

Is remote supervision feasible?

Richard Hough, a practitioner in pharmacy law, looks at the legal aspects of the currently contentious topic of remote supervision



Amid much controversy within the profession, the Health Act 2006, by amending sections 70-72 of The Medicines Act 1968, etched into law the concept of the “responsible pharmacist” (RP) which replaced the requirement for exercising “personal control” over activities undertaken within a pharmacy. The Medicines (Pharmacies) (Responsible Pharmacist) Regulations 2008, which came into force on October 1, 2009 attempt to put (some) meat on the bones of this new conceptual skeleton.

Arguably, the most contentious provision within these regulations is that which allows for a maximum period of two hours for the RP to be absent from the premises during the pharmacy’s business hours [Article 3(1)]. The dual primary purpose of this provision is to support the development of a more flexible, clinical role for pharmacists and to place greater reliance and responsibility upon pharmacy support staff. The pursuit of this purpose should rightly be applauded but the manner in which it is to be realised has not been universally welcomed. This is because, unless the pharmacy is to grind to a stuttering halt during the pharmacist’s absence, Article 3 (1) sets the legislative framework for the possibility of remote supervision by the RP of certain activities undertaken in the pharmacy during his/her absence.

Statutory responsibility

The RP is now under a new statutory responsibility to ensure the safe and effective running of a pharmacy insofar as it relates to the sale and supply of medicines, and with this responsibility comes greater accountability. This then raises the following question: which RP is going to feel entirely comfortable knowing that, while he or she is absent for a significant period of time pursuing the advancement of their clinical role (or otherwise), the pharmacy will remain open and the support staff will be undertaking activities permitted by law, particularly when greater accountability rests with the RP when things

go wrong? The answer, I suspect, will be not many, even if the law governing the undertaking of such activities was clear. However, unfortunately the law surrounding even the most fundamental tasks undertaken within a pharmacy is confusingly drawn from disparate sources, which quite understandably has left many pharmacists concerned and confused.

Concern

Concern among pharmacists abounds in relation to the conceptual notion of remote supervision and whether this can be effectively achieved in practice, not only in respect of the new statutory accountability of RPs but also the detrimental impact reduced levels of supervision might have on patient safety. Further, confusion exists surrounding the scope of what remote supervision entails. In attempting to resolve this confusion (and perhaps consequently allay pharmacists’ concerns), the Royal Pharmaceutical Society of Great Britain has recently issued guidance¹ by categorising the most commonly undertaken (but non-exhaustive) activities within a pharmacy, the level of supervision required and whether the physical presence of the pharmacist is necessary in relation to that activity.

For instance, the “sale or supply” of pharmacy (P) and prescription only (POM) medicines are activities which may be undertaken only when the RP is “in charge” of the premises and may only take place under the “supervision” of a pharmacist, who must be physically present on the premises. The legal foundations for undertaking these fundamental activities are based on a combination of case law and sections 52 and 70-72A of the Medicines Act.

Undefined

“Supervision”, however, is not defined in the Medicines Act and subsequent amendments to it have not addressed this issue. Somewhat unhelpfully, the courts have given “supervision” different meanings in relation to, firstly, the

“sale or supply” of medicines, and secondly their “assembly”. For the purposes of “sale or supply” of medicinal products, where supervision by a pharmacist is required, the actual transaction cannot take place without the physical presence of a pharmacist, who is able to advise and intervene, even though he or she will not need to carry out or be aware of the transaction themselves. However, the level of supervision required for the “assembly” of medicinal products is less clear and reference must be made to what “supervision” means in the context of professional supervision. The current position is that “supervision” in this context means the degree of supervision required by what is regarded as good practice within the profession, having regard to the qualifications and experience of the person being supervised, but actual physical presence may not be necessary.²

The sale or supply of general sales list medicinal products, which, to highlight the complexity of the law, is now governed by a combination of sections 51, 53, 70-72A and 130 of the Medicines Act and Article 3(6) of the Regulations, may now occur from the premises during a period of absence of the RP, but does not require his or her “supervision” of the sale or supply. Further to interpretation of the previous legislation by the statutory committee in 2004, it has been commonly understood that sales of all medicines (including GSLs) within a pharmacy were required to be made under the “personal control” of a pharmacist.

Assembly

However, further to section 10(1) of the Medicines Act, all aspects of the “assembly” process of medicinal products (which is defined as being essentially the enclosing and labelling activities undertaken prior to sale or supply) require the RP to be in charge of the premises (ie, he or she will be signed on as the RP) and must take place under the “supervision” of a pharmacist, but the pharmacist may not need to be physically present at the premises. The legislation therefore allows for suitably qualified non-pharmacist members of staff in the absence of the RP to: generate dispensing labels against a prescription; take medicines off the dispensary shelves; assemble the item; label the containers and undertake accuracy checking. Note that “supervision” in this context may not require the physical presence of a pharmacist and the level of supervision required of the suitably trained staff who undertake work of this nature will depend on what is regarded as good practice within the pharmacy profession. Whether this is permissible in any given pharmacy, and hence creating scope for considerable uncertainty, will

Continued on page 30

Pharmacy and the Law (Continued from p14)

vary upon the procedures in place and the level of training of the supervised staff.

Another concern surrounding remote supervision is that, while the RP is absent, enduring damage will be being done to the public's perception, based partly upon the National Pharmacy Association's "Ask your Pharmacist" campaigns, that the pharmacist is always accessible. This has traditionally been one of pharmacy's strengths but, in pursuing a desire to undertake a more flexible, clinical role, this strength could quickly erode. Further to this, during the pharmacist's absence, disgruntled customers will inevitably place unwelcome and ill-advised pressure on the non-pharmacist members of staff to act outside the boundaries of their responsibilities.

Finally, concerns have been expressed over the pressure which superintendent pharmacists and pharmacy owners may put on pharmacist

employees or long-term locums to sign in remotely as the RP, or to remain signed on during statutory rest breaks, so that assembly activities may be undertaken by lower paid staff during his or her unpaid absence. The law, as it currently stands, would appear to support the former scenario, but utilising the provisions solely as an operational costs reduction mechanism would be an inappropriate misuse of the regulations.

Responsible pharmacists should remember their statutory duty to ensure the safe and effective running of a pharmacy insofar as it relates to the sale and supply of medicines and the greater accountability which accompanies this before considering requests to assume responsibility without remuneration. While superintendents or owners, who may be under financial pressure to reduce operational costs, are nevertheless responsible for the operational control of their pharmacies and should think

carefully about these responsibilities before adopting such practices.

Finally, the Department of Health recognises that supervision requirements are in need of reform alongside "personal control" and has promised that consultations will be conducted later this year.

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References

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