



## **The Community Pharmacy Wales response**

**to**

## **THE RESPONSIBLE PHARMACIST: A Consultation on Proposals for the Content of the Responsible Pharmacist Regulations**

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## Part 1: Introduction

This response is submitted by Community Pharmacy Wales to the Responsible Pharmacist Consultation: **A Consultation on Proposals for the Content of the Responsible Pharmacist Regulations.**

Community Pharmacy Wales (CPW) is the body whose function is to represent and negotiate NHS contractual matters on behalf of the 708 pharmacy contractors in Wales.

The Community Pharmacy Wales Board is constituted to ensure proportional representation of all of the community pharmacy contractors in Wales and the following response constitutes the agreed views of the CPW Board in relation to this important consultation.

## Part 2: Overview

CPW would like to make the following general comments;

### 1) Accessibility of Community Pharmacy Services

One of the key strengths of the current community pharmacy network is the ability of a member of the public or patient to access professional support and advice without undue delay. Any changes to legislation should be mindful of the risk they pose to this level of access.

### 2) Opportunities to develop the role of community pharmacists

Community pharmacists are the most underutilised resource in Primary Care and the network of community pharmacies in Wales constitutes a significant potential to support the transfer of services from secondary care to community based services. To effectively release this capacity, community pharmacists need to operate within a legislative framework that is sufficiently flexible to support the development of new roles and improved patient services. A general principle of any legislative change should be that it is 'enabling' rather than 'restricting'.

### 3) Community Pharmacists are subject to a high degree of regulation and control

Community pharmacy is one of the most highly regulated professions and currently operates under a burden of significant legislative, regulatory and operational requirements. With this in mind it is essential that any proposed changes to regulations do not create additional and unnecessary complication or regulatory burden. It would be inappropriate and unrealistic for the full weight of legislation, through Regulations, to be used to determine the day to day operation of a business. It is too inflexible a method and cannot allow for the inevitable changes over time in the nature and context of healthcare and community pharmacy businesses. If the proposals are to be introduced, then some other method of implementation such as guidance would be less inappropriate.

#### 4) Terminology

The use of the term 'Responsible Pharmacist' is not helpful. It is clear from our own consultation process that it leads to misunderstanding and confusion between roles. It implies that not all pharmacists are responsible which is not helpful for the continued growth of pharmacy.

#### 5) Regulations on Supervision

Every effort has been made by CPW to submit a comprehensive response to this consultation; however this has been made extremely difficult in the absence of the proposals for supervision of medicines supply in the pharmacy. CPW would recommend that any final decision on the Responsible Pharmacist regulations be made in conjunction with the consultation on supervision.

### Part 3: Detailed Response

#### THE PHARMACY PROCEDURES: Chapter 3

*The Government believes there is a need for a balance to achieve some consistency in the content of the pharmacy procedures whilst allowing the Responsible Pharmacist sufficient flexibility to ensure these meet the operational needs of the individual pharmacy.*

*Q. Do you agree with this approach? If not, what are your reasons for this and what do you propose instead?*

Yes.

*The proposal is the procedures cover, as a minimum requirement, the areas specified in the regulations. Chapter 3 sets out what these minimum areas might be.*

*Q. Do you think the proposed minimum areas are the right areas?*

CPW believe that the proposed minimum areas as listed are correct with the following exception:

CPW has for some time been concerned at the inequity in regulation of community pharmacies in relation to other suppliers of GSL medicines. CPW would therefore not wish to see any new requirements applied to the sale of GSL medicines through community pharmacies that are not being equally applied to other suppliers of GSL medicines.

*Q. Are there any other areas that you feel the regulations should specify be covered in the procedures? If so, what are these and why should these be covered*

CPW believe that it is unnecessary to include other procedures in the regulations. We believe that the regulations should only cover those key elements essential to

ensure patient safety and that all other requirements should be encompassed in the form of professional guidance. As community pharmacy roles develop new issues currently unforeseen will no doubt arise and that these can be more swiftly and effectively provided for through an alteration to professional guidance.

*Q. Do you agree the pharmacy procedures should include arrangements for the sale of GSL medicines?*

It is inherent in the nature of a community pharmacy and the competence of its staff that there will be a greater duty of care exhibited than might be expected in other locations. As previously stated, CPW has for some time been concerned at the inequity in regulation of community pharmacies in relation to other suppliers of GSL medicines. CPW would therefore not wish to see any requirements applied to the sale of GSL medicines through community pharmacies that are not being equally applied to other suppliers of GSL medicines

*Q. Do you agree that the inclusion of areas, over and above the specified minimum areas, should be a matter for the pharmacy owner/Superintendent Pharmacist and the Responsible Pharmacist? If not, what do you propose and what are your reasons for this?*

CPW agrees that the inclusion of areas, over and above the specified minimum areas, should be a matter for the Superintendent Pharmacist and the Responsible Pharmacist and that there should be no restrictions on any pharmacy seeking to achieve standards above the minimum standards.

*The proposal is that pharmacy procedures may be set out on paper or electronically, provided these are readily available and accessible to those needing to consult them.*

*Q. Do you agree with this approach? Are there any other requirements (other than readily available and accessible) that you consider should be set out in the regulations? If so, what are these and your reasons for putting them forward?*

CPW believe that the form in which the procedures are written up should be that which best meets the needs and the operational requirements of the pharmacy to which they pertain provided they are readily accessible for those required to use or view them.

*The proposal is that regulations do not specify the format used for setting out the pharmacy procedures*

*Q. Do you agree with this approach? If not, what do you propose and what are your reasons for this?*

CPW does not feel that it is necessary for the regulations to specify the format of the pharmacy procedures. We would however be content that professional guidance is used to specify the areas that the pharmacy procedures should cover.

*Q. Do you agree with the view, set out in the consultation paper, on requiring the format used to allow the Responsible Pharmacist to “sign off” that s/he has checked the procedures and is content these support safe working in the pharmacy? If so, what are your reasons for supporting that view?*

No. A pharmacist is already professionally and ethically bound to operate within ‘safe’ SOPs so CPW does not believe there is any need to introduce additional legislative requirements.

CPW believes that with proper development of SOPs, amendments to these will be rare and in circumstances only where there have been significant change to the normal running of a pharmacy. Any changes to SOPs should therefore be the responsibility of both the responsible and the superintendent pharmacist, acting jointly.

*Q. Are there other matters that you feel should be included in the regulations in relation to the format of the pharmacy procedures?*

CPW does not feel that it is necessary to include any other matters relating to pharmacy procedures in the regulations.

*The Government’s view is the Responsible Pharmacist should check the procedures on taking on responsibility for the pharmacy and assess the need for review and/or amendment as appropriate.*

*Q. Do you agree with this approach? If not, what do you propose and what are your reasons for this?*

This has been covered above. Periodic review of SOPs is also a professional requirement, making additional legislation unnecessary.

*The Government is seeking views on the review and/or amendment of the pharmacy procedures*

*Q. Do you agree that guidance may be a more appropriate means of providing information and advice on the review of procedures? If so, what are your reasons for supporting that view?*

CPW believe that professional guidance is more able to quickly and effectively cover any review or amendment to pharmacy procedures and other matters of professional practice than alterations to regulations. Regulations should only seek to cover those areas that are necessary for patient safety and which are likely to change infrequently.

*Q. Are there proposal(s) that you wish to put forward in relation to the review of procedures? What are the reasons supporting your proposals?*

No.

*The consultation paper looks at the role of the Responsible Pharmacist, the pharmacy owner, the Superintendent Pharmacist, and the professional regulatory bodies in relation to the pharmacy procedures.*

*Q. What is your view of their role and what are your reasons for taking that view?*

CPW believe that the overall responsibility for professional practice within the business should lie with the Superintendent Pharmacist.

CPW believe that the key roles of the Superintendent Pharmacist in relation to pharmacy procedures are:

- 1) To understand legal, professional and ethical guidance and to provide overarching policy guidance to the pharmacists and pharmacy staff employed in their business.
- 2) Ensure that pharmacists and pharmacy staff operate within legal, professional and ethical standards.
- 3) To ensure safe and effective working practices are employed in all pharmacies in the business and to lay down guidance on staffing levels, structures, roles and educational requirements.
- 4) To establish clinical governance procedures and ensure compliance with contractual arrangements.
- 5) To oversee the quality of service delivery and to take action to remedy any identified shortcomings.

CPW believe that the role of the Superintendent Pharmacist is to formulate overall policy and the role of the Responsible Pharmacist is to implement policy and to tailor policy in consultation with the Superintendent Pharmacist to meet local requirements.

CPW believe that the role of the Responsible Pharmacist is to take accountability of the safe and effective management of the pharmacy on a day to day basis, to safeguard patient safety and to ensure that agreed SOPs are implemented. The Responsible Pharmacist should be responsible for the activities and behaviour of the support staff in the pharmacy and to take a professional judgement as to their competence and ability to accept delegated responsibility.

#### **THE PHARMACY RECORD: Chapter 4**

*The Government proposes the regulations require the Responsible Pharmacist to include minimum specified information in the pharmacy record. Other information for inclusion in the record would be a matter for the pharmacy owner/ the Superintendent Pharmacist*

*Q. Do you agree with this approach and the proposed minimum information requirements?*

CPW is happy that there is a requirement in the legislation to keep a record. However, the details of what should be kept in that record and its format should be a matter for local determination subject to professional guidance.

*Q. What are your views on proposals set out in the consultation paper for other information requirements in relation to the pharmacy record?*

CPW considers it unnecessary to record any additional information and is fully supportive of the Government's belief that unnecessary regulatory requirements and disproportionate burdens on businesses should be avoided.

*Q. Do you think there is a need for other information requirements in relation to the record? If so, what are these and your reasons for putting these forward?*

As above.

*The proposal is the pharmacy record may be kept electronically or on paper, provided it is readily accessible and available to those who need to consult it. The Government does not propose that regulations specify the format for the record – instead the regulations will specify the fields of information to be included in the record.*

*Q. Do you agree with this approach? If not, what do you propose and what are your reasons for putting your proposals forward?*

As above.

*The Government proposes the regulations set out the minimum period that the pharmacy owner is required to preserve the pharmacy record and that the minimum period should be 5 years from the date of the last entry to the record.*

*Q. Do you agree? If not, what do you propose? What do you think should be the minimum period specified in the regulations and why?*

CPW agrees that a period of five years is appropriate for the keeping of any internal records relating to the pharmacist responsible for the pharmacy.

### **ABSENCE FROM THE PHARMACY: Chapter 5**

*The Government has stated the regulations should specify the minimum proportion of time that the Responsible Pharmacist should spend in the pharmacy and this should be the majority of his/her time (i.e. more than 50% of each period when s/he is the Responsible Pharmacist and the pharmacy is operational).*

*Q. Do you support this view? What are your reasons for this?*

The Responsible Pharmacist is the pharmacist responsible for ensuring that the SOPs support safe working on a day to day basis. To discharge his or her duties they will need to be satisfied that the SOPs work as intended, the appropriate skill mix of

staff are present, and that no exceptional circumstances have arisen. This will require presence in the pharmacy for substantial periods.

In setting up a framework for the new role of Responsible Pharmacist, there should be no unnecessary shackles, and he or she should be able, subject to the directions of the superintendent pharmacist, to decide for himself, how to ensure patient and public safety.

The proposed Responsible Pharmacist Regulations will exist within a legislative regime which includes supervision of the sale and supply of medicines. The sale or supply of medicines is also one of the pharmaceutical services which are accessible without appointment in NHS pharmacies. Because the principal interest of CPW relates to how NHS pharmacies will provide a safe and accessible pharmaceutical service, a conclusion could not be reached about the amount of absence of the responsible pharmacist that may be permitted, due to the uncertainty about the provisions relating to supervision and NHS Regulations which are not being considered at this time.

CPW requests that the consultation on supervision and discussions about the NHS requirements be brought forward, so that these matters can be properly addressed before the proposed Responsible Pharmacist regulations are drafted.

*The Government proposes the maximum time during any one period of absence that the Responsible Pharmacist may be away from the pharmacy should be three hours. The Government seeks views on whether this period might vary in certain circumstances*

*Q. Do you agree the regulations should specify a maximum time? If so, should this be set at three hours?*

As above.

*Q. Do you think the maximum time might vary, subject to meeting conditions set out in the regulations? E.g. where another pharmacist or a suitably trained and registered pharmacy technician remain present in the pharmacy? If so, how might this vary and what are your reasons for putting that view forward?*

As above.

*The proposal is the regulations specify that the Responsible Pharmacist must be able to return to the pharmacy with reasonable promptness.*

*Q. Do you agree? If not, what do you propose and what are your reasons for this?*

As above.

*The proposal is the regulations require the Responsible Pharmacist to be readily contactable by pharmacy staff during any period of absence but do not specify the arrangements to be made – however, it may be appropriate to provide advice on this*

*in guidance.*

*Q. Do you agree with this approach, including that guidance may be a more appropriate way of providing advice on arrangements for being readily contactable by pharmacy staff?*

As above.

*The proposal is that the Responsible Pharmacist is required to arrange for another pharmacist to be available to provide advice when s/he is absent from the pharmacy and is unable to be contacted by pharmacy staff. The Government is also seeking views on whether the other pharmacist should also be a Responsible Pharmacist or eligible to take on that role*

*Q. Do you think that the regulations should require the Responsible Pharmacist to arrange for another pharmacist to provide advice where s/he is unable to maintain contact with the pharmacy? If so, should the other pharmacist also be a Responsible Pharmacist or eligible to take on this role?*

As above.

*Q. Do you agree with this approach? If not, what do you propose and why?*

As above.

## **QUALIFICATIONS AND EXPERIENCE: Chapter 6**

*The Government is seeking views on an annotation to the registrar against those pharmacists with sufficient length of registration and experience to be a Responsible Pharmacist.*

*Q. What is your view and your reasons for this?*

CPW does not feel that there is a need to introduce what is effectively an additional level of pharmacist the 'Responsible Pharmacist'. CPW believe that if the undergraduate programme and pre-registration experience are sufficiently robust then all qualifying pharmacists should be capable of managing the effective and safe operation of a community pharmacy. CPW believe that to introduce a specific role of 'Responsible Pharmacist' will result in unnecessary complication and regulation and could have a significant operational impact on community pharmacy. CPW therefore feels that annotation of the register is unnecessary.

*Should there be a requirement that a pharmacist have a minimum period of experience following registration before taking on the role of the Responsible Pharmacist? In addition, could the period vary in specified circumstances?*

*Q. What is your view on a requirement for a minimum period of experience following registration before becoming a Responsible Pharmacist?*

CPW feels that there should be no specified minimum period of experience following registration before a pharmacist is able to operate as a Responsible Pharmacist. CPW also feels that any definition of competence that is based solely on the passage of time and not on the particular qualities of the pharmacist is inappropriate. Employers (i.e. the superintendent pharmacist) have a responsibility to ensure that the pharmacist employed in the pharmacy is suitably competent.

We believe that if a pharmacist is employed from another sector of pharmacy then it is for the pharmacist and the employer to reach agreement on a suitable induction process. CPW believe that it is inappropriate to specify periods of 'work experience' as in each individual case the skills of the pharmacist and the requirements of the role will vary.

*Q. Do you think the period could vary in certain circumstances? If so, what might these circumstances be and what is your reason for putting these forward?*

As above

*The proposal is that regulations could specify a minimum period of experience in the relevant pharmacy sector and this, e.g., could be expressed as 'x' period of experience in the last 'y' years.*

*Q. Do you agree with this approach? If so, what are your reasons for doing so?*

As implied above CPW believe that, if a pharmacist is employed from another sector of pharmacy, it is for the pharmacist and the employer to reach agreement on a suitable induction process that meets the needs of both parties. CPW believe that it is inappropriate to specify periods of 'work experience' as in each individual case the skills of the pharmacist and the requirements of the role will vary.

In addition CPW feels that to introduce any minimum period of experience requirements would have the potential to limit movement between disciplines at a time when the focus should be on eroding boundaries and developing new roles at the interface between the disciplines.

*Q. What do you think should be the minimum period and how should this be defined?*

CPW believe that there should be no minimum period specified in the regulations.

*Q. If you do not agree, what do you propose instead and what are your reasons for this alternative approach?*

The knowledge requirement and competence framework for the undergraduate and pre-registration should be clearly defined in guidance. Similarly the competencies for post-graduate pharmacists should be agreed and defined by the regulatory body.

CPW believe that a combination of CPD, competence assessment and robust HR policies have served us well to date and we believe that there is little evidence that the current system is failing in any way or is adversely affecting patient safety.

*Views are also sought on a proposal for a required minimum period of experience before taking on the role of the Responsible Pharmacist where a pharmacist has not practised for three years or more.*

*Q. Do you agree that a minimum period of experience might differ where a pharmacist is returning to practise following an absence of three years or more? If so, what are your reasons for this? If you do not agree, what do you propose instead?*

CPW believe that it would be inappropriate to include any references to minimum periods of experience in the regulations. All pharmacists are required under their Code of Ethics to only practice in areas where they feel competent to practice. As stated previously CPW believe that it is for the pharmacist and the employer to reach agreement on a suitable induction process that meets professional requirements.

### **ONE PHARMACY/ONE RESPONSIBLE PHARMACIST: Chapter 7**

*The consultation paper sets out two examples of possible exceptional circumstances that might support allowing a pharmacist to be responsible for more than one pharmacy at the same time.*

*Q. What are your views on the examples given?*

While CPW believe that as a founding principle there should be one pharmacist responsible for one pharmacy at all times. We recognise that exceptional circumstances do arise and that in these exceptional circumstances patients may be better served by the continuation of a pharmacy service albeit at a reduced level than the complete cessation of the service.

We believe that it is for the Superintendent Pharmacist, or someone operating with their delegated authority, to decide what constitutes exceptional circumstances and the nature of any arrangements that should be put in place to maintain a safe and effective service to patients.

As stated previously, it is extremely difficult, if not impossible, to consider this issue fully without knowing the requirements of the supervision requirements.

*Q. Are there any other exceptional circumstances that you think should be considered?*

Exceptional circumstances, by definition, are exceptional, unpredictable and therefore difficult to define. CPW believe they should not be defined in regulation. It should be at the discretion of the responsible and superintendent pharmacist to decide if a circumstance is exceptional, supported by professional guidance.

*To permit a pharmacist to be responsible for more than one pharmacy at the same time, there will need to be compliance with exceptional circumstances and certain*

*specified conditions. The Government is seeking views on what these conditions might be*

*Q. What are your views on each of the proposed conditions set out in chapter 6 and what are your reasons for supporting these views?*

As above.

*Q. Do you think the regulations should specify all or only some of the proposed conditions? What are your reasons for putting these forward?*

As above.

### **SUPERVISION BY THE RESPONSIBLE PHARMACIST IN A PHARMACY WHERE S/HE IS NOT THE RESPONSIBLE PHARMACIST: Chapter 8**

*The Government is seeking views on possible conditions supporting a Responsible Pharmacist's ability to supervise activities in another pharmacy where s/he is not the Responsible Pharmacist. Eg, such conditions (in addition to conditions set for the pharmacist's absence) might include that one or both pharmacies should employ certain staff (eg a registered pharmacy technician) and that both pharmacies have the same owner*

*Q. What are your views on conditions supporting supervision by a Responsible Pharmacist in a pharmacy where s/he is not the Responsible Pharmacist and the possible conditions set out in chapter 8?*

CPW is concerned that matters relating to supervision are being addressed in this consultation at a time when the consultation on supervision remains unpublished and that these circumstances make it impossible to answer these questions effectively.

*Q. Are there other conditions that you feel need to be specified in the regulations?*

CPW does not feel that there are any other conditions that should be specified in the regulations.

### **INTRODUCING THE RESPONSIBLE PHARMACIST REGULATIONS: PREPARING FOR CHANGE: Chapter 9**

*The Government is seeking views on the time needed to prepare for the introduction of the Responsible Pharmacist regulations. Firstly, the Government proposes to introduce the regulations that provide a statutory framework supporting the safe and effective running of the pharmacy. That is, the regulations relating to*

- *The pharmacy procedures*
- *The pharmacy record*
- *Absence from the pharmacy*

- *Requirements relating to recent and relevant experience*

*Q. What are your views on this proposal and your reasons for putting these forward?*

CPW believe that, in the public interest, relaxation of the requirements in relation to the supply of GSL medicines should be implemented as soon as it is practical to do so.

While the consultation on supervision remains unpublished CPW believe it is inappropriate to introduce any changes relating to the supervision of a pharmacy until the requirements for supervision have been discussed and agreed.

*There is a view more time is needed to prepare for introduction of other Responsible Pharmacist regulations - in particular, those linked to the pharmacist supervision regulations. In chapter 9, the Government is seeking views on a phased approach to introducing these regulations.*

*Q. Do you think it would be helpful to take a phased approach to introducing further Responsible Pharmacist regulations? If so, what are your reasons for your view?*

CPW believe that any changes to regulations require a period of notice before introduction so that pharmacists, pharmacy staff, NHS organisations, the public and other healthcare professionals can become familiar with the changes.

It is difficult to identify a definitive notice period as this will be dependent on the degree of change to be introduced and whether the change also needs to be introduced into the undergraduate training and pre-registration training programmes.

*Q. Who should provide this guidance? For example, is there scope for a joint approach to developing guidance by the Government and the regulator bodies?*

Again this is dependent on the nature and magnitude of the change to be introduced. CPW would expect guidance initially to be provided by the DH and the regulatory body. There will then be a role for others such as the pharmacy organisations, educational institutes and employers to provide supportive guidance and education to pharmacists and pharmacy staff.

CPW would expect there to be a multi-agency approach to the planning of the guidance and communication process once the changes have been agreed.

**CPW is content for this response to be made freely available.**

**END**