

Change law to facilitate error reporting

A recent meeting of the Pharmacy Law and Ethics Association discussed the legal and ethical implications of dispensing error reporting.

Joy Wingfield, professor of pharmacy law and ethics, Nottingham University, reports

As long as reporting errors can result in civil action or criminal prosecution, legal privilege (confidentiality of communications between solicitor and client made in anticipation of litigation) should apply, said Kay Wheat, reader in law, Nottingham Trent University. She concluded this from the “basic principle in English law of protection against self-incrimination”.

The seminar recognised that the NHS is increasingly aware of the levels of mistakes and errors in its service with the consequent risk to patient safety. The National Patient Safety Agency, set up in 2001 specifically to develop ways of dealing with this problem, insists that health professionals should be allowed to work within a “blame-free” (now called a “fair-blame”) culture, and that anonymity of the patient, institution and health professional is essential to this culture. The Chief Medical Officer’s report, “Making amends”, reinforces this approach by suggesting that no health professional who properly reports errors to his or her organisation should be subject to further discipline (in most cases) and that legal privilege should attach to the collated error reports of NHS organisations. The Council for the Regulation of Healthcare Professionals has, however, rejected both of these suggestions.

Attributable patient safety incident data

Primary care trusts in England are now seeking to collate attributable “patient safety incident” data in an effort to support their contractors and manage their performance. However, if this information is provided, community pharmacists should know that most dispensing errors will provide *prima facie* evidence of an absolute offence under section 64 of the Medicines Act — thus putting them at risk of prosecution, disciplinary action and contractual sanction.

Kay Wheat argued that when the Kennedy report recommended immunity from disciplinary action unless there was a criminal offence, no account was taken of the particular jeopardy attached to community pharmacy practice by the Medicines Act. Thus, pharmacists can be criminally prosecuted under the Medicines Act.

Turning to the Human Rights Act, she further suggested that the European Court precedent of the *Saunders v UK 1996* judgment (the Guinness case) might have relevance to the position of error reporting from community pharmacies. Although there have been exemp-

tions allowing violation by prosecuting authorities of the privilege against self-incrimination, the Saunders case ruled that self-incriminatory information obtained for a different purpose should not have been used against him in a prosecution under the Companies Act 1985.

Contractual issues

Ms Wheat went on to say that employers and contractors are in a difficult position in requiring error information from employees and locums. It is possible for the employer to undertake not to discipline, sue for breach or regard the contract as repudiated, but then there is the dilemma of how to deal with underperforming individuals. Ms Wheat believed that there might be grounds to repudiate such an undertaking should there be evidence of a catalogue of errors attributed to one person. Even with an employer-employee contract, this could not bind any third party or a prosecuting authority. Furthermore, an obligation to breach a confidentiality agreement might arise for an NHS body or its staff if disclosure were in the “public interest”. Professionals can be held liable to third parties for failure to breach confidence despite a real risk of serious consequences to others (as in the Bristol events, for example), although *Palmer v Tees HA 1999* ruled that this would only apply if the danger were to a “specified person” rather than the public at large.

Finally, Ms Wheat stated that the Data Protection Act made it clear that information including personal data can only be obtained for one or more specific and lawful purposes and should not be used for any other incompatible purpose. Therefore, the question is whether or not information collected for the purposes of error reporting is incompatible with the use of this information for prosecution or professional sanction? The answer depends on the stated purpose for which error-reporting information is being used. If it were used for identifying areas of error alone, then using the information for regulatory purposes would arguably, be unlawful.

Statutory Committee cases

Geoff Hudson, solicitor for Penningtons, the legal firm frequently used by the Royal Pharmaceutical Society for prosecuting Statutory Committee business, confirmed that the Committee is regularly concerned with dispensing error inquiries. He indicated that one in five of the new decisions given by the Statutory Committee during 2003 involved such cases. Although these cases usually follow multiple errors, single errors are brought before the Committee where there are aggravating circumstances, particularly lack of

appropriate action on the part of the respondent pharmacist. The Committee will usually defer its final decision to give the pharmacist an opportunity to demonstrate that actions have been implemented to improve those practices that led to the error in the first place. Mr Hudson did, however, point to a case (currently under appeal) where a pharmacist was judged not to have carried out his undertakings and, at a resumed hearing, his name was directed to be removed from the register. Mr Hudson added that prosecutions under the Medicines Act for dispensing errors are rare, though not unknown, and for this reason such cases are usually referred to the Statutory Committee in the form of a complaint of misconduct.

Martin Fletcher, a delegate from the NPSA, told the meeting that the NPSA had no mandate to report or investigate dispensing errors and its system would remove any identifying information; indeed, it will not collect confidential information. In the next few months the NPSA will be publishing a paper addressing the issue of how it will meet the test of public interest versus confidentiality.

Mark Koziol, a delegate and director of the Pharmacists Defence Association, pointed out that the information used by Kennedy was as a result of an investigation made into a number of serious deaths. The Kennedy recommendations were now being applied to all levels of error, regardless of their seriousness or the potential risk to the patient. Consequently, the collection of error reporting data for the purposes of regulation has been disproportionately applied at significant detriment to the risk management agenda.

Opportunity compromised

The meeting concluded that a major opportunity to improve patient safety is being compromised and pharmacists and contractors will continue to be reluctant to supply information on errors unless:

- Pharmacists can be assured of anonymity and confidentiality, and legal privilege is afforded to them
- Policy direction is given to PCTs that the risk management agenda is paramount and error reports are to be exclusively used as learning opportunities as opposed to any disciplinary or regulatory measures
- Individual PCTs (and similar organisations in Northern Ireland, Scotland and Wales) work together to develop consistent, fair and confidential mechanisms for managing the local pharmacy patient safety agenda

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The Pharmacy Law and Ethics Association seminar took place in London on 12 May