Pharmacist, Mr B

A Pharmacy

A Report by the

Deputy Health and Disability Commissioner

(Case 07HDC21772)

Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

Information gathered during investigation

Overview

On 29 November 2007, Mr A, aged 21, collected his three-month supply of insulin from a pharmacy (the Pharmacy). The script for Humalog insulin and Humulin NPH had been faxed to the Pharmacy by nurse practitioner Ms C, and was dispensed by the sole charge pharmacist, Mr B. Mr A was given Humulin R instead of his usual insulin type, Humulin NPH. He queried this with Mr B, who informed him that Humulin N had been discontinued by the pharmaceutical company, Eli Lilly and Company Ltd, and replaced with Humulin R. Mr B told Mr A that he could use Humulin R in the same way he would use Humulin N.

On Sunday 9 December, when Mr A was due to start his new supply of insulin, he telephoned Mr B and again queried the use of Humulin R. Mr B repeated that he had given Mr A the correct insulin. Mr A used this insulin for two days and began to suffer adverse effects. When he contacted a specialist diabetes nurse, she advised him that he had been given the wrong type of insulin.

The Humulin R dispensed to Mr A had passed its expiry date 18 months earlier.

Complaint and Investigation

On 17 December 2007, the Health and Disability Commissioner received a complaint from Mr A about the services provided to him by Mr B. The following issues were subsequently identified for investigation:

- *The appropriateness of the services Mr B provided Mr A from 29 November to 31 December 2007, including the information provided about the type of insulin dispensed.*
- *The adequacy of pharmacy practices at the Pharmacy, including the dispensing procedures and stock management.*

The investigation commenced on 22 January 2008. Information was obtained from:

Mr A — Consumer
Mr B — Pharmacist / Provider
The Pharmacy — Provider
Ms C — Nurse Practitioner
Ms D — Diabetes Nurse Specialist, the District Health Board
Ms E — Eli Lilly and Company Ltd representative
Independent advice was obtained from pharmacist John Fraser and is attached as **Appendix 1**.

What Happened?

Background
In March 2006, the pharmaceutical company, Eli Lilly and Company Ltd, made minor changes to the names of two of its insulin products. Information about this was widely circulated, including to pharmacies.

Humulin N is an intermediate-acting insulin, which takes effect within one hour of administration and lasts for 16 to 18 hours. It was renamed Humulin NPH, while another product, Humulin 70/30 (a pre-mixed insulin), became Humulin 30/70. The formulation and dosage of these products remained unchanged. Although the packaging was altered, the international colour coding remained the same. Green was the colour code for Humulin N and it continued to be used for Humulin NPH.

A third insulin product, Humulin R, was not renamed or changed in any way. Humulin R is a short-acting insulin, which takes effect within 30 minutes of administration and lasts six to eight hours. It is internationally colour coded yellow.

Wrong medication
Mr A has been a type one (insulin-dependent) diabetic for six years, taking two types of insulin: Humulin NPH and Humalog (fast-acting insulin).[1] The Pharmacy has dispensed his prescriptions since May 2007.

On 29 November 2007, Mr A collected his three-month supply of insulin. His prescription correctly stated Humulin NPH but Mr A observed that he had been given Humulin R instead. He asked about the difference. Mr B told him that the drug company no longer supplied Humulin N, and Mr A was to use Humulin R in the same way as he would have previously used Humulin N.

On Sunday 9 December 2007, Mr A was due to begin his new insulin. As he had "second doubts" about whether the Humulin R insulin dispensed to him on 29 November was correct, he telephoned the Pharmacy. Mr B again told him that the company had changed the insulin and he was to administer it in the same dose, and at the same times, as he would have used Humulin NPH (or N). The following day Mr A felt unwell, with hyperglycaemic symptoms (an excess of glucose in the bloodstream). He felt "gluggy" for the rest of the day. Believing there had been a manufacturing problem with this dose of insulin, he took a second dose that night. The following day, 11 December, he felt worse and contacted the District Health Board's specialist diabetes nurse, Ms D. She told him that Humulin NPH had not been replaced, and that Humulin R was not appropriate for him. She arranged for him to attend the Diabetes Centre, where she gave him the correct medication. Ms D said that Mr A was quite ill,

[1] Humalog is a fast-acting, short duration insulin. There is no concern regarding the dispensing of Mr A's Humalog, therefore it is not referred to further in this report.

and had he continued taking Humulin R he would have gone into a diabetic coma. Mr A subsequently noted that the Humulin R he had taken had expired in June 2006.

Ms D reported the incident to Ms E, the drug representative for Eli Lilly and Company Ltd. On about 12 December, Ms E visited the Pharmacy to speak with Mr B and check his drug management system. Mr B told her that he thought Humulin N had been discontinued and replaced with Humulin R. He could not recall where this information had come from. Mr B told her that he did not check the Humulin insulin product information on either occasion when Mr A queried his dispensing. Mr B had "thought" his information on the product was correct.

Ms E was very concerned that Mr B had dispensed insulin that had expired in June 2006. She checked Mr B's insulin stock. Ms E confirmed that the remaining insulin was within date. She provided Mr B with an Eli Lilly and Company Ltd insulin range chart and a card outlining the minor changes that had occurred to the brand names of the two Humulin products.

Mr B contacted nurse practitioner Ms C and explained that an error had occurred with the dispensing of Mr A's insulin. Ms C said that Mr B acknowledged that her prescription had been correct; that the error was his; and that it was possibly due to a recent bout of ill health and the effect on his memory of the medications he was taking.

Mr B's response

Mr B has been a pharmacist for 54 years, and has owned four pharmacies during this time. He is the owner and sole pharmacist at the Pharmacy and, on 29 November 2007, he dispensed Mr A's insulin as follows: "1 only 3ml vial of Humulin R insulin and 1 only 3ml vial of Humalog".

Mr B said that he thought he had dispensed Mr A's usual insulin,[2] and this is why, when Mr A queried the type R insulin, Mr B confirmed that it was correct. He stated: "Being the sole pharmacist here I had no way of re-checking my actions."

He said that his "confusion at the time" originated from the fact that the Humulin N insulin name had changed about 18 months earlier to Humulin NPH.

He also acknowledged that the Humulin R he dispensed to Mr A had expired. He stated:

> "Humulin R insulin had been discontinued some time ago and admittedly it should have been disposed of but it missed the scrutiny of a locum Pharmacist that was

[2] Mr B provided a copy of Mr A's Pharmacy's patient history report which showed that from May 2007 up to 29 November 2007, Mr A received Humulin NPH on seven occasions.

> employed here for a short period of time and who made a point of checking and discarding outdated dispensary stock items."

Mr B believed that some Humulin R must have remained in the back of the fridge.

Mr B said that he did not investigate this event as he accepted that he had made a "genuine error … and the lesson learned was that it would not happen again". He did not complete an incident report but instead entered information in his diary. He said that he explained to Mr A that the mistake was not deliberate and he "naturally felt very sorry" and was "very apologetic to him" for the way the insulin affected him. Mr B stated that it should be seen in the context that he had not made such an error before.

Mr B has not changed the systems or his practice of dispensing following this error because this is the first time such an event has occurred and he feels his systems, which he had been taught originally, have stood the test of time. He said that stock management occurs daily as new stock arrives, is recorded, and current stock sold. The same system is on all four of the Pharmacy's computers.

Mr B provided a copy of part of the Pharmacy's Standard Operating Procedures (SOPs). "Policy Number 1, Dispensing. Procedure 1.6 Selecting the correct medicine" asks that the pharmacist check the selected medicine against the prescription (strength, dose, name, dosage form etc), the selected brand and the expiry date.

Mr B said that in July 2007, he had a serious angina attack requiring heart surgery. He was advised to remain off work for two months but returned to his business sooner because he was unable to retain locum cover. He stated:

> "My explanation of my 'memory lapse' at the time of dispensing [Mr A's] incorrect insulin, can surely be attributed to this course of events including possible 'memory effects' of the cardiac recovery drugs."

Mr B said that he has now recovered and taken on temporary qualified support staff, allowing him to work fewer hours, although he is again working as the sole pharmacist.

Mr B's response to my provisional opinion

Mr B said that for ten months leading up to this incident, he had dispensed Mr A with the correct insulin. Although he is still unable to provide a clear explanation of why this error occurred, he has reiterated his belief that it was a consequence of his medical condition and treatment. Mr B said that following his coronary by-pass surgery he had to return to work one month earlier than planned as he had been unable to retain locum cover. Mr B said that he had employed eight different locums between July,

when he had his first angina attack, and November 2007, when he returned to work as his last locum had to leave because of illness. He acknowledged that he was unwell and was adjusting to drug therapy.

Mr B advised:

> "My health is back to normal and I am (and have been since November 2007) practising fulltime as a very busy pharmacist. I have not breached any service contract rules and am not likely to do so."

Although Mr B acknowledged that he had a MIMS New Ethicals (drug product information) directory by his computer for technical assistance, he did not use this when Mr A queried whether the insulin he had been given was correct. Mr B stated:

> "When [Mr A] phoned me wanting clarification information on the Humulin R insulin that he had received without further checking, I thought I had dispensed to him Humulin N insulin."

Mr B said that Mr A did not alert him to the date on the product.

Mr B stated that he has now included in his SOPs a policy for investigating errors in the Pharmacy's standard operating procedures. He has reviewed his dispensing and checking procedures and stock management system, with particular focus on identifying and managing out-of-date stock.

Mr B said that he is embarrassed to have made such an uncharacteristic error. He deeply regrets what occurred. He has written Mr A a letter of apology outlining this.

Opinion:

This report is the opinion of Rae Lamb, Deputy Commissioner, and is made in accordance with the power delegated to her by the Commissioner.

Breach — Mr B

Under Rights 4(1) and 4(2) of the Code of Health and Disability Services Consumers' Rights (the Code) Mr A had a right to pharmacy services of an appropriate standard in compliance with professional standards.

The standards that apply in this case are the Pharmacy Council of New Zealand Code of Ethics, 2004, and the Pharmacy Council of New Zealand Competence Standards, August 2006.

For the reasons set out below, Mr B breached Rights 4(1) and 4(2) of the Code. In my view, his errors are serious, because he not only dispensed the wrong drug, he dispensed an out-of-date drug, and he missed key opportunities to rectify this before it affected Mr A.

Insulin dispensing
As a type one diabetic, Mr A relies on receiving the correct insulin to control his blood sugar levels. At the time of these events, he was already known to Mr B, who had filled his prescriptions for Humulin NPH, apparently without any problems, from May 2007.

On 29 November 2007, Mr B gave Mr A the wrong insulin, with potentially serious consequences. Mr A's diabetes was not controlled for two days and he developed symptoms of hyperglacaemia (high blood sugar). Specialist diabetes nurse Ms D is of the view that, had Mr A not sought assistance from her when he did, he could have gone into a diabetic coma.

There is no doubt that the correct prescription was presented to the Pharmacy on that day. It is also accepted that what was dispensed to Mr A was Humulin R, a short-acting insulin, lasting six to eight hours, instead of his normal insulin (Humulin NPH), which would last 16 to 18 hours. Mr B has also acknowledged that the "use by" date on the Humulin R had expired in June 2006.

The reasons for the error are less clear. Mr B said that he thought he had dispensed Mr A the correct insulin. He initially told Mr A that Humulin R had replaced Humulin N when the names were changed by the drug company. He is not clear on how he reached this conclusion, and has subsequently acknowledged that it was actually Humulin NPH that replaced the Humulin N insulin. In his response to this Office, he inferred that it was Humulin R that had been discontinued. It has not.

My expert advisor, Mr John Fraser, said that it is understandable that renaming a medicine can cause confusion, but these changes were relatively minor, occurred almost two years previously, and were heavily promoted by the pharmaceutical company. He said it was evident that Mr B's understanding of the Humulin insulin range was neither accurate nor current. Given this, Mr B could have considered a range of information relevant to correctly dispensing Mr A's insulin. For instance, Mr A's patient history record showed that he had previously been dispensed Humulin NPH. It is also noted that both the formerly named Humulin N and its replacement, Humulin NPH, are colour coded green while Humulin R is coded yellow. These colour codes are intended to minimise the risk of insulin dispensing errors.

Furthermore, on two occasions Mr A questioned why he had received a different type of insulin from usual. Mr A has had diabetes for six years and is very familiar with his medications. In twice dismissing Mr A's concerns, Mr B missed important opportunities to clarify the matter and rectify his earlier mistake.

The Pharmacy Council of New Zealand Code of Ethics requires a pharmacist (section 1.1) to provide patients with accurate and current information. Mr Fraser commented that reliance on memory is risky as it can be imperfect. A pharmacist should consult available literature or reference material on a product, particularly when the veracity of the product is being questioned by a patient. Mr B should have checked his Eli Lilly and Company Ltd insulin product reference material, rather than solely relying on the accuracy of his memory.

As Mr Fraser correctly stated: "Given that [Mr A] telephoned specifically for reassurance about a variation in his prescription for a life-sustaining drug, [Mr B] should have made more of an effort."

Mr B sees his error as a single incident. However, I agree with Mr Fraser's assessment that Mr B made a series of errors and false assumptions. He believed Humulin N had been discontinued rather than re-branded NPH; he considered Humulin R was an acceptable substitute for Humulin N; he dispensed Mr A the wrong insulin; he dispensed insulin that had expired in June 2006; and he falsely reassured Mr A that he had received the correct medication. Lastly, Mr B (in his response to this complaint) incorrectly said that Humulin R had been discontinued.

Mr B's response to the error

Mr B's response to this incident is as concerning as the error itself. We know from a large study of pharmacy errors in the United Kingdom[3] that, on average, for every 10,000 items dispensed in community pharmacies there are around 22 near misses and four dispensing errors. Therefore, the response to an error is extremely important as it provides an opportunity for learning from the event and to take steps to avoid it happening again.

Mr Fraser advised:

> "While an error might be due to a genuine, unforeseeable mistake, the pharmacist has full control over what he or she does once notified of the error … It is the duty of the pharmacist to minimise ongoing harm, to prevent recurrence, and as a matter of natural justice cover any reasonable costs arising from the error. Every error of any significance must prompt a full review which should be documented."

[3] Ashcroft, D.M., Quinlan, P. and Belinkinsopp, A. (2005). Prospective study of the incidence, nature and causes of dispensing errors in community pharmacies. *Pharmacoepidemiology and Drug Safety*. **14**:327–332.

I agree with Mr Fraser's view that Mr B did not respond to the error in "an appropriate and timely manner, implying that he had not assumed full responsibility for the mistake".

Mr B initially did little apart from offering an apology. He did not investigate the error, complete an incident form, or review the dispensing policy. Mr B stated that the lesson to be learned is "that it will not happen again". Like Mr Fraser, I am of the view that "[Mr B's] earlier statements seem dismissive".

However, I note that Mr B has, following this investigation, included in his SOP a policy for the investigation of errors; reviewed his dispensing and checking procedures and stock management; and written Mr A an apology.

Mr B's health

Mr B has raised the matter of his health leading up to this incident. He believes this error may have occurred because of his angina, heart operation, and the effect the medication had on his memory. He said that he was forced to return earlier to his work as a sole pharmacist following surgery because he was unable to engage a locum to cover the period of convalescence suggested by his doctor.

Mr Fraser has commented that "older pharmacists with less-than-perfect health, … cannot gloss over errors or ask for special dispensations on [their] practice. Any patient walking into any pharmacy has the right to expect the same minimum standards of care, regardless of who the pharmacist on duty is."

While I have some sympathy for the situation Mr B found himself in, a pharmacy is a business where the safety of patients must come first. Mr B had a duty to put Mr A's safety ahead of his business interests. As a sole charge pharmacist this was even more important.

Despite this, Mr B went back to work earlier than he should have. He was working as a lone pharmacist and he was taking medications that he has now said may have affected his memory and therefore contributed to the dispensing error and his response to it. This is not acceptable.

Furthermore, Section 3.1 of the Pharmacy Council's Code of Ethics clearly states that a pharmacist has an obligation to report to his or her professional body any concerns regarding his or her personal health status and its possible impact on practice. There is no evidence that Mr B took this action.

Summary

This was a serious dispensing error involving several incorrect assumptions by Mr B, who then failed on two occasions to respond appropriately to concerns raised by Mr A; and subsequently failed to follow up the error as he should have.

By failing to provide pharmacy services with reasonable care and skill and in accordance with professional standards, Mr B breached Rights 4(1) and 4(2) of the Code.

Opinion: Breach — the Pharmacy

The second matter I have considered is whether the Pharmacy had adequate pharmacy practices operating on 29 November 2007, particularly in relation to dispensing procedures and stock management.

Dispensing systems

Mr B is the owner of the Pharmacy, and he was the sole pharmacist when this error occurred. He is very experienced and initially he said that he did not believe the Pharmacy needed to review its dispensing systems, as these systems had stood the test of time. I strongly disagree with this.

Mr Fraser has advised that the Pharmacy's written policy and SOPs for dispensing appear adequate, and that the error occurred because Mr B did not follow these. However, he also noted that, at the time of these events, the SOPs had not been updated since December 2003. It is normal practice to update these documents more regularly, around every 24 months.

Mr Fraser also advised that the dispensing SOPs could be improved to emphasise the need for self-checking by a sole pharmacist. Mr B said that as the sole pharmacist on site, he had no way of rechecking his actions in dispensing Mr A's prescription. Mr Fraser suggested a number of methods a sole pharmacist can use to self-check. These include creating a slight delay in the dispensing procedure to "psychologically reset" before confirming the relevant prescription details.

In my view, in order to ensure public safety, the Pharmacy has an obligation to make sure that a sole pharmacist does have a robust method of self-checking the medications he or she is dispensing. Furthermore, its SOPs must be regularly reviewed.

Stock management

As noted previously, the Humulin R that Mr B dispensed was almost 18 months out of date. Mr B said that Humulin R had been discontinued, and he assumed that a locum, who had taken on the task of checking and discarding outdated dispensary stock, would have found this and removed it.

Mr B stated that the Pharmacy's stock rotation is checked daily, and he does not believe the system needs changing because it has stood the test of time. He said that the dispensing of this incorrect and outdated stock was "human error" and the first that had occurred in his 54 years as a pharmacist.

Like Mr Fraser, I am concerned that a product like Humulin R, which requires refrigeration, could remain undetected in a pharmacy fridge for eighteen months (although it is reassuring to note that shortly after this incident an Eli Lilly and Company Ltd representative, Ms E, audited the Pharmacy's stock and did not find any further date-expired stock).

In my view, this incident clearly demonstrates inadequate stock management, particularly when the outdated insulin remained undetected for so long.

Incident reporting
I also note that the Pharmacy does not appear to have a formal incident investigation policy that clearly outlines what actions an employee of the Pharmacy should take to manage an incident such as a dispensing error.

Mr B said that he did not complete an incident report on this matter and he relies on a diary entry when incidents occur. In my view, this is not a sound mechanism for conducting a comprehensive review of an error that ensures the confidence of the Pharmacy's SOPs, and reduces the risk of the error being repeated.

Further to this, Mr Fraser identified a number of sub-elements from the Pharmacy Council of New Zealand Competence Standards, August 2006 that Mr B failed to achieve. Mr Fraser suggested that the Pharmacy "develop a firm policy on what must be done in the event that another error happens; this policy should incorporate the PDA [Pharmacy Defence Association] suggestions … and should be adhered to rigorously".

Summary
In my opinion, the Pharmacy did not have an up-to-date dispensing SOP that was appropriate for a business reliant mainly on a sole pharmacist; it did not have an adequate stock management system; and its procedures for documenting incidents and responding to errors were seriously deficient. Therefore, I find that the Pharmacy did not provide Mr A with services with reasonable care and skill. The Pharmacy has breached Right 4(1) of the Code.

Action taken

As previously stated, Mr B has sent this Office a written apology to be forwarded to Mr A. He has also

- Included in his SOP a policy for investigating errors
- reviewed his dispensing and checking procedures for a sole pharmacist, and his stock management system

Follow-up actions

I intend to:

- Send a copy of this report to the Pharmacy Council of New Zealand with the recommendation that it consider Mr B's competence to practise.

- Send a copy of this report to the Ministry of Health (Medicines Control) with a recommendation that it consider auditing the Pharmacy, including a review of its SOPs, particularly regarding dispensing and checking and stock management procedures.

- Send a copy of this report, with details identifying the parties removed, to the Pharmaceutical Society; the Pharmacy Industry Training Organisation; the Safe and Quality Use of Medicines Group; and Eli Lilly and Company Ltd, and place it on the Health and Disability Commissioner's website, www.hdc.org.nz, for educational purposes.

Non-referral to Director of Proceedings

This was a significant incident with potentially serious consequences. Mr B made a number of errors and Mr A was harmed. Of particular concern was Mr B's failure to listen to Mr A on the two occasions when he questioned the insulin dispensed to him. Mr A was an informed consumer and Mr B missed vital opportunities to catch this error before any harm occurred. For these reasons, a referral of Mr B to the Director of Proceedings for possible disciplinary action was carefully considered. Mr A indicated that he would support such a referral.

However, I have decided not to refer Mr B to the Director of Proceedings. In making this decision I have taken into account the circumstances in which this incident occurred; Mr B's actions in apologising and subsequently reviewing his procedures and policies; and, most importantly, public safety. In my view, the referral of Mr B to the Pharmacy Council of New Zealand, and the referral of the Pharmacy to the Ministry of Health will allow any issues of competence and practices to be appropriately addressed. Additionally, the public interest in highlighting appropriate professional standards will be sufficiently achieved by holding Mr B accountable for breaching the Code, and publishing an anonymised version of this report on the HDC website. Little more would be achieved by the additional step of disciplinary proceedings.

Appendix 1

"**1. Introductory comments**

1.1. Introduction

I would like to thank the Commissioner for asking me to review this case, number 07/21772, regarding [Mr A] and [the Pharmacy]. This matter was referred to me for my opinion on 13 March 2008.

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; I also hold the degree of Bachelor of Science in Physiology (Otago). I have 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 junior apprentice to proprietor/manager.

I was formerly the President of the 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 of pharmaceutical agents. I have been involved as a label safety consultant to the pharmaceutical industry although at present I have no financial interests in this area.

In June 2006, my work in developing an error prevention program for New Zealand Pharmacies led to me receiving the New Zealand Pharmacy Award for Innovation in Pharmacy Practice, as well as the Supreme Pharmacy Award.

In March 2008, I retired from full-time pharmacy work. However, I was still working full-time when the events of the current case occurred.

1.3 Declarations

I have read, and agree to follow, the Commissioner's Guidelines for Independent Advisors.

I understand that my report is subject to the Privacy Act 1993 and the Official Information Act 1982, and that under those Acts my advice may be requested and disclosed. I understand that the Commissioner's policy is to name his advisors where any advice is relied upon in making a decision.

I have previously entered into a formal confidentiality agreement relating to any advice I give the Commissioner.

I have compiled this report in good faith, based on the information available to me, All opinions stated herein are solely my own.

1.4 Directions from the Commissioner

[Mr Fraser included the background and a list of the material supplied by the Commissioner's Office. As these are referred to or included in his response they have been omitted for the sake of brevity.]

1.5 Material examined

In providing my opinion, I have examined … material supplied to me by the HDC.

I have also referred to the following:

The Medicines Act 1981; Medicines Regulations 1984; Code of Ethics 2004; Pharmacy Competence Standards 2006; Pharmacy Practice Handbook 2003.

2. Summary of Facts

[Mr A] is a 21-year-old diabetic who has controlled his diabetes using insulin for the past six years. He is a regular customer at [the Pharmacy], which is owned and operated by pharmacist [Mr B]. [Mr B] usually operates as a sole pharmacist and dispenses alone.

On Thursday 29 November 2007, [Mr A] faxed a prescription to [the Pharmacy] for Humalog insulin (one 100IU/1ml cartridge) and Humulin NPH (one 100IU/1ml cartridge). The prescription sheet itself was accurate and up-to-date in all aspects.

Later on the same day, [Mr A] attended [the Pharmacy] in person to collect his insulin. [Mr B] informed [Mr A] that 'Humulin N' (i.e. Humulin NPH) had been discontinued. He said that he would dispense a different type of insulin, Humulin R, in its place. [Mr B] assured him that type R was an appropriate substitute for type N.

In fact, Humulin N had not been discontinued, although it had undergone a name change in March 2006, from 'N' to 'NPH.' Furthermore, type R was not an appropriate substitute for type NPH. Humulin R is a short acting form of insulin (duration 6–8 hours) while Humulin NPH is an intermediate-acting form (duration 16–18 hours).

On Sunday 9 December 2007, [Mr A] was due to start taking his new insulin prescription and was sufficiently concerned that he telephoned [Mr B] to confirm that he had been given the right sort of insulin. [Mr B] assured him that the dispensing was correct.

[Mr A] started to take the Humulin R in the normal manner and over the next two days suffered adverse effects, probably a direct consequence of using the wrong type

of insulin. He felt 'very ill' and was concerned that he might be 'heading into [diabetic ketoacidosis]' which is a severe and potentially life-threatening complication for a diabetic.

[Mr A] contacted his diabetes nurse, who reviewed his medication and confirmed that he had been given the wrong type of insulin, and told him that the information provided to him by [Mr B] was incorrect. This was later confirmed by a representative from Eli Lilly and Company Ltd, the company which manufactures Humulin.

It was later noted that the Humulin R given to [Mr A] had expired some 18 months previously, in June 2006.

In later written correspondence, [Mr B] claimed that Humulin R had also been discontinued (apparently in addition to Humulin N), but he was unable to state why he had developed this opinion. Neither 'R' nor 'N' had been discontinued, although they had undergone minor branding changes about 20 months previously.

To summarise, [Mr B] made several independent mistakes.

1) He incorrectly believed that Humulin N had been discontinued.
2) He incorrectly believed that Humulin R was an acceptable substitute for Humulin N.
3) On the basis of 1) and 2) he dispensed an inappropriate medication for [Mr A].
4) The medication dispensed in 3) had expired 18 months previously.
5) When later contacted, he reassured [Mr A] that the dispensing in 3) was correct.
6) In later discussions, he expressed the belief that Humulin R had also been discontinued.

3. Commissioner's questions

3.1 What standards apply to [a] sole pharmacist when managing a prescription such as [Mr A's] (on 29 November 2007)? Did [Mr B's] actions comply with those standards?

The standards that apply in this case are the standards that would apply to all practising pharmacists in New Zealand at the time that the incident occurred. Irrespective of whether a pharmacist is a sole operator, or working in a large team, the basic obligations to healthcare consumers are the same.

There are a very large number of applicable rules and regulations affecting pharmacy, including at least 20 separate statutes; but the following are particularly relevant to this case:

- Pharmacy Council of New Zealand Code of Ethics, 2004[4]
- Pharmacy Council of New Zealand Competence Standards, updated August 2006. [5]

While most aspects of these standards were met, there were unfortunately some breaches of these standards, Below, I outline certain specific standards relevant to this case, and explain why I think [Mr B's] actions did not meet these standards. (Note: where possible, I have grouped related standards together; however due to overlap of standards, some degree of repetition is unavoidable.)

Pharmacy Council of New Zealand Code of Ethics, 2004

Obligation 1.1 — Accurate and current information

'The pharmacist providing any professional service or intervention must do so on the basis of accurate and current information'.

It is fairly obvious that, at least temporarily, [Mr B's] understanding of the Humulin product range was neither accurate nor current. He believed that Humulin N was discontinued; he believed that Humulin R was an acceptable replacement for Humulin N. He later stated that Humulin R was itself discontinued (implying that he replaced one 'discontinued' product with another). On the basis of these erroneous beliefs he committed the dispensing error.

[Mr B] persisted in these beliefs even when telephoned by [Mr A] for reassurance. Given the amount of informational material about Humulin distributed to pharmacies, it should have been a relatively simple matter to check a reference chart and discover the error.

It is understandable that renaming a medicine can cause confusion but this particular renaming was relatively minor, occurred almost two years previously, and was heavily promoted by the manufacturer, Eli Lilly and Company Ltd.

Based on these facts, it must be concluded that this standard was not met for [Mr A's] dispensing.

[4] Pharmacy Council of New Zealand (2004). Code of Ethics 2004. Available on the world wide web at http://www.pharmacycouncil.org.n/pharmacists/standard/documents/CODEofEthics20.

[5] 2 Pharmacy Council of New Zealand Competence Standards. Available on the world wide web at http://www.pharmacycouncil.org.nz/pharmacists/standard/documents/Standards-7UpdatedAug2006.pdf

Obligation 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'.

This standard was not met. The medication dispensed was not what the doctor prescribed, nor was it an appropriate substitute for what the doctor prescribed. Further, the vial was significantly beyond its stated expiry date and as such was not appropriate for dispensing in any case.

Obligation 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'.

The particular emphasis here is 'when asked for advice … the pharmacist must ensure that sufficient information is obtained …' In other words, when [Mr B] dispensed the prescription (and also when [Mr A] telephoned for clarification), [Mr B] should have made more of an effort to check readily-available information sources regarding the dispensing. Eli Lilly and Company Ltd had distributed a high quality reference chart relating to the new Humulin range. They also have a free-phone number (0800-500-909) for any enquiries about the products. Given that [Mr B] apparently only went by memory, and apparently did not check any sources despite explicit requests for reassurance, I can only conclude that this standard was not met.

Obligation 5.1 — Maintaining competence

'The pharmacist must maintain the level of professional competence relative to their sphere of activity and demonstrate competence in the area in which they practise, within their scope of practice'.

&

Obligation 5.2 — Pharmaceutical knowledge

'The pharmacist must keep abreast of pharmaceutical knowledge applicable to the area in which they practise'.

The primary cause of this error seems to be [Mr B's] confusion regarding the Humulin product range, and his failure to check any references when prompted

to do so. As already stated, he appeared to hold several misconceptions about Humulin — and at least one misconception seemed to persist in his letter written months after the error.

I should note that [Mr B] has no doubt dispensed Humulin hundreds of times without error, so this error would hopefully have been a 'one-off.' It is concerning, however, to observe that [Mr B] did not hold one misconception but several related misconceptions.

I must conclude that, at least in the specific area of his understanding of the Humulin range in late 2007, these standards were not met.

Pharmacy Council of New Zealand Competence Standards, August 2006

Sub-element 1.1.3 Accepts responsibility for own work tasks and performance

'Examples of Evidence: Owns the results of her/his work, Identifies tasks / aspects of practice for which she/he is personally responsible, Identifies wider effect of his/her actions on individuals and the community'.

&

Sub-element 1.1.5 — Works accurately

'Examples of Evidence: Minimises mistakes; Acts immediately to rectify harm arising from mistakes; Documents errors & steps taken to prevent their recurrence'.

I feel that neither of these sub-elements was adhered to. The facts suggest that [Mr B] did not respond to the error in an appropriate and timely manner, implying that he had not assumed full responsibility for the mistake. I have been especially concerned by [Mr B's] actions and statements in response to this error.

Based on the information I have reviewed, [Mr B] did little apart from offer a verbal apology to [Mr A] when first notified of the error around 10 December 2007. In his letter to Deputy Commissioner Rae Lamb, [Mr B] wrote, 'I can not provide an internal review or details of an investigation because there was not one. The fact was accepted that a genuine error had been made at the time by myself, and the lesson learned was that it would not happen again...' and, 'I do not have an incident report...' and, 'the dispensing policy at this pharmacy has not changed ...'

While I am sure [Mr B] is usually a conscientious pharmacist, these statements seem dismissive. This incident should have prompted [Mr B] to undertake a full investigation. (This need not be an onerous undertaking, but merely requires some time to reflect and review procedures.)

Whenever a dispensing error occurs, the response to the error is an aspect almost as important as the error itself. While an error might be due to a genuine, unforeseeable mistake, the pharmacist has full control over what he or she does once notified of the error. It is the duty of the pharmacist to minimise any ongoing harm, prevent recurrence, and as a matter of natural justice cover any reasonable costs arising from the error. Every error of any significance must prompt a full review which should be documented.

[The Pharmacy] Defence Association (PDA) spells out the appropriate steps to take in response to a medication error:

- if a patient notifies an error, the appropriate response is to express immediate concern;
- if the error is obvious, then the pharmacist should acknowledge the error and apologise;
- if the error is not obvious, the pharmacist should inform the patient they will investigate the situation and report back to the patient as quickly as possible;
- the pharmacist should ask questions of the patient to find out whether he or she has taken any of the incorrect medication and, if so, what symptoms have been experienced;
- the pharmacist should inform the patient about what the incorrectly dispensed medication is normally used for and its possible side effects;
- if appropriate, the patient should be reassured that the symptoms experienced are side effects of the medication and advised when they are likely to abate;
- if necessary, the patient should be referred to the prescriber, and [the Pharmacy] should offer to pay for the visit;
- the pharmacist should notify the prescriber of the situation, how the patient is, and what actions have been taken to date; and
- all aspects of the incident should be documented.

I would like to suggest that [Mr B] does at some stage develop a firm policy on what must be done in the event that another error happens; this policy should incorporate the PDA suggestions above and should be adhered to rigorously.

Sub-element 2.2.1 — Identifies common medicines by their approved generic, trade or common names

'Examples of Evidence: If given one form of a common medicine name, promptly identifies other forms from memory or a reference source'.

&

Sub-element 2.2.2 — Evaluates the available medicines, dose forms and methods of administration

'Examples of Evidence: Using readily available references, determines the advantages & disadvantages of different medicines, their dosages & dose forms for spec situations or patients'.

&

Sub-element 6.3.1 — Identifies prescribed medicines

'Examples of Evidence: Identifies trade, generic & common names for prescribed medicines; Uses reference sources to find medicine names'.

&

Sub-element 6.5.1 — Confirms that each selected medicine is suitable for the patient

'Examples of Evidence: Confirms that dosage, route of administration & duration of therapy are suitable; Identifies possible interactions or incompatibilities'.

These four sub-elements were not adhered to in this case.

Obviously, [Mr B] had incorrect understanding of the use and pharmaceutical attributes of Humulin N/NPH and Humulin R, and failed to check any references on these medications which might have resolved his misunderstanding. These errors resulted in him dispensing a drug which was not suitable for the patient.

I also note that the drug dispensed was significantly beyond its expiry date. Given that an expired item apparently sat in [the Pharmacy] fridge for a whole 18 months, I am concerned that the stock management in the refrigerator left much to be desired. While not illegal, it is poor practise for current and expired stock to be mixed together, especially for such a prolonged period.

[The Pharmacy] dispensing procedure clearly refers to checking expiry dates before dispensing, and under normal circumstances such an expired product should never have been given to the patient.

Sub-element 5.1.2 — Finds information in reference sources

'Examples of Evidence: Accesses tertiary medicine information sources e.g. BNF, MIMS New Ethicals; Accesses secondary medicines information sources e.g. Martindale, Medline; Selects optimal reference sources for situation; Finds spec information in a timely manner, including information on: patient factors, interactions, precautions & contraindications, therapeutic efficacy, dosages, dose forms, methods of administration & side effects'.

In response to [Mr A's] telephone enquiry seeking reassurance that his medicine was correct, [Mr B] should have consulted readily available reference material, rather than relying on memory alone. (For instance, Eli Lilly and Company Ltd had widely distributed a Humulin reference chart which [Mr B] should have been able to obtain with little effort.)

It is important for a pharmacist to refer to reference material when appropriate, even if they "know" the answer, because memory is imperfect, and drug information can change. Some patients seeking reassurance find it very helpful when a pharmacist mentions, or shows them, a written reference. One can not expect a pharmacist to look up a book every time they are asked a question, but in this case, given that [Mr A] telephoned specifically for reassurance about a variation in his prescription for a life-sustaining drug, [Mr B] should have made more of an effort.

If [Mr B] had referred to a reference such as the Eli Lilly and Company Ltd Humulin chart, I feel this error could have been resolved promptly.

As [Mr B] apparently did not refer to any reference sources during the dispensing, nor when asked for reassurance, I feel this standard was not met.

Sub-element 6.9.1 — Explains the general potential for errors in the dispensing process.

'Examples of Evidence: Identifies steps in dispensing procedure that are potential problem areas; Identifies actions to minimise actual/potential problem areas'.

&

Sub-element 6.9.2 — Acts to minimise the effects of his/her dispensing errors

'Examples of Evidence: Identifies potential/actual errors in own dispensing; Acts to minimise effect on patient, e.g. contacts patient, contacts prescriber, supplies correct medicine; Documents own dispensing errors & actions undertaken to minimise their effects; Complies with workplace procedures for documenting dispensing errors'.

&

Sub-element 6.9.3 — Rectifies dispensing errors immediately

'Examples of Evidence: Alters own dispensing procedure to prevent recurrence of previous errors'.

As already detailed, [Mr B's] comments and actions in response to the error were less than desirable, and I feel that his written correspondence to Rae Lamb reveals a somewhat dismissive approach to the error.

3.2 Please comment on actions taken by [Mr B] in discussing [Mr A's] concerns regarding the type of insulin he was being provided.

I believe I have dealt with this question in answer 3.1 above. To recap, it seems [Mr B] breached standards because he dispensed an inappropriate drug; dispensed a drug significantly beyond expiry date; and failed to check references in a situation when a pharmacist would normally have been expected to do so.

3.3 Please comment on [Mr A's] 9 December 2007 telephone conversation with [Mr B] regarding [Mr A's] concerns that he had not been given the correct medication.

I believe I have dealt with this question in answer 3.1 above. To recap, it seems [Mr B] again breached standards by failing to re-check references in a situation when a pharmacist would normally have been expected to do so.

(I note that [Mr B] later wrote of this call, 'being the sole pharmacist here I had no way of rechecking my actions.' I cannot agree with this statement. [Mr B] had several ways of rechecking his actions. He could have checked the dispensing history on his computer; he could have asked [Mr A] for the name of the insulin on the dispensed container; he could have referred to many sources for information. With the right questions and consultation of a reference chart, the error might have been detected within seconds.)

3.4 Please comment on [Mr B's] dispensing policy.

[Mr B's] written dispensing policy generally appears robust and well written. The error that occurred here was not a failure of policy as such, but a failure to adhere to the policy.

The written Standard Operating Procedure (SOP) for dispensing has relevant procedures for checking 'name, form and strength of medicine' (procedure 1.2) and 'selecting the correct medicine' and 'expiry dates' (procedure 1.6).

This said, I have a couple of minor issues with the [Mr B's] SOPs. I note that they have not been reviewed or updated since December 2003. It is normal practise to update policies at least every 24 months, even if just to re-read, initial and date the policy at the bottom of the page to confirm it is still current. I suggest that [Mr B] goes through his policies and confirms they are still up to date. This is a minor point and I would not regard it as a particularly serious departure from normal practise; it is more of an issue of keeping up-to-date records.

There is one aspect of the dispensing SOP that I feel could be improved — and that is to emphasise the importance of self-checking. It is perfectly possible, and important, for the sole dispenser to critically re-check their own dispensing. I believe that as a part of good pharmacy practise, all sole pharmacists should develop and adhere to a self-check regime. The current SOP (procedure 1.8) does not clearly define a self-checking procedure.

Self-checking can be achieved by introducing a temporal separation (i.e. a delay, even a few seconds) and a physical separation (i.e. checking in a slightly different place to where the original dispensing was done — even if just the other side of the bench). This helps the pharmacist to 'psychologically reset.' It is then a simple matter of re-confirming relevant details such as patient name and drug. [Mr B] should consider amending his dispensing policy to highlight this self-check.

I should emphasise that the old policy is in fact quite adequate and this can not be said to depart from any standard of care. My suggestion here is a significant improvement by adding another safety net, but that should not necessarily be interpreted as addressing a deficiency.

3.5 Please comment on [Mr B's] understanding of [Eli Lilly's] change of two insulin product names and that insulin R had been discontinued.

By now it is quite clear that [Mr B] was rather confused with the status of Eli Lilly and Company Ltd's Humulin range. As stated earlier, he made several independent errors.

A) That Humulin R had been discontinued: incorrect.

B) That Humulin NPH had been discontinued: incorrect.

C) That Humulin R was a suitable substitute for Humulin NPH: incorrect.

D) It is noteworthy that [Mr B] thought one 'discontinued' product (type R) was an appropriate substitute for another 'discontinued' product (type NPH). With the benefit of hindsight it seems he had poor understanding on the use and status of Eli Lilly and Company Ltd insulin products.

It is not [Mr B's] misunderstanding per se that is the issue here (although it is concerning). It is unreasonable to expect pharmacists to be walking drug encyclopaedias who never get confused. However, it is reasonable to expect pharmacists to have a robust dispensing process and to regularly check reference sources whenever necessary. The real issue is that [Mr B] dispensed the wrong drug, and verbally reassured the patient, without actually checking any resources when he should have.

3.6 Are there any aspects of the care provided by [Mr B] that you consider warrant additional comment?

There is one additional comment I would like to make. It has not escaped my notice that [Mr B] is, like me, one of the older pharmacists in New Zealand; and his health has been of concern recently. Being in a similar situation, I understand very well the day-to-day stresses [Mr B] may be facing.

Generally speaking, the older pharmacist doesn't have quite the visual acuity or cognitive dexterity as a younger pharmacist. We must acknowledge this and monitor our practice accordingly.

Over the past fifty or so years there have been an enormous number of changes in drug names and formulations, dispensing procedures, and legal requirements. Currently, especially with PHARMAC making regular changes to drug funding, it can be difficult for older pharmacists to keep track of all the changes.

It can also be hard for an older pharmacist, educated in a prior era, to adapt to the 'new age' of professional accountability and meticulous documentation. However, these are not optional. As older pharmacists with less-than-perfect health, we cannot gloss over errors or ask for special dispensations on our practice. Any patient walking into any pharmacy has the right to expect the same minimum standards of care, regardless of who the pharmacist on duty is.

4. Conclusion

Overall, considering all aspects of this case, I feel that [Mr B's] peers would regard his departure from pharmacy standards with moderate disapproval.

I am very sorry that this error occurred — and I am sure that all parties involved share my sentiments. I hope that this incident should be seen as a learning experience, and that constructive measures will be taken to prevent such a mistake recurring.