Decriminalising dispensing errors

Pharmacy law practitioner Richard Hough considers what the Berwick review means in relation to sanctions for dispensing errors

The Berwick review, ‘A promise to learn – a commitment to act. Improving the Safety of Patients in England’, was published in August 2013. Professor Denys Gough, an international expert in patient safety, chaired an advisory group to review patient care and safety within the NHS following the publication of the Francis Report into the breakdown of care at Mid Staffordshire hospitals. The review highlights the main problems currently affecting patient safety within the NHS and makes a number of recommendations to address them, including the following, which have direct relevance to pharmacy:

- A ‘blame culture’ should be discouraged
- Quantitative targets should be used with caution – they should never disguise the primary goal of better care
- Transparency is essential and should be insisted upon
- Pride and joy in work, not fear, should inform the NHS.

Responsive healthcare regulation

One of the review’s recommendations is the support for responsive healthcare regulation, with a hierarchy of response and with recognition to criminal sanctions being extremely rare, functioning primarily as a deterrent to wilful or reckless neglect or mistreatment. While the review’s remit is broad in its applications to healthcare, it appears to support pharmacy’s attempts to ensure protection for pharmacists from prosecution for simple dispensing errors.

The review makes the sensible recommendation that any new legislation should avoid criminalising unintended errors, which should be handled very differently from severe misconduct. Criminal sanctions should only be imposed if the failure in the provision of care was the fault of the individual alone and the individual was acting in a recklessly or wilfully negligent manner. Liability should be proportionate to past conduct for both individuals and organisations.

Arguably, the threat of criminal sanctions has hindered the reporting of dispensing errors since the issue was brought to the fore by the Elizabeth Lee case, which in turn led to a culture of defensive practice among pharmacists. Understandably, pharmacy professionals are less inclined to report an innocent human error if they consider that such a mistake would lead to criminal prosecution.

While Crown Prosecution Service (CPS) guidance sets out the circumstances considered appropriate for the prosecution of dispensing errors under the Medicines Act 1968, the Elizabeth Lee case exposed the inadequacy of current legislation at protecting from criminal prosecution otherwise diligent pharmacists who have made an innocent mistake. While the CPS guidance is welcome, there is still much uncertainty surrounding the way in which the current law deals with dispensing errors.

Allowing for innovation

It is hoped that promoting a fair, open and transparent culture within the profession, as advocated by Berwick, will lead to pharmacists providing a better service to the general public. It will also help the profession to learn from its mistakes, allowing for innovation and helping to reduce future errors.

The recommendations suggest that change is imminent. This view is supported by the appointment of a government board – the Rebalancing Medicines Legislation and Pharmacy Regulation Programme Board – to assess the scope of pharmacy legislation and regulation including the Pharmacy Order 2010, the Medicines Act 1968 (as amended) and the Human Medicines Regulations 2012, which consolidated much of the Medicines Act. The board, chaired by Ken Jerrold, has made the issue of criminal prosecution for single dispensing errors one of its key priorities, and plans to work alongside the Department of Health and the Medicines and Healthcare products Regulatory Agency (MHRA) to change the law in this area.

The Board is proposing an order under Section 60 of the Health Act 1999 as the most likely legislative instrument for effecting changes to the law. A Section 60 Order is a secondary legislative instrument that permits changes to primary legislation (ie Acts of Parliament). Essentially, the Board is seeking to make an exemption from prosecution for community pharmacists and pharmacy technicians for single unintended breaches of section 64 (the supply of a medicine not of the nature or quality demanded) or section 85 (the supply of a medicine with a misleading label on the package) of the Medicines Act 1968, convictions for which are currently punishable by up to two years’ imprisonment. If adopted, pharmacists who make an innocent dispensing error would be subject only to professional regulation and, if necessary, fitness to practise procedures.

Proposed conditions for this exception might include that:

- The medicine was sold or supplied by a registered pharmacist or registered pharmacy technician.
- The sale or supply was in pursuance of a prescription.
- The registered pharmacist or pharmacy technician was acting in the course of their profession.

Responsibilities remain

While there is concern that decriminalisation of unintended dispensing errors would reduce pharmacists’ responsibilities to their patients, pharmacists would still remain accountable to the GPHC. Concerns that decriminalising dispensing errors would run counter to the central theme of the Corporate Manslaughter and Corporate Homicide Act 2007, which holds corporations criminally liable for death resulting from their negligence or recklessness, also do not appear to be valid.

The Board has made it clear that criminal sanctions would still remain applicable in certain circumstances, for example, where a pharmacist deliberately dispensed the wrong medicine. And the criminal law would still continue to operate in the same way in gross negligence manslaughter cases.

There is no doubt that the proposed changes would be a positive step for the profession. They would encourage error reporting without the fear of criminal prosecution and, in doing so, help change pharmacy professionals’ behaviour and improve patient safety within pharmacy. The more difficult issue, and arguably the most important one for the Board, is to ensure that the public is adequately safeguarded in any new arrangement. For this reason, the Board has acknowledged the need to be careful of any unintended consequences of changes to legislation.

The next step in the process is for the Board to consult a partners forum on the matter, further to which any proposals to change the law must be debated in Parliament before being expected to come into force around the end of December 2014.

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