

**Response of the Pharmaceutical  
Society of Northern Ireland to  
the Content of the Responsible  
Pharmacist Regulations:**

*Ensuring Patient Safety*



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## COVERING LETTER

The Responsible Pharmacist Consultation  
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20 January 2008

Dear Sir or Madam,

**PSNI response on the Content of the Responsible Pharmacist Regulations:**  
*“Ensuring patient safety”*

The Pharmaceutical Society of Northern Ireland wishes to relay its concerns to the Department of Health and DHSSPS in respect of the Responsible Pharmacist Regulation consultation. Our primary source of unease is that the proposed responsible pharmacist regulations will diminish the principle that a pharmacy should not operate and serve members of the public without a qualified pharmacist present to offer advice on, and supervise sales and the dispensing of prescribed and pharmacy medicines. The Society views this as fundamental to ensuring the appropriate protection of the health, safety, and well-being of members of the public in Northern Ireland. We see an essential conflict between the responsible pharmacist’s statutory duty *“to secure the safe and effective running of the pharmacy”* and the possibility of leaving a pharmacy operational without a pharmacist for prolonged periods of time on a regular basis.

The Society would oppose the extension of the responsible pharmacist regulations to Northern Ireland if HPSSNI regulations permitted pharmacies to provide pharmaceutical services without a pharmacist present.

Accordingly, we therefore make the following points to the Department of Health and DHSSPS in response to the published areas of consultation:

**Maintaining the principle of a pharmacist being present in a pharmacy**

## **PSNI response on the Content of the Responsible Pharmacist Regulations:**

### *Ensuring patient safety*

The “responsible pharmacist” regulations, as proposed in the consultation document, suggest that there may be circumstances in which it is acceptable for a pharmacy to operate in the absence of a pharmacist. The PSNI consider that operation of a pharmacy where a pharmacist is not present to provide clinical checking or intervene in the provision of medicines represents an increase in risk to the public and is therefore unacceptable.

The institution of the “responsible pharmacist” regulations should in no sense become a pre-cursor to regular absence of a pharmacist from a pharmacy. The responsible pharmacist regulations should make clear the need for a registered pharmacist to be present within a pharmacy *at all times* during opening hours.

The Society’s concerns on the issue of absence are raised in four areas in particular:

#### *1) Increasing risk to the public*

The PSNI consider that any absence from the pharmacy where a pharmacist is unable to provide clinical checking or the ability to intervene in the provision of medicines endangers the safe dispensing of medicines. The removal of the ability of a pharmacist to intervene will weaken the clinical governance arrangements surrounding the dispensing and provision of Prescription Only Medicines and represents an increased risk to the public.

If anything, there is an increased need for a pharmacist to be present and to be in a position to intervene due to the greater complexity of prescribed medicines and the large number of Prescription Only Medicines that have been deregulated and are now available to be supplied over the counter.

#### *2) Delivering a diminished service to the public*

The general public has a right to have the same quality, safety and access to services that pharmacy’s currently offer. Members of the public who visit a pharmacy expect to find a pharmacist available within the pharmacy. This may be to: discuss their medication; consult for advice; check for contradictions or side effects; make appropriate purchases of OTC medicines for the self treatment of minor conditions; or any of the many new roles pharmacists are increasingly taking on. Any regulations that result in the reduced availability of the pharmacist will therefore diminish the current service provision.

For example, areas of practice that cannot be delegated to other pharmacy staff include:

- Aspects of dispensing process (e.g. professional assessment of prescriptions, supply of controlled drugs)
- Sale of certain pharmacy medicines e.g. newly deregulated classes of medicines, medicines of potential abuse

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- Oversight of public health interventions
- Elements of enhanced and advanced level services in the community pharmacy NHS services contract
- Advice to other healthcare professionals

In this respect the Society considers that the responsible pharmacist regulations, with its current proposals to give permission for the absence of a pharmacist from a pharmacy, will result in a *decrease* in the service and safety profile offered to the public. We view this as against the spirit of the Health Act 2006.

*3) Damaging public perception of the pharmacy as a place for expert advice*

Members of the public in Northern Ireland view pharmacies as a clinical environment where the provision of expert and qualified healthcare and medicines advice is allied to medicines sales. The general public know and utilise pharmacy for its walk in service, '*Health In The High Street*'. This could be severely undermined if the public in Northern Ireland were to regularly find there is no registered pharmacist available in their local pharmacy.

The Society recognises the opportunity for supplementation of the pharmacy workforce and views the increasing use of pharmacy technicians as vital in the development of new and enhanced services within pharmacies. However we see this as a technical supporting role and not replacing the skills knowledge and application of the pharmacist.

*4) Undermining professional concepts of responsibility*

The Society foresees enforcement difficulties in future in terms of a pharmacist taking full legal and professional responsibility for events that occur in his or her absence. We are concerned that even the most competent pharmacy support staff, when faced with dilemmas in the pharmacist's absence may feel pressurised into acting outside their sphere of competence and/or the boundary of the law.

**Responsible pharmacists and the status of other pharmacists**

The Society asks if the Department of Health and DHSSPS have considered the impacts of the proposed Responsible Pharmacist regulations in terms of creating a new tier within the pharmacy workforce.

**PSNI response on the Content of the Responsible Pharmacist Regulations:**  
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*The implications on responsible behaviour*

It is the view of the PSNI that the new classification of “responsible pharmacist” may diminish the status and individual sense of responsibility felt by other registered pharmacists within a pharmacy. The PSNI hold a concern that the distinct designation of one pharmacist within a pharmacy as “responsible” could have an unintended consequence of other pharmacists feeling a diminished sense of personal accountability. This would not be in the best interests of the health service and members of the public. All pharmacists are ultimately responsible for the safe control, of sales, dispensing and distribution of medicines.

Any outcome in which pharmacists operating under a responsible pharmacist felt a *lesser* sense of responsibility for the safe and effective running of the pharmacy would clearly be detrimental to the service received by members of the public in Northern Ireland and/or a loss of confidence in certain practitioners

*The implications of creating a new tier in the pharmacy workforce*

The introduction of the responsible pharmacist status would create a new tier within Northern Ireland's pharmacy workforce. This can have two possible effects: one is to create a new work incentive, the other is to potentially create demoralisation for those who are unsuccessful at, or feel excluded from, becoming a responsible pharmacist. For example, concerns remain that newly registered pharmacists, or those gaining experience to become a responsible pharmacist, could be placed at a disadvantage in seeking or gaining posts in the community or hospital pharmacy sectors.

The PSNI are interested to hear from the Department of Health and DHSSPS what evaluation or assessment has been conducted into these potential areas of impact from the proposed regulations.

The PSNI holds ongoing concerns about the long term impacts for patients, the public and the NHS workforce arising from the responsible pharmacist regulation, as currently proposed – in particular the principle of absence from a pharmacy. We support the spirit of the Health Act 2006, to make best use of the pharmacy workforce. However this change must not occur at the cost of public safety. It remains the opinion of the Society that a pharmacy must not operate to the public without a registered pharmacist present. Instead, it is the Society's view that pharmacists should be enabled to widen their service offering to the public by more pharmacies having two or more pharmacists present.

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We therefore request an increased dialogue with the Department of Health and DHSSPS in advance of regulations being published in order that we may more fully spell out our areas of concern and reasoning for these, particularly in respect of any extension of such regulations to Northern Ireland.

The Society also request that, as health is a devolved matter the DHSSPS and Health Minister fully consult on the proposed regulations within Northern Ireland.

The enclosed response from the Society to the Responsible Pharmacist Regulations consultation questions should therefore be read in light of the PSNI's concerns described above.

Yours Faithfully,



Raymond Anderson  
President  
Pharmaceutical Society of Northern Ireland

## SUMMARY OF CONSULTATION QUESTIONS

### THE PHARMACY PROCEDURES: Chapter 3

#### Section 3.1 – consistency of content in pharmacy procedures

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?*

The Pharmaceutical Society of Northern Ireland supports a balanced and consistent approach to the application of procedures by the responsible pharmacist [RP] in each pharmacy. The RP should be aware of and have opportunity to amend any procedures for which s/he is responsible.

Review of procedures should be governed by professional guidance and not in regulation. The Society already requires this of its members through the use of Standard Operating Procedures [SOPS] which are unique to all pharmacies. Regulatory bodies such as the PSNI have a key role to play in achieving consistency of content in pharmacy procedures.

The Society would highlight certain groups of pharmacists who may require sector specific guidance, including:

- the locum workforce;
- newly registered pharmacists; and
- practitioners crossing disciplines within pharmacy

Recent case histories have suggested that while SOPs are produced, these are not always readily available especially to locums. The Society is concerned by this and would seek to implement professional guidance to mandate the accessibility of documentation of pharmacy procedures.

As highlighted in the covering letter to this consultation, the Society are resolutely of the view that the Responsible Pharmacist regulations should stipulate that a pharmacy should only remain open to the public if a registered pharmacist is present. The locum workforce is therefore essential in our view to the efficacious introduction of the responsible pharmacist regulations in Northern Ireland.

**Section 3.2 – minimum required areas and arrangements for GSL sales**

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?*

*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?*

The Pharmaceutical Society of Northern Ireland is in general agreement with these areas as a minimum requirement. A primary fundamental activity in a pharmacy is the safe provision of advise on, sales of and dispensing of medicines by the pharmacy to the public.

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

The Society has indicated in previous responses that it recognises the case for a change in legislation to enable GSL medicines to be sold without personal supervision by a pharmacist. However the differences in the public perception of a sales outlet such as a petrol station or supermarket, and a pharmacy need to be recognised. The public see a pharmacy as an environment where the provision of accurate and effective advice is allied to medicines sales. Therefore there must always be competent staff available in any sales or advice process, working under agreed protocols, *with provision for referral to a pharmacist*. This should be detailed within the pharmacy's SOPs.

The Pharmaceutical Society of Northern Ireland view it as essential that pharmacy counter staff have appropriate training with respect to the sale of GSL medicines. An individual SOP for each GSL medicine should not be required; however product group training should be undertaken especially where a product has an indication associated to risk or to abuse.

Furthermore, the Society do not see how a pharmacist can be reliably referred to for GSL sales advice by staff if a pharmacy is permitted to operate without a pharmacist present for prolonged periods of time on a regular basis, as proposed in the consultation document (see covering letter). This further underlines the Society's position that a pharmacy must not operate to the public without a pharmacist on the premises.

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**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?*

It is the view of the PSNI that the responsible pharmacist regulations should not specify any other areas that pharmacy procedures must cover other than those listed by the Department of Health in the consultation document. There is a professional responsibility on the owner or superintendent and the responsible pharmacist to ensure good governance and processes. This can be established in professional ethics guidelines delivered by guidance-issuing bodies such as the PSNI.

**Section 3.3 – format of pharmacy procedures**

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?*

Pharmacy procedures should be maintained either electronically or on paper in a permanent and retrievable form by every pharmacy. Regulations should state that the procedures are to be readily available and accessible. The professional body should provide further detail on availability and accessibility through issued guidance.

As with any electronic records, safeguards will be required to ensure the pharmacy procedures are not lost as a result of a systems failure. Adequate backups must be made and arrangements will need to be in place so that it is possible to examine these records with minimal disruption to the dispensing process. Backup should be routine and regular in a similar fashion to that used for pharmacy PMR data. Such requirements should be stipulated in guidance rather than regulation.

Overall, the Pharmaceutical Society urges the Government to err on the side of specifying the minimum amount necessary in regulation in terms of the detail of procedures. The onus should remain with professional regulatory bodies to provide guidance to pharmacists on such matters. This will help to ensure appropriate and timely mechanisms for enforcement and amendment.

The procedures should be living documents and updated as and when necessary. A minimum period should be detailed in guidance for each procedure to be reviewed. Pharmacy staff should comply with the procedures and not simply use them as reference points.

Provision must also be included in guidance to facilitate a mechanism for recording/verification of the individual's signature to show that the person has read and understood the procedures laid down.

The Society are content with procedures being kept in written version rather than electronic. We do however envisage a general movement towards electronic forms of information retention in future. For this reason, amongst others, the detail *in regulation* regarding the keeping of procedures should be kept to a minimum, leaving the majority of specification to come from guidance.

#### **Section 3.4 – signing off procedures**

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

The PSNI agrees that the regulations should not specify the exact format of the procedures but merely that these procedures should be recorded

However, guidance on the fields of information would be helpful to provide similarity of format of the information, particularly for locum pharmacists and regulatory bodies.

The responsible pharmacist [RP] should have the opportunity daily, to familiarise and affirm the pharmacy procedures. There should not be a requirement to keep a daily log of this affirmation

but merely notate when changes are made. These aspects of the regulations should be left to guidance to specify.

Locum pharmacists should be especially vigilant where they operate in unfamiliar premises and are not conversant with the pharmacy procedures.

There should be a professional requirement for pharmacists to record their signature to indicate their acceptance of the pharmacy procedures or to detail how they have amended these.

### **Section 3.5 – reviewing and amending procedure**

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?***

The PSNI agree broadly with this approach. It is incumbent on each RP to ensure that they are familiar and in agreement with the pharmacy procedures in any pharmacy which they are responsible for. There should therefore be an opportunity for the assessment and review of these procedures - this is fundamental to the practice of pharmacy.

The Society suggests that this requirement on checking procedures would most suitably be written in professional guidance, rather than regulation. The professional body is well positioned to issue detailed guidance on the transfer of responsibilities between responsible pharmacists. This would include details on the approach to checking procedures and how any changes to procedure should be communicated to support staff and the owner / superintendent.

**Section 3.6 – guidance as a means of advice on procedures**

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?*

*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?*

The PSNI agrees with the Government that guidance is a more appropriate means of providing information and advice on the review of procedures than regulation.

The PSNI introduced a requirement for pharmacy premises to have Standard Operating Procedures' as of 1st Jan 2005. There is therefore a precedent for the profession itself regulating procedures utilising self governance and audit. The Society will require the RP to ensure the provision and review of the procedures. It is therefore not necessary to have these detailed in regulation.

Regular and ad hoc review of the procedures should be undertaken. Full documentary evidence must be maintained in a log giving details of what has changed if anything and who reviewed the procedure. The procedures must be reviewed at least annually and all staff must indicate they have read and acknowledged by signature their understanding of the revised procedures.

The RP will also have a duty to ensure the owner and or superintendent is informed of the procedures and any changes made to them. This should be recorded in a verifiable and permanent record.

**Section 3.7 – the role of the RP, pharmacy owner, superintendent pharmacist and regulatory body**

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?*

The Pharmaceutical Society of Northern Ireland have concerns that the introduction of the Responsible Pharmacist regulations has the potential to lead to confusion in terms of where responsibility and accountability lies between responsible pharmacist, the pharmacy owner, the

**PSNI response on the Content of the Responsible Pharmacist Regulations:**

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superintendent pharmacist and other pharmacy staff. Ultimately the PSNI see all pharmacists as responsible for their own conduct and practice, in much the same way as GPs are within a GP practice, or dentists are within a dental practice. We would welcome some further clarity from the Department of Health on this issue.

The Pharmaceutical Society of Northern Ireland through its Code of Ethics details the responsibilities of the pharmacist, the superintendent and the requirements for administration and management of the pharmacy.

The pharmacy owners and superintendents have overarching responsibility for the provision of pharmaceutical services in a pharmacy. There is also a duty on the responsible pharmacist [RP] to ensure that the procedures are in place, actioned and reviewed and to ensure that appropriate levels of competent staff are in situ to provide quality care. This is supplementary to and an adjunct to the governance required by the owner/superintendent.

Where local pharmacy procedures differ from those of the organisation [e.g. a multiple], these should be evidence based and be sanctioned by the appropriate authorised person e.g. RP/owner/superintendent. Professional guidance should provide further detail on such procedure.

The RP should be responsible for clinical governance on a daily basis and must ensure adherence to procedures. This must include all aspects of risk management, the limits of competence and the authority of staff working to the procedures. This should apply to all registered pharmacies.

## THE PHARMACY RECORD: Chapter 4

### Section 4.1 – minimum information requirements

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?*

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

*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?*

The Society supports the proposed minimum fields of information required for the pharmacy records to be specified in regulation.

The regulations should specify that the responsible pharmacist will be required to be clearly identifiable to the public, and an accurate, up to date record of the responsible pharmacist must be available in each pharmacy for a minimum period of 5 years. Guidance should detail appropriate security measures to be in place to ensure records cannot be falsified.

The Society further considers that information should be retained on all qualified staff working in the pharmacy on any given day. By qualified staff we include the responsible pharmacist, a pharmacist, technician, dispensing assistant and medicines counter assistant. The inclusion of information on members of staff present other than the responsible pharmacist should be governed by guidelines from the Society and not to be placed in regulations. As noted in the Government's consultation document, this information should already be available from the pharmacy's HR records and so should not therefore constitute an additional administrative burden. However, this information should be available locally for inspection and be kept for a period of 5 years with appropriate backup procedures

Where absence of the RP is appropriate, records should be kept giving detail of the reason and time of absence. This requirement should be provided for in guidance rather than regulation. However, as stated in our covering letter to this consultation response, the PSNI remain deeply concerned about the principal of pharmacists being absent from a pharmacy premises and wish to discuss these further with the Department. It is the view of the PSNI that a pharmacy should only operate in the absence of a pharmacist in truly exceptional circumstances,

**Section 4.2 – format for recording the pharmacy record**

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?***

The Society agrees that the pharmacy record may be kept electronically or on paper and that the fields alone should be defined in regulation.

Additional fields may be specified in guidance form the Society as good practice

**Section 4.3 – preservation of the pharmacy record**

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?***

The PSNI supports the proposal that records should be preserved for a minimum period of five years. The pharmacy owner, in conjunction with the RP, must insure the preservation of this data and this should be detailed in guidance.

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

### **STATEMENT OF POSITION FROM THE PSNI ON ABSENCE OF A RESPONSIBLE PHARMACIST FROM A PHARMACY:**

The “responsible pharmacist” regulations, as proposed in the consultation document, suggests that there may be circumstances in which it is acceptable for a pharmacy to operate in the absence of a pharmacist. The PSNI consider that operation of a pharmacy where a pharmacist is not present to provide clinical checking or intervene in the provision of medicines represents an increase in risk to the public and is therefore unacceptable.

The institution of the “responsible pharmacist” regulations should in no sense become a pre-cursor to regular absence of a pharmacist from a pharmacy. The responsible pharmacist regulations should make clear the need for a registered pharmacist to be present within a pharmacy *at all times* during opening hours.

The Society’s concerns on the issue of absence are raised in 4 areas in particular:

#### *1. Increasing risk to the public*

The PSNI consider that any absence from the pharmacy where a pharmacist is unable to provide clinical checking or the ability to intervene in the provision of medicines endangers the safe dispensing of medicines. The removal of the ability of a pharmacist to intervene will weaken the clinical governance arrangements surrounding the dispensing and provision of Prescription Only Medicines and represents an increased risk to the public.

The removal of the ability of a pharmacist to intervene will weaken the clinical governance arrangements surrounding the dispensing and provision of Prescription Only Medicines and increase the potential risk to the public.

If anything, there is an increased need for a pharmacist to be present and to be in a position to intervene due to the increased complexity of prescribed medicines and the large number of Prescription Only Medicines that have been deregulated and are now available to be supplied over the counter.

## *2. Delivering a diminished service to the public*

Members of the public who visit a pharmacy expect to find a pharmacist available. This may be to discuss their medication, consult for advice, check for contraindications or side effects, make appropriate purchases of OTC medicines for self treatment of minor conditions, etc.

The Society considers it to be the case that the public will be receiving a lesser service than has been permissible under regulations to date if the proposed regulations on a responsible pharmacist go ahead.

For example, areas of practice that cannot be delegated to other pharmacy staff include:

- Aspects of dispensing process (e.g. professional assessment of prescriptions, supply of controlled drugs)
- Sale of certain pharmacy medicines e.g. newly deregulated classes of medicines, medicines of potential abuse
- Oversight of public health interventions
- Elements of enhanced and advanced level services in the community pharmacy NHS services contract
- Advice to other healthcare professionals

In this respect the Society considers that the responsible pharmacist regulations, with its current proposals to give permission for the absence of a pharmacist from a pharmacy, will result in a *decrease* in the service and safety profile offered to the public. We view this as against the spirit of the Health Act 2006.

## *3. Damaging public perception of the pharmacy as a place for expert advice*

Members of the public in Northern Ireland view pharmacies as a clinical environment where the provision of expert and qualified healthcare and medicines advice is allied to medicines sales. The general public know and utilise pharmacy for its walk in service, '*Health In The High Street*'. This could be severely undermined if the public in Northern Ireland regularly find there is no registered pharmacist available in their local pharmacy.

## *4. The concept of responsibility*

The Society foresees enforcement difficulties in future in terms of a pharmacist taking full legal and professional responsibility for events that occur in his or her absence. We are concerned that even the most competent support staff, when faced with dilemmas in the pharmacist's absence may be pressurised into acting outside their sphere of competence and/or the boundary of the law.

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The Society would oppose the extension of the responsible pharmacist regulations to Northern Ireland if such HPSSNI regulations permitted pharmacies to provide pharmaceutical services without a pharmacist present. It is the view of the Society that the operation of a pharmacy without a pharmacist present represents an increase in risk to the public. Instead, it is the Society's view that pharmacists should be enabled to widen their service offering to the public by more pharmacies having two or more pharmacists present.

The enclosed response from the Society to the Responsible Pharmacist Regulations consultation questions should therefore be read in light of the strong concerns raised by the PSNI on the issue of a pharmacist being absent from a pharmacy.

**Section 5.1 – minimum proportion of time an RP should spend in the pharmacy**

The Government has stated the regulations 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 (ie 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?*

*Q. What do you think should be the minimum proportion of time that the responsible pharmacist should be required to be present in the pharmacy? What are your reasons for this?*

*Q. If you do not agree, what do you propose and why?*

As a principle of public safety, a responsible pharmacist should not be absent from a pharmacy for prolonged periods of time without another pharmacist being able to take over responsibility. This should be set out in regulation. The further concerns from the Society in relation to the principle of absence are more fully expressed in the covering letter to this consultation.

Where a pharmacy is open in excess of normal opening hours (i.e. 9am to 6pm) then defined periods of responsibility need to be outlined and an individual responsible pharmacist logged for each period of responsibility. This should be outlined in guidance.

Issues in relation to the minimum period of time for a responsible pharmacist to be present in a pharmacy should be set out in guidance. The Society does not wish to commit to a particular percentage at this stage.

**Section 5.2 – maximum period of absence**

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?*

*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?*

*Q. If you do not agree, what do you propose and why?*

The Pharmaceutical Society of Northern Ireland propose that that the responsible pharmacist regulations stipulate that a responsible pharmacist may not be absent from a premises unless another pharmacist is present in the pharmacy.

Issues in relation to the maximum number of hours that a responsible pharmacist may be absent from a pharmacy should be set out in guidance. The Society does not wish to commit to a particular value at this stage.

It should be noted that the Pharmaceutical Society of Northern Ireland does not currently register or regulate technicians. NI legislation does not currently recognise the professional status of technicians. The Society has already indicated to government its wish to regulate technicians in NI pending legislative change. We seek discussions with the DHSSPS on this matter.

The Society would oppose the extension of responsible pharmacist regulations to Northern Ireland if such hssps regulations permitted pharmacies to remain open to the public without a pharmacist present for prolonged periods of time on a regular basis.

A fuller statement of the Society's position is included in the covering letter to this consultation.

**Section 5.3 – reasonable promptness**

The proposal is the regulations specify 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?***

The PSNI do not support the principle that a pharmacy can operate without a pharmacist present for prolonged periods of time on a regular basis. It requests that any regulations extended to Northern Ireland stipulate a pharmacist must always be present in a pharmacy during opening hours.

Provided another pharmacist is available in the pharmacy premises during the responsible pharmacist's absence, but where the remaining pharmacist is not eligible to take over as a responsible pharmacist, the Society is in agreement that the regulations specify the responsible pharmacist must be able to return to the pharmacy with reasonable promptness.

The definition of reasonable promptness should be made in guidance.

**Section 5.4 – arrangements for an RP to be readily contactable**

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?***

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

The PSNI do not support the principle that a pharmacy can operate without a pharmacist present for prolonged periods of time on a regular basis. It requests that any regulations extended to Northern Ireland stipulate a pharmacist must always be present in a pharmacy during opening hours.

Provided another pharmacist is available in the pharmacy premises during the responsible pharmacist's absence, but where the remaining pharmacist is not eligible to take over as the responsible pharmacist, the Society is in agreement that the regulations specify that the RP must be readily contactable.

The definition of readily contactable should be made in guidance.

**Section 5.5 – arrangements for another pharmacist to provide advice**

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?***

***Q. If you do not agree, you propose and why?***

It is the position of the Pharmaceutical Society of Northern Ireland that a pharmacy should not operate services to the public without a registered pharmacist present. The PSNI therefore support the suggestion that another pharmacist must be in a position to provide advice on the pharmacy premises in circumstances in which the responsible pharmacist is absent. However this pharmacist should be available on the premises, not remotely.

The PSNI support a scenario whereby all pharmacists can be eligible to be a responsible pharmacist in their career beginning from the point of registration. Therefore all pharmacists must be able to provide advice in this situation.

It would be helpful if the university curriculum and the pre registration year were developed to accommodate this as they currently undertake for pharmacist prescribing.

**Section 5.6 – arrangements for another pharmacist to provide advice during RP absence**

The regulations should not set out how the responsible pharmacist is to arrange for another pharmacist to provide advice during his/her absence. However, this might be a matter to be included in guidance.

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

It is the position of the Pharmaceutical Society of Northern Ireland that a pharmacy should not operate services to the public without a registered pharmacist present. The PSNI therefore support the suggestion that another pharmacist must be in a position to provide advice in circumstances in which the responsible pharmacist is absent. However this pharmacist should be available on the premises, not remotely. It should be for professional regulatory bodies to outline further guidance on best practice in these situations, rather than in regulation.

## QUALIFICATIONS AND EXPERIENCE: Chapter 6

### Section 6.1 – annotation to the registrar

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?*

*Q. Do you think there are other matters to consider in addition to those outlined in chapter 6? If so what are these and your reasons for putting them forward?*

The Pharmaceutical Society of Northern Ireland wish to ensure that that all pharmacists must be eligible to be a responsible pharmacist in their career beginning from the point of registration

The Pharmaceutical Society of Northern Ireland agrees with the Government that all pharmacists who have attained sufficient levels of competence should be annotated as responsible pharmacists. This should be competence based and not subject solely to a period of time on the register. It should be evidence based and be part of CPD. Potential pharmacists could be prepared for this role during pre registration training levels e.g. appropriate focus on competency based assessments. This can be defined in professional guidance. There is also a role for the employer in assessing whether an individual is competent to be a responsible pharmacist in their premises. This role should be further defined in professional guidance.

The Society asks if the Department of Health and DHSSPS have considered the impacts of creating a new tier within the pharmacy workforce.

*The implications on responsible behaviour*

It is the view of the PSNI that the new classification of “responsible pharmacist” may diminish the status and individual sense of responsibility felt by other registered pharmacists within a pharmacy. The PSNI hold a concern that the distinct designation of one pharmacist within a pharmacy as “responsible” could have an unintended consequence of other pharmacists feeling a diminished sense of personal accountability. This would not be in the best interests of the health service and members of the public. All pharmacists are ultimately responsible for the safe control, dispensing and distribution of medicine.

The Responsible Pharmacists regulations should therefore make clear the ongoing accountability of all pharmacists working in premises, distinct from the responsible pharmacist. Communications

from the Department of Health and DHSSPS to the pharmacy profession on the responsible pharmacist regulations should also ensure all pharmacists are aware of their responsibilities and accountability under the new system of governance. Any outcome in which pharmacists operating under a responsible pharmacist felt a lesser sense of responsibility for the safe and effective running of the pharmacy would clearly be detrimental to the service and safety profile received by members of the public in Northern Ireland.

*The implications of creating a new tier in the pharmacy workforce*

The introduction of the responsible pharmacist status would create a new tier within Northern Ireland's pharmacy workforce. This can have two possible effects: one is to create a new work incentive, the other is to potentially create demoralisation for those who are unsuccessful at, or feel excluded from, gaining qualification as a responsible pharmacist. For example, concerns remain that newly registered pharmacists, or those gaining experience to become a responsible pharmacist, could be placed at a disadvantage in seeking or gaining posts in the community or hospital pharmacy sectors.

The PSNI are interested to hear from the Department of Health and DHSSPS what evaluation or assessment has been conducted into these potential areas of impact from the proposed regulations.

**Section 6.2 – minimum period of experience**

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?*

*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?*

A minimum period of experience required before taking on the role of responsible pharmacist should not be defined in regulation as each pharmacist should be viewed on their individual merits and be competency based. Professional guidance is the appropriate mechanism for detailing this.

An important requirement for becoming a responsible pharmacist is competency within the pharmacist's area of practice, for example hospital or community pharmacy, or in certain cases within a specialised area in hospital such as dispensary management/sterile unit/manufacturing.

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A pharmacist returning to the practice situation after a period out of the profession, or changing careers, may not initially have the required competency to be an RP but should be able to attain the annotation through evidence based assessment

The PSNI restate their concerns in section 6.1 that full consideration be made of the implications for responsible behaviour and workforce morale as a result of creating a new tier within the pharmacy profession.

**Section 6.3 – relevant pharmacy sectors**

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?*

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

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

In terms of a responsible pharmacist requiring sufficient experience to judge whether pharmacy staff are able to maintain arrangements for safe working involving the sale and supply of medicines when he or she is away from the pharmacy, the Society are strongly of the view that a pharmacy should not remain open to the public without a registered pharmacist present. The Society request this be stipulated in regulation.

The Pharmaceutical Society consider that it is not appropriate to use a time based indicator of experience to assess the fitness of a pharmacist to become a responsible pharmacist as this does not necessarily indicate an automatic achievement of competence.

However, the Society do agree that a pharmacist must demonstrate a level of recent experience in the relevant pharmacy sector before becoming a responsible pharmacist, for example, hospital to community. This should be set out in guidance by the professional regulatory body.

The PSNI restate their concerns in section 6.1 that full consideration be made of the implications for responsible behaviour and workforce morale as a result of creating a new tier within the pharmacy profession.

**Section 6.4 – circumstance where a pharmacist has been out of practice**

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?***

The Pharmaceutical Society considers that it should be for the professional regulatory body to give professional guidance on how a pharmacist is deemed competent to perform the role of responsible pharmacist. This should not be set out in regulation but should be competency based and detailed in guidance by the regulatory body i.e. the PSNI.

The minimum period of experience required before taking on the role of the responsible pharmacist will depend on the individual concerned and their competency.

The Society envisages a role for employers in assessing a member of staff's ability to assume additional responsibilities. Therefore there is a responsibility on employers to ensure that a member of staff employed as a Responsible Pharmacist is competent and fit for the role. This should be a legal obligation. Guidance should be issued by the Society to help employers fulfil this obligation.

The PSNI restate their concerns in section 6.1 that full consideration be made of the implications for responsible behaviour and workforce morale as a result of creating a new tier within the pharmacy profession.

## ONE PHARMACY/ONE RESPONSIBLE PHARMACIST: Chapter 7

### Section 7.1 – example scenarios

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?*

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

It is the view of the Pharmaceutical Society of Northern Ireland that a pharmacist should only be responsible for one pharmacy at any one time. If, regulations were to be drafted to permit a responsible pharmacist to be responsible for more than one pharmacy this should only be in truly exceptional circumstances. Criteria for exceptional circumstances should be drawn up by the Pharmaceutical Society of Northern Ireland and where the circumstance do not match these then prior permission needs to be obtained before any period of responsibility starts.

This should be in guidance as a “must do” rather than a “should do”.

It is hard to conceive of circumstances in which there could be shared responsibility. The PSNI do not consider it appropriate that there is a need for a temporary pharmacy at festivals or agriculture shows, as mentioned in the consultation document’s potential scenarios. The status of robotic dispensing, still in its developing stages, needs further consideration and should be kept under review by both DH/DHSSPS and the professional regulatory bodies.

### Section 7.2 – exceptional circumstances

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?*

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

*Q. Do you think there is a need to specify other conditions? If so, what are these and what are your reasons for putting these forward?*

The Pharmaceutical Society of Northern Ireland does not readily foresee circumstances whereby a responsible pharmacist can be in control of more than one pharmacy at one time. The Society does not recognise the need identified in the consultation document’s two potential scenarios – an

outdoor music festival, and an agricultural show, nor does the Society easily foresee other exceptional circumstances for remote supervision which require legislation.

Robotic dispensing is still in its early stages of development. No decision should be taken as to the safety of remote pharmacist supervision of robotic dispensing until further scenario testing has been conducted. As members of the public are ultimately being issued with P and POM medicines there is certainly a need to ensure advice from a pharmacist is available, and that the pharmacist has an opportunity to intervene. The Pharmaceutical Society of Northern Ireland presently finds it difficult to conceive how such advice and intervention can be reliably offered without the physical presence of a pharmacist.

**Other Questions raised in Chapter 7:**

***The inclusion of conditions on the staff employed in a pharmacy;***

It is the position of the PSNI that a pharmacy should not operate in the absence of a pharmacist, except in “exceptional circumstances”. It should be for professional regulatory bodies to outline guidance on what constitutes exceptional circumstances and procedures for pharmacy staff present.

***Whether each pharmacy where a pharmacist is responsible for more than one pharmacy at one time should be owned by the same company; and,***

It is the position of the PSNI that a pharmacy should not operate in the absence of a pharmacist, except in “exceptional circumstances”. Therefore, we do not foresee the ownership of the pharmacy being a particular issue of difficulty and certainly not something to be detailed in regulation. The Society restates its view that a pharmacy should not operate without a pharmacist present (see covering letter to consultation).

***Who should notify the PSNI/RPSGB of circumstances where a pharmacist is required to be responsible for more than one pharmacy – the RP, or the owner?***

The Society does not recognise the need for regulation enabling remote supervision of a pharmacy. In the interests of public safety, a pharmacist should always be present during the sale and dispensing of medicines.

***The maximum number of pharmacies which an RP can be responsible for***

The PSNI suggest the maximum number of pharmacies which an RP can be responsible for is one.

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

### **Section 8.1 – Supervision conditions**

The Government is seeking views on possible conditions supporting a responsible pharmacist's ability to supervising 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?***

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

***Q. If you do not agree this approach, what do you propose instead?***

The Pharmaceutical Society of Northern Ireland does not wish to comment in detail on supervision at this time as this will be subject to further attention in the next phase of this consultation process. However, the position of this Society is that each pharmacy should have a pharmacist present even if there is not the presence of a responsible pharmacist. The levels of qualification and experience of a registered pharmacist do not have equivalence in a technical qualification and so the responsibilities undertaken cannot be the same.

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

### Section 9.1 – time needed to prepare for introduction

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?*

*Q. How long do you think that pharmacy owners, pharmacists and others need to prepare for the introduction of these regulations? What are your reasons for this?*

**What period of time do you believe is necessary to introduce the above?**

- 6months
- 12months

The Society restates its depth of concern that, as currently constituted, the responsible pharmacist regulations will diminish the principle that a pharmacy should not operate without the presence of a pharmacist. In terms of enforcement therefore, the PSNI wish to enforce regulations that clearly state that a pharmacy should not operate without the presence of a registered pharmacist.

Given our concerns, the Society deems that the new regulations should be subject to a carefully monitored trial period to assess the impact of the regulations on public safety, and ensure the ability to achieve successful outcomes. The professional regulatory bodies should be involved in this trial assessment alongside the Departments. We look forward to speaking to the Department for Health and the DHSSPS on this matter in the months ahead.

There will need to be a working party for the Society to develop with academics, government and employers how the responsible pharmacist can be phased into the workforce without unduly impacting on the public by restrictions on the pharmacy network.

So a trial project would be appropriate along with education of the profession and public as to the need for this annotation. We do not wish to create a distinction in pharmacists whereby not being

a responsible pharmacist is seen to be a lesser professional in the eyes of the public or the allied health professions (see our response in section 6.1).

The Society supports a grand parenting arrangement in Northern Ireland on introduction of the responsible pharmacist regulations, for example, the provision of appropriate training to facilitate the introduction of the role of a responsible pharmacist without unduly disrupting the workforce.

All pharmacies also require an adequate time period to ensure the provision of robust procedures which are detailed, documented and signed off and agreed. This time frame is likely to be at least one year to allow the development of regulations and professional guidance. The Pharmaceutical Society of Northern Ireland would therefore conclude this may take at least 12 months post publication of Northern Ireland regulations to implement this in the community

#### **Section 9.2 – phased approach to introduction**

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?***

***Q. What are your views on the option outlined in chapter 9 and your reasons for putting forward these views?***

***Q. If you not agree with the approach outlined, what do you propose instead?***

In light of the strong concerns felt by the PSNI regarding aspects of the responsible pharmacist regulations (particularly those covering absence of an RP) the Society advocate a phased approach to introduction to allow maximum opportunity for evaluation and assessment of impacts.

This may be an opportunity to pilot some aspects of the approach to ensure consistency in the implementation of the regulations and to allow detailed professional guidance to develop. Any future systems will need “road tested” and it is the public as well as the profession which need to be prepared for any changes.

A phased piloted model would have best outcomes for all.

**Section 9.3 – the role of guidance**

The Government welcomes views on the need for guidance to support introduction of the responsible pharmacist regulations

***Q. Do you think there is a need for guidance? If so, what matters should this cover?***

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

There is a definite need for clear and robust guidance associated with the Responsible Pharmacist regulations

The Society would welcome a joint approach with the RPSGB and Government Departments in developing guidance and will add supplementary professional guidance within its Code of Ethics after a due process is completed.

To facilitate the consultation the Society has indicated in tabular form what elements in this consultation should be defined in regulation and which should be defined in professional guidance.

The Society would like to see the issues of remote supervision and the supervision of activities in a pharmacy where a pharmacist is not the responsible pharmacist subject to further consultation within the forthcoming consultation on the supervision elements of the responsible pharmacist regulations.

## Appendix A: PSNI view on regulation versus guidance

| AREA  | REGULATION FROM DH/DHSSPS   | GUIDANCE FROM PSNI  |
|---|---|---|
| <p><i>Chapter 3</i><br/> <i>Pharmacy procedures</i></p>                 | <ul style="list-style-type: none"> <li>• Regulations to state that pharmacy procedures be “readily available and accessible”</li> <li>• Regulations to harmonise GSL sales with other retail outlets</li> </ul>   | <ul style="list-style-type: none"> <li>• Guidance on detail of procedures e.g. storage, backups, format and compliance</li> <li>• Guidance on procedures in relation to locum workforce, newly registered pharmacists and pharmacists changing discipline or returning to practice</li> <li>• Guidance on procedures and transferring between RPs</li> <li>• Guidance on sale of GSL medicines and pharmacy staff training</li> <li>• Guidance on affirming, reviewing and amending procedures</li> <li>• Guidance on the fields of information within pharmacy procedures</li> <li>• Guidance on constituent local pharmacy procedures differing from those of its multiple</li> <li>• Individual guidance and SOP for each GSL medicine not required</li> </ul> |
| <p><i>Chapter 4</i><br/> <i>Pharmacy Record</i></p>                     | <ul style="list-style-type: none"> <li>• Regulations to define the minimum fields of information for Pharmacy Record</li> <li>• Regulations to set a minimum period of 5 years for preserving the Pharmacy Record</li> <li>• Regulations to specify that the RP be clearly identifiable to the public.</li> </ul>   | <ul style="list-style-type: none"> <li>• Guidance on keeping information on all qualified staff in the Pharmacy Record, not just the responsible pharmacist</li> <li>• Guidance on security measures to ensure against falsification of the Record</li> <li>• Guidance on any additional fields of information beyond regulatory requirements</li> <li>• Guidance on recording absence of an RP</li> </ul>  |
| <p><i>Chapter 5</i><br/> <i>Absence of a Responsible Pharmacist</i></p> | <ul style="list-style-type: none"> <li>• <b>Regulations to specify a pharmacist must be present in the pharmacy during pharmacy opening.</b></li> <li>• New regulations needed in Northern Ireland to enable the PSNI to register technicians</li> <li>• Regulations to specify an RP, when absent, is readily contactable and able to return with reasonable promptness</li> </ul> | <ul style="list-style-type: none"> <li>• Guidance on defined periods of responsibility</li> <li>• Guidance on interpretation of “readily contactable” and “reasonable promptness”</li> </ul>  |

**PSNI response on the Content of the Responsible Pharmacist Regulations:**

*Ensuring patient safety*

|  |  |   |
|--|--|---|
| <p><b>Chapter 6</b><br/><b>Qualification</b></p>   | <ul style="list-style-type: none"> <li>Regulation should not state a minimum period of time to become an RP – this should be competence based</li> <li>Regulations should enable pharmacists to be eligible to be a responsible pharmacist from the point of registration</li> <li>Regulations should place a responsibility on employers to ensure a member of staff employed as an RP is competent and fit for the role.</li> </ul>            | <ul style="list-style-type: none"> <li>Guidance to define competency based assessment, potentially within pre-registration</li> <li>Guidance to employers on their responsibilities in relation to assessing the competence of a member of staff to be a Responsible Pharmacist</li> <li>Guidance on how status of RP relates to different practice areas</li> <li>Guidance on pharmacists returning to practice after a period out of practice, or changing careers</li> </ul> <p><i>The PSNI has concerns about the implications of a new tier within the pharmacy workforce and seek further discussions with the DH and DHSSPS on this point.</i></p> |
| <p><b>Chapter 7</b><br/><b>Responsibility for more than one pharmacy</b></p>                     | <ul style="list-style-type: none"> <li>Regulations to permit responsibility for more than one pharmacy only in “exceptional circumstances”</li> <li>PSNI propose regulations state from whom permission be requested (e.g. the PSNI). This could operate retrospectively in circumstances to be defined in guidance.</li> </ul>  | <ul style="list-style-type: none"> <li>Guidance to outline the criteria for “exceptional circumstances”</li> <li>Guidance on mechanisms for seeking permission for a responsible pharmacist to be responsible for more than one pharmacy.</li> </ul> <p><i>Further consideration to be given by DH, DHSSPS and professional regulatory bodies as to the case of robotic pharmacies</i></p>  |
| <p><b>Chapter 8</b><br/><b>Supervision by an RP in a pharmacy where he/she is not the RP</b></p> | <ul style="list-style-type: none"> <li>Each pharmacy should have a pharmacist present even if there is not the presence of a responsible pharmacist</li> </ul> <p><i>Further comment reserved until publication of forthcoming consultation on supervision elements of the RP regulations.</i></p>   | <p><i>Comment reserved until publication of forthcoming consultation on supervision elements of the RP regulations.</i></p>   |
| <p><b>Chapter 9</b><br/><b>Introducing the Responsible Pharmacist Regulations</b></p>            | <ul style="list-style-type: none"> <li>Regulations should clearly state that a pharmacy should not operate without the presence of a registered pharmacist.</li> <li>Introduction of regulations to be subject to carefully monitored trial and evaluation period</li> <li>12 month period from publication of final publication of regulations to enactment in order for best guidance to be drawn up and communicated to profession</li> </ul> | <ul style="list-style-type: none"> <li>Introduction of guidance to be subject to carefully monitored trial and evaluation period</li> <li>12 month period from publication of final publication of regulations to enactment in order for best guidance to be drawn up and communicated to profession</li> <li>Joint approach by PSNI, RPSGB, DH and DHSSPS in developing guidance</li> </ul>  |