

Workplace pressure

Richard Hough, a practitioner in pharmacy law, considers the issue of workplace pressure in light of a recent controversial prosecution



break when working in a busy pharmacy, certainly when customer expectations dictate that the pharmacist should always be accessible. However, in light of this case, it is likely that locum pharmacists who might previously have opted to forego their rest breaks for fear of not securing future work, will now be more reluctant to do so for reasons of potentially far greater consequence.

The appalling treatment of Elizabeth Lee at the hands of the English judicial system has brought to the forefront of pharmacy's collective consciousness two issues which require urgent further discussion. The first is the adequacy, or otherwise, of legislation enacted to protect workers' health and safety. The second is the need for repeal of the outdated provisions of the Medicines Act 1968, which have brought into the ambit of criminal activity the making of an innocent labelling mistake.

As has been widely reported, Mrs Lee, a former locum pharmacist, received a three-month jail term, suspended for 18 months, and ordered to complete a 12 month supervision requirement with the probation service for making a one-off dispensing error. In August, 2007, Mrs Lee mistakenly dispensed a beta-blocker (propranolol) instead of steroids (prednisolone) to a 72 year old patient, Carmel Sheller, who died three days after taking the drug. Although the presiding judge acknowledged that Mrs Lee, who was of previously unblemished character, "bore no factual or legal responsibility for the patient's death", which a pathologist determined was due to the patient's underlying long-term illness, the judge said a prison sentence was needed "to mark the gravity of the offence".

Mrs Lee, who on the day she made the dispensing error, was working a 10 hour shift without a break because the pharmacy "could not function without her presence", admitted supplying a medicinal product with a misleading label on the package — a charge brought under section 85 of the Medicines Act. Workplace pressure, precipitated by understaffing and a perceived inability to take a rest break, was cited as a reason for the error.

Statutory legislation exists which places obligations on employers to ensure that workers take adequate rest breaks and on workers not to risk their own or other's health or safety by foregoing rest breaks. But, in light of customer expectations that a pharmacist will always be present during a pharmacy's opening hours and commercial pressures to meet these expectations, how effective is this legislation?

Working time regulations

The Working Time Regulations 1998 introduced rules of general application limiting working hours and providing for rest breaks and holidays. In relation to pharmacy practice, the regulations impose the following obligations on employers to:

- Take all reasonable steps to ensure that each worker's average working time does not exceed 48 hours per week
- Allow workers 11 hours' uninterrupted rest per day and, additionally, 24 hours' uninterrupted rest per week, and a rest break of 20 minutes when working more than 6 hours per day
- Allow workers 28 days' paid holiday (inclusive of bank holidays) per year with pro-rata entitlement for part-time workers.

“ This conviction will do much to dissuade pharmacists from reporting future dispensing errors, which is surely to the detriment of patient safety ”

The regulations only protect "workers", defined as all those working under:

- A contract of employment; or
- Any other contract whereby the individual undertakes to perform personally any work or services for the other party to the contract, where the other party is not by virtue of the contract a client or customer of any profession or business undertaking carried on by the individual

This definition, therefore, includes employees, temporary workers and freelancers, but not the self-employed genuinely pursuing a business activity on their own account. The distinction between the two is not always clear. Locums, such as Mrs Lee, are covered by the regulations.

Employers must ensure that workers can take their rest breaks but are not required to force workers to take them. Workers can elect to work through a rest break provided they do not risk their own or others' health or safety and, if they do so, it is the employer's responsibility to ensure that compensatory rest is allocated.

It is often difficult for a pharmacist to take a

European jurisprudence gives guidance that employers must actively ensure that: an atmosphere is created in which minimum rest periods are observed; such breaks are scheduled as part of the organisation of working time; and workers are not under pressure to forego breaks (*Commission v UK: Case 484/04*).

In acknowledging that many pharmacists feel worn down by working long hours with inadequate rest breaks, the Royal Pharmaceutical Society launched a Workplace Pressure campaign in January, the aim of which is to find practical solutions to workload and stress issues. Solutions are certainly identifiable but the degree to which they will prove to be practical will require a greater assumption of responsibility by employers and workers, alike. Employers need to play their part by minimising workers' hours, ensuring adequate staffing levels and reviewing workloads. Workers need reminding of their obligations not to put their own or others' health or safety at risk by opting to forego their rest breaks. Both need to manage patient expectations of pharmacists' ever-accessibility and be less hasty in looking to circumvent the provisions of the working time regulations.

Although undeniably a contributory factor, mistakes are still made in the absence of workplace pressure and RPSGB research conducted in 2006 established that, each month in England and Wales, 114,000 near-misses and 20,000 dispensing errors occur, the prevalence of which makes the existence of legislation which criminalises the making of a one-off dispensing error all the more unacceptable.

Medicines Act review

Mrs Lee's conviction has understandably concerned many pharmacists, who are looking to the RPSGB to make representations to amend the Medicines Act. Although currently unable to comment on the specifics of the case, the RPSGB has stated that dispensing errors should not constitute a criminal offence and that these should properly be dealt with by the pharmacy regulator. To this end, the RPSGB has recently sent a submission to the Medicines and Healthcare products Regulatory Agency (MHRA), which is seeking views on its proposals to review and consolidate medicines legislation.

On the issue of decriminalisation of dispensing errors the RPSGB said the following: "The RPSGB requests that the MHRA review the Medicines Act 1968, and in

particular section 64, in the context of dispensing errors made by pharmacists. The Society's Council considered this issue in December, 2006, and fully supported the decriminalisation of dispensing errors and agreed that a change to the legislation, which would have the effect of decriminalising errors, be sought."

Mrs Lee faced two charges under sections 64 and 85, respectively, of the Medicines Act. She admitted the section 85 offence of supplying a medicinal product with a misleading label on the package. The section 64 charge, however, remains on file. Section 64 states that, for medicinal products supplied in pursuance of a prescription given by a practitioner "no person shall, to the prejudice of the purchaser, sell any medicinal product which is not of the nature or quality specified in the prescription".

To obtain a conviction for a dispensing error under either section, prosecutors will rely on a literal interpretation of the wording. However, it is also vital to examine the purpose of these provisions. Dispensing practices 40 years ago were very different to those of today: extemporaneous dispensing was far more common whereas, today, industrially manufactured medicines are almost universally prescribed and dispensed. The purpose of Section 64 was to guard against the supply of substandard products. The purpose of Section 85 was, and is, to guard against the supply of counterfeit medicines. Taking into account the statistics for the prevalence of dispensing errors, these provisions are being inappropriately relied upon by Crown Prosecution Service prosecutors, who seek a prosecution based on a literal interpretation of their terms as a fallback when a manslaughter conviction is unattainable. This is surely not what was intended when the legislation was drafted.

It is a tragedy that a patient has died. It was, however, stated in court that Mrs Lee "bore no factual or legal responsibility for the patient's death". It is, therefore, also an undeniable tragedy that because of prosecutors' reliance on a literal interpretation of outdated provisions of the Medicines Act, Mrs Lee's professional and personal life lies in ruins. (The registrar of the RPSGB has subsequently allowed an application from Mrs Lee voluntarily to remove herself from the Register of Pharmacists.) Further, the prosecutions brought under the Medicines Act run contrary to the culture of openness in reporting dispensing errors, a process which enhances patient safety. This conviction will do much to dissuade pharmacists from reporting future dispensing errors, which is surely to the long-term detriment of patient safety. For all our sakes, this legislation cannot be changed quickly enough.

*Richard Hough is a solicitor and pharmacist in the commercial and intellectual property team at Bradbourns Chaffe Street LLP Solicitors, and is based in their Liverpool office
richard.hough@bradbourns.com
tel 0151 600 3302*