclox elixir** 62.5mg po qds (½ 125mg)
Sig: 2.5, Four Times Daily
Mitte: 50
Fluc.1
588303/0
29May05
Y3

**Fucidin Topical 2% Crm 15g**
Sig: 1 g, Three Times Daily
Mitte: 1 wks
FUCI.2
588304/0
29May05

**Amoxycillin syrup**
Sig: 2.5, Three Times Daily
Mitte: 53
Amox.1
588305/0
29May05
Y3

Claim op Balance
not used by

**Maxolon 5mg/5ml Oral Soln**
Sig: 3 mls Three Times Daily
Mitte: 63 mls



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