



Criminal Liability for Dispensing Errors

In April 2009, a British pharmacist was given a three-month suspended jail sentence after mistakenly dispensing the wrong medicine.¹

The jail sentence was suspended for 18 months and caused significant controversy amongst the pharmacy profession in the UK, with the Royal Pharmaceutical Society of Great Britain (RPSGB) calling for the decriminalisation of dispensing errors.²

This case raises concern as to the potential criminal and civil liability of Australian pharmacists in respect of dispensing errors. It also highlights concerns that our regulators and Parliament may be supportive of the extension of the civil liability for professional negligence to criminal sanctions.

As in any profession errors can be made and usually result from basic human error as a result of fatigue or stress.

Background

Carmel Sheller, an elderly 72-year-old lady with several chronic illnesses, attended a Tesco pharmacy with a prescription for prednisolone in September 2007. She was given propranolol in error by the locum pharmacist Elizabeth Lee (Lee).

A side-effect of taking this drug (prescribed in an excessive dose) was a reduced heart rate. Mrs Sheller already had a slow heart rate.

Mrs Lee dispensed the drug from the store and then signed-off the prescription as having been checked. Ideally, these two tasks would be completed by different people, however Tesco's standard operating procedure allowed the same person to do both with a recommendation that breaks be taken in between. It was unknown whether Mrs Lee had a break here.

Mrs Sheller collapsed soon after taking the drug and died in hospital three days later.

Mrs Lee was initially charged with manslaughter as well as two offences under the *Medicines Act 1968* (UK):

- Supplying a medicinal product labelled in such a way that it falsely describes the product or is likely to mislead as to the nature or quality of the product (section 85); and
- Supplying a medicinal product which is not of the nature or quality demanded by the purchaser (section 64).

The manslaughter charge was withdrawn after the pathologist found that the cause of Mrs Sheller's death was her underlying long-term illness not the drugs she had taken. The charge under section 64 of the Act was also not pursued Mrs Lee pleaded guilty to the charge of supplying a falsely labelled product.

¹ *The Pharmaceutical Journal* 2009; 282: 401.

² Royal Pharmaceutical Society of Great Britain, News Release 1 May 2009.



In sentencing, Judge Peter Beaumont held that the public “are entitled to expect the highest standard of care from those responsible for the dispensing of medication” and that a prison sentence was warranted to “mark the gravity of her offence”.

The prison sentence was fortunately suspended for Ms Lee, , as the judge took into account that Mrs Lees was a decent person with consideration for others who had not sought to avoid responsibility for what had occurred.

Mrs Lee was also ordered to complete a 12-month supervision period. She resigned from her membership to the Pharmacy Society indicating that she will not practise in the profession again.

No doubt the events which were clearly unintended, had a deep impact on Mrs Lee’s life and professional career.

The Criminal offence

It remains unclear whether Mrs Lee would have been found guilty of manslaughter had the pathologist found that the dispensing error caused or contributed to Mrs Sheller’s death.

To prove a charge of manslaughter, the burden on the prosecution is very high. They must show the defendant was grossly negligent, they must prove a charge beyond reasonable doubt and the death resulted from a failure to exercise the standard of care a reasonable person would have exercised.

The prosecution would need to also show the defendant had a disregard for the life and safety of others.

Dispensing errors

A UK study on the incidence, nature and cause of dispensing errors in community pharmacies estimated that on average, for every 10,000 items dispensed there are approximately 22 near misses and 4 dispensing errors.³ It has been estimated that on average, a pharmacist will make a dispensing error every month.⁴ While not all of these errors are serious enough to cause death or injury, the fact remains errors can so easily be made, even by the best pharmacists and with the best practises as Errors usually result from distraction or loss of concentration.

Accordingly, it seems unlikely that a manslaughter conviction could be proved arising from an inadvertent mistake.

However, in cases where a death occurs from a dispensing error, public pressure for punishment and retribution (such as that seen in this case by the family of Mrs Sheller) may place pressure on the authorities to bring a criminal charge.

In the UK, the number of health care professionals charged and convicted of manslaughter increased appreciably from 1970s to the 1990s. The prosecutors success rate for medical manslaughter convictions was found to be much lower

³ Roberts DE, Spencer MG, Burfield R, Bowden S. An analysis of dispensing errors in NHS hospitals. International Journal of Pharmacy Practice 2002; 10(Suppl): R6.

⁴ Ashcroft D, Morecroft C, Parker D, Noyce P. Patient safety in community pharmacy: understanding errors and managing risk. London: Royal Pharmaceutical Society, 2005.



than that for manslaughter generally, perhaps demonstrating the difficulty in proving gross negligence in these types of cases.⁵

It is unclear whether these trends have occurred similarly in Australia.

Medicines Act charges

Many pharmacists argued in the wake of the Lee case that the provisions of the UK Medicines Act were out of date and that the legislation should be changed to decriminalise dispensing errors. They argued the Medicines Act was enacted in the 1960s when a significant proportion of pharmacy medicines were made up in the pharmacy (as opposed to the mass produced products from manufacturers suppliers today). Therefore that time, there was a need to prohibit pharmacists from supplying medicines that were substandard which they prepared.⁶

They argue the provisions of the Act were never meant to cover such dispensing errors, and that criminalisation of such errors will do little to prevent such errors and would increase the likelihood of cover-ups instead of encouraging a culture that records, investigates and addresses the reasons for errors being made.

Australia

The legislation governing pharmacists in force Federally and in the States and Territories does not include provisions similar to sections 64 or 85 of the Medicines Act UK.

There is no other legislation in Australia that would make Mrs Lee's actions criminal under Australian law (unless the dispensing error was found to have caused death or injury and the pharmacist was grossly or deliberately negligent).

Provisions in the *Health Professions Registration Act 2005* (Vic) regulate the dispensing and recording of prescriptions by pharmacists. Those provisions state a pharmacist must take reasonable steps to ensure that the medicine being dispensed is consistent with the safety of the person named in the prescription, and records must be kept of prescriptions supplied. However, a failure to comply with these provisions will not, under the Act, lead to criminal sanctions.

Civil liability

While a pharmacist is unlikely to face criminal charges for a dispensing error in Australia, civil liability still arises from:

- Breach of contract, as the customer has not been provided with the product that they contracted to buy;
- Misleading and deceptive conduct contrary to the *Trade Practices Act 1974* (Cth) and similar provisions under state or territory based fair trading legislation; and
- Negligence, if the error causes the customer loss, such as injury or illness.

⁵ Dyer, C. Doctors face trial for manslaughter as criminal charges against doctors continue to rise. *BMJ* Volume 325 13 July 2002.

⁶ Guild of Healthcare Pharmacists MHRA Consultation: Concept Paper on the Project to Consolidate and Review Medicines Legislation, 27 March 2009.



A pharmacist found to have made a dispensing error might also face disciplinary proceedings by the pharmacy board for unprofessional conduct or professional misconduct, leading to sanctions including deregistration.

The Lee case highlights the importance of documenting, maintaining and implementing systems and protocols to avoid an error or identify an error before its too late.