
General Practitioner, Dr C / Pharmacist, Mr D / A Pharmacy

Opinion – Case 99HDC01986**Complaint**

The Commissioner received a complaint from Mrs A about services provided to her granddaughter, Miss B, by general practitioner, Dr C and pharmacist, Mr D. The complaint is that:

- *On 25 January 1999 Mrs A took her seven-week-old granddaughter to see Dr C. Dr C prescribed Codeine Linctus 5ml sos to q4h for Miss B. Miss B took 3 doses of the medication and was admitted to hospital for 4 days. On 26 January 1999, Dr C confirmed that Miss B should have been prescribed 1.5 ml of Codeine Linctus.*
- *On 25 January 1999 Mrs A presented a prescription for her seven-week-old granddaughter at a pharmacy. The prescription was for Codeine Linctus 5ml sos to q4h. Miss B took 3 doses of the medication and was subsequently admitted to hospital for 4 days. The dispensing pharmacist failed to recognise that the dose was not appropriate for a child of 7 weeks.*

Investigation Process

The Commissioner received the complaint on 8 February 1999 and an investigation was commenced on 13 May 1999. Information was obtained from:

Mrs A	Complainant / Consumer's grandmother
Mrs B	Consumer's mother
Ms E	Consumer's aunt
Dr C	Provider / General Practitioner
Mr D	Provider / Pharmacist

Copies of Miss B's medical records were viewed and the bottle of Codeine Linctus was obtained. The Commissioner received advice from two independent general practitioners and an independent pharmacist. The Codeine Linctus preparation was analysed by the Institute of Environmental Science and Research Limited (ESR).

General Practitioner, Dr C / Pharmacist, Mr D / A Pharmacy

Opinion – Case 99HDC01986, continued**Information
Gathered
During
Investigation**

On 25 January 1999 Mrs A and her husband took their granddaughter, Miss B, to Dr C's clinic. Miss B was seven weeks old and suffering from a cough, vomiting and diarrhoea. Dr C diagnosed acute bronchitis.

Dr C informed the Commissioner that he did not think that Miss B was very ill and he was not going to prescribe any medication for her. However, he advised the Commissioner that he felt under some pressure to "at least do something about the cough", because it was keeping Mr and Mrs A awake at night.

Dr C prescribed Codeine Linctus "5ml if necessary up to every four hours" and an antibiotic, Amoxycillin 1.25ml three times daily. Dr C's consultation note of 25 January 1999 recorded, "vomiting, chesty, loose BM," and the prescribed treatment was recorded as, "codeine linct, amoxycillin 125mg/1.25 drops".

Dr C advised the Commissioner that he did not know why he prescribed Codeine Linctus. (Codeine Linctus is an analgesic, cough suppressant and an anti-diarrhoeal agent). He said he had intended to prescribe Linctus Pholcodine, a cough suppressant. Dr C said he had only ever prescribed Codeine Linctus for children over the age of two suffering from diarrhoea. He further said that he was under the impression that the Codeine Linctus strength was 5mg/5ml. Dr C did not specify the strength of the linctus on the prescription.

Codeine Linctus is available in two strengths. The adult formulation is 15 mg of Codeine Phosphate per 5 ml of Linctus and the paediatric version is 3mg Codeine Phosphate per 5ml of Linctus.

Mr and Mrs A had the prescription filled at the pharmacy on the same day. The pharmacist on duty was Mr D. Mr D is the proprietor of the pharmacy. Mr D dispensed the Codeine Linctus and Amoxycillin in accordance with the prescription written by Dr C. Miss B's date of birth was correctly stated on the prescription as "04/12/1998". The GMS coding scale recorded on the prescription was circled as "Y1", which covers the age group from birth to six years of age.

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Opinion – Case 99HDC01986, continued**Information
Gathered
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Mr D advised that he checked that the prescription “*was for the weaker product of the Codeine liquid preparations and that the preparation was suitable for a child under the age of six*”. Mr D said he was under the impression that the child was three years old and not three months old. Mr D told the Commissioner that he was not sure why he had this impression. He advised the Commissioner that he was confident that the dose was suitable for the age of the child. There were no written dispensing protocols in place at the pharmacy at the time. Written protocols have since been introduced.

Mrs A gave her granddaughter two doses of the Codeine Linctus that day. During the evening Miss B appeared to stop breathing for a few seconds but then started breathing again. The following morning Miss B was still coughing and sick, so Mrs A gave her another dose of the Codeine Linctus. At lunchtime Mrs A noticed that Miss B was very limp and “*not looking good*” so she gave Miss B a further 2.5ml dose of Codeine Linctus. Mrs A asked Miss B’s mother, Mrs B, to take Miss B back to the doctor as she “*didn’t at all like the look of her*”. Mrs B and her sister-in-law, Ms E, took Miss B back to Dr C. Mrs B lives on an island. This second consultation, on 26 January, took place at Dr C’s clinic on the island, not at his surgery in the town.

Mrs B was unable to recall what happened during the consultation, but Ms E advised the Commissioner that Dr C was initially not sure what was wrong with Miss B. Miss B was very sleepy and Dr C recorded this in his consultation notes. Ms E recalled that Dr C thought that Miss B had been drugged. Mrs A advised the Commissioner that the only medicine given to Miss B was that prescribed by Dr C. Dr C asked them to go home and get the medicine bottle. Ms E sat in the waiting room with Miss B and Mrs A went home and brought the bottle back.

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Opinion – Case 99HDC01986, continued**Information
Gathered
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continued**

Dr C advised that he telephoned the dispensing chemist and was informed that the strength of the Codeine Linctus was 15mg/5ml. Dr C diagnosed a codeine overdose and Ms E recalled that he advised Mrs B and Ms E that the medicine should “wear off” later that day. Dr C’s consultation notes for 26 January record, “*very sleepy. Too much codeine. Not dehydrated. Stop codeine. Diagnosis: Sedative /Hypnotic poisoning*”.

Ms E recalled telling Dr C during the consultation that Miss B had stopped breathing the night before. She remembered that Dr C informed them that they should have taken Miss B straight to the hospital when this had happened. Dr C told them that if Miss B stopped breathing again to go straight to the hospital.

That evening Miss B appeared to look worse so Mrs A rang the surgery again. Dr C was not there and Mrs A spoke to an after hours doctor who was on duty. He advised Mrs A to take Miss B straight to hospital.

Miss B was admitted to hospital on 27 January 1999. She was diagnosed with a mild/moderate codeine overdose and viral gastro-enteritis. Miss B was discharged from hospital on 29 January 1999.

Dr C advised that after Miss B was admitted to hospital he telephoned her grandmother. He thought the telephone call was on the day following the second consultation. Dr C was horrified to hear that the baby had stopped breathing after the first dose of Codeine Linctus and that the family had not realised the significance of this, as they had given Miss B some more medication later that evening.

Dr C advised the Commissioner:

“I have agonised over how close I came to killing the baby and am reminded of it every time I see the baby at the [island] Clinic where I have treated it for three respiratory infections since.”

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Opinion – Case 99HDC01986, continued**Information
Gathered
During
Investigation
continued**

During the investigation the Commissioner obtained the bottle of the Codeine Linctus given to Miss B. The label on the bottle was typewritten at the pharmacy and recorded, “100 ml Codeine phosphate Linctus (PHA) Give 5ml when required up to every for hours...”. The bottle as received by the Commissioner also had some hand writing in blue ball point pen which crossed out of the “5ml” and substituted “1.5”. The words ‘Pain’, ‘cough’ and ‘diarrhoea’ are also hand-written on the label and circled.

**Independent
Advice to
Commissioner**

The Commissioner obtained independent advice from two general practitioners and a pharmacist. The Codeine Linctus preparation dispensed to Mrs A was analysed by the Institute of Environmental Science and Research Limited.

General practitioner advisor (1)

The first general practitioner advisor stated that Linctus Codeine was not an appropriate medication to have prescribed in this instance, “*In a child of this age for these symptoms, one would not normally prescribe codeine linctus. Dr C also comments that he would normally only prescribe this in children over the age of two years*”.

The advisor stated, “*At the concentration of 15mg/5mls, this would be an excessive dose. An appropriate dose is more likely to be 1-2mls qid, however as above, this is an inappropriate medication in this instance*”.

In the advisor's view, Dr C should have written the desired concentration of the medication on the prescription.

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**Independent
Advice to
Commissioner
continued**

The advisor noted:

“[Dr C] comments that the child was very sleepy to examination and it is my opinion that at this time [Miss B] should have been admitted. At the second consultation, if [Dr C] had any knowledge of the child stopping breathing with the first dose, then most definitely the child should have been admitted for assessment. Other features that should have been taken into account include the parents ability to understand and follow instructions, seek medical advice, transport, family supports, and other measures of compliance that might encourage one to be cautiously conservative.”

The advisor was asked to comment on whether Dr C's advice at the second consultation was appropriate:

“No – as per above. It is my opinion that this child required admission. [Dr C's] advice is only good advice if:

- (a) [Dr C] believed the dose was insignificant and no further reactions would occur.*
- (b) [Dr C] believed that the family had the understanding and health access means to deal with an emergency situation e.g. telephone, transport, care-givers to regularly observe baby and recognise the signs of apnoea, experience in CPR etc.”*

The advisor stated that the main effects of codeine overdose that a general practitioner would be expected to be aware of were: *“those of central nervous system depression. The most relevant danger here would be depression of respiration causing brain damage and potentially death”*.

The advisor noted that, *“In the absence of any prolonged periods of apnoea (cessation of breathing) it is unlikely that there would be any long term consequences”*.

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Opinion – Case 99HDC01986, continued

**Independent
Advice to
Commissioner
continued**

The advisor summarised as follows:

“In summary I believe there are two issues:

- 1. Prescriber Error – there is a recognised prescriber error that must initially be completely placed at the feet of the prescriber, [Dr C], regardless of pharmacy and software issues.*
- 2. Clinical Decision Making – It is my opinion that a GP in this situation should have arranged admission on the basis of:
 - a) Lethargic baby to examination*
 - b) Baby's age*
 - c) Dose ingested*
 - d) Possible social factors influencing compliance and understanding (for example [Dr C] later paid for barge fees-but maybe this implies there are substantial transport difficulties also).”**

General practitioner advisor (2)

The second advisor informed the Commissioner stated as follows:

“Linctus Pholcodine is a codeine-based preparation which acts upon the cough suppressant area of the brain to suppress the urge to cough. I in fact do not believe that Linctus Pholcodine is ever an appropriate medication to prescribe to a baby and thus I feel that it was a mistake to prescribe it at all. Because Pholcodine is narcotic based it can suppress respiration and, in any event, a lot of times coughing is a mechanism that you do not want to suppress in a baby as it is possible that by suppressing a cough you may be worsening the situation.

As I do not believe there is ever any place for prescribing Linctus Pholcodine for a child of this age, I cannot say what appropriate dosage should be used. I simply cannot conceive of a situation where one would want to prescribe this drug to a baby of seven weeks.”

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**Independent
Advice to
Commissioner
continued**

The advisor commented further:

“Codeine Linctus is a variant of Pholcodine but is used more in the treatment of diarrhoea. Codeine is certainly not an appropriate medication to prescribe to a seven-week-old baby with the symptoms displayed by [Miss B]. [Dr C] himself states that he made a mistake in the prescription as written. I do not believe that it is ever appropriate to prescribe Codeine Linctus and certainly 5ml is a grossly excessive amount to prescribe to a child this age and size. 1.5ml would be a more appropriate dose in terms of safety but again I simply would not use it.”

The advisor commented:

“[Dr C] should certainly have specified Codeine Linctus paediatric rather than just Codeine Linctus on the prescription as this would have changed the amount prescribed.”

The advisor commented on the appropriateness of Dr C sending Miss B home when he realised his mistake with the medication:

“... I do not believe he should have sent the child home. The child should have been referred forthwith to the public hospital as respiratory depression and possible death are all significant risks of codeine overdose in a child this size.”

and further:

“I think it was inappropriate of [Dr C] to have told [Ms E] that the baby should be taken straight to hospital if she stopped breathing again and instead the baby should have been referred straight to hospital in the first instance. If the advice given is as stated by [Ms E], it was inappropriate.”

The advisor informed that: *“The effects /dangers of an overdose of Codeine Linctus are respiratory depression and possible death”*.

The advisor stated that, *“There are no likely long term effects from the overdose. Once the acute problem of respiratory depression is overcome, then there are no long term sequelae likely”*.

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**Independent
Advice to
Commissioner
continued**

“This was clearly a mistake made by [Dr C]. Firstly I cannot see why one would wish to prescribe Linctus Pholcodine for a child this age in any event and secondly, although he meant to prescribe this medication in the appropriate dose, he ended up prescribing Codeine Linctus in a quite inappropriate dose.

The checks and balances in the system did not work as this was not picked up by the pharmacist and the pharmacist is actually quite wrong to state that 5ml is a reasonable dose for a child this age to tolerate. 5 ml is in fact a dangerous dose and could have had very serious sequelae for this baby.

All in all it is a very unfortunate set of circumstances where [Dr C] made a very definite mistake, which he acknowledges, but which could have led to a disastrous outcome for [Miss B].

Overall, I believe [Dr C] did not exercise reasonable care and skill in providing services to [Miss B] and those services were not of an appropriate professional standard. In this case the problem was compounded by the fact that the pharmacist did not pick up the error.”

Pharmacist advisor

The pharmacist advisor stated:

“If I was presented with a prescription for cough mixture for a baby of that age, I would consider the matter carefully. Babies do not generally tolerate cough mixtures well at that age and as I indicated, there are two formulations for Linctus Codeine (adult formulation and paediatric formulation). The paediatric formulation is 20% of the adult strength.

I believe the pharmacist should have contacted the doctor to ascertain the strength of the medication required and then, if not able to contact him, should have dispensed the paediatric formulation ... and then only with caution. It is unfortunate that both parties seem to have slipped up.”

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Opinion – Case 99HDC01986, continued**Independent
Advice to
Commissioner
*continued***

Institute of Environmental Science and Research Limited

The Institute of Environmental Science and Research (ESR) analysed the Codeine Linctus preparation and reported that the sample contained 270mg/100ml codeine phosphate (i.e. 13.5mg/5ml). As the sample that was tested had expired, this value was only approximate but would be within a maximum of 10 % of the true value.

**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.*

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Opinion – Case 99HDC01986, continued

Other Relevant Standards Pharmaceutical Society of New Zealand ‘Code of Ethics’

Rule 2.11 A pharmacist must be responsible for maintaining and supervising a disciplined dispensing procedure that ensures a high standard is achieved. The pharmacist's responsibilities include:

...

- *evaluating a prescription for correctness and completeness;*
- *verifying the authenticity and appropriateness of prescriptions.*

...

...

Rule 2.18 Where a pharmacist has reasonable grounds to suspect that a prescribed medicine could be detrimental to a consumer's health, the pharmacist must consult with the prescriber ...

...

Pharmaceutical Society of New Zealand ‘Quality Standards for Pharmacy in New Zealand’**Standard 6.2 Dispensing:**

6.2a Procedures for dispensing and supply of pharmaceuticals are developed, documented and approved by the pharmacist.

The Medicines Regulations 1984

Rule 41 of the Medicines Regulations states:

“Every prescription given under these regulations shall –

- a) Be legibly and indelibly printed; and*
- b) Be signed personally by the prescriber with his usual signature (not being a facsimile or other stamp), and dated; and*
- c) Set out the address of the prescriber; and*
- d) Set out - ...*

(ii) in the case of a child under the age of thirteen years, the date and birth of the child; and

(e) Indicate by name the medicine and, where appropriate, the strength that is required to be dispensed;”

General Practitioner, Dr C / Pharmacist, Mr D / A Pharmacy

Opinion – Case 99HDC01986, continued

Opinion: In my opinion Dr C breached Right 4(1) and Right 4(2) of the Code.
Breach
Dr C **Right 4(1)**

Prescribing inappropriate medication

When Miss B first presented at Dr C's clinic she was seven weeks old and suffering from a cough, vomiting and diarrhoea. Dr C diagnosed acute bronchitis and prescribed Codeine Linctus, "5mls if necessary up to every four hours".

Both my independent general practitioner advisors informed me that Codeine Linctus was an inappropriate medication to prescribe in the circumstances. My first advisor noted that had Codeine Linctus been appropriate medication to prescribe, the correct dose would have been 1-2mls four times a day, not 5mls. Furthermore, both my advisors stated that Dr C should have written the desired concentration of the medication on the prescription, ie that the paediatric formula was required.

Dr C stated that he did not know why he prescribed Codeine Linctus for Miss B. He said he had intended to prescribe Linctus Pholcodine. Dr C recorded in his consultation notes "*Codeine Linct, Amoxicillin 125mgs / 1.25 drops*". Even if this were so, my first advisor considered that "*5mls if necessary every four hours*" of Linctus Pholcodine would not have been an appropriate prescription for a seven week old baby. My second advisor also considered that Linctus Pholcodine was an inappropriate medication to prescribe for a baby and did not believe that there was ever any place for prescribing Linctus Pholcodine for a child of Miss B's age. The advisor could not say what was the appropriate dosage of Linctus Pholcodine, as the advisor could not conceive of a situation where a doctor would want to prescribe this drug to a baby of seven weeks.

In my opinion, Dr C prescribed inappropriate medication in the circumstances. Further, Dr C prescribed an inappropriate dose of the medication and failed to indicate on the prescription the strength of the medication required to be dispensed. In my opinion, Dr C failed to carry out his prescribing duties with reasonable care and skill and therefore breached Right 4(1) of the Code.

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General Practitioner, Dr C / Pharmacist, Mr D / A Pharmacy

Opinion – Case 99HDC01986, continued

**Opinion:
Breach
Dr C
continued***The second consultation*

Concerned about her baby, Mrs B took her daughter to Dr C's clinic on the island on 26 January 1999 for a second consultation. Dr C noted that Miss B was "very sleepy". After Mrs B produced the bottle of Codeine Linctus that Dr C had prescribed, Dr C telephoned the dispensing chemist to clarify its strength. On learning that the strength of Codeine Linctus was 15mg/5ml, Dr C diagnosed a codeine overdose. The only instruction recorded in Dr C's consultation notes was a direction to stop administering the Codeine Linctus medication. Both my advisors considered that Miss B should have been admitted to hospital at this stage. Miss B's aunt, Ms E, stated that she told Dr C that Miss B had stopped breathing the night before the second consultation. However, Dr C states that no one informed him of this fact. In my opinion, it is not necessary to conclude one way or the other on this point. My first advisor informed me that a general practitioner in Dr C's position should have arranged for Miss B to be admitted to hospital, based on:

- the dosage of codeine ingested;
- the presentation of a lethargic baby;
- the baby's age; and
- social factors, such as a distance to the hospital.

My first advisor further informed me that a general practitioner would be expected to be aware of the dangers associated with a codeine overdose, that is, depression of respiration causing brain damage and potentially death. Given the factors set out above and the gravity of the risks associated with a codeine overdose, reasonable prudence would have required that Miss B be transferred to hospital as a precautionary measure. In my opinion, by failing to refer Miss B to hospital on 26 January 1999, Dr C did not exercise reasonable care and skill and therefore breached Right 4(1) of the Code.

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General Practitioner, Dr C / Pharmacist, Mr D / A Pharmacy

Opinion – Case 99HDC01986, continued

Opinion:
Breach
Dr C
continued

Right 4(2)

Dr C failed to write the required concentration of the medication he prescribed Miss B on the prescription.

Clause 41(e) of the Medicines Regulations 1984 states that every prescription shall “*indicate by name the medicine and, where appropriate, the strength required to be dispensed*”. Both my advisors consider Dr C should have written the desired concentration of the medication he was dispensing on the prescription. By failing to record the desired concentration of the medication he dispensed to a seven-week-old baby, Miss B, Dr C did not comply with clause 41(e) of the Medicines Regulations. Accordingly, by failing to comply with a legal standard, Dr C breached Right 4(2) of the Code.

General Practitioner, Dr C / Pharmacist, Mr D / A Pharmacy

Opinion – Case 99HDC01986, continued

Opinion: In my opinion Mr D breached Right 4(1) and Right 4(2) of the Code.
Breach
Mr D **Right 4(2)**

Mr D was presented with a Codeine Linctus prescription for a seven-week-old baby. The baby's date of birth was clearly stated on the prescription. The dosage was stated as "5mls if necessary up to every four hours". The strength of the preparation was not specified and the prescription did not indicate whether an adult or paediatric formulation was to be dispensed. Mr D advised that he thought that Miss B was three years of age and not three months old and was confident that the dose was suitable for the age of the child. Miss B was in fact only seven weeks old.

My independent pharmacist advisor informed me that there are two formulations for Codeine Linctus; an adult formulation and a paediatric formulation, which is 20% of the adult strength. My advisor further noted that babies do not generally tolerate cough mixtures well at seven weeks of age. In my opinion, Miss B's age, which was clearly recorded on the prescription, the nature of the medication prescribed and the lack of specificity of the prescription should have alerted Mr D to query the appropriateness of the prescription. In the circumstances, Mr D should have consulted with Miss B's general practitioner, Dr C, and verified Miss B's prescription. In my opinion by failing to consult with Dr C, Mr D failed to comply with the ethical standards set out in Rules 2.11 and 2.18 of the Pharmaceutical Society Code of Ethics and therefore breached Right 4(2) of the Code.

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General Practitioner, Dr C / Pharmacist, Mr D / A Pharmacy

Opinion – Case 99HDC01986, continued

**Opinion:
Breach
Mr D
continued**

Right 4(1)

As discussed above, Codeine Linctus is available in two strengths. The adult formulation is 15mgs of Codeine Phosphate per 5mls of Linctus and the paediatric version is 3mgs of Codeine Phosphate per 5mls of Linctus.

The Institute of Environmental Science and Research (“ESR”) analysed a sample of the Codeine Linctus preparation dispensed by Mr D and reported that the sample contained 13.5mgs of Codeine Phosphate per 5mls of Linctus. ESR advised that this was an approximate analysis, which would be within a maximum of 10% of the true value.

The strength of the Codeine Phosphate in the formulation dispensed by Mr D would not have been suitable for a young child, let alone a seven week old baby. By dispensing the adult formulation of the Codeine Linctus to Miss B, Mr D failed to provide services of reasonable care and skill and in my opinion breached Right 4(1) of the Code.

**Opinion:
Breach
The Pharmacy**

In my opinion the pharmacy breached Right 4(2) of the Code of Rights.

On 25 January 1999, when Mr D dispensed the Codeine Linctus, there were no written dispensing protocols in place at the pharmacy. In my opinion, the absence of documented dispensing procedures indicates a failure on the part of the pharmacy to comply with Standard 6.2(a) of the Pharmaceutical Society of New Zealand ‘Quality Standards for Pharmacy in New Zealand’ and amounts to a breach of Right 4(2) of the Code.

General Practitioner, Dr C / Pharmacist, Mr D / A Pharmacy

Opinion – Case 99HDC01986, continued**Actions**

I recommend that Dr C takes the following action:

- Apologises in writing to Miss B's family. This apology is to be sent to the Commissioner and will be forwarded to the family.

I recommend that Mr D takes the following action:

- Apologises in writing to Miss B's family. This apology is to be sent to the Commissioner and will be forwarded to the family.

I note that written dispensing procedures have since been introduced at the pharmacy. I recommend that the pharmacy submit a copy of its dispensing protocols to the Pharmaceutical Society for the Society's approval.

Other Actions

A copy of this report will be forwarded to the Medical Council of New Zealand. The Medical Council will be requested to undertake a review of Dr C's competence to practise medicine. A copy of the report will also be referred to the Pharmaceutical Society of New Zealand.

This matter will be referred to the Director of Proceedings under section 45(f) of the Health and Disability Commissioner Act 1994 for the purpose of deciding whether any actions should be taken.

Addendum

The Director of Proceedings laid before the Medical Practitioners Disciplinary Tribunal a charge alleging professional misconduct. The charge was upheld by the Tribunal and it imposed a penalty of censure and ordered payment of \$4,000 towards the costs and expenses of and incidental to the investigation, prosecution and hearing.