



# Only two hours' absence to be allowed

The Government's initial decisions following the responsible pharmacist consultation are limited and have been met with mixed reactions from pharmacy organisations. **Debbie Andalo** reports

A responsible pharmacist will in future be allowed to be away from the pharmacy for up to two hours in every 24 — an hour less than the Government had originally proposed, the Department of Health confirmed this week.

The announcement is one of the few firm decisions made by the DoH following its consultation on proposals for new regulations that will govern how pharmacies, both those in the community and registered hospital pharmacies, will be run in future. The regulations at the centre of the consultation are linked to changes in personal control of a pharmacy laid down in the Medicines Act 1968, which is being replaced by the Health Act 2006.

Many of the key questions have, however, been left unanswered which brought a sigh of relief from the Pharmaceutical Services Negotiating Committee and prompted hospital pharmacists to repeat their warning that the proposed regulations are unworkable in their sector.

The DoH's decision to allow the responsible pharmacist to be absent for two hours was revealed in its document published this week called "The responsible pharmacist regulations: a summary of the responses to public consultation on proposals for the content of the regulations".

The document considered the responses to the consultation the DoH launched last October and ran until January this year, and included some final proposals.

Although the DoH came to a decision on hours of absence and that pharmacy procedures could be kept in paper or electronic form, it left other issues unresolved (see Panel).

The PSNC said the lack of firm proposals following the 13-week consultation reflected the complexity of the issues. Its head of regulation Steve Lutener said: "I have some sympathy with the DoH here as I think this is the biggest and most complex consultation carried out in my memory because of the complexities of the Medicines Act — which I think isn't fit for purpose any more — and issues around patient safety and the flexibility for pharmacists to be broader clinicians."

Despite the key unanswered questions, there was a mixed response from the profession over the decision to reduce the absence of a responsible pharmacist from the pharmacy from the originally recommended three hours down to two hours.

The Royal Pharmaceutical Society said it was pleased that the DoH had endorsed its own recommendation for a two-hour limit. Priya Sejpal, the Society's head of professional ethics, said: "The Society is pleased that the Government has listened to calls for ensuring that these regulations are not overly burden-

some, while still ensuring patient safety is maintained.

"The introduction of a limited period of absence is good news for the public and the profession as it will rectify the anomaly that currently exists whereby General Sale List medicines can only be sold when the pharmacist is present, even though pharmacist presence is not necessary for other retail outlets."

Noel Baumber, a community pharmacist in Grantham, Lincolnshire, and a non-executive director of the Independent Pharmacy Federation, welcomed the decision to restrict the hours of absence from a pharmacy from three to two hours. He said: "I think this is a fairly significant decision. We were pretty much opposed to a definition of a long absence which was where we were heading with the three-hour rule. Two hours is much more workable than three."

Mr Lutener was disappointed that the DoH had defined the period of absence at all. The PSNC had recommended that no time limit be set; instead it wanted the regulation to stipulate that the responsible pharmacist should spend a "substantial" amount of time in the pharmacy. He said: "These regulations are all about patient safety and what they are saying is that if you are a responsible pharmacist away for one hour and 59 minutes then patients are safe but if you are away for two hours and one minute they are not. How can you justify a time limit?"

Collette McCreedy, chief pharmacist and director of practice at the National Pharmaceutical Association said: "I am pleased to see that some of the issues, such as the fact that no formal qualifications are put down or

specific experience needed to be a responsible pharmacist and the comments on record keeping, are in line with our submission. But the issue of absence from the pharmacy has the potential to cause more confusion than it already has as it's again addressed separately from supervision."

However, the decision to reduce the hours of absence made little difference to hospital pharmacists who argued that the package of proposals around regulation and the introduction of a responsible pharmacist was unworkable in a hospital pharmacy.

David Miller, president of the Guild of Healthcare Pharmacists, said: "There appears to have been some listening to the comments put forward from the hospital sector and we welcome an opportunity to assist in clarifying the role between the superintendent or chief pharmacist, the responsible pharmacist (and the duty pharmacist who in a hospital are often not the same individual) and the employing organisation. However the concern that most hospitals may simply de-register has not been addressed. The whole issue of the Medicines Act and how hospital pharmacy operates in the legislative framework is something guild is keen to discuss with the DoH.

"The other key concern, namely, the opportunity to define the required competencies for a responsible pharmacist in the managed sector should one be needed, is hopefully an option that will be revisited in later discussions."

Immediate past president of the guild Anthony Oxley said another issue for hospital pharmacy will be the final definition of a responsible pharmacist. He said: "If for example it is decided that the chief pharmacist is the responsible pharmacist then the two-hour absence rule isn't going to work because they could be out for four hours at a meeting.

"If it was acceptable that the responsible pharmacist was the dispensary duty pharmacist you would then have to deal with the complicated paperwork around handing over responsible pharmacist duties two or three times a day as the shifts ended."

The guild, however, was pleased that the DoH has decided to leave the eligibility of a responsible pharmacist to the professional and regulatory organisations as it is keen to see the role linked to professional competencies rather than just length of experience.

The PSNC was also pleased that there were no proposals to link the training and education of a responsible pharmacist to statutory regulations. But Mr Lutener said: "If this however became a code of ethics requirement then that would be the same as a statutory requirement which would not offer the flexibility we would prefer."

## Unresolved issues

- The report fails to define who will be eligible to become a responsible pharmacist. (The DoH has decided to leave the issue of necessary qualifications and experience up to the regulatory authorities and other professional organisations.)
- What happens to the dispensing and sale of medicines by a responsible pharmacist in a pharmacy where he or she is not a responsible pharmacist has been put on hold. (That question will now form part of the future consultation on proposals for new regulations to accompany the new Health Act 2006 which focus on the supervision of pharmacies under responsible pharmacists.)
- The DoH was also unable to reach a conclusion on what exemptions there should be to the general rule that a responsible pharmacist should only be responsible for a single pharmacy. (It will look again at the possible exemptions before making a final ruling.)