

**the code of ethics** a consultation...

by the Pharmacists' Defence Association



## Consultation

on the professional standards  
and guidance document for  
responsible pharmacists

**March 2009**

[www.the-pda.org](http://www.the-pda.org)

A document answering questions  
on the proposed draft for the  
revised Code of Ethics.

## The response of the Pharmacists' Defence Association (PDA)

The Pharmacists' Defence Association (PDA) is a not for profit organisation which is a defence association and a union for pharmacists. The aim of the PDA is to act upon and support the needs of individual pharmacists and, when necessary, to defend their reputation. PDA currently has more than 14,000 members.

The primary aims of the PDA are to;

- Support pharmacists in their legal, practice and employment needs.
- Provide insurance cover to safeguard and defend the reputation of the individual pharmacist.
- Provide representation for its members.
- Proactively seek to influence the professional, practice and employment agenda to support members.
- Lead and support initiatives designed to improve the knowledge and skills of pharmacists in managing risk and safe practices, so improving patient care.
- Work with like-minded organisations to further improve the membership benefits to individual pharmacists.

The views contained in this consultation were developed after an analysis of members views who were involved in surveys and focus group meetings. Additionally an expert group of pharmacists, lawyers and barristers were convened to ensure appropriate context.

### Question 1.

Do you understand the changes that will come into effect on 1 October 2009, in terms of the responsible pharmacist regulations?

Yes      No      Not sure

Those drafting the regulations appear to have little insight into the practical realities of community pharmacy in particular. This will leave the regulator with the very difficult position of offering guidance on legal requirements – some of which will be almost impossible to deliver without causing unacceptable inconvenience to patients. Examples of such matters will be provided later in this response.

We anticipate that this will produce a raft of problems for the regulator in so far as it will be unable to offer truly practical hands on guidance in many areas that the regulations seek to cover.

### Question 2.

Do you think the draft Professional Standards and Regulatory guidance for the Responsible Pharmacist document is clear and easy to understand?

Yes      No      Not sure

The guidance is clear enough – What is far from clear is how it will ever be possible to comply with these regulations and this guidance in the day to day operational environment of the average community pharmacy.

### Question 3.

Does anything need to be added or removed from this document?

Yes      No      Not sure

1. Some clarification as to where the Society sees the greatest priority. Will this be '**Making the care of patients the first concern**' or whether this will be the **requirement to comply with the regulations**. This is important, because what is clear is that in many situations, Responsible Pharmacists will only be able to operate a service to the public, if one or more of the regulations are not adhered to because it will be very difficult indeed for them to do so. Alternatively, the public will only receive a partial service whilst the Responsible Pharmacist closes down aspects of the service for certain periods of time whilst he/she busies him/herself in an attempt achieve the legal requirements e.g. becoming familiar with an extensive pharmacy SOP or amending the SOP in writing in light of a development in the pharmacy.

2. A series of Questions and Answers would be very helpful in this guidance for both owners and potential Responsible Pharmacists - especially in areas where the regulations will create significant practical difficulties.
- e.g. a) If a pharmacist takes a rest-break, he/she is required to ensure that another pharmacist becomes available for contact and advice in case of emergencies. What does the pharmacist do if no such other pharmacist can be found? If the answer is that the pharmacy will need to close – then this answer reproduced in the Society's guidance will act to support many pharmacists in decisions to close down pharmacies whilst they take lunch – knowing that they will be supported by the Society's guidance.
- b) What can be the expected outcome of a complaint to the Society made by a member of the public who claims that he/she could not collect prescription medication from a pharmacy because a pharmacist was not able to operate the pharmacy because;
- i) upon arrival he had to first familiarise himself with the pharmacy SOP.
  - ii) no method (written or electronic) was available in which to sign on as a Responsible Pharmacist (a criminal offence for the pharmacist in question if the pharmacy then operates).
  - iii) because he felt that he could not secure the safe and effective running of the pharmacy.

#### Question 4.

Are there any areas of the document that require further clarification?

Yes      No      Not sure

1. By the nature of pharmacy procedures, they are usually applicable in situations where there is a regular staff compliment and/or when a regular manager is in place. The arrival of a locum will usually result in the normal dynamics of a pharmacy being significantly changed and consequently the need for a new procedure automatically arises, moreover, it is inappropriate for anything other than a proposed procedure for the locum RP to be established by the regular manager since all locums who will be coming in to take up the Responsible Pharmacists role will be different in their respective experiences and levels of confidence.

The current draft Code and guidance states;

***The Responsible Pharmacist has a statutory duty to establish (if not already established) maintain and review pharmacy procedures.***

However, this wording appears to give the impression that the incoming Responsible Pharmacist should not establish a procedure if one is already in place. We feel that the wording 'if not already established' is inappropriate and misleading and further clarification should be provided indicating that there will be situations where despite existing procedures being in place that fresh ones may be established.

2. It should be made explicit that only the Responsible Pharmacist can decide whether or not their absence will occur, and that the RP should never be obliged to be absent by an employer. Indeed, such clarification is in keeping with the assurances made in the Houses of Parliament when these provision were debated.
3. 'Version Control' will need some further explanation.

### Question 5.

Do you think that when the Responsible Pharmacist is absent from the pharmacy, a record of the reason for their absence should be made:

Always

Only when their absence is unplanned

Never

Other

We believe that for a variety of reasons a record for the reasons for the absence should always be kept.

1. One such reason is that there is no doubt that when a pharmacist is absent from the pharmacy, the service that can be provided from that pharmacy is of a lesser quality and the safety profile of that pharmacy is lowered – this may be why the draft guidance seeks to describe a planned absence. However, the planned absence will be difficult to define in the event that a problematic incident occurs. The over-arching patient focused principle should surely be that the right place for a pharmacist is in the pharmacy, which is where the public can expect access to a highly qualified healthcare professional. Consequently, any such absence which will inevitably result in a 'safety and quality compromise' should only be allowed to occur for genuine professional emergency scenarios. Should these absences become matter of fact – no reasons required – or worse still, should they be undertaken routinely and in a 'planned' fashion for cost cutting or commercial reasons, then the quality offering that the public expect from the pharmacy will be undermined and with it the public confidence in which pharmacies are held.

As a quality assurance and professional protection measure, any such absence must not only be recorded, but the reasons for such absence should also be recorded.

2. Another reason is that there will be situations where a pharmacist will need to provide evidence or explanations as to why he was absent – say to a coroner's inquest or to a judge in a potential prosecution. In these situations, the pharmacists defence will almost certainly be supported if he/she can provide a written record of what the absence was for – so long as the absence is for an appropriate reason. (see next point).

### Question 6.

Do you think that the Professional Standards and Regulatory guidance document should restrict the reasons why the Responsible Pharmacist may be absent from the pharmacy?

Yes      No      Not sure

Remembering that an absence will inevitably result in a reduction in quality and safety profile, we argue that the reasons for absence should be restricted. However, such a restriction should be flexible enough to allow the RP to decide what is appropriate in any given situation. One way that this could be achieved is indicating that an absence is permitted but the RP will need to record the reasons and may need to justify any such absence to their peers or other similar test.

### Question 7.

Do you think that this document is useful?

Yes      No      Not sure

Yes, in so far as it can add clarification and emphasis in areas and on matters that the regulations have failed to deal with.

### Further comments;

1. Pharmacists have an ethical duty to ensure that they can take on new roles and responsibilities competently. There is no doubt that the Responsible Pharmacist regulations introduce new, very significant and increased responsibilities requiring the exercise of new skills and competencies. However, the Society (and the DoH) are silent on the issue of what additional training and competencies are needed and also where and when these can be gained. By accepting the implementation date of October the 1st 2009, the Society appears to be giving its tacit approval to allowing pharmacists to take on these new roles knowing that it is probable that many pharmacists may be unable to undertake the relevant training or gain the necessary competencies in the interim. This puts the Society in a very difficult situation as it appears to support a situation which may see many pharmacists working outside of the Code of Ethics in this important regard. What the Society should be doing is laying out the new competencies that will be required and also arranging for the necessary training to be available for the profession. Most importantly of all – from a public protection point of view, the Society should be pushing for an appropriate bedding in period of at least two to three years to allow the profession to acquire the new skills and competencies required.
2. The Society through this draft Code appears to be supporting the notion of a two hour absence – however no proper impact assessment has been undertaken on this matter. In the more commercial community pharmacy environment, the absence of a pharmacist will not improve the patient experience and almost certainly will detract from it. It is surely a paradox that the Society is producing guidance on a policy which will lead to a poorer service to the public.
3. Transparency surrounding any pharmacist absences is extremely important. The public must easily be able to determine whether a pharmacist is present or absent. This code should require the pharmacy to clearly display a sign stating “Pharmacist Absent”. Such a measure would inform the public that this important quality and safety measure is absent.

4. Under the procedures required by the regulations, Responsible Pharmacists are required to determine whether the available staff compliment in the pharmacy can support its safe and effective running. To do this, the incoming pharmacist must be able to establish quickly and effectively what are the normal staffing levels – in terms of both quality and quantity and whether the pharmacy enjoys such a level on the day in question. In the event that it does not, then the pharmacist may need to establish new procedures to deal with the staff shortage situation. Consequently, we suggest that the Code requires all pharmacies to have a readily available staffing template so that at any time, the Responsible Pharmacist is able to quickly establish and determine what changes to procedures (if any) need to be made to deal with any differences from the normal staffing levels that may exist.

Further information is available from:

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