Report on Opinion - Case 97HDC9338

Complaint

The Commissioner received a complaint about services provided by a pharmacy to the consumer. The complaint is that:

- The consumer received the incorrect medication from a pharmacy on a date in mid-September 1997.
- In mid-September 1997 a health officer prescribed the consumer sulphadiazine and folinic acid at a Crown Health Enterprise. However, when the prescription was taken to the pharmacy, the consumer was provided with sulphasalazine and Folic Acid, which resulted in serious side effects.

Investigation

The Commissioner received the complaint on 21 October 1997, and an investigation was undertaken. Information was obtained from the following:

The Consumer
The Pharmacy's Managing Director
Dispensary Manager
Pharmacy Manager
Pharmacy Intern
Health Officer (Prescribing Doctor)
Chief Executive Officer, Crown Health Enterprise

The consumer's medical records were obtained from the Crown Health Enterprise and reviewed. The Commissioner obtained advice from an independent pharmacist.

4 June 1999 Page 1 of 13

Report on Opinion - Case 97HDC9338, continued

Outcome of Investigation

The Prescription

The consumer was admitted to the hospital on a date in early September 1997 and was diagnosed as having ocular toxoplasmosis. About five days later, the consumer was discharged from the hospital and given a prescription by the health officer for the following medication:

- a) Sulphadiazine tablets 1 gm Q10 (four times daily), duration 1 month;
- b) Pyrimethamine tablets 25 mgm daily, duration 1 month;
- c) Folinic acid tablets 30 mgm once daily, for 3 days of every week, duration 1 month.

In September 1997 the health officer was working under an infectious diseases physician. The health officer stated that at the time he had no experience in prescribing these particular drugs and recalled the infectious diseases physician verbally instructing him as to which drugs the consumer was to continue taking and of the dosage required. He also recalled writing the script himself and giving it to the consumer at discharge. The health officer advised the Commissioner that until he was approached by the Commissioner's office, he was not aware that the drugs listed in the prescription were only available at hospital pharmacies.

When the consumer received his prescription from the health officer, he was not informed that it could only be dispensed at a hospital pharmacy. The health officer presumed that the infectious diseases physician would have informed the consumer of any unusual requirements prior to discharge. In a letter obtained from the hospital file dated mid-October 1997, the infectious diseases physician addresses this issue and states:

"He was given a prescription for sulphadiazine when he left the hospital about a month ago. Unfortunately the person who gave the prescription wasn't told by me or anyone else that sulphadiazine is not available from community pharmacies and to add to that problem, the pharmacy in [the region] then gave him a prescription for sulphasalazine."

Continued on next page

4 June 1999 Page 2 of 13

Report on Opinion - Case 97HDC9338, continued

Outcome of Investigation continued

In its response to the Commissioner, the Crown Health Enterprise stated:

"At the present time patients are advised as to the availability of dispensing of medicines to the best of the prescribing doctor's knowledge. In [the hospital] 'hospital only medicines' are dispensed through nominated community pharmacies.

In a vast majority of cases our clinicians do not have a problem with advising patients of the availability of medications, however there is the occasional inconvenience. This is when it is difficult or impossible for the clinician to keep up to date with the availability of dispensing medicines due to the constant changing conditions and requirements of dispensing medications.

Medical staff make the correct identification when prescribing medications through experience alone as the constant change in dispensing requirements makes it impossible to maintain perfect knowledge of the changes. Senior medical staff do try to maintain a working knowledge of these requirements and endeavour to pass this on to the junior medical staff.

[The Crown Health Enterprise] does not yet have such information computer-based and any improvement to this current state of our present information systems could only be achieved at great expense and increased staff time. Even then this would not be able to be perfect...

In addition to these measures we have improved the situation by having a community pharmacy to dispense 'hospital only medicines' in the [hospital's] foyer."

Dispensing the Medication

On the day the consumer was discharged from hospital, a relative of the consumer's, along with another woman, took the prescription to the pharmacy on the consumer's behalf. Three members of the pharmacy staff attended to the prescription. It was recorded in the computer by the managing pharmacist and then dispensed and checked by another pharmacist and the pharmacy intern.

Continued on next page

4 June 1999 Page 3 of 13

Report on Opinion - Case 97HDC9338, continued

Outcome of Investigation continued

The pharmacy dispensed the following medication:

- a) Sulphasalazine 500 mgm 2 times daily; and
- b) Folic acid 5 mgm.

The pyrimethamine could not be supplied in accordance with the prescription, as this drug could not be obtained by the pharmacy. The dispensing manager informed the family member who collected the prescription of this and asked her to tell the consumer to query his doctor about the medication.

The dispensing manager advised the Commissioner that in the course of dispensing the drugs, she telephoned a second hospital to locate the prescribing doctor and to query some aspects of the prescription. Although she telephoned the second hospital, it is clear from the prescription form that the prescribing doctor practised at the first hospital. As a result of calling the incorrect hospital, the dispensing manager was unable to talk to the health officer and the labelling on the medication incorrectly identifies the second hospital as the prescribing agency. It is not clear from the dispensing manager's response why she attempted to contact the health officer at the second hospital.

The relative who picked up the prescription on the consumer's behalf informed the dispensing manager that the consumer would be returning to the hospital in the next two days. The dispensing manager then photocopied the prescription and added a note to the health officer, along with her name and telephone number, so that he could contact her and clarify the prescription. She then gave the photocopy to the consumer's relative on his behalf. The health officer did not receive the photocopy and advised the Commissioner that the dispensing manager did not contact him at any time.

The dispensing manager advised the Commissioner that she considered that the confusion was partly due to the health officer's handwriting, and partly due to the fact that sulphadiazine and folinic acid are only available through hospital dispensing pharmacies. The pharmacy manager took the same view in his response to the Commissioner:

"I feel that the doctor's writing is a factor, a point that is confirmed by three chemists here coming up with the same interpretation."

Continued on next page

4 June 1999 Page 4 of 13

Report on Opinion - Case 97HDC9338, continued

Outcome of Investigation continued

The pharmacy manager, the dispensing manager and the pharmacy intern all understood the prescription to be for sulphasalazine tablets, 500 mgm with a dosage of 2 tablets 4 times daily. According to them, sulphadiazine is administered by injection and comes in 250mg/ml 4ml ampoules.

In his response to the Commissioner, the health officer clearly stated that the first item on the prescription was for "suphadiazine tablets. 1 gram QID (i.e. four times daily). Duration one month". The health officer did not state that sulphadiazine was administered by injection.

The pharmacy manager told the Commissioner that every prescription dispensed at the pharmacy is double-checked and every patient receives counselling by a pharmacist at the final check. He also noted:

"I would have thought that the obvious difference in medical administration to what was expected would have been a point for discussion on the consumer receiving the medicine."

This point was also made by the pharmacy's managing director in his response to the Commissioner:

"I would have thought that our chemist would have been queried by the consumer or his caregiver because of the different method of administration, i.e. by injection rather than by mouth. We would then have queried this with the prescriber. There was mention that the two ladies would be going back to the hospital and the doctor 'in a couple of days'".

Side Effects

The consumer became aware of the mistake approximately 3½ weeks later when he developed a generalised itchy rash. The consumer also had headaches, fevers and sweats. The consumer told the Commissioner that as a result of taking the sulphasalazine, he is now unable to tolerate any sulpha-based drugs. In a letter on the hospital file dated mid-October 1997, the infectious diseases physician states that in his opinion these symptoms may have been partly due to the sulpha allergy problem.

4 June 1999 Page 5 of 13

Report on Opinion - Case 97HDC9338, continued

Code of Health and Disability Services Consumers' Rights

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.
- 4) Every consumer has the right to have services provided in a manner that minimises the potential harm to, and optimises the quality of life of, that consumer.

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
 - e) Any other information required by legal, professional, ethical, and other relevant standards; and

Professional Standards

The following rules in the Code of Ethics of the Pharmaceutical Society of New Zealand are applicable to this complaint:

- Rule 2.1: A pharmacist must safeguard the interest of the public in the supply of health and medicinal products.
- 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:
- *a) Interpreting a prescription;*
- b) Verifying the authenticity and appropriateness of prescriptions.

The following guideline in the Pharmacy Practice Handbook, January 1998 is applicable to this complaint:

Part 4: The prescriber should be contacted if there are any problems with the medicine prescribed.

Continued on next page

4 June 1999 Page 6 of 13

Report on Opinion - Case 97HDC9338, continued

Professional Standards, continued

The following comment recorded in the Pharmaceutical Society of New Zealand's Preceptor Manual 1999 is applicable to this complaint:

Remember than an intern must still be under your supervision when performing any functions of a pharmacist, and that you must still provide the final check.

The following regulation in the Pharmacy Regulations 1975 is applicable to this complaint:

Practical training shall be served under the direct personal supervision and as the sole pupil of a pharmacist.

Opinion: Breach the Dispensing Manager

In my opinion the dispensing manager has breached Rights 4(1), 4(2) and 4(4) of the Code of Health and Disability Services Consumers' Rights as follows:

Right 4(1)

In my opinion the dispensing manager breached Right 4(1) of the Code of Rights. The first item on the consumer's prescription read "sulphadiazine". Instead, sulphasalazine was dispensed. The pharmacist who advised the Commissioner stated that:

"The usual practice in dispensing is that if the pharmacist is unsure of the prescriber's intention, he would seek another pharmacist's opinion. If between them they agree and are happy with the decision it ends there. If there is any doubt at all the pharmacist should try and contact the prescriber. If this fails contact could be made with the clinic (in this case at the hospital) for a registered nurse to check the drug chart. If this cannot be done, I would discuss the problem with the patient or with his agent, indicating that we were in some doubt as to the prescriber's intention and did the patient know what they had been taking. If the answer was still uncertain, the pharmacist should not hand over the medicine."

At the time, the dispensing manager was sufficiently concerned about the prescription to try and contact the prescribing doctor, the health officer. It is unfortunate that she was not able to do so because, had she spoken to the health officer, the dispensing error may have been avoided.

Continued on next page

4 June 1999 Page 7 of 13

Report on Opinion - Case 97HDC9338, continued

Opinion: Breach the Dispensing Manager continued The dispensing manager made one attempt to telephone the health officer at the second hospital when the call quite clearly should have been directed to the first hospital. In my opinion, the dispensing manager should have followed this call up with further attempts to make direct contact either with the health officer or the hospital, who would have been able to check the consumer's drug chart. The dispensing manager did write a note to pass on to the health officer, but it is unclear what this related to. In any event, writing a note to be passed on at some future time was clearly insufficient. The consumer took the incorrect medication for a period of approximately 3½ weeks. In my opinion, the consumer's medication should not have been handed over while any doubt remained about the prescription. In not taking these further measures, in my opinion, the dispensing manager did not provide services to the consumer with reasonable care and skill.

The error in dispensing folic acid instead of folinic acid had less serious consequences. However, in my opinion this was a matter that would have been clarified, had the dispensing manager made sufficient efforts to contact the health officer.

The dispensing manager's suggestion that the confusion was partly due to the health officer's writing is not sustainable. If, as in this situation, there was any confusion with the doctor's handwriting, the prescribing doctor should have been contacted. The error of misreading poor writing was a risk that should not have been taken by a reasonable pharmacist, particularly due to the different administration of the medication.

Right 4(2)

In my opinion the dispensing manager also breached Right 4(2) of the Code of Rights. The Code of Ethics of the Pharmaceutical Society of New Zealand Rules 2.1 and 2.4 provide a guide to the standard of professional conduct required to ensure members of the public receive an adequate level of service from pharmacists.

In addition, part 4 of the Pharmacy Practice Handbook, January 1998, provides guidelines for meeting the Code of Ethics.

Continued on next page

4 June 1999 Page 8 of 13

Report on Opinion - Case 97HDC9338, continued

Opinion: Breach the Dispensing Manager continued In my opinion, insufficient steps were taken to safeguard the interests of the consumer in the supply of his medication and to ensure that the drugs supplied to him were correct. Further, the dispensing manager, as the dispensing pharmacist, did not interpret the prescription in a manner that complied with professional and ethical standards. These required her to endeavour to contact the health officer, and in the event that this was not possible, to not dispense the drugs.

Right 4(4)

In my opinion the dispensing manager also breached Right 4(4) of the Code of Rights. She did not provide services to the consumer in a manner that minimised potential harm to him. The dispensing manager was sufficiently concerned about the prescription to try and contact the health officer but took no further action. By dispensing the medication to the consumer while doubt remained about the prescription, the dispensing manager's actions did not minimise potential harm to the consumer.

Opinion: Breach the Pharmacy Manager In my opinion the pharmacy manager breached Rights 4(1), 4(2) and 4(4) of the Code of Rights as follows:

Rights 4(1) and 4(2)

As well as inputting the prescription into the computer, the pharmacy manager confirmed the interpretation of the prescription along with the dispensing manager and the pharmacy intern. The pharmacy manager bears responsibility for ensuring that procedures are followed to guarantee that medication is correctly dispensed to members of the public. The checks in place in the pharmacy were insufficient. Specifically, a protocol should have been in place for dealing with prescriptions about which the dispensing pharmacist has doubts. As stated above, the passing of a note to someone picking up a prescription on behalf of a consumer is insufficient. In my opinion, the pharmacy manager did not meet the appropriate standard of care expected of a pharmacist, and, in particular, a managing pharmacist.

Continued on next page

4 June 1999 Page 9 of 13

Report on Opinion - Case 97HDC9338, continued

Opinion: Breach the Pharmacy Manager continued I do not accept the suggestion made by the pharmacy manager that the consumer should have queried the different method of administration of the drug and therefore alerted the health officer or the pharmacy to the fact that there may have been an error. In my opinion the consumer did not have the onus to determine whether he had been given the correct medication and instructions. It was reasonable for him to assume that his medication had been correctly dispensed. Further, the pharmacy manager's comment that the health officer's handwriting was a factor in the misinterpretation is no excuse. As soon as there were difficulties in interpretation, attempts should have been made to contact the health officer or the hospital.

Rights 4(2) and 4(4)

In my opinion the pharmacy manager also breached Rights 4(2) and 4(4) of the Code of Rights. The Code of Ethics of the Pharmaceutical Society of New Zealand provides that a pharmacist must safeguard the interests of the public in the supply of health and medicinal products. In my opinion, insufficient steps were taken to safeguard the consumer's interests by ensuring the drugs supplied to him were correct. Although the pharmacy manager did not directly supply the incorrect medication, as manager he was responsible for ensuring that adequate safeguards were in place and acted upon.

In my opinion the pharmacy manager did not ensure that an appropriate standard of service was provided in a manner that minimised the potential harm to the consumer. Additionally, the pharmacy manager inputted the prescription into the computer and knew that there was a problem with interpretation of this prescription. He failed to ensure that further steps were taken to interpret the prescription. The pharmacy manager should have either attempted to call the health officer directly or instructed the dispensing manager or the pharmacy intern to do so.

4 June 1999 Page 10 of 13

Report on Opinion - Case 97HDC9338, continued

Opinion: No Breach the Pharmacy Intern In my opinion the pharmacy intern did not breach the Code of Rights. As a part of his internship, he was working under the direct supervision of a practising pharmacist.

The following comment is recorded in the Pharmaceutical Society of New Zealand's Preceptor Manual 1999:

"Remember than an intern must still be under your supervision when performing any functions of a pharmacist, and that you must still provide the final check."

Further, Regulation 37(1) of the Pharmacy Regulations 1975 states:

"Practical training shall be served under the direct personal supervision and as the sole pupil of a pharmacist..."

The pharmacy intern therefore has no personal liability for the errors that occurred in relation to the consumer's prescription. However, his involvement in this dispensing error should be a lesson to him about the importance of taking steps to clarify the terms of a prescription where there is doubt about what has been prescribed.

Opinion: Breach The Pharmacy

In my opinion the pharmacy breached Rights 4(1) 4(2) and 4(4) of the Code of Rights.

The pharmacy has not shown that reasonably practicable steps were taken to prevent breaches of the Code. In my opinion the systems in place at the pharmacy were not sufficient to prevent an error such as this occurring. As a result, services were not provided with reasonable care and skill and did not comply with professional and ethical standards as set out above. Further, in my opinion this failure exacerbated potential harm to the consumer.

4 June 1999 Page 11 of 13

Report on Opinion – Case 97HDC9338, continued

Opinion: No Breach the Health Officer In my opinion the health officer did not breach the Code of Rights. At the time the health officer wrote the prescription and handed it to the consumer he was working as a second year house officer at the hospital. The health officer wrote the prescription under the instructions of the infectious diseases physician. The health officer had no experience in prescribing the particular medication and until notified by the Commissioner, was unaware that the prescribed items were only available at a hospital dispensary or a retail pharmacy with a hospital-dispensing contract.

Opinion: Breach Crown Health Enterprise In my opinion, the hospital breached Right 6(1)(e) of the Code of Rights.

The health officer was a second year house officer when he provided the prescription and was acting under instructions from the infectious diseases physician. In a letter obtained from the hospital records dated 16 October 1997, the infectious diseases physician acknowledges to the consumer's general practitioner that neither he nor the health officer had advised the consumer that the medication was not available from a community pharmacy. The hospital clearly does not have protocols in place that ensure consumers are given information on availability of medication. As noted above, they advised me that:

"Medical staff make the correct identification when prescribing medications through experience alone as the constant change in dispensing requirements makes it impossible to maintain a perfect knowledge of these changes. Senior medical staff do try to maintain a working knowledge of these requirements and endeavour to pass this on to junior staff."

In my opinion, relying on senior medical staff to try and maintain such working knowledge and endeavour to pass this on to junior staff, is not acceptable. Such information must be computerised and be available to all medical staff in order for prescribers to have ready access to the information and be able to pass this on to consumers.

I note that a community pharmacy dispensing "hospital only medicines" in the hospital foyer is only practical if medical staff have knowledge of which medicines are only available from the hospital.

4 June 1999 Page 12 of 13

Report on Opinion - Case 97HDC9338, continued

Actions

I recommend the dispensing manager, the pharmacy manager and the Crown Health Enterprise provide written apologies to the consumer for breaching the Code of Rights. These letters are to be sent to my office and I will forward them to the consumer.

I recommend the pharmacy review its procedures and institute a protocol outlining steps to be followed in cases where a dispensing pharmacist has doubts over a prescription. The protocol should provide that medication must not be dispensed if there is any uncertainty about the prescription.

I recommend the Crown Health Enterprise develop information systems to ensure medical practitioners can inform consumers when medications are not available through community pharmacies.

A copy of this opinion will be sent to the Pharmaceutical Society of New Zealand.

4 June 1999 Page 13 of 13