25 February 2003

Mr A
Provider / Pharmacist

Dear Mr A

Consumer, Mr B

Thank you for your response to my provisional opinion concerning Mrs B's complaint against you. Your comments have been considered, but it remains my opinion that you breached the Code. I note that the pharmacy has revised and implemented its complaints policy as recommended in my provisional opinion.

I have now finalised my opinion concerning Mrs B's complaint against you. Mrs B's concerns were that:

- In the week beginning 22 April 2002 the family called in to your after-hours pharmacy for medication to relieve Mr B's flu symptoms. Mrs B explained that her husband had a heart condition and was diabetic. You supplied Mrs B with a box of Nurofen Plus.
- Outside the shop Mrs B read the labelling on the box and saw the manufacturers warned that it should not be given to persons with heart conditions or allergies to aspirin. Mrs B returned to the pharmacy and queried this with you, and you reassured her that they would be safe for her husband to take.
- On 25 April Mr B developed an itchy rash and generalised swelling and was treated for aspirin allergy at an accident and medical clinic.

During the investigation, information was obtained from you, Mrs B, Mr B's general practitioner, and the Medical Affairs Associate for the manufacturer. I also obtained expert advice from Mr Alan Fraser, an independent pharmacist.

My opinion is that you breached Rights 4(1) and 4(2) of the Code by supplying Mr B with medication inappropriate to his circumstances and by failing to provide him with accurate information about the medication.

The information gathered during my investigation is as follows:

Background
On the evening of Monday 24 April 2002, Mrs B, her husband and son, called at the pharmacy to obtain medication to relieve Mr B's influenza symptoms.

Mrs B informed me that she spoke to the pharmacist (who she later learnt was you) and told you that her husband had the start of the flu and needed something to relieve his symptoms. The pharmacy was not the family's usual pharmacy. She also told you that her husband suffered from diabetes and had a heart condition.

Mrs B recalled that you suggested Nurofen Plus. You dispute this and informed me that Mr B selected the Nurofen Plus from the shelf himself, and Mrs B queried whether the Nurofen Plus was suitable for her husband. You reassured Mrs B that it was. She paid for the medication and left.

Before leaving the environs of the shopping area, Mrs B went to take a tablet from the packet to give to her husband. As she went to do this she read the wording on the packet and understood from the warning that the tablets contained aspirin.

The wording on the side of the packet of Nurofen Plus stated:

> "DO NOT TAKE IF: you have a stomach ulcer, or other stomach disorders, kidney or heart problems or are allergic to aspirin, ibuprofen or other anti-inflammatory medicines. Before taking Nurofen Plus check with your doctor or pharmacist if you are asthmatic or receiving regular treatment with other medications."

Mrs B returned to the pharmacy and spoke to you again and said that she had forgotten to say that her husband was allergic to aspirin. You told her that the Nurofen Plus would be "fine" for her husband. Mrs B indicated the information on the box. Mrs B recalled that you replied, "They just put it on there to cover themselves." Mrs B asked you who "they" were. You informed her that "they" were the drug company. You reassured Mrs B again that her husband would not suffer any ill effects from taking the Nurofen Plus, and she left the shop.

You informed me:

> "I would like to state that I do not have recollection of events as stated in the complainant's letter. There is no way I would recommend this medication to a patient with this medical record. I would possibly recommend Paracetamol tablets and maybe antihistamines if congestion was a problem and also tell them to see a doctor if they got any worse.
>
> I … certainly do not use statements like 'Directions on the packet are to protect the manufacturer'. This would be ludicrous and dangerous."

On 25 April (Anzac Day) Mr B developed an itchy rash and generalised swelling. He was seen at the accident and medical clinic by his usual GP, who was working as an after-hours locum at the clinic. Mr B was diagnosed as suffering from aspirin allergy.

Mr A's general practitioner noted at 9.50am on 25 April 2001:

> "Had Nurofen for URTI [upper respiratory tract infection]
> Urticaria – generalised. 1/7 [one day]
> Puffy eyes
>
> Allergies: aspirin
>
> Δ Urticaria
>
> Rx
> – Claratyne
> – Prednisone
> – IM Phenergan 2.5mg."

Mrs B informed me that she went back to the pharmacy some days later, after work, to tell them about the mistake. She said that she spoke to your partner, Mr C, who advised her to return to the pharmacy between 9am and 5pm when you were working. Mrs B asked if you could telephone her at work to discuss her concerns. Mr C told Mrs B that she would have to call in to the pharmacy to discuss her concerns with you. Mrs B gained the impression that her complaint was not taken seriously.

You later informed me:

> "I would like to point out that I did not supply a box of Nurofen Plus to [Mr B], nor did I recommend this product to him. [Mr B] selected the product from the shop himself and simply mentioned that he was allergic to aspirin. I would have told him the product did not contain Aspirin. Normally I only recommend Nurofen products for toothache only. I roughly recollect [Mr B] returning to the shop with the product. I probably once again mentioned that the product did not contain aspirin and would have asked if [Mr B] was asthmatic.
>
> …
>
> Cautions are printed on medicine packets to warn the person taking the medicine. The cautions are not up for debate!"

Additional information
The *New Ethicals Catalogue* (2001) states:

> "NUROFEN PLUS
> 200mg ibuprofen; 12.8mg codeine phosphate
> ***USE:*** Nonsteroidal anti-inflammatory analgesic agent with codeine. Tension headaches, pain and discomfort associated with migraine, cramping period pain, dental pain, neuralgia, sciatica, lumbago, rheumatic pain. (*Adults and children over 12 years,* initially, 2 tablets then 1-2 tablets every 4 to 6 hours. Maximum 6 tablets per 24 hours.)

> **Special precautions:** GI disorders, dehydration, asthmatics sensitive to NSAIs/salicylates [aspirin], renal impairment, constipation, breathing difficulties, head injury
> ***Patient Information:*** Take with a glass of water. May cause drowsiness, so do not drive or operate machinery."

The manufacturer
The Medical Affairs Associate for the manufacturer informed me:

> "Thank you for your request for further information and incidence of aspirin sensitive asthma whilst taking Nurofen, contraindications, adverse reactions and general product information on Nurofen.
>
> A recent review suggests the prevalence of aspirin-sensitivity within the general population of asthmatics is approximately 10%. No data exists on the prevalence of ibuprofen sensitive asthma. However people who are truly aspirin sensitive will also be ibuprofen sensitive."

She stated that Nurofen is to be taken with caution by persons with cardiac, renal and hepatic conditions. She said that if the patient had a known aspirin allergy, Nurofen is contraindicated.

Actions taken
You wrote to the Administrator, Pharmacy Defence Association, on 14 August 2002, to inform her that you had no recollection of the events as outlined in Mrs B's letter of complaint and would not have recommended Nurofen to Mr B if you had been aware of his medical record. You stated: "If there has been a misunderstanding I apologise for not being clearer in the conversation with [Mr and Mrs B]."

On 14 August 2002 you wrote to Mrs B apologising for any misunderstanding and enclosing a cheque for $70.75 (refunding the cost of the Nurofen Plus and the medical fee).

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.*

Professional Standards
The Pharmaceutical Society of New Zealand's *Code of Ethics*, June 2001, states:

"1.3. Medicines and therapies not prescribed by another provider

Where the patient is seeking to purchase, from the pharmacist or from other personnel for whom he or she has responsibility, any medicine, complementary therapy, herbal remedy or other healthcare product not prescribed by another healthcare provider, the pharmacist must ensure that the patient is provided with credible, understandable information about its safe and effective use, expected outcomes of therapy within the limitations of available information, what to do if side effects occur, and storage and disposal requirements, and any significant risk of therapy or insufficiency of evidence about efficacy of the therapy, to allow the patient to make an informed choice.

2.7 Assessment prior to sale of medicines and other therapies

When asked for advice on treatment involving any medicine, complementary therapy, herbal remedy or other healthcare product not prescribed by another healthcare provider, the pharmacist must endeavour to ensure that sufficient information is obtained to allow an assessment to be made that such is appropriate, safe and efficacious and to enable a suitable recommendation to be made."

Commissioner's Opinion

Opinion: Breach – Mr A

Failing to provide sufficient information about Nurofen
I am advised that Nurofen is a 'pharmacy only medicine' which means that it does not require entry into the Sale of Medicine Register or a secure area for storage. Nurofen contains ibuprofen. There are significant similarities in the chemical and pharmacological activities between aspirin and ibuprofen. It follows that ibuprofen is contraindicated in patients with a history of hypersensitivity or allergy to aspirin.

There are conflicting recollections on some aspects of what occurred, for example you dispute the comments attributed to you by Mrs B about the manufacturer's warning on the packaging. These are not important. What is clear is that you were advised that Mr B had a history of adverse reaction to aspirin, and when specifically asked whether Nurofen Plus was contraindicated in this situation you stated that there was no risk.

My advisor commented that this error occurred because of the misunderstanding about whether or not Nurofen Plus tablets contain aspirin. My advisor said that you were correct in stating that Nurofen Plus did not contain aspirin but you erred because you did not take into account the similarities between the chemical and pharmacological activities of aspirin and ibuprofen. I am advised that you should have told Mrs B that Nurofen Plus was not a suitable medication for her husband and recommended an alternative product.

The Pharmaceutical Society of New Zealand's *Code of Ethics* specifies that the pharmacist, when supplying a consumer with a medicine, must ensure that the consumer is provided with credible, understandable information about its safe and effective use and any significant risk of therapy, to allow the consumer to make an informed choice. The pharmacist must also, when asked for advice on treatment involving any medicine, ensure that sufficient information is provided to the consumer to allow him or her to make an assessment that the medication is safe and efficacious.

I accept my expert's advice that you did not provide Mr B with medication that was appropriate to his circumstances as disclosed, and did not provide accurate information about the risks associated with Nurofen Plus. Accordingly, in my opinion, you did not provide services to Mr B with reasonable care and skill and in compliance with professional standards, and therefore breached Rights 4(1) and 4(2) of the Code.

Comments

Complaints policy

I note that Mrs B returned to the pharmacy some days after her husband was treated for the allergic reaction to Nurofen Plus to discuss her concerns about the service she and her husband had received. Mrs B informed me that she believed that her concerns about this matter was not taken seriously and that there did not appear to be any responsibility taken for recording or addressing her complaint.

You informed me that Mrs B's complaint was taken seriously, and that Mr C, pharmacist, asked her to return to discuss the matter with you. Mr C informed you of his conversation with Mrs B, but as he did not take her contact details you were not able to take this further.

In your response to the investigation you did not provide me with any evidence that the pharmacy had a policy to guide staff in the processing of a consumer complaint. Right 10 of the Code states that every consumer has the right to complain, and that every provider must facilitate the fair, simple, speedy and efficient resolution of complaints.

In response to my provisional opinion you supplied the pharmacy's amended complaints policy, which specifies the 'Guidelines for Handling Complaints', and provided a copy of the 'Client Complaint Form'. You state that staff will receive training on the revised policy. You also provided a copy of your 'Incident Reporting' form which advises staff, amongst other things, how to manage reports of adverse reactions.

Adverse event reporting

I also note that the manufacturer has a process for notification of adverse events in relation to their products. They ask patients or health professionals to report allergic reactions to the ingredients of one of their products, and state, "It is through information that we receive from our patients that allows us to maintain our Adverse Drug Reaction database and keep it as up-to-date as possible." It would be reasonable to assume that a chemist would be aware of the importance of reporting any adverse drug reaction that had been brought to his/her attention. However, it appears that insufficient note was taken of Mrs B's concerns and that this event was not reported

as an adverse reaction. I note you have now provided me with a copy of the pharmacy's Incident Reporting policy, as requested.

Educational opportunity
My advisor recommended that a report on this complaint be forwarded to the Pharmaceutical Society of New Zealand for publication in "Interactions", which would benefit many pharmacists who could learn from the events that led to this complaint.

Action

- A copy of my final opinion will be sent to the Pharmaceutical Society of New Zealand.

Yours sincerely

Ron Paterson
Health and Disability Commissioner

Ref: 02/06951

Independent Expert Advice

"Re: [Mr B] – Complaint File: 02HDC06951

Thank you for forwarding me the correspondence relating to the above complaint. Having reviewed the file I would make the following observations and comments.

In the week commencing 22 April 2002, [Mrs B] purchased from the pharmacy, a packet of Nurofen Plus tablets. The medication was intended for [Mrs B's] husband who had symptoms of influenza. The pharmacist [Mr A] made the sale of the Nurofen Plus tablets. [Mrs B] states that she informed the pharmacist that her husband was diabetic, had a heart condition and she produced [Mr B's] medication card that clearly recorded an anaphylaxis to aspirin. After leaving the pharmacy [Mrs B] read on the packet of Nurofen Plus – **DO NOT TAKE if – you have a stomach ulcer or other stomach disorders, kidney or heart problems. You are allergic to aspirin, ibuprofen or other anti-inflammatory medicines, codeine or other opioid analgesics**. [Mrs B] returned to the pharmacy and informed [Mr A] that her husband was allergic to aspirin. She was reassured that Nurofen Plus was suitable for him.

In the notes of the phone call between [an investigation officer] of the Commissioner's Office and [Mr A] on 26 September 2002 it is recorded that [Mr A] remembered being informed that [Mr B] was allergic to aspirin and that he gave the usual information about the contra-indications for taking Nurofen. In [Mr A's] letter to the Health and Disability Commissioner dated 4 October 2002 he states '*[Mr B] (not [Mrs B]) selected the product from the shop himself and simply mentioned that he was allergic to aspirin. I would have told him the product did not contain aspirin.*'

Following ingestion of Nurofen Plus tablets [Mr B] presented with a pruritus of the skin and generalised swelling at the … Accident and Medical Clinic on 25 April 2002. The duty doctor was their family general practitioner, who diagnosed a generalised urticaria and puffy eyes. He gave [Mr B] an intramuscular injection of the antihistamine phenergan and prescribed the long acting histamine antagonist Claratyne and the corticosteroid prednisone for oral ingestion.

Nurofen Plus is a formulation containing ibuprofen 200mg (a non-steroidal anti-inflammatory analgesic) and codeine phosphate 12.8mg (an opioid analgesic). Nurofen Plus is indicated for strong pain and for inflammation and is commonly used for relief of muscular pain, dental pain, headache, dysmenorrhoea and rheumatic/ arthritic pain.

Ibuprofen, aspirin and other non-steroidal anti-inflammatory drugs act via inhibition of Cox-l (cyclo-oxygenase-l) and Cox-2 (cyclo-oxygenase-2). There are significant similarities in the chemical and the pharmacological activities between aspirin and ibuprofen. It follows then that ibuprofen is contraindicated in patients with a history of hypersensitivity or allergy to aspirin.

Nurofen Plus tablets are a 'pharmacy only medicine'. They are not subject to the special requirements that pertain to 'pharmacist only medicines'. 'Pharmacy only medicines' do not require an entry into a Sale of Medicine Register nor do they require a secure area for storage. The products in this category do not require the

pharmacist to be involved in the sale and can be self-selected by members of the public.

[Mr A] strongly refutes many of the allegations in [Mrs B's] letter of 14 May 2002 to … the Pharmaceutical Society of New Zealand. He states that he did not recommend Nurofen Plus. The product was self-selected. He states that normally he recommends Nurofen products only for toothache. He states that he did not see [Mr B's] medication card, nor did he state that the warnings on the Nurofen Plus packet were there for the manufacturer's protection.

I was interested to read from the report of [the HDC investigation officer] of a phone call with [Mrs B] on 16 October 2002, of an earlier adverse event involving Nurofen Plus tablets when [Mr B] had toothache in Australia. [Mr B] experienced a similar adverse reaction, which required medical intervention. I would have thought that following that unfortunate experience that he would have avoided all Nurofen products. Advice of that particular event would have been helpful to the pharmacist.

I believe that a misunderstanding has come about over the question of whether or not Nurofen Plus tablets contain aspirin. [Mr A] was correct in stating that Nurofen Plus did not contain aspirin. However, as he had been informed, and he acknowledges this fact, that [Mr B] is allergic to aspirin, in my opinion I believe he has erred due to a lack of knowledge of the similarities between the chemical and pharmacological activities of aspirin and ibuprofen. As ibuprofen is contraindicated in patients with a history of hypersensitivity or allergy to aspirin he should have told [Mrs B] that Nurofen Plus was not a suitable medication for her husband and accordingly recommended an alternative product.

There are a number of conflicting versions by both [Mrs B] and [Mr A]. [Mr A] in his letter of 14 August 2002 has apologised for the misunderstanding and reimbursed [Mrs B] for the medical expenses. Whilst this is compensation for costs I acknowledge that it does not make up for the suffering that [Mr B] has experienced and the anxiety caused to the family.

I personally believe that there is little to be gained by pursuing this issue. I would recommend that [Mrs B] be encouraged to cash the cheque that was forwarded in good faith. I would further recommend that a synopsis of the complaint be forwarded to the Pharmaceutical Society of New Zealand for publication in 'Interactions'. If this was done many pharmacists in New Zealand could benefit and learn from the events that led to this complaint.

Yours sincerely

Alan A Fraser"