

Independent Community Pharmacist Magazine

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Pharmacy and the Law

Streamlining and reducing regulatory burdens

Richard Hough, a practitioner in pharmacy law, looks at a recent Medicines and Healthcare products Regulatory Agency's consultation on revising medicines legislation



Since 2008, the Medicines and Healthcare products Regulatory Agency (MHRA) has been undertaking a project to consolidate and review UK medicines legislation. As part of this project it has recently concluded an informal consultation — "Streamlining and Reducing Regulatory Burdens" — which outlined opportunities the MHRA has identified to reduce regulatory burdens and rectify legislative confusion and inadequacies.

The first phase of the project involves consolidating existing UK medicines legislation into one set of regulations, which should be clearer in meaning and easier to navigate. The second phase involves identifying and reviewing areas where substantive changes might be made to existing legislation and making amendments, where allowable under EU law, to the draft regulations.

The MHRA has previously published a concept paper in which it outlined its preferred approach to consolidating existing medicines legislation and has also published a working draft of the consolidated text. The recent informal consultation is part of the review process, which is a precursor to a formal consultation on its review proposals and ultimately the publication of new draft consolidated regulations which, subject to parliamentary approval, will be brought into force in spring, 2012.

Wholesaling

Of the 13 questions posed in the informal consultation, two are of particular importance to community pharmacists and concern wholesaling. It has been claimed that as many as 10 per cent of community pharmacies have recently been involved in wholesale dealing and parallel exporting, the practice of which is governed by sections 8(3) and 10(7) of the Medicines Act 1968. Section 8(3) of the Act prohibits wholesale dealing of medicinal products in the course of business, unless done so in accordance with a wholesale dealer's licence. Section 10(7) carves out an exemption

to this prohibition by stating that the "restrictions imposed by section 8(3) of this Act do not apply to anything which is done in a registered pharmacy by or under the supervision of a pharmacist and amounts to wholesale dealing, where such dealing constitutes no more than an inconsiderable part of the business carried on by the pharmacist at that pharmacy".

The MHRA submits that, as a result of amendments made to the Act over the years, section 10 has become complicated and is in need of review to ensure its compatibility with EU legislation and current professional practice.

“If every dispensing error made by a pharmacist was dealt with strictly under the relevant sections of the Act, the vast majority of pharmacists would now have a criminal record”

The interpretation of section 10 is not helped by the use of vague language. For example, the meaning of "inconsiderable" is ambiguous, although it is widely believed that a pharmacy which engages in wholesaling activity which constitutes no more than 5 per cent of its medicines turnover would fall within the section 10(7) exemption.

The Royal Pharmaceutical Society (RPS) has responded to the consultation by recommending that section 10(7) should be retained, citing the operational freedom which is required to enable the many small transactions in medicine supply which occur

within the course of operating a pharmacy (eg, selling medicines to other community pharmacies or to other healthcare professionals). If section 10(7) is removed, pharmacists wishing to undertake these common activities would be required to purchase and comply with the conditions of a wholesale dealer's licence, which would be disproportionate to its safeguarding benefits and would increase the regulatory burden on pharmacists. The RPS has also sensibly called for clarification over the vagueness of the term "inconsiderable" and has requested that this word is replaced with a more specific phrase.

A joint response from other representative bodies, which included the views of, amongst others, the National Pharmacy Association, the Pharmaceutical Services Negotiating Committee and the Company Chemists' Association, disagreed with the MHRA. The joint response stated that the provisions of section 10 are in fact straightforward, and that the interests of patients are best served by community pharmacists continuing to be permitted to carry out limited amounts of wholesale dealing activities without the need to obtain a wholesale dealer's licence.

Dispensing errors

More emotively, the MHRA is seeking to introduce medicines legislation which will ensure proportionate prosecution of dispensing errors whilst maintaining the necessary safeguards for patient safety and public health. The prosecution of Elizabeth Lee placed firmly into the profession's collective consciousness the existence of legislation which imposes criminal liability on any pharmacist who breaches sections 64, 85 or 86 of the Act. Section 64 stipulates that any medicinal product sold must be of "the nature or quality demanded by the purchaser". Section 85 stipulates that the labelling or marking on containers or packages must not "falsely describe the product or mislead as to its nature, quality, uses or effects".

Section 86 contains a similar provision to section 85 but in relation to the leaflets provided with medicinal products. It is an offence, punishable by a fine or by imprisonment of up to two years, to contravene any of these sections. Innocently made prescribing and dispensing errors are commonplace. Most are minor, cause no harm to the patient and result in no further action being taken against the prescriber or pharmacist.

However, prescribing and dispensing errors may be dealt with very differently under existing legislation. If every dispensing error made by a pharmacist was dealt with strictly under the relevant sections of the Act, the vast majority of pharmacists would now have a

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criminal record. This would be in stark contrast to GPs who are not subject to equivalent draconian legislative provisions for prescribing errors. This anomaly needs to be changed.

The MHRA is considering whether these provisions should be amended so that, where the defendant is a regulated healthcare professional, an offence is committed only if they are found to have acted with intent or negligence.

RPS view

The RPS recommends that, rather than making amendments to the Act, the relevant sections should be removed in relation to individual pharmacists on the basis that the criminalisation of a single dispensing error acts as a disincentive for error reporting. The RPS recommends that only where there is evidence of criminal negligence manslaughter, as assessed by the police, should criminal action be taken against pharmacists. If no such evidence exists, the General Pharmaceutical Council (GPhC) should be allowed to exercise its regulatory powers.

The joint response concurred with the RPS's view and stated further that the introduction of negligence as a determinant for criminal action may actually confuse matters.

The Pharmacists' Defence Association has, unsurprisingly, called for the repeal of section 64(1), which it refers to as being "outdated and inappropriate legislation", which is "no longer fit for purpose".

Detriment

It is hoped that the MHRA gives serious consideration to the responses it has received from pharmacy's representative bodies. Criminal prosecution of negligently made dispensing errors should be resisted and a much higher threshold should be required before criminal sanctions are imposed, for instance, in the case of gross negligence manslaughter. Pharmacy is a well regulated and highly regarded profession and it is surely to its detriment that legislative provisions exist which promote the defensive practice of pharmacy by encouraging pharmacists to remain silent on the issue of their innocently made mistakes for fear of criminal repercussions where none should exist. The actions of pharmacists are adequately regulated by the GPhC and it is about time that legislation governing the actions of pharmacists allowed the regulators to do their job.

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