

Primary and Community Care Directorate

Pharmacy Division

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25 October 2007



Dear Colleague

Health Act 2006: Consultation on Regulations Relating to the Responsible Pharmacist

I am writing to invite your views on the attached consultation document, which sets out proposals for developing pharmacy services throughout the UK. The results of this consultation will be considered along with the results of separate consultations to be carried out in England, Wales and Northern Ireland and will inform regulations to be made under the UK Health Act 2006.

The Health Act amends the Medicines Act 1968 and related NHS legislation in a number of important respects. It replaces personal control with a requirement that each registered pharmacy is to have a responsible pharmacist with a statutory duty to secure the safe and effective running of the pharmacy. Together with existing provisions in the Medicines Act, the Health Act also provides for changes in the pharmacist supervision requirements.

These are complex changes. Therefore, it has been agreed to begin the regulation-making process by consulting on the responsible pharmacist provisions, which are mandatory. Consultation on the pharmacist supervision regulations will follow later.

The regulations under the Health Act 2006 will set out how the responsible pharmacist is to exercise the statutory duty, which will be underpinned by a quality systems approach. To inform the regulations, the attached consultation letter is seeking views on:

- proposals on the content of the responsible pharmacist regulations;
- the timing of introduction of the responsible pharmacist regulations and the time needed to prepare for change;
- the need for guidance to support introduction of the regulations.

Responses are invited **by 20 January 2008** by email to Mary.waugh@scotland.gsi.gov.uk or to:

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The Responsible Pharmacist Consultation
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Primary & Community Care Directorate, Pharmacy Division
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This consultation and all other Scottish Government consultation exercises can be viewed online at <http://www.scotland.gov.uk/consultations/current> You can telephone Freephone 0800 77 1234 to find out where your nearest public internet access point is.

The Responsible Pharmacist

The Scottish Government now has an email alert system for consultations (SEconsult: <http://www.scotland.gov.uk/consultations>). This system allows stakeholder individuals and organisations to register and receive a weekly email containing details of all new consultations (including web links). SEconsult complements, but in no way replaces Scottish Government distribution lists, and is designed to allow stakeholders to keep up to date with all consultation activity, and therefore be alerted at the earliest opportunity to those of most interest. We would encourage you to register.

Handling your response

We need to know how you wish your response to be handled and, in particular, whether you are happy for your response to be made public. Please complete and return the **Respondent Information Form** enclosed with this consultation paper as this will ensure that we treat your response appropriately. If you ask for your response not to be published we will regard it as confidential and treat it accordingly.

All respondents should be aware that the Scottish Government are subject to the provisions of the Freedom of Information (Scotland) Act 2002 and would therefore have to consider any request made to it under the Act for information relating to responses made to this consultation exercise.

Where respondents have given permission for their response to be made public, these will be made available to the public in the Scottish Government Library and on the Scottish Government web pages by the end of February 2008. All responses not marked confidential will be checked for any potentially defamatory material before logging them in the Library or placing them on the website. You can make arrangements to view responses by contacting the Library on 0131 244 4565. Responses can be copied and sent to you, but a charge may be made for this service.

Next steps

Following the closing date, all responses will be analysed and the results of this consultation together with the results of the England, Wales and Northern Ireland consultations will inform UK regulations on the responsible pharmacist provisions.

Comments and complaints

If you have any comments or queries about how this consultation exercise has been conducted please send them to the address above.

Thank you for your help.

Yours sincerely

Bill Scott

Professor Bill Scott
Chief Pharmaceutical Officer

RESPONDENT INFORMATION FORM

Health Act 2006: Consultation on Regulations Relating to the Responsible Pharmacist

Please complete the details below and attach it with your response. This will help ensure we handle your response appropriately: Thank you for your help.

Name:

Postal Address:

1. Are you responding as: (please tick one box)
- | | | | |
|-----|---|--------------------------|-------------------------|
| (a) | an individual | <input type="checkbox"/> | go to Q2a/b and then Q4 |
| (b) | on behalf of a group or organisation | <input type="checkbox"/> | go to Q3 and then Q4 |

INDIVIDUALS

- 2a. Do you agree to your response being made available to the public (in SG library and/or on SG website)?

Yes (go to 2b below)

No, not at all We will treat your response as confidential

- 2b. **Where confidentiality is not requested**, we will make your response available to the public on the following basis (**please tick one** of the following boxes)

Yes, make my response, name and address all available

Yes, make my response available, but not my name or address

Yes, make my response and name available, but not my address

ON BEHALF OF GROUPS OR ORGANISATIONS:

3. The name and address of your organisation **will be** made available to the public (in the SG library and/or on SG website). Are you also content for your response to be made available?

Yes

No We will treat your response as confidential

4. We will share your response internally with other SG policy teams who may be addressing the issues you discuss. They may wish to contact you again in the future, but we require your permission to do so. Are you content for the Scottish Government to contact you again in the future in relation to this consultation response?

Yes

No

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Executive Summary: Proposals for the Responsible Pharmacist Regulations

1. This consultation paper is seeking views on
 - proposals on the content of the responsible pharmacist regulations
 - the timing of introduction of the responsible pharmacist regulations and the time needed to prepare for change
 - the need for guidance to support introduction of the regulations
2. A summary of proposals for the content of the regulations and other matters raised in the paper are set out below. Appendix A summarises questions posed in the following chapters and provides a format that you may wish to use in responding to the consultation. Appendix B lists some frequently asked questions from the informal consultation events held in early 2007 and other meetings.

Pharmacy Procedures (Chapter 3)

3. The responsible pharmacist is required to establish (if these are not already established), maintain and review pharmacy procedures designed to secure the safe and effective running of the pharmacy. The Government is seeking views on
 - Allowing the responsible pharmacist to use his/her professional judgement in ensuring pharmacy procedures support safe working in the pharmacy for which s/he is responsible and the need for review or amendment of the procedures
 - The minimum areas to be covered by the pharmacy procedures, including a requirement that pharmacy procedures should include arrangements for the sale of General Sales List (GSL) medicines from the pharmacy
 - That, over and above the matters specified in the regulations on pharmacy procedures, any further matters to be included in the pharmacy procedures are a matter for the pharmacy owner, the superintendent pharmacist, and the responsible pharmacist, as appropriate.
 - The regulations should allow the responsible pharmacist to set out the written pharmacy procedures on paper or electronically, provided these are readily available and accessible to those who need to consult the procedures
 - The regulations should not prescribe a format for pharmacy procedures
 - A proposal that regulations should require the format used for pharmacy procedures to allow the responsible pharmacist to “sign off” the procedures in a way that indicates that, on taking responsibility for the pharmacy, s/he is content that the procedures support safe working in the pharmacy.
 - Proposals relating to the review of the pharmacy procedures, including the role of guidance
 - The role of the responsible pharmacist, the superintendent pharmacist, the pharmacy owner and the professional regulatory bodies

The Pharmacy Record (Chapter 4)

4. The responsible pharmacist is required to keep a record, in the pharmacy, of the pharmacist responsible for the pharmacy on any date and at any time. The Government is seeking views on
 - A proposal that the regulations specify the minimum information to be included in the pharmacy record
 - That, over and above meeting these minimum requirements, the inclusion of additional information in the record will be a matter for the pharmacy owner
 - A proposal that the regulations allow the responsible pharmacist to keep the record in paper form or electronically, provided the record is readily available and accessible to those wishing to consult the record
 - It is proposed that the regulations do not prescribe the format of the pharmacy record but specify the fields of information to be included in the record
5. The pharmacy owner has a statutory duty to ensure the responsible pharmacist properly keeps the record and to preserve the record for the period set out in regulations. The Government welcomes views on
 - The required minimum period for which the pharmacy owner must preserve the record – the Government is proposing that this is five years from the date of the last entry to the record
 - That, over and above the requirement to meet this minimum requirement, the preservation of the record for a longer period is a matter for the pharmacy owner

Absence from the Pharmacy (Chapter 5)

6. The statutory duty on the responsible pharmacist now makes clear that s/he must secure the safe and effective running of the pharmacy – setting out procedures designed to ensure safe operation of the pharmacy and keeping a record of the pharmacist responsible for the pharmacy at any time and on any date. These explicit requirements and added safeguards make clear that safe working is not dependent on the responsible pharmacist's physical presence in the pharmacy at all times when it is operating. Subject to certain conditions, the responsible pharmacist will be able to leave the pharmacy. For example, the pharmacist will be able to use his/her clinical training to offer services other than the sale and supply of medicines in the same building, adjacent to the registered pharmacy premises (such as a consulting room) or to provide clinical services away from the pharmacy (eg in health centres and patients' homes).
7. However, the Government has made clear its view that the pharmacist should consider the pharmacy to be his/her main place of work, when responsible for the pharmacy, to ensure that s/he is able to meet the statutory duty fully and effectively.
8. The Government is seeking views on how the regulations should define absence from the pharmacy and the conditions that will allow the responsible pharmacist to be absent.

The Responsible Pharmacist

9. To define absence from the pharmacy, the Government proposes
 - That the regulations specify the minimum proportion of time, during any one period in which s/he is responsible for the pharmacy and the pharmacy is operational, the responsible pharmacist should spend in the pharmacy. Further, this should be the majority of that time (ie more than 50% of each period for which s/he is responsible for the pharmacy and the pharmacy is operating).
 - The regulations also specify three hours as the maximum time the responsible pharmacist may be away from the pharmacy in any one period of absence.
 - In addition, the Government is seeking views on whether this maximum time might vary – for example, where another pharmacist or certain other pharmacy staff (eg a registered pharmacy technician) remain present in the pharmacy during the responsible pharmacist's absence - and, if so, how this should vary.
10. The Government welcomes views on proposals that the responsible pharmacist must comply with the following conditions in order to be absent from the pharmacy for the maximum time specified in the regulations. The Government also welcomes proposals for any further conditions in relation to the responsible pharmacist's absence from the pharmacy.
 - A proposal that, as a condition supporting absence from the pharmacy, the responsible pharmacist should be required to return to the pharmacy with reasonable promptness where requested/required to do so. The Government's view is that it will be difficult to define in the regulations all circumstances that may arise to prompt a return to the pharmacy. The Government also believes that the responsible pharmacist must be able to use his/her professional judgement in deciding how to meet this condition, taking into account the circumstances concerned. Therefore, the Government does not propose to define "reasonable promptness" in the regulations.
 - That, as necessary, the responsible pharmacist maintains contact with pharmacy staff to provide professional advice or to respond to a request to return to the pharmacy. For example, where s/he is absent and there is no other pharmacist working in the pharmacy. The Government does not propose to specify in the regulations the ways in which the responsible pharmacist is to maintain readily contactable by pharmacy staff but welcomes views on the role of guidance as a more appropriate way of advising the responsible pharmacist in this respect.
 - As another condition supporting absence from the pharmacy, that where s/he is unable to maintain contact with pharmacy staff whilst away from the pharmacy. the responsible pharmacist is required to arrange for another pharmacist to provide advice. Again, the Government does not propose that the regulations specify how the responsible pharmacist is to make such arrangements, as this will also involve professional judgement. The Government is also seeking views on whether the other pharmacist providing advice should be a responsible pharmacist or eligible to take on this role.

Qualifications and Experience (Chapter 6)

11. The regulations may set out the qualifications and experience needed to be a responsible pharmacist. The Government has no intention to introduce a qualification over and above registration as a qualified pharmacist. However, given the statutory duty on the responsible pharmacist and changes in the pharmacist supervision requirements, the Government welcomes views on, for example, the experience needed to take on this important role and the proposals set out in the consultation paper. These include
- A proposal that an annotation to the register be made against the names of those pharmacists with the necessary experience to be a responsible pharmacist
 - A proposal that regulations specify that before taking on responsibility for a pharmacy, a responsible pharmacist is required to have a minimum period of experience following registration as a pharmacist. Alternatively, that this requirement might only apply, for example, as a further condition enabling the responsible pharmacist to be absent from the pharmacy or to allow a suitably trained and registered healthcare professional (eg a pharmacy technician) to supervise certain aspects of the sale and supply of medicines
 - A proposal that a pharmacist wishing to take on the role of a responsible pharmacist is required to have recent experience in the pharmacy sector concerned (eg community or hospital). The Government is also seeking views on what the minimum period of relevant experience might be and how this might be set out in the regulations – for example “x” period of experience in the last “y” years.
 - A proposal that, where a pharmacist has not practised as a pharmacist for a specified period (eg three years) that s/he has a minimum period of experience in the relevant pharmacy sector before taking on the role of a responsible pharmacist.
12. The Government is also seeking views on the time needed to prepare for the introduction of the regulations relating to the qualifications and experience needed to be a responsible pharmacist – in particular whether some of these regulations might be introduced before others. See also Chapter 9.

One Pharmacy/One Responsible Pharmacist (Chapter 7)

13. The general “rule” remains – that each registered pharmacy must have a responsible pharmacist. The new section 72A in the Medicines Act makes clear that a pharmacist may only be responsible for one pharmacy at the same time, except in circumstances specified in regulations and then only subject to compliance with certain conditions. During passage of the Health Act, the Government stated its intention to draw these regulations tightly to maintain public safeguards in relation to the sale and supply of medicines.

The Responsible Pharmacist

14. The Government welcomes views on two possible examples of such exceptional circumstances and invites others to be put forward. Subject to the response to consultation, the Government also puts forward a view that it may be more appropriate to introduce regulations allowing a pharmacist to be responsible for more than one pharmacy later. For example, these might be introduced as further exceptional circumstances arise or following introduction of the pharmacist supervision regulations and those permitting a responsible pharmacist to supervise remotely. (See chapter 9). Again, views are welcome on this proposal.
15. The Government is seeking views on proposals relating to the required conditions that, together with specified exceptional circumstances, will allow a pharmacist to be responsible for more than one pharmacy at the same time. These are
 - A proposed requirement that the responsible pharmacist must be able to meet the statutory duty in relation to each of the pharmacies for which s/he is responsible
 - A proposal that, subject to specified circumstances, a pharmacist may be responsible for more than one pharmacy at the same time only for the limited period specified in the regulations – views are also sought on what that period might be
 - A proposal that the pharmacy owner or the responsible pharmacist notify the Royal Pharmaceutical Society of Great Britain (in Northern Ireland, the Pharmaceutical Society of Northern Ireland) of any arrangements in which the pharmacist is responsible for more than one pharmacy at the same time
 - A proposal that a condition allowing a pharmacist to be responsible for more than one pharmacy is that each pharmacy concerned should be owned and managed by the same company, partnership or individual
 - A proposal that certain pharmacy staff (eg another pharmacist or a registered pharmacy technician) are employed in at least one or all of the pharmacies concerned
 - A proposal that the regulations specify, depending on the nature of the exceptional circumstances concerned, the maximum number of pharmacies for which a pharmacist may be responsible at the same time – the Government proposes that the maximum number should be two pharmacies.

Supervision by the Responsible Pharmacist of activities in a pharmacy where s/he is not the Responsible Pharmacist (Chapter 8)

16. The responsible pharmacist regulations may set out the circumstances in which a pharmacist responsible for one pharmacy may supervise the preparation, assembly, sale and supply of medicines in a pharmacy where s/he is not the responsible pharmacist. To do so, the pharmacist will need to meet the conditions for absence.

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17. The Government also recognises that these regulations link with regulations relating to remote supervision and, more generally, the pharmacist supervision regulations on which the Government is consulting later. Therefore, in responding to this consultation, there may be a view that it is more appropriate to consider the content of these regulations within the context of that later consultation. The Government welcomes views on this. (See chapter 9).
18. In the meantime, the Government welcomes views on the following proposals for conditions relating to the ability of a pharmacist responsible for one pharmacy to supervise individual transactions involving the sale and supply of medicines from another pharmacy where s/he is not the responsible pharmacist. The Government also welcomes proposals for any further conditions that might be included in these regulations.
 - A proposal that a condition should be that certain pharmacy staff (eg a registered pharmacy technician) should be employed in one or both of the pharmacies concerned
 - A proposal that both pharmacies have the same pharmacy owner

Other Matters Relating to the Responsible Pharmacist (Chapter 9)

19. In chapter 9, the Government sets out other matters relating to the responsible pharmacist regulations. That is
 - enforcement of the regulations
 - the time needed to prepare for the introduction of the majority of the responsible pharmacist regulations
 - taking a phased approach to the introduction of other responsible pharmacist regulations
 - the role of guidance in supporting introduction of these changes
20. The Government welcomes views on a proposal to introduce the majority of the responsible pharmacist regulations at the same time and the time needed to prepare for introduction.
21. The Government welcomes views on introducing some of the responsible pharmacist regulations later – for example, at the same time or following introduction of the pharmacist supervision regulations.
22. At this stage of consultation, the Government is not consulting on the responsible pharmacist regulations relating to remote supervision. The Government intends to consult on these proposals later, as part of wider consultation on the pharmacist supervision regulations.
23. The Government welcomes views on the need for guidance to support introduction of the responsible pharmacist regulations, in particular what the guidance should cover and whether certain matters are more appropriate for guidance issued by the professional regulatory bodies and others (eg updating existing guidance on pharmacy standard operating procedures (SOPs)).

CHAPTER 1

INTRODUCTION

- 1.1 The four UK Health Departments have published strategies for developing NHS pharmaceutical services, which highlight the importance of making the best use of all staff working in pharmacies. These strategies are set out in
- *Remedies for Success: A Strategy for Pharmacy in Wales (2002)*
 - *The Right Medicine: A Strategy for Pharmaceutical Care in Scotland (2002)*
 - *A Vision for Pharmacy in the New NHS: (England 2003)*
 - *Making it Better – a Strategy for Pharmacy in the Community (Northern Ireland 2004)*
- 1.2 These plans for NHS pharmacy services, together with the introduction of changes to the NHS community pharmacy contractual arrangements (in England and Wales from 1 April 2005, in Scotland from 1 April 2006 and expected in Northern Ireland in the future), are part of action to improve
- patients' choice and experience through wider access to services that are convenient to modern lifestyles
 - public health and how we tackle inequalities
 - support in the community for people with long term conditions
 - professional advice and support for self care
- 1.3 If pharmacists are to make full use of their clinical training and expertise in the actions, uses and side effects of medicines and to develop their important role and contribution to professional healthcare teams working in the community and in hospitals, they need to be able to extend the range of services they can offer. For example, in the community, pharmacists have a long and valued tradition of providing the public with readily accessible professional advice in pharmacies on high streets and in shopping centres. Community pharmacies can offer more than the safe and efficient dispensing of NHS prescriptions and the sale of medicines – such as advice on healthy lifestyles (eg stopping smoking), diagnostic testing (eg ensuring the right dose of medicine to slow the clotting rate of blood) and the provision of professional clinical advice to patients experiencing problems in using their medicines.
- 1.4 To support pharmacists in developing their clinical role and contribution to improving healthcare services, better and more flexible use must also be made of the skills of pharmacy staff (such as pharmacy technicians, dispensing assistants and others) to maintain the safe and effective delivery of dispensing services and the sale of medicines. However, many pharmacists and pharmacy organisations feel that the current legal framework limits the ability of pharmacists to enhance their clinical role and to extend the range of pharmacy services offered, as this will involve pharmacists' ability to be absent from the registered pharmacy premises from time to time.

The Responsible Pharmacist

- 1.5 Therefore, in 2005, the Government consulted on the scope for changes to the Medicines Act 1968 (the Medicines Act) and related NHS legislation. That is, legislation concerning the requirements on the pharmacist in charge of a registered pharmacy and the requirements on the pharmacist to supervise the preparation, assembly, sale and supply of medicines.
- 1.6 The consultation paper, *Making Better Use of the Pharmacy Workforce*, published in England in December 2004 also formed the basis of consultation by the Welsh Assembly Government. Consultation took place in Scotland from February 2005 and in Northern Ireland from April 2005. The paper and a summary of the responses to this consultation are available on the Department of Health website at www.dh.gov.uk/consultations/consultationslibrary.
- 1.7 The overall response to consultation was strong and clear. The majority of respondents felt there was a need for legislative change to allow pharmacists and pharmacy owners to make better use of the skills and training of all those working in pharmacies to
 - underpin the further development of pharmacy services (including pharmacy's contribution to public health), in particular through the NHS community pharmacy contractual arrangements
 - improve the public's access to medicines

The Medicines Act 1968: The Personal Control Requirement

- 1.8 Currently, the Medicines Act, which is UK-wide, requires the business of the retail sale and supply of medicines through registered pharmacies to be under the "personal control" of a pharmacist.
- 1.9 The Medicines Act does not define "personal control" nor does the Act set out how the pharmacist in charge of the pharmacy is to exercise this requirement. In 1981, the case of *R v Logan* indicated that some physical presence of the pharmacist in the pharmacy would be required for the pharmacist to exercise personal control. However, that decision also indicated that the sale of General Sales List (GSL) (– ie those medicines that other retail premises, as well as pharmacies, may sell,) could take place when the pharmacist was away from the pharmacy. More recently, the Royal Pharmaceutical Society's Statutory Committee advised that if a pharmacist is not in personal control of a pharmacy (for instance, because s/he is not on the registered pharmacy premises), transactions involving the sale or supply of medicines, including the sale of GSL medicines, may not take place.
- 1.10 This lack of clarity in the Medicines Act – and the availability of limited case law – means that a common interpretation has emerged requiring the pharmacist to be physically present in the pharmacy at all times if s/he is to exercise control and allow the sale and supply of medicines to continue from the pharmacy. This includes the sale of GSL medicines. In order to buy GSL medicines from a pharmacy, if the pharmacist is absent, people must await his/her return or visit another pharmacy where the pharmacist is present. Yet there is no requirement for a pharmacist to be present when people purchase these medicines from retail outlets such as garage shops or newsagents.

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- 1.11 Importantly, there is a view that this interpretation also limits the pharmacist's ability to use fully his/her clinical training in providing services, other than the dispensing and sale of medicines, from pharmacies. Currently, pharmacists are constrained in using their extensive training and expertise in medicines to enhance their clinical role and contribution to improving services for patients in the community and in hospital. Further, there is a need for clarity on what is required of a pharmacist who is in charge of a pharmacy, resulting in an emphasis on the physical presence of the pharmacist in the pharmacy to meet the "personal control" requirement.
- 1.12 In England, 75% of respondents to the consultation in 2005 called for greater clarity on the Medicines Act requirement that each registered pharmacy must be under the personal control of a pharmacist where this concerns the preparation, assembly, sale and supply of medicines. Of those expressing a view on redefining the "personal control" requirement, around 50% wanted to see this expressed in terms of the pharmacist's professional responsibilities. About 60% of respondents supported the need for legislative changes in relation to the sale of General Sales List (GSL) medicines to bring pharmacies more into line with other retail outlets selling these medicines.

The Medicines Act 1968 and related NHS Legislation: The Pharmacist Supervision Requirements

- 1.13 Under the Medicines Act the sale and supply of medicines, other than GSL medicines, is required to be under the supervision of a pharmacist. However, in England, Scotland and Wales, where supplied through a pharmacy via an NHS prescription, current NHS legislation requires a pharmacist to supervise directly the supply of all medicines. The Pharmaceutical Services Regulations (Northern Ireland) 1997 make a similar provision for Northern Ireland.
- 1.14 The majority of those responding to the 2005 consultation (80%) wanted to see changes to the pharmacist supervision requirements to
- reflect modern pharmacy practice
 - take into account the increasing availability of modern technologies
 - allow pharmacists more flexibility in using the skills of pharmacy staff
 - improve pharmacists' ability to offer services other than the dispensing and sale of medicines

The Health Act 2006

- 1.15 The Government responded to the call for legislative changes. The Health Act 2006 (the Health Act) amends the Medicines Act and related NHS legislation in ways that reflect the support for legislative change. However, these changes do not affect the fundamental principle of the Medicines Act – to protect the public in relation to the sale and supply of medicines. Public and patient safety remains paramount.

The Responsible Pharmacist

The Health Act 2006: Key Changes

1.16 The Health Act amends the Medicines Act, and related NHS legislation, in a number of important ways. These are as follows.

“Personal Control” and the Responsible Pharmacist

1.17 The Health Act amends sections 70, 71 and 72 of the Medicines Act replacing “personal control” with a requirement that each pharmacy is to have a responsible pharmacist. Therefore, the Act continues to require a pharmacist to be in charge of each pharmacy. Further, this change does not affect what the Government believes to be the underlying concept of “personal control” – that is, a pharmacist must be in charge of each registered pharmacy to ensure that it is operating safely where this concerns the sale and supply of medicines to the public. It is now more explicit how the pharmacist in charge of the pharmacy is to meet this requirement.

The Superintendent Pharmacist

1.18 There are no changes to the Medicines Act requirement on a pharmacy owned by a body corporate to have a superintendent pharmacist to manage the pharmacy business in relation to the keeping, preparation and dispensing of medicines (other than GSL medicines). Where the superintendent pharmacist is not also in charge of a pharmacy operated by the business, the pharmacy must have a responsible pharmacist who remains subject to the directions of the superintendent pharmacist.

The Responsible Pharmacist: The Statutory Duty

1.19 The Health Act provides further clarification of the responsible pharmacist requirement with the insertion of a new section 72A into the Medicines Act. This new section places a statutory duty on the responsible pharmacist to secure the safe and effective running of the pharmacy. Section 72A makes clear that in exercising his/her statutory duty, the responsible pharmacist must

- establish (where these are not already in place), maintain, and review procedures for safe working in the pharmacy
- keep a record, in the pharmacy, of the pharmacist responsible for the pharmacy at any one time

The Pharmacy Owner: The Statutory Duty

1.20 There is a statutory duty on the pharmacy owner to ensure the responsible pharmacist properly maintains the pharmacy record. The pharmacy owner must also preserve the record for the period specified in regulations.

The Responsible Pharmacist

One Pharmacy/One Responsible Pharmacist

- 1.21 There is no change in the requirement that a pharmacist must be in charge of each pharmacy. The general “rule” remains that there is to be a pharmacist responsible for each pharmacy and that s/he may only be responsible for one pharmacy at the same time.
- 1.22 As now, each registered pharmacy (within hospitals and in the community) must have a responsible pharmacist. Where the pharmacy is operating without a responsible pharmacist, it must close for the sale and supply of medicines. Where there is more than one pharmacist working in the pharmacy, only one may be the responsible pharmacist at any one time. Further safeguards introduced through the Health Act are the statutory requirement on the responsible pharmacist to keep a record of the pharmacist responsible for the pharmacy on any date and at any time and the statutory requirement on the pharmacy owner to ensure the responsible pharmacist properly maintains the record. The pharmacy owner must also preserve the record for the period set out in regulations. To be absent from the pharmacy, the responsible pharmacist will also need to comply with conditions for absence set out in the regulations.
- 1.23 However, recognising the need for some flexibility to respond to future changes in pharmacy practice and the pace of development of modern technologies, Health Ministers may set out in regulations exceptions to this general “rule” – that is, where a pharmacist may be responsible for more than one pharmacy at the same time. During passage of the Health Act, the Government made clear its intention that these regulations tightly define any such exceptions, with a need to comply with the specified circumstances and conditions that will permit a pharmacist to be responsible for more than one pharmacy at the same time.

The Annual Return to the Registrar

- 1.24 The requirement to keep a record of the responsible pharmacist, in each registered pharmacy, replaces the requirement on the pharmacy owner (in section 77 of the Medicines Act) to send an annual return to the registrar stating the name of the pharmacist in personal control of the pharmacy. In practice, the annual return provided details of the pharmacist in charge of a pharmacy only on the date it was sent to the registrar, whereas the pharmacy record will provide details of the pharmacist in charge of the pharmacy on any date and at any time.

The Responsible Pharmacist Regulations

- 1.25 The new section 72A allows Health Ministers to set out, in regulations, further details on how the responsible pharmacist is to exercise the statutory duty to secure the safe and effective running of the pharmacy. In the following chapters, the Government is seeking views on the content of these regulations, which may cover matters such as
- the qualifications and experience that a pharmacist must have to be a responsible pharmacist
 - the ability of the responsible pharmacist to be absent from the pharmacy
 - the ability of the responsible pharmacist to supervise individual transactions involving the preparation, assembly, sale and supply of medicines in the pharmacy from another location (what is known as “remote supervision)
 - the circumstances in which a responsible pharmacist may supervise individual transactions involving the preparation, assembly, sale and supply of medicines in a pharmacy where s/he is not the responsible pharmacist
 - the matters to be covered in the pharmacy procedures and the form in which the procedures are to be kept
 - the information to be included in the pharmacy record and the form in which the record is to be kept

The Pharmacist’s Registration Certificate

- 1.26 The Government took the opportunity to amend the requirement in sections 70, 71 and 72 of the Medicines Act on the pharmacist in personal control of the pharmacy to display his/her registration certificate conspicuously in the pharmacy. In practice, although not required to do so, most (if not all) pharmacists working in the pharmacy display their registration certificates even when they are not the pharmacist in charge. This can make it difficult for the public and others to identify the pharmacist in personal control of the pharmacy.
- 1.27 Therefore, sections 27, 28 and 29 of the Health Act amend sections 70, 71 and 72 of the Medicines Act to replace the requirement on the pharmacist in personal control of the pharmacy to display his/her registration certificate. Instead, the responsible pharmacist is required to display a notice, conspicuously, in the pharmacy stating that he/she is the pharmacist in charge of the pharmacy on that particular day and time with details of his/her registration number.

General Sales List (GSL) Medicines

- 1.28 Sections 51 and 53 of the Medicines Act relate to GSL medicines (ie medicines sold from retail premises, as well as pharmacies, without the supervision of a pharmacist). The responsible pharmacist requirement clarifies that the exercise of the statutory duty to ensure the safe and effective running of the pharmacy is not dependent on the responsible pharmacist's physical presence in the pharmacy. To meet this requirement, the responsible pharmacist must be sure that effective procedures are in place to support the safe sale and supply of all medicines from the pharmacy, whether or not s/he is present in the pharmacy. Thus, the responsible pharmacist's presence in the pharmacy is not required to permit the sale of GSL medicines - bringing the sale of these medicines more in line with other retail outlets where there is no requirement for a pharmacist to be present on the premises to permit sale.
- 1.29 However, where GSL medicines are part of an NHS prescription, the pharmacist supervision requirements will continue to apply. This is because the Government continues to believe that it is important to make a clinical assessment of the whole prescription, not just part of the treatment – for example, so the pharmacist can ensure there are no interactions between the different medicines. Therefore, as now, supervision of the dispensing of any GSL medicine, where part of an NHS prescription, is required to be on the same basis as Pharmacy (P) and Prescription Only Medicines (POM).

The Pharmacist Supervision Requirements

- 1.30 Amendments to the Medicines Act, made by the Health Act, also provide for regulation making powers to clarify what a pharmacist must do in order to discharge the requirements in Section 10 and Section 52 of the Medicines Act. That is, the requirement on the pharmacist to supervise the preparation, assembly, sale and supply of medicines and the circumstances in which a pharmacist may supervise these activities remotely (eg from a location away from the pharmacy). Section 10 allows pharmacists (and those acting under the supervision of a pharmacist) to prepare and assemble medicinal products, other than in accordance with a licence granted by the Medicines and Healthcare Products Regulatory Authority (MHRA), in community and hospital pharmacies.
- 1.31 In tandem with existing powers in the Medicines Act, the changes introduced by the Health Act will allow the pharmacist to permit a suitably trained and registered pharmacy technician (or another suitably trained and registered healthcare professional) to supervise certain aspects of dispensing involving the preparation, assembly, sale and supply of medicines. This will be subject to meeting specified conditions to be set out in regulations. Thus, subject to compliance with these specified conditions, the pharmacist will be able to maintain a safe and effective dispensing service whilst also using his/her clinical expertise to develop and provide other pharmacy services.

Pharmacy Services, other than the Preparation, Sale and Supply of Medicines

- 1.32 It is important to be clear that these legislative changes relate to requirements in the Medicines Act concerning the preparation, assembly, sale and supply of medicines through pharmacies and the requirements in the Medicines Act and NHS legislation relating to pharmacist supervision of these activities. These changes concern all registered pharmacies – in the community and in hospitals.

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- 1.33 These changes do not concern other activities in the pharmacy unrelated to the sale or supply of medicines. NHS legislation governs wider NHS pharmaceutical services such as those provided through community pharmacy contractual arrangements. For example, these services will include
- health promotion
 - support for self-care
 - medicines use reviews (MURs) to improve the way people use their medicines and
 - working as part of multi-professional or multi-agency teams to deliver services commissioned by Primary Care Trusts and Local Health Boards to meet specific local health needs, other than the sale or supply of medicines

These do not form part of this consultation paper.

Regulations under the Health Act 2006

- 1.34 In January 2006, the UK Health Departments published an information paper setting out some initial thinking on how regulations under the Health Act might be developed. The information paper made clear the Government's commitment to consult with all interested parties on work to develop the regulations. It is available on the Department of Health website at www.dh.gov.uk/publicationsandstatistics/publicationsandguidance

Consultation on the Regulations

- 1.35 These are complex changes. Therefore, the Government has decided to take a phased approach to consultation on the content of the regulations and on the timing of commencement – ie the date for introducing the changes set out in the regulations.
- 1.36 The statutory requirements relating to the responsible pharmacist are largely mandatory. Every registered pharmacy must have a pharmacist responsible for the safe and effective running of the pharmacy. Those relating to the supervision requirements are enabling, subject to certain circumstances and conditions being in place in the pharmacy.
- 1.37 As the responsible pharmacist provisions set the framework for the quality assurance system underpinning the safe operation of each pharmacy, the Government believes that it is important to put this regulatory framework in place before introducing the changes relating to pharmacist supervision. Therefore, the Government is starting with consultation on the content of the responsible pharmacist regulations. Consultation on the pharmacist supervision requirements will follow later.
- 1.38 As a first step, in February and March 2007, the UK Health Departments hosted a series of informal consultation events to allow all interested parties an opportunity to discuss and inform the development of the responsible pharmacist regulations. Those attending these events, and others, also had an opportunity to respond to outline proposals via e-mail or, where requested, further meetings with the Health Departments. The Government thanks all those who contributed to these discussions and, in particular, for providing valuable feedback to inform the preparation of this consultation paper.
- 1.39 This paper builds on previous consultations and provides a further opportunity to respond to proposals on the content of the responsible regulations setting out how the responsible pharmacist is to discharge his/her statutory duty to secure the safe and effective running of the pharmacy insofar as this relates to the preparation, assembly, sale and supply of medicines.

Timetable for Consultation

- 1.40 In accordance with best practice on public consultation, the Government has allowed 12 weeks for the receipt of responses, commencing with the date of issue of this paper.

Confidentiality Disclaimer

- 1.41 Information provided in response to this consultation, including personal information, may be published or disclosed in accordance with access to information regimes (primarily, the Freedom of Information Act 2000 (FOIA), the Data Protection Act 1998 (DPA) and the Environmental Information Regulations 2004).
- 1.42 If you want the information that you provide to be treated as confidential, please be aware that under the FOIA there is a statutory Code of Practice with which public authorities must comply and which deals, amongst other things, with obligations of confidence. In view of this, it would be helpful if you could explain why you regard the information that you have provided to us as confidential. If we receive a request for disclosure of the information, we will take full account of your explanation but we cannot give an assurance that we can maintain confidentiality in all circumstances. The Department will not regard, of itself, any automatic confidentiality disclaimer generated by your IT system as binding on the Department. The Department will process your personal data in accordance with the DPA. In the majority of circumstances, this will mean the Department will not disclose your personal data to a third party.

Compliance with Cabinet Office Code of Practice on Consultation

- 1.43 This public consultation follows the Cabinet Office Code of Practice on Consultation. This document is available in the consultations section of the Department of Health website. In due course, a summary of views received in response to the consultation will also be available on the website, together with the Government's response and proposals for action. The six consultation criteria set out in the Code of Practice are as follows:
1. Consult widely throughout the process, allowing a minimum of 12 weeks for written consultation at least once during the development of policy
 2. Be clear about your proposals, who may be affected, what questions are being asked, and the timescale for responses
 3. Ensure that your consultation is clear, concise and widely accessible
 4. Give feedback regarding the responses received and how the consultation process influenced the policy
 5. Monitor your department's effectiveness at consultation, including through use of a designated consultation co-ordinator
 6. Ensure your consultation follows better regulation best practice, including carrying out a Regulatory Impact Assessment, if appropriate

Impact Assessment

- 1.45 The Government is committed to action to reduce unnecessary regulatory burdens and, therefore, has examined the need to carry out an impact assessment on these regulations. The conclusion is this is not required, as the regulations do not pose any additional burden for the sectors that are likely to be affected. The regulations do not introduce a new policy but continue to support existing principles underlying the Medicines Act 1968 that safeguard the public in relation to the sale and supply of medicines from registered pharmacies. The regulations *clarify* how the pharmacist is to exercise his/her responsibilities when in charge of a pharmacy to secure safe and effective working in the pharmacy.

Responding to this Consultation

- 1.46 The Government is allowing extra time for response to this consultation as this includes the Christmas holiday period. In Scotland, responses to the consultation may be e-mailed to mary.waugh@scotland.gsi.gov.uk or sent to

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- 1.47 Responses are invited by no later than **20 January 2008**. A summary of the response to consultation will be published in due course.

CHAPTER 2

THE RESPONSIBLE PHARMACIST

The Medicines Act: The “Personal Control” Requirement

- 2.1 Currently, sections 70, 71 and 72 of the Medicines Act require each registered pharmacy premises, operated by individual pharmacists, partnerships, bodies corporate or a representative of a pharmacist, to be under the “personal control” of a pharmacist.

The Medicines Act: The Pharmacist Supervision Requirements

- 2.2 Section 10 and Section 52 of the Medicines Act place a requirement on the pharmacist to undertake or supervise individual transactions involving the preparation, assembly, sale and supply of medicines, other than those on the General Sales List (GSL medicines).

Interpretation of these separate statutory requirements

- 2.3 The Medicines Act does not define “personal control” nor does it set out how the pharmacist in charge of the pharmacy is to exercise this requirement. This lack of clarity and limited case law has meant that, over the years, a common interpretation has emerged requiring the pharmacist to be physically present in the pharmacy at all times when it is operating in order to meet both of these separate and different Medicines Act requirements – ie the personal control and the pharmacist supervision requirements.
- 2.4 Many community pharmacies operate with a single pharmacist. As such, s/he is the pharmacist in personal control of the pharmacy and the pharmacist supervising individual transactions. The Government believes this contributes to the perceived requirement on the pharmacist in charge to be present in the pharmacy at all times in order to exercise “personal control” and to permit the sale and supply of medicines from the pharmacy.
- 2.5. Many pharmacists, pharmacy organisations and others have made clear the need for changes to the current statutory framework to remove constraints on pharmacists’ ability to offer services other than the dispensing or sale of medicines in the pharmacy, including where this might be in partnership with other healthcare professionals. In addition, it has resulted in an anomaly in relation to the sale of GSL medicines from pharmacies and from other retail outlets. People are unable to buy a GSL medicine from a pharmacy unless a pharmacist is present in the pharmacy at the time of sale. If the pharmacist is absent, the purchaser must go elsewhere to buy the medicines or await the return of the pharmacist. However, the sale of GSL medicines from other retail outlets (eg a corner shop or newsagents) is not dependent on the presence of a pharmacist in order to permit sale. Thus, pharmacies are out of line with other retail outlets with regard to the sale of GSL medicines, which limits the public’s access to these medicines.
- 2.6 Following the response to consultation in 2005, which indicated strong and clear support for change, the Government brought forward legislation in 2006 to clarify the “personal control” requirement in the Medicines Act. The Health Act 2006 amends the Medicines Act in a way that makes explicit that “personal control” relates to the day-to-day management of the pharmacy with the pharmacist in charge (the responsible pharmacist) ensuring the pharmacy operates safely and effectively in relation to the sale and supply of medicines to the public. Further, the duty on the responsible pharmacist to secure

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the safe and effective running of the pharmacy makes clear that his/her responsibilities extend beyond the requirement to supervise individual transactions involving the sale and supply of medicines. These include, for example, arrangements for the safe ordering, storage and disposal of medicines (including controlled drugs) and for ensuring the availability of trained, competent, pharmacy staff to undertake specific tasks in the pharmacy.

- 2.7 If the pharmacy is to operate safely and effectively, the pharmacist in charge must set out arrangements that continue to support safe working whether or not s/he is physically present in the pharmacy. Either the pharmacy is operating safely or it is not and this is not dependent on the pharmacist in charge of the pharmacy being physically present in the pharmacy at all times whilst it is operating.

Personal Control and the Responsible Pharmacist

- 2.8 Sections 27, 28 and 29 of the Health Act amend sections 70, 71 and 72 of the Medicines Act to replace “personal control” with a new requirement for each registered pharmacy premises to have a responsible pharmacist, whether operated by an individual pharmacist, a partnership, a body corporate or a representative of a pharmacist. He or she will be the pharmacist in day-to-day charge of the business insofar as this relates to the retail sale or supply of medicines. This role is distinct from that of the superintendent pharmacist, who has overarching responsibilities within a body corporate to ensure that a pharmacist is in charge of each pharmacy owned by the company and the company meets statutory, ethical and professional requirements and standards.

The Responsible Pharmacist: Statutory Duty

- 2.9 To provide further clarification on the responsible pharmacist requirement, section 30 of the Health Act inserts a new section 72A into the Medicines Act to place a statutory duty on the responsible pharmacist to secure the safe and effective running of the pharmacy and to set out how the responsible pharmacist is to carry out that duty.
- 2.10 Each pharmacy is to have a responsible pharmacist. Only one pharmacist may be responsible for a pharmacy at any one time. The responsible pharmacist
- may not be responsible for more than one pharmacy at any one time except in specified circumstances set out in regulations and then only if certain conditions are met
 - must establish (where these are not already established), maintain and review procedures (eg Standing Operating Procedures (SOPs)) that determine how activities are to be carried out in the pharmacy
 - must maintain a record, at the pharmacy premises, of the pharmacist responsible for that pharmacy on any date and at any time.
- 2.11 There is also a statutory duty on the pharmacy owner to ensure that the responsible pharmacist properly maintains the pharmacy record. The pharmacy owner is required to preserve the record for the period specified in the regulations

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- 2.12 The new section 72A also allows Health Ministers to set out in regulations further detail as to how the responsible pharmacist is to exercise the duty, including
- the qualifications and experience that a pharmacist must have to be a responsible pharmacist
 - the ability of the responsible pharmacist to be absent from the pharmacy
 - the ability of the responsible pharmacist to supervise individual transactions involving the preparation, assembly, sale and supply of medicines in the pharmacy from another location (what is known as “remote” supervision)
 - the circumstances in which a responsible pharmacist may supervise individual transactions involving the preparation, assembly, sale and supply of medicines in a pharmacy where s/he is not the responsible pharmacist
 - the matters to be covered in the pharmacy procedures and the form in which the procedures are to be kept
 - the information to be included in the pharmacy record and the form in which the record is to be kept

The Government believes that this regulatory framework will underpin quality assurance systems in the pharmacy that support the responsible pharmacist in exercising the statutory duty to secure safe and effective operation of the pharmacy.

Pharmacy Businesses Carried on by a Body Corporate: The Superintendent Pharmacist and the Responsible Pharmacist

- 2.13 The Health Act amendments to section 71 of the Medicines Act do not affect the role and responsibilities of the superintendent pharmacist of a body corporate. The pharmacy business is required to ensure that the sale and supply of medicines is under the management of a superintendent pharmacist. Where the superintendent pharmacist is not the pharmacist responsible for a pharmacy operated by the business, another pharmacist must be available to meet this requirement. The superintendent pharmacist continues to have overall management accountability and the pharmacist responsible for a pharmacy will remain subject to the directions of the superintendent pharmacist.
- 2.14 The Government considers it is important to ensure clarity on the different statutory role of the superintendent pharmacist and that of the responsible pharmacist. The Government’s view is that the superintendent pharmacist has an overall governance and monitoring role – for example,
- within the pharmacy business, to ensure a company’s policies and governance framework, within which pharmacists and other pharmacy staff work, support safe, effective and professional pharmacy practice
 - to ensure that pharmacists employed by the company are able to meet legal, ethical and professional standards
 - to monitor the service quality and professional standards set for the pharmacy business, ensuring that processes are in place to maintain standards and to act to improve standards further

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2.15 The superintendent pharmacist, as part of his/her statutory and professional responsibility, has a duty to ensure that all the company's pharmacies operate within the legislative framework, to ensure that pharmacists and other staff employed by the company understand these requirements, and that each company pharmacy operates safely. The Government believes this role is distinct from, but complementary to, the responsible pharmacist's role to secure the safe and effective day-to-day operation of the individual pharmacy.

Pharmacy Businesses Carried on by Individuals or Partnerships or a Representative of a Pharmacist: The Responsible Pharmacist

2.16 The legislation addresses the need to ensure the safe and effective operation of all registered pharmacies. Not all registered pharmacies are part of a body corporate with a requirement to have a superintendent pharmacist. Section 70 of the Medicines Act relates to pharmacy businesses carried on by individuals or partnerships and Section 72 to businesses carried on by a representative of a pharmacist (for example, someone who carries on the business following the death of a pharmacist).

2.17 As with bodies corporate, there is a need to ensure clarity of the role of the responsible pharmacist in relation to a pharmacy business carried on by an individual owner, a partnership or someone representing a pharmacist. There will be a number of possible arrangements. For example,

- A individual pharmacy business owned and operated by a pharmacist who is both the pharmacy owner and the responsible pharmacist for that pharmacy
- A pharmacist with three pharmacies operating as part of his business, who has appointed responsible pharmacists for two of these pharmacies at any one time, will be the pharmacy owner and responsible pharmacist for only one of the pharmacies. For the other two pharmacies, he is the pharmacy owner
- A partnership, in which only one partner is a pharmacist, owns two pharmacies. Both have responsibilities as pharmacy owners but only the partner who is a registered pharmacist may be responsible for one of the pharmacies at any one time. They will need to appoint another pharmacist as the responsible pharmacist for the second pharmacy.
- A pharmacy business carried on by a representative of a pharmacist. Again, if that representative is not a pharmacist, he must appoint a responsible pharmacist to be in charge of each of the pharmacies carried on by that business. He may not be in charge of any of the pharmacies and, in representing the pharmacy owner, must carry out the owner's statutory responsibilities.

For each of these, the Government's view is that the pharmacy owner(s) should be clear as to their statutory responsibilities and of those they appoint to be in charge of a pharmacy.

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2.18 Thus, the pharmacy owner, where not also the responsible pharmacist and in the case of a body corporate the superintendent pharmacist, must

- Ensure that a pharmacist is appointed as the responsible pharmacist for each of the pharmacies within the pharmacy business
- Enable the responsible pharmacist to meet the statutory duty placed on him/her to ensure the pharmacy is operating safely and effectively – including allowing the responsible pharmacist to exercise his/her professional judgement, where appropriate, as to pharmacy procedures and staffing requirements for that pharmacy
- Ensure the responsible pharmacist properly keeps the pharmacy record
- Ensure the pharmacy record is preserved for each pharmacy for as long as specified in the regulations

2.19 The Royal Pharmaceutical Society of Great Britain has recently issued a revised Code of Ethics, together with professional standards for pharmacists and pharmacy technicians in positions of authority. These standards will apply where a pharmacist owns a pharmacy business, is a superintendent pharmacist or is a pharmacist responsible for an individual pharmacy. The Pharmaceutical Society of Northern Ireland Code of Ethics for pharmacists and superintendent pharmacists sets out principles and obligations, together with guidance on standards of good professional practice¹.

¹ Royal Pharmaceutical Society of Great Britain Code of Ethics for Pharmacists and Pharmacy Technicians and Royal Professional Standards for Pharmacists and Pharmacy Technicians in Positions of Authority (August 2007).
Pharmaceutical Society of Northern Ireland Code of Ethics and guidance on ethics and practice (2006)

The Responsible Pharmacist Regulations

2.20 In the following chapters, this consultation paper considers a range of proposals relating to the content of the responsible pharmacist regulations. These take into account the views put forward during the informal consultation events hosted by the UK Health Departments in February and March 2007 and in further meetings with a number of pharmacy organisations.

- Chapter 3 sets out proposals relating to pharmacy procedures
- Chapter 4 sets out proposals relating to the pharmacy record of the pharmacist responsible for the pharmacy on any date and at any time
- Chapter 5 looks at the ability of the responsible pharmacist to be absent from the pharmacy
- Chapter 6 considers matters relating to the qualifications and experience needed to be a responsible pharmacist
- Chapter 7 looks at the statutory requirement that each pharmacy is to have a responsible pharmacist who may only be responsible for one pharmacy at the same time. Chapter 7 also considers possible exceptional circumstances, together with specified conditions, that will allow a pharmacist to be responsible for more than one pharmacy at the same time
- Chapter 8 puts forward possible conditions to be met if a responsible pharmacist is to supervise individual transactions involving the sale and supply of medicines in a pharmacy where s/he is not the responsible pharmacist
- Chapter 9 looks at other matters relating to the responsible pharmacist regulations, such as enforcement. It also seeks views on the timing of introduction of the responsible pharmacist regulations (such as the time needed to prepare for these changes) and the need for guidance to support introduction of the regulations

Remote Supervision by the Responsible Pharmacist: Later Consultation

2.21 At this stage, the Government is not seeking views on the content of regulations relating to the ability of the responsible pharmacist to supervise the preparation, assembly, sale and supply of medicines when he or she is away from the pharmacy. That is, to supervise activities from another location (or remotely) with the aid of new technologies. This is because the Government believes it will be more helpful and appropriate to seek views on these provisions within the context of wider consultation on proposals for the content of the regulations relating to pharmacist supervision. The Government will be consulting on the pharmacist supervision regulations later.

CHAPTER 3

THE PHARMACY PROCEDURES

- 3.1 Section 30 of the Health Act inserts a new section 72A into the Medicines Act, placing a statutory duty on the responsible pharmacist to secure the safe and effective running of the pharmacy business ((including registered pharmacies in hospitals) in relation to the supply and sale of medicines.
- 3.2 As added safeguards supporting the pharmacy's operation, in carrying out the duty the pharmacist responsible for a registered pharmacy must establish (if these are not already established), maintain and review pharmacy procedures to support the safe and effective running of the pharmacy and maintain the pharmacy record. The Government's view is that these requirements now make clear that the safe running of the pharmacy is not dependent on the pharmacist in charge being physically present in the pharmacy at all times.
- 3.3 In setting down effective pharmacy procedures, the responsible pharmacist can ensure that pharmacy staff continue to work under his/her direction and authority when he or she is present or away from the registered pharmacy premises. For example, this may be where the responsible pharmacist is working in an adjacent area of the same building which is not part of the registered pharmacy premises (eg in a consulting room) or is absent during a lunch break or during some other period of absence.
- 3.4 The Royal Pharmaceutical Society of Great Britain (RPSGB) has made the use of Standard Operating Procedures (SOPs) a professional commitment on pharmacists in the revised Code of Ethics and the supporting professional standards and guidance documents that came into effect on 1 August 2007. Since 2003, the Pharmaceutical Society of Northern Ireland has made SOPs a professional requirement.² Thus, pharmacists will already be aware of the professional regulatory bodies' guidance supporting the development of Standard Operating Procedures (SOPs). In addition, the superintendent pharmacist or the pharmacy owner may also provide guidance and other information on establishing pharmacy procedures. The Government's view is that, generally, the regulations on pharmacy procedures should reflect and underpin these professional standards and other guidance.
- 3.5 The responsible pharmacist regulations may specify the matters covered in pharmacy procedures and the form in which the procedures are to be set out.

Pharmacy Procedures: Consistency and Flexibility

- 3.6 The Government's view is that there is a balance to be struck in providing some degree of consistency in the content of pharmacy procedures whilst allowing the responsible pharmacist sufficient flexibility to ensure that the procedures support the operational needs of the individual pharmacy.

² Royal Pharmaceutical Society of Great Britain Code of Ethics for Pharmacists and Pharmacy Technicians and Professional Standards and Guidance for the Sale and Supply of Medicines (August 2007). Pharmaceutical Society of Northern Ireland Code of Ethics and guidance on ethics and practice (2006)

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3.7 Some consistency in the content of the procedures will support an incoming responsible pharmacist when assessing the comprehensiveness of the procedures, or those with responsibilities for ensuring standards of pharmacy practice wishing to consult the procedures. However, the responsible pharmacist must also be able to use his/her professional knowledge and judgement of the pharmacy and its staff, as appropriate, to satisfy himself/herself that the procedures support safe working in that pharmacy. Where not satisfied, the responsible pharmacist will need to consider any need to review or amend the procedures. For example, this might be required where there are changes in the availability of trained staff in the pharmacy.

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

Establishing Procedures: Matters to be included in Pharmacy Procedures

3.8 To achieve some consistency in the content of pharmacy procedures, the Government proposes that the regulations set out the minimum areas that the Government would expect to see covered in procedures, including

- arrangements for the safe, secure and effective ordering, storage, preparation, dispensing, sale or supply, delivery (delivery will include the handing over of a medicine to a patient or carer either in the pharmacy or as part of a pharmacy's arrangements for delivery of medicines to, for example, a patient's home) and disposal of medicines
- arrangements that demonstrate adherence to the legislative framework relating to the supply of controlled drugs ³
- activities that may be undertaken by specified pharmacy staff and the level of training/qualification/competence required to undertake these tasks
- record keeping
- arrangements for the provision of advice to patients and the public on the use of medicines by the pharmacist and by pharmacy staff, including general sales list (GSL) medicines, and when pharmacy staff should seek the advice or the involvement of the pharmacist
- arrangements when the responsible pharmacist is absent from the pharmacy
- arrangements for recording amendments to the procedures
- arrangements for responding to complaints and adverse incidents relating to the sale and supply of medicines from the pharmacy
- arrangements for the transfer of responsibility for the pharmacy from the responsible pharmacist to an incoming responsible pharmacist

³ The Government does not propose to include in the responsible pharmacist regulations detailed requirements concerning controlled drugs. Sections 17 to 25 of the Health Act 2006, and subsequent regulations, set out the legal governance framework for the safe use and management of controlled drugs and the Misuse of Drugs Regulations 2001 set out the legal framework for the possession and supply of controlled drugs. In developing pharmacy procedures, pharmacists must ensure compliance with these statutory requirements.

The Responsible Pharmacist

- Q. Do you think these are the right, minimum, areas to be included in the regulations on pharmacy procedures?**
- Q. Are there any other areas that you feel should be specified in the regulations? If so, what are these and why should these be included?**

Procedures: The sale of General Sales List (GSL) medicines

3.9 In responding to consultation in 2005, about 60% of respondents considered there was a need for change in relation to the sale of GSL medicines to bring pharmacies more in line with other retail outlets. The replacement of the personal control requirement with the responsible pharmacist requirement, with greater clarity on the exercise of this requirement, makes clear that the safe operation of the pharmacy is not dependent on the responsible pharmacist's presence in the pharmacy at all times. It also makes clear that the sale of GSL medicines may take place other than under the supervision of a pharmacist (ie where these are not part of an NHS prescription) and when the responsible pharmacist is not in the pharmacy. This brings pharmacies more into line with other retail outlets selling these medicines. People will not have to await the responsible pharmacist's return or need to visit another pharmacy where a pharmacist is available to permit the sale of GSL medicines.

3.10 The Government recognises that people may choose to buy a GSL medicine from a pharmacy so they can seek the pharmacist's professional advice on using the medicine, which is not available in other outlets. (A point made by 7% of respondents to the 2005 consultation). Therefore, the Government proposes that the regulations require pharmacy procedures to include arrangements for the sale of GSL medicines from the pharmacy, including when pharmacy staff need to seek the pharmacist's advice or involvement prior to sale. As such, pharmacy staff will continue to work under his/her authority to support the safe sale of GSL medicines when the responsible pharmacist is away from the registered pharmacy premises.

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

Other Matters that may be included in the Pharmacy Procedures

3.11 There may be other matters that a responsible pharmacist or the superintendent pharmacist or pharmacy owner may feel should be included in the procedures supporting the operation of individual pharmacies. Subject to the response to consultation on the minimum areas to be included, the Government's view is that it is open to the responsible pharmacist, in discussion with the superintendent pharmacist or the pharmacy owner, as appropriate, to consider other areas, over and above the minimum requirements, for inclusion in the pharmacy procedures.

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

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3.12 The duty on the responsible pharmacist relates to the Medicines Act requirement in relation to the safe sale and supply of medicines not the provision of other aspects of NHS pharmaceutical services. During informal consultation, there were suggestions that the regulations should require matters such as clinical governance arrangements to be included in the pharmacy procedures. However, the Government's view is that clinical governance and other matters relating to the provision of NHS pharmaceutical services are more appropriate for consideration within wider NHS legislation and the pharmaceutical services contractual frameworks in the four countries of the United Kingdom.

Form of the Pharmacy Procedures

3.13 The Government proposes that regulations allow the responsible pharmacist to set out the written pharmacy procedures on paper or electronically - provided the procedures are readily available and accessible to those who need to consult them – for example, pharmacy staff, an incoming responsible pharmacist, the superintendent pharmacist and the pharmacy owner.

3.14 One view put forward during informal consultation was that the regulations should require the written procedures (particularly if set out in electronic form) to be kept securely. It was felt, for example, that such a requirement would help prevent unauthorised changes to the procedures. Another view was that regulations should specify that pharmacy procedures should not be in handwritten form to ensure these are legible to those needing to consult them. The Government agrees that pharmacy procedures must be kept secure and be legible to those who need to consult them. The new section 72A, inserted into the Medicines Act, makes clear the requirement for pharmacy procedures “designed to secure the safe and effective running of the pharmacy. To meet this statutory requirement, the procedures must be secure and legible and, therefore, the Government does not believe there is a need to include further requirements as to security and legibility in the regulations.

Q. *Do you agree that the written procedures may be set down on paper or electronically?*

Q. *Other than being readily available and accessible to those that need to consult the procedures, do you think the regulations should include other requirements? If so, what are these requirements and what are your reasons for putting these forward?*

3.15 Whilst a degree of consistency will help those wishing to consult pharmacy procedures, the Government's view is that the regulations do not need to set out a prescribed format for the procedures. This will allow the responsible pharmacist some flexibility in establishing procedures that support the differing operational needs of individual pharmacies.

Q. *Do you agree that the regulations do not need to specify a prescribed format for the pharmacy procedures? If not, what do you propose and what are your reasons for this?*

“Signing off” Pharmacy Procedures

3.16 One view put forward, during informal consultation, was the format used for the pharmacy procedures should enable an incoming responsible pharmacist to “sign off” that s/he is satisfied that the pharmacy procedures support safe and effective working at the time s/he took on responsibility for the pharmacy. The Government recognises that such a requirement may be helpful in supporting greater transparency that the incoming responsible pharmacist is content with the procedures but would welcome further views on this.

Q. *Do you think the regulations should specify that the format used should allow the responsible pharmacist to “sign off” the pharmacy procedures in a way that confirms s/he has checked procedures on becoming the responsible pharmacist and is content that these support safe working in the pharmacy? If so, what are your reasons for supporting that view?*

Q. *Are there other matters that you think the regulations should include in relation to the format of pharmacy procedures? What are your reasons for putting these forward?*

Review of Pharmacy Procedures

3.17 The responsible pharmacist is required to keep the pharmacy procedures under review. The Government believes this requirement will underpin up-to-date pharmacy procedures that reflect changes in professional and other guidance on modern pharmacy practice as well as changes within an individual pharmacy. The Government’s view is that, where there is a change that could affect the safe running of the pharmacy (such as the absence of a key member of pharmacy staff), the expectation should be that the responsible pharmacist will review and amend procedures so that these continue to support the safe running of the pharmacy and inform pharmacy staff accordingly.

3.18 Further, the Government believes the responsible pharmacist’s knowledge and professional judgement, as appropriate, will play an important part in assessing the need to review and amend the procedures. For example, the responsible pharmacist will wish to consider whether a review is timely and necessary to support continued safe working in the pharmacy. Following any review, there will also be a need to ensure pharmacy staff understand new or amended procedures and how these relate to their individual responsibilities. Any practice resulting in numerous, frequent, changes to procedures could result in unsafe working in a pharmacy where pharmacy staff have had insufficient time and training to gain an understanding of changes in the ways in which they are required to work.

3.19 The Government’s view is that the responsible pharmacist should check the pharmacy procedures when s/he becomes responsible for the pharmacy to assess the need for any changes. In doing so, the responsible pharmacist will use his/her knowledge of the pharmacy business and the skills and experience of staff working in the pharmacy to satisfy him/herself that the procedures in place support safe working in the pharmacy and that staff are working to these procedures.

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

Possible Circumstances Supporting Review of Pharmacy Procedures

3.20 When taking on responsibility for a pharmacy and checking the pharmacy procedures, there may be few, if any, changes required. However, circumstances may prompt the responsible pharmacist to review and/or amend the pharmacy procedures. Some possible scenarios are set out below:

Scenario 1

A pharmacy is open for extended hours. During the day, the responsible pharmacist changes, as there is a shift pattern of working in operation to support the pharmacy's longer opening hours.

At 8.30am, the pharmacist responsible for the pharmacy during the first shift checks the pharmacy procedures and the pharmacy staff available in the pharmacy. There are no absences. The pharmacist considers that the procedures will continue to support safe working given the volume of business expected and the staff present in the pharmacy.

At 5.30pm, there is a handover to the responsible pharmacist in charge of the pharmacy until the pharmacy closes at midnight. However, whereas a pharmacy technician has been available in the pharmacy for the first shift, when he leaves at 5.30pm, there is a gap. His replacement is ill. The incoming responsible pharmacist checks the pharmacy procedures to assess the need for review in the light of the estimated volume of business in the pharmacy up until midnight and the absence of a trained member of staff who is unavailable to take on specified activities in the pharmacy. The responsible pharmacist decides that the procedures do not need to be changed. In his judgement, given the volume of business expected, he will be able to devote sufficient time to ensure that he is able to cover the pharmacy technician's absence for that shift. However, the pharmacy is likely to see a peak in the volume of business later in the week. Therefore, if the pharmacy technician remains sick, there may be a need to amend the procedures to reflect her absence or to use a locum during evening opening to ensure there is adherence to pharmacy procedures for continued safe working in the pharmacy.

Scenario 2

A locum pharmacist takes on responsibility for a pharmacy for the whole of a working day. When she arrives at the pharmacy, she checks the pharmacy procedures to satisfy herself that these will support safe working in the pharmacy on that day. One member of staff has only worked in the pharmacy for a few days and a key member of the pharmacy's trained staff has taken a day's holiday. The pharmacist does not feel she has sufficient knowledge of the individual pharmacy business and the extent of pharmacy staff experience and competence to be sure that the procedures will support safe working. Some changes may be needed and she contacts the superintendent pharmacist to discuss these. They agree, for that day, changes to the procedures are not necessary.

Scenario 3

A pharmacist takes on responsibility for a busy, independent, pharmacy. On arrival, he checks the pharmacy procedures and is satisfied that these support safe working in the pharmacy given the number of trained staff working in the pharmacy. However, over the coming weeks, a checking technician leaves for a new job in the local hospital and the responsible pharmacist has been unable to find a replacement in time to fill the gap. Two new staff in the pharmacy also need further training and support before he is satisfied that they have reached the required level of competency to take on the full range of their responsibilities. He decides that it is necessary to review the pharmacy procedures and to consider amending these to reflect the staff changes in the pharmacy and discusses these changes with the pharmacy owner.

Scenario 4

The pharmacy has a new consulting room, where the responsible pharmacist is offering services such as medicines use review (MURs) and advice on stopping smoking. To support these new services, the pharmacy owner is using a locum pharmacist to supervise individual transactions in the pharmacy for the dedicated day each week that the responsible pharmacist is working in the consulting room. The responsible pharmacist has reviewed and amended the pharmacy procedures to ensure that all pharmacy staff understand and work to new working arrangements in the pharmacy.

A Minimum Period for Review of Pharmacy Procedures

- 3.21 The above scenarios help to illustrate the varying circumstances in which the responsible pharmacist may need to consider the review or amendment of the pharmacy procedures. Different circumstances will affect the timing of review or amendment of procedures in individual pharmacies. Given these different circumstances, the Government's view is that it will be difficult to set down a specific period in the regulations within which all responsible pharmacists must review pharmacy procedures but sought views on this during informal consultation. One view suggested a requirement on the responsible pharmacist to review procedures twice a year (eg at six-month intervals). Another view put forward was that the responsible pharmacist would only need to review procedures every two years. Others felt that it would be more appropriate if guidance, rather than regulations, set out a minimum period for the review of pharmacy procedures. This would also support a responsible pharmacist in looking at the need for review of procedures in the context of differing circumstances.
- 3.22 The Government recognises the value of guidance and that it may be more practical to look to guidance to set out the range of circumstances that might prompt review of the pharmacy procedures. For example, there are opportunities to build on existing guidelines on developing standard operating procedures (SOPs), such as those available from the professional regulatory bodies, superintendent pharmacists and pharmacy owners. There is also the argument that guidance can offer a more flexible way of providing detailed advice on the review of procedures, including up to date information on good practice. The Government welcomes further views on the use of guidance to offer advice on any minimum requirements for review of pharmacy procedures. For example, following any serious incident involving the sale or supply of medicines from the pharmacy or where, for some time, there have been no changes in pharmacy staff and thus no changes to the procedures – including a suggested maximum period between reviews.

- Q. Do you agree that it may be more helpful and appropriate to provide advice on the review of procedures in guidance rather than in the regulations? If so, what are your reasons for your view?**
- Q. Are there other proposal(s) that you wish to put forward in relation to the review of pharmacy procedures? What are your reasons for putting these forward?**

Pharmacy Procedures: The Role of the Superintendent Pharmacist

- 3.23 The Health Act does not change the responsibilities of the superintendent pharmacist. Section 71 of the Medicines Act requires a body corporate to have a superintendent pharmacist managing the keeping, preparing, dispensing and sale of medicines (other than GSL medicines). Where the superintendent pharmacist is not the pharmacist in charge of a pharmacy operated by the business, another pharmacist must be the responsible pharmacist for the pharmacy and s/he remains subject to the directions of the superintendent pharmacist.
- 3.24 The Government's view is that the superintendent pharmacist's statutory role and responsibilities are distinct from, but complementary to, those of the responsible pharmacist. The superintendent pharmacist has company wide responsibilities which overarch and support the requirements on the responsible pharmacist, who is in day-to-day charge of an individual pharmacy owned by the body corporate. In setting out the company wide policies and governance framework for safe operation of the pharmacies to meet legal, ethical and professional standards, the superintendent pharmacist will enable the responsible pharmacist to exercise the statutory requirement relating to pharmacy procedures.
- 3.25 In early 2007, the Government informally sought views on the different roles of the superintendent pharmacist and the responsible pharmacist in setting out pharmacy procedures for safe and effective working. There was general agreement that the greater clarity on the responsibilities of the pharmacist in charge of each individual pharmacy also helped to define more clearly the superintendent pharmacist's responsibility to set out and oversee professional standards across the company and to provide an overarching operational framework for the company's pharmacies. The availability of company wide policies and guidance to pharmacies within the company will help support the responsible pharmacist in ensuring that procedures developed for his/her pharmacy maintain safe and effective day-to-day working.
- 3.26 The superintendent pharmacist, as part of his/her overall management responsibility, will have a duty to ensure each pharmacy has procedures in place, with arrangements for review and amendment as required. In exercising that responsibility, the superintendent pharmacist may choose to develop company guidance on procedures, including model procedures. However, the Government's view is that, in doing so, the superintendent will need to allow the responsible pharmacist sufficient flexibility, as necessary, to tailor procedures to the operational needs of the pharmacy for which he/she is responsible. There is scope for the superintendent pharmacist and individual responsible pharmacists to work together in developing the overall framework for pharmacy procedures within the company and in discussing and agreeing the need for local variations.
- Q. Do you agree with this approach? If not, what are the reasons for putting forward your view?**

Pharmacy Procedures: The Hospital Chief Pharmacist

3.27 Where an NHS Trust or Foundation Trust registers the pharmacy or pharmacies within the hospital, each set of registered pharmacy premises must have a responsible pharmacist. Within the hospital setting, the Trust Chief Pharmacist is regarded as having the role and responsibilities of the superintendent pharmacist.

Q. *Do you agree with this approach? If not, what are the reasons for putting forward your view?*

Pharmacy Procedures: The Role of the Pharmacy Owner

3.28 Chapter 2 looks at the role of the pharmacy owner, including a body corporate and those pharmacy businesses carried on by an individual, a partnership or a representative of a pharmacist (in cases, for example of death or disability). In some cases, the pharmacy owner will also be the responsible pharmacist for that pharmacy (for example, an individual pharmacist who owns an independent pharmacy). Others, such as a body corporate, are required to have a superintendent pharmacist with overall management responsibility for the sale and supply of medicines. There will also be pharmacy businesses run by partners or those representing a pharmacist, including where the partners or representative are not pharmacists. However, in all cases, the pharmacy owner must be clear as to his/her role in enabling the pharmacist responsible for a pharmacy to carry out his/her statutory duty, including the requirement on the responsible pharmacist in relation to pharmacy procedures. The pharmacy owner will need to allow the responsible pharmacist to use his/her professional knowledge and judgement, as appropriate, in deciding the procedures that best meet the operational needs of the individual pharmacy.

Pharmacy Procedures: The Role of the Professional Regulatory Bodies

3.29 The professional regulatory bodies - the Royal Pharmaceutical Society of Great Britain (RPSGB) and the Pharmaceutical Society of Northern Ireland (PSNI) - have set out requirements in relation to legal, ethical and professional standards for pharmacists. In August 2007, the RPSGB issued a revised Code of Ethics, with supporting professional standards and guidance documents, which include the standards for pharmacists in positions of authority such as a superintendent pharmacist and the pharmacist responsible for an individual pharmacy. The PSNI reviewed the Code of Ethics and Practice in 2006 and this includes guidance on the role of the superintendent pharmacist.

3.30 The professional regulatory bodies also have an important role in promoting and supporting best practice and in the provision of advice and support to pharmacists. For example, the RPSGB has already made the development of standard operating procedures (SOPs) a professional requirement on pharmacists. Therefore, the professional regulatory bodies might be involved in the provision of guidance on the development of pharmacy procedures (see Chapter 9).

Q. *What is your view, in relation to pharmacy procedures, on the role of the*

- I.** *responsible pharmacist*
- II.** *superintendent pharmacist*
- III.** *pharmacy owner*
- IV.** *professional regulatory bodies*

Q. *What are your reasons for taking that view?*

CHAPTER 4

THE PHARMACY RECORD

- 4.1 Each registered pharmacy (including registered pharmacies in hospitals) is to have a responsible pharmacist. Where more than one pharmacist is working in the pharmacy, only one of them may be the pharmacist responsible for that pharmacy at any one time.
- 4.2 The pharmacist responsible for a pharmacy will be the pharmacist appointed by the pharmacy owner (and, in the case of a body corporate, the superintendent pharmacist) to take on this important role. Where an individual pharmacist owns and operates an independent pharmacy, he or she is both the owner and the responsible pharmacist.

The Registration Certificate

- 4.3 Currently, sections 70, 71 and 72 of the Medicines Act require the pharmacist in personal control of the pharmacy to display his/her registration certificate conspicuously in the pharmacy. As most pharmacists working in a pharmacy will display their certificates, it can be difficult to identify the pharmacist in charge if more than one pharmacist is working in a pharmacy at the same time. The Health Act amends these sections of the Medicines Act, requiring the responsible pharmacist to display a notice conspicuously in the pharmacy stating that he/she is the pharmacist in charge of the pharmacy on that date and at that time, together with details of his/her registration number. This will make it easier for those visiting the pharmacy to identify the responsible pharmacist.

The Annual Return to the Registrar and the Pharmacy Record

- 4.4 In addition, there is a change to the requirement on the pharmacy owner to make an annual return to the registrar with details of the pharmacist in personal control of the pharmacy (section 77 of the Medicines Act). Instead, the new section 72A requires the responsible pharmacist to keep a record, in the pharmacy, of the pharmacist responsible for that pharmacy on any date and at any time. Section 72A also places a statutory duty on the pharmacy owner to make sure the responsible pharmacist keeps the record properly and to preserve the pharmacy record for the period set out in the regulations. The regulations may specify the form in which the record is kept and the matters to be included in the record.

Information to be included in the Pharmacy Record

- 4.5 The Government believes the pharmacy record will be an important document that makes clear to pharmacy staff, the public and others:
 - who is the pharmacist in charge of the pharmacy at any time and on any day
 - that the pharmacy is operating legally (ie meeting the requirement that each registered pharmacy is to have a responsible pharmacist)

The Responsible Pharmacist

4.6 The Government is committed to avoiding unnecessary regulatory requirements that impose disproportionate burdens on businesses. Therefore, the Government proposes that regulations require the responsible pharmacist to include minimum specified information in the pharmacy record. That is

- The name and registration number of the responsible pharmacist
- The date and time at which the responsible pharmacist assumes responsibility for the pharmacy
- The date and time(s) at which the responsible pharmacist is absent from the pharmacy
- The date and time at which the responsible pharmacy ceases to have responsibility for the pharmacy.

Provided the record includes these minimum information requirements, the Government's view is that the inclusion of other information in the pharmacy record is a matter for the pharmacy owner, the superintendent pharmacist and the responsible pharmacist.

Q. *Do you agree with this approach and the proposals for the minimum information to be included in the pharmacy record?*

4.7 However, the Government has also sought views, informally, on what other information the regulations should require the responsible pharmacist to include in the pharmacy record – that is, in addition to the information requirements listed above. The views put forward are set out below.

- **Details of the responsible pharmacist's registration date.**

A number of people considered that, on becoming the pharmacist responsible for a pharmacy, the responsible pharmacist should include in the pharmacy record the date on which s/he became a registered pharmacist. (A view put forward in discussions on the pharmacy record, not the qualifications and experience needed to be a responsible pharmacist.) The Government does not support this proposal. It is for the professional regulatory bodies to hold this information on the register. A requirement on the responsible pharmacist to include this information in the individual pharmacy record would duplicate information already held more appropriately elsewhere. Further, the Government believes such a requirement is out of step with its commitment to reduce unnecessary regulatory burdens on businesses.

The Responsible Pharmacist

- **The reason(s) for the responsible pharmacist's absence during the period in question**

The Government does not believe there should be a requirement to include the reason(s) for absence in the pharmacy record. Primary legislation places a duty on the responsible pharmacist to secure the safe and effective running of the pharmacy at all times when s/he is responsible for the pharmacy. Whilst responsible for the pharmacy, the responsible pharmacist must ensure the pharmacy is operating safely when s/he is on the registered pharmacy premises, in another (non-registered) part of the same building or away from the pharmacy. This is not dependent on giving a specific reason for absence from the pharmacy (eg lunch break, attendance at a local health services planning meeting etc). Further, in this consultation paper, the Government puts forward separate proposals for regulations relating to the responsible pharmacist's absence from the pharmacy – see chapter 5.

- **The record should include any amendment to the pharmacy record (eg to correct an error) and the reason for this.**

One view put forward is this requirement will support the pharmacy owner in exercising his/her duty to ensure the responsible pharmacist keeps the pharmacy record properly. However, the Government's view is that it is unnecessary to specify this requirement in these regulations, as it is existing, accepted, practice to correct, date and sign any identified error in such a record.

- **The record should include information on pharmacists, other than the responsible pharmacist, and other staff working in the pharmacy (including the date and hours of working).**

The Government does not support this view as information on pharmacists and other staff working in a pharmacy will be part of the pharmacy business's staff employment records. Therefore, such a requirement will involve the responsible pharmacist duplicating this information in the pharmacy record. The Government's view is that this will place an unnecessary regulatory burden on the pharmacy business and the responsible pharmacist.

Q. What are your views on the proposals put forward above?

Pharmacy Procedures and the Pharmacy Record

4.8 During informal consultation, a number of people proposed the inclusion of similar information in both the pharmacy procedures and the pharmacy record. For example:

- Information relating to any significant or serious event occurring in the pharmacy on any day and at any time
- Confirmation that the responsible pharmacist has read and is content with pharmacy procedures

The Responsible Pharmacist

- 4.9 The Government's view is that the pharmacy procedures should include all information that allows those consulting them to identify the need for review, for any amendments and the reasons for changes. Further, the Government is aware that supporting professional standards, issued with the revised RPSGB Code of Ethics in August 2007, makes clear the requirement on a pharmacist in a position of authority to ensure "procedures are in place to record errors or near miss incidents....and review procedures as appropriate". The Government believes that it is unnecessary to provide the same information on a serious or significant event in both the pharmacy procedures and the pharmacy record. There should be no additional requirement on the responsible pharmacist to duplicate this information in the pharmacy record and, thus, be required to consult two separate documents on changes to the pharmacy procedures
- 4.10 As set out in Chapter 3, the Government's view is that the responsible pharmacist should be able to confirm that s/he has read and is content with the pharmacy procedures within the pharmacy procedures themselves, not the record.
- 4.11. During informal consultation, the majority view was that regulations should not require the responsible pharmacist to record the same information in the pharmacy record as that included in pharmacy procedures. However, the Government welcomes further views.

Q. *Do you think there are other matters that the regulations should require to be included in the pharmacy record? If so, what are these and what are your reasons for putting these forward?*

Form in which the written pharmacy record is to be kept

- 4.12 As with pharmacy procedures, the Government proposes that regulations allow the responsible pharmacist to keep the written pharmacy record in paper form or electronically, provided the record is readily accessible to those wishing to examine or consult it. Further, the Government proposes that, rather than requiring the responsible pharmacist to use a format prescribed in the regulations, the regulations set out that the responsible pharmacist include specified fields of information in the record. For example, those set out in paragraph 4.6 above and possibly others, subject to the outcome of consultation on the pharmacy record regulations.

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

The Pharmacy Owner and the Pharmacy Record

- 4.13 The new section 72A of the Medicines Act places a statutory requirement on the pharmacy owner to ensure the responsible pharmacist properly maintains the pharmacy record. In addition, the pharmacy owner must preserve the record for as least as long as the period specified in the regulations.

The Responsible Pharmacist

- 4.14 The Government proposes that the regulations should set out a minimum period for preserving the record. During informal consultation, a wide range of views emerged on a minimum period for retention of the pharmacy record – from two years to more than twenty years. However, the majority view was that any period specified in the regulations should have some consistency with other legislation relating to records and record keeping (eg public records or professional and other liability). There was also a view that the period specified for preservation of the pharmacy record should take into account guidance on records and record keeping issued by the professional regulatory bodies and that issued to NHS organisations.
- 4.15 As no clear view has emerged on a period for preserving the pharmacy record, the Government proposes that, as a minimum, the regulations should specify that the pharmacy owner must preserve the pharmacy record for five years from the date of the last entry to the record. Further, that it should remain open to the pharmacy owner to decide if he or she wishes to preserve the pharmacy record for a longer period than that specified in the regulations.

Q. ***Do you agree with this approach? If not, what do you think should be the minimum period and why?***

CHAPTER 5

CONDITIONS RELATING TO THE RESPONSIBLE PHARMACIST: ABSENCE FROM THE PHARMACY

Absence and the “personal control” requirement

- 5.1 Sections 70, 71 and 72 of the Medicines Act require the business of the retail sale and supply of medicines to be under the “personal control” of a pharmacist. However, the Medicines Act does not define “personal control” nor does the Act define how the pharmacist is to meet this requirement. The concept of “personal control” derives from the Pharmacy and Poisons Act 1933 but this provision did not attract extensive debate in the passage of that legislation or the Medicines Act 1968. In 1981, the case of *R v Logan* indicated that some physical presence on the pharmacy premises was required if a pharmacist was to be considered in control of the pharmacy. However, that decision also indicated that the sale of GSL medicines could take place when the pharmacist was not in the pharmacy. A more recent statement by the RPSGB Statutory Committee indicated that if a pharmacist is not in personal control (for instance because s/he is not on the registered pharmacy premises) transactions involving the sale or supply of medicines, including GSL medicines, could not take place.
- 5.2 In response to the continuing debate about the exercise of the personal control requirement, the Government proposed a fresh look at this requirement in the light of modern pharmacy practice. The response to the 2005 public consultation paper, *Making the Best Use of the Pharmacy Workforce* confirmed strong support for clarification of the personal control requirement with some 75% of respondents calling for changes to the legislation.
- 5.3 The Health Act amends sections 70, 71 and 72 of the Medicines Act to replace “personal control” with a requirement that each pharmacy is to have a responsible pharmacist. The new section 72A inserted into the Medicines Act, by the Health Act, provides further details on this requirement. The pharmacist in charge of a pharmacy now has an explicit statutory duty to secure the safe and effective running of the pharmacy. S/he will be responsible for ensuring that all activities involving the preparation, assembly, sale and supply of medicines are undertaken safely. The responsible pharmacist is required to set down pharmacy procedures for working in the pharmacy, including the training and experience required of pharmacy staff with specific responsibilities within the pharmacy. The responsible pharmacist must also keep a record of the pharmacist responsible for the pharmacy on any date and at any time.
- 5.4 The Government believes these explicit requirements on the responsible pharmacist ensure safeguards are in place to maintain patient safety whilst allowing the responsible pharmacist to be absent from the pharmacy. These changes also make clear that the presence of the pharmacist is not required to permit the sale of GSL medicines.

The Responsible Pharmacist

- 5.5 Section 72A provides for regulations on how the responsible pharmacist is to exercise the statutory duty, including the ability of the responsible pharmacist to be absent from the pharmacy. Again, it is important to be clear that these regulations concern the Medicines Act requirements relating to the preparation, assembly, sale and supply of medicines from registered pharmacies. Wider NHS legislation and the NHS pharmaceutical services contractual frameworks in the four countries of the United Kingdom relate to other services available from the pharmacy - for example, any requirement to be available in the pharmacy in core hours in order to provide NHS services. Amendment of NHS regulations can address the availability of a pharmacist in the pharmacy to provide the full range of NHS services. The Government will be looking at possible amendments to NHS regulations later, as part of proposals for the pharmacist supervision regulations.

Absence and the responsible pharmacist requirement

- 5.6 The Government's view is that the responsible pharmacist should be able to leave the pharmacy – for example, to use his/her training and clinical expertise in working with other healthcare professionals (such as GPs) to provide a wider range of health services in the community and in patients' own homes. Many share this view, believing that, in particular, this will enhance the pharmacist's clinical role and the pharmacist's contribution to improving health and healthcare services in the community. In hospitals, pharmacists work within the pharmacy and on hospital wards, as members of the clinical team responsible for the care and treatment of patients.
- 5.7 In the majority of community pharmacies, there is only one pharmacist working in the pharmacy. The Government recognises concerns raised that allowing the responsible pharmacist to be absent may lead to circumstances where a pharmacy is without a pharmacist. However, it remains a statutory requirement that each pharmacy is to have a pharmacist in charge of the pharmacy – that is a responsible pharmacist with a statutory duty to ensure that the pharmacy is operating safely. Where a pharmacy is without a responsible pharmacist, it must close to the public for the sale and supply of medicines.
- 5.8 There are other safeguards. The requirement to keep the pharmacy record will provide details of the pharmacist who is responsible for a pharmacy at any time and on any date. There is also the requirement on the responsible pharmacist that s/he must display a notice conspicuously in the pharmacy stating that s/he is the pharmacist in charge of the pharmacy at that time, together with details of his/her registration number.
- 5.9 The Government also recognises concerns that the pharmacist's ability to be absent from the pharmacy may mean that members of the public will be unable to rely on seeing a pharmacist when they visit a pharmacy. This direct access to professional advice on medicines and self-care is greatly valued by the public and, like others, the Government wishes to see this continue.
- 5.10 During passage of the Health Act, the Government stated clearly its view that, in order to fulfil the statutory duty fully and effectively, a responsible pharmacist should consider the pharmacy to be his/her main place of work whilst s/he is responsible for the pharmacy. The Government believes the responsible pharmacist will need to spend the majority of his/her time in the pharmacy during the period in which s/he is in charge of the pharmacy. The responsible pharmacist must be able to maintain his/her knowledge and experience of the pharmacy's activities and the skills and competencies of pharmacy staff and to ensure adherence to pharmacy procedures for safe working.

The Responsible Pharmacist

- 5.11 Where a pharmacist is responsible for a pharmacy, s/he is under a statutory duty to secure the safe running of the pharmacy, including during any period of absence from the pharmacy. Therefore, the Government's view is that, during any period of absence, the responsible pharmacist will need to remain available to provide professional advice to pharmacy staff, patients and the public and to respond to any request to return to the pharmacy.
- 5.12 However, the ability to be absent from the pharmacy will provide the responsible pharmacist with opportunities to use his/her clinical training to provide pharmacy services elsewhere. For example, this may be in another part of the same building adjacent to the registered pharmacy (eg a consulting room) or away from the pharmacy (eg in clinics, nursing homes or in patients' own homes). Therefore, the Government believes the regulations relating to the responsible pharmacist's absence from the pharmacy will need to achieve a balance. These must be consistent with the responsible pharmacist's overall statutory duty to secure safe and effective running of the pharmacy, whilst allowing sufficient time and flexibility for him/her to offer pharmacy services, other than the dispensing and sale of medicines, in the pharmacy itself or away from the pharmacy. In this way, the responsible pharmacist will be able to develop his/her clinical role and contribute to pharmacy's developing role in local health service planning and service delivery.

Defining Absence from the Pharmacy

- 5.13 To achieve this balance, and given the primary aim of the Medicines Act to safeguard the public, the Government proposes that the regulations define absence from the pharmacy in a number of ways. That is
- the extent to which the responsible pharmacist must be present in the pharmacy during any one period for which s/he is responsible for that pharmacy and the pharmacy is operational
 - the maximum time that the responsible pharmacist may be away from the pharmacy during any one period of absence

The extent to which the responsible pharmacist must be present in the pharmacy during any one period for which s/he is responsible for that pharmacy and the pharmacy is operational

5.14 The Government proposes that the regulations specify the minimum proportion of time that the responsible pharmacist should spend in the pharmacy in order to exercise the statutory duty to secure safe and effective running of the pharmacy. That is,

- as a minimum, the responsible pharmacist should be in the pharmacy for the majority of his/her time when the pharmacy is operating
- the majority of time should be more than 50% of each period for which he/she is the responsible pharmacist when the pharmacy is operating

Most of those responding to informal consultation on this proposal agreed that the responsible pharmacist should spend the majority of his/her working time in the pharmacy when it is operating but the Government welcomes wider views on this proposal.

Q. *If you do not agree that the regulations should specify the minimum proportion of time the responsible pharmacist should spend in the pharmacy and this should be the majority of the time s/he is responsible for the pharmacy, what do you propose and what are your reasons for supporting your proposal?*

The minimum proportion of time set out in regulations

5.15 During informal consultation, no majority view emerged on a minimum proportion of time to be set out in the regulations. One view put forward was the minimum requirement should be that the proportion of the responsible pharmacist's time spent in the pharmacy should be 75-90%. However, there is an argument that, as a minimum proportion of time, this may not allow the responsible pharmacist sufficient time or flexibility to allow him/her to work outside the pharmacy with healthcare professionals and others in the planning and delivery of services. Another view was that any specified minimum proportion of time should support safe working but should not hamper service development or the better use of the pharmacist's clinical skills and those of pharmacy staff.

5.16 A number of people also felt there was a need to consider the minimum proportion of time specified in these regulations in the context of changes in the pharmacist supervision requirements. The Government agrees with this view. Changes in the pharmacist supervision requirements will permit a responsible pharmacist, subject to conditions set out in the regulations, to allow a suitably trained registered healthcare professional (such as a pharmacy technician) to supervise certain aspects of individual transactions involving the sale and supply of medicines from the pharmacy. Where there is compliance with the pharmacist supervision regulations, the responsible pharmacist will be able to be absent from the pharmacy provided specified, suitably trained and registered pharmacy staff are available to supervise certain aspects of dispensing, supported by other competent pharmacy staff, working to pharmacy procedures set down by the responsible pharmacist. However, the Government is not consulting on proposals for the pharmacist supervision regulations until later.

The Responsible Pharmacist

5.17 In the meantime, the Government recognises that many responsible pharmacists will be limited in their ability to be absent from the pharmacy until the introduction of the pharmacist supervision regulations. However, at this stage, a responsible pharmacist may be able to meet the specified conditions for absence where more than one pharmacist is working in the pharmacy at the same time. The other pharmacist working in the pharmacy will continue to be present in the pharmacy to meet the current pharmacist supervision requirements. Meanwhile, the Government welcomes views on the minimum proportion of time the responsible pharmacist is required to spend in the pharmacy in any one period for which s/he is in charge of the pharmacy and the pharmacy is in operation. In addition, views are welcome on how the responsible pharmacist regulations should specify this requirement. The Government has already stated its view that this will need to be the majority of the responsible pharmacist's time – ie more than 50% of his/her time during any one period in which s/he is responsible for the pharmacy and the pharmacy is operating.

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 during each period that s/he is the responsible pharmacist? What are your reasons for this?*

A maximum period of absence from the pharmacy

5.18 During informal consultation, a majority view was that the regulations should specify a maximum time of between two to three hours for any one period of absence, during which a responsible pharmacist may be away from the pharmacy. The majority also felt this period could vary for a number of reasons, including

- in some rural areas, the responsible pharmacist would need time to take into account distances between different localities to enable him/her to offer services outside the pharmacy
- the presence of another pharmacist in the pharmacy
- the presence of another suitably trained registered healthcare professional (eg a pharmacy technician) in the pharmacy
- the volume and range of the pharmacy's main business activities

However, the view was also taken that any conditions supporting any variation should be considered in the context of the maximum period specified. Following informal consultation, the Government proposes that the regulations specify three hours be specified as the maximum time for any one period of absence when the pharmacy is operating but welcomes further views on this proposal. The Government also welcomes views on whether the maximum period might vary, subject to certain conditions - for example, where another pharmacist remains present in the pharmacy when the responsible pharmacist is absent.

The Responsible Pharmacist

- Q.** *Do you agree that regulations should specify the maximum time that the responsible pharmacist may be absent from the pharmacy during any one period of absence? If so, should this be set at three hours?*
- Q.** *Do you think the specified maximum time could vary - subject to specified conditions set out in the regulations? For example, where another pharmacist or certain other pharmacy staff (eg a suitably trained and registered pharmacy technician) are present in the pharmacy? If so, how might this vary and what are your reasons for supporting that view?*
- Q.** *If you do not agree with these proposals, what do you propose and what are your reasons for supporting your proposal?*

Other Conditions relating to the Responsible Pharmacist's Absence from the Pharmacy

5.19 Further, the Government proposes that the pharmacist's ability to be absent from the pharmacy should be subject to a number of other conditions specified in the regulations. That is:

- the responsible pharmacist must be able to return to the pharmacy with reasonable promptness
- during any period of absence, as necessary, the responsible pharmacist should remain readily contactable so that pharmacy staff are able to seek advice or request his/her return to the pharmacy
- where the responsible pharmacist is unable to remain contactable, he or she must arrange for another pharmacist to be available to provide advice (who may not need to be present in the pharmacy) until s/he is able to return to the pharmacy

Returning with Reasonable Promptness

- 5.20 The responsible pharmacist's absence from the pharmacy will be subject to the maximum time specified in the regulations that s/he is able to be away from the pharmacy during any one period of absence. However, as a further safeguard, the Government proposes that regulations require the responsible pharmacist to be able to return to the pharmacy with reasonable promptness.
- 5.21 The Government's view is that it will be difficult to define "reasonable promptness" in the regulations in a way that meets all possible circumstances. The Government also believes that the responsible pharmacist should be able to use his/her professional judgement to decide, in individual circumstances, what might be "reasonable promptness" in returning to the pharmacy – having regard to the maximum time that s/he is able to be away in any one period of absence.
- Q.** *Do you agree that the responsible pharmacist be required to return to the pharmacy with "reasonable promptness" and the approach taken? If not, what do you propose and what are your reasons for this?*

Contacting the Responsible Pharmacist when absent from the pharmacy

- 5.22 The responsible pharmacist is required to set down written procedures for safe working in the pharmacy, which will continue to support pharmacy staff in working under the responsible pharmacist's authority when s/he is absent from the pharmacy. The procedures should set out clear arrangements relating to the responsible pharmacist's absence from the pharmacy, including the circumstances in which pharmacy staff must seek advice from the responsible pharmacist. However, as a further safeguard, the Government believes the regulations should require the responsible pharmacist to ensure that, as necessary, pharmacy staff may readily contact him/her during his/her absence to obtain advice or to request his/her return to the pharmacy. For example, where another pharmacist is not also working in the pharmacy or where the responsible pharmacist has not arranged for another pharmacist to be available to provide advice.
- 5.23 The Government does not propose that the regulations should set out the ways in which the responsible pharmacist is to maintain contact with pharmacy staff when absent from the pharmacy. Nevertheless, the Government believes that it is important to consider some of the practical implications before placing too much reliance on, for example, telephone contact because of possible mobile telephone network failure (as occurred during the terrorist attacks in London in July 2005) or poor quality or lack of reception in some areas.
- 5.24 During informal consultation, the Government sought views on the kind of arrangements that a responsible pharmacist will need to consider. A number proposed a requirement that details of the responsible pharmacist's location and contact(s) at that location should be included in the pharmacy procedures or the pharmacy record. The Government's view is that it may not be practical to specify in regulations that pharmacy procedures include such detail – for example, this may result in the need for frequent amendment of procedures each time the responsible pharmacist is away at a different location. Another proposal was that it would be more appropriate to provide advice on maintaining contact with pharmacy staff in guidance rather than in the regulations. The Government welcomes further views on maintaining contact with pharmacy staff and the need for guidance.
- Q. *Do you agree the regulations should require the responsible pharmacist, as necessary, to remain readily contactable by pharmacy staff?***
- Q. *What is your view on the proposal that it may be more practical and appropriate to offer advice on this in guidance?***
- Q. *If you do not agree with these proposals, what do you propose and what are your reasons for putting your proposals forward?***

Arrangements where the responsible pharmacist may be unable to maintain contact with pharmacy staff during his/her absence from the pharmacy

5.25 In some circumstances, the responsible pharmacist may be unable to maintain contact with pharmacy staff. For example, where for the whole of the period of absence the responsible pharmacist is engaged in required activities to maintain his/her professional skills or s/he is engaged in a number of consultations with patients. In such circumstances, the responsible pharmacist may not be in a position to respond quickly to a call from pharmacy staff to provide advice. Again, as an additional safeguard, the Government sought views informally on whether the regulations should require the responsible pharmacist to arrange for another pharmacist to provide professional advice where s/he is unable to maintain contact with pharmacy staff during any period of absence from the pharmacy. The Government also sought views on whether the responsible pharmacist should be required to make such arrangements only with another responsible pharmacist or a pharmacist that is eligible to be a responsible pharmacist.

5.26 Where a responsible pharmacist is unable to maintain contact with pharmacy staff during any period of absence, the majority considered the regulations should require him/her to arrange for another pharmacist to provide professional advice. However, this requirement should not specify that the other pharmacist must be a responsible pharmacist or eligible to take on this role. The Government is now seeking wider views on these proposals.

Q. *Do you agree 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 during his/her absence?*

Q. *Further, do you agree that it is unnecessary for the regulations to specify that the other pharmacist should also be a responsible pharmacist or a pharmacist eligible to take on this role?*

Q. *If you do not agree with one or either of these proposals, what do you propose and what are your reasons for putting this view forward?*

5.27 Again, the Government does not propose the regulations should specify how the responsible pharmacist is to ensure another pharmacist is available to provide advice where s/he is not contactable by pharmacy staff during his/her absence. This is because the responsible pharmacist will need to take into account the other proposed conditions for absence. In addition, the responsible pharmacist and the other pharmacist with whom s/he makes such arrangements will need to exercise professional judgement in assessing how these arrangements will maintain safe working in the pharmacy.

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

The Responsible Pharmacist

- 5.28 It may be helpful to set how the responsible pharmacist will meet the proposed conditions supporting absence from the pharmacy. For example:

Scenario 1

The responsible pharmacist is the only pharmacist working in a pharmacy. If wishing to be absent from the pharmacy, s/he must take into account the specified maximum time for absence and this will include the pharmacist's journey time from and back to the pharmacy. The responsible pharmacist must also judge how journey time will affect the requirement to return with reasonable promptness as, in these circumstances, the period of absence may be significantly less than the proposed maximum of three hours. In addition, the responsible pharmacist must set out arrangements for pharmacy staff to contact him/her during that absence, taking into account any time within that period when s/he is not contactable and whether this requires arrangements with another pharmacist (who will not be present in the pharmacy) to provide advice during that time. Both pharmacists will need to use their professional judgement in agreeing that arrangements made will continue to support the safe running of the pharmacy.

Scenario 2

There are two pharmacists working in the pharmacy. The responsible pharmacist will be absent from the pharmacy, leaving the other pharmacist present in the pharmacy whilst s/he is away. As another pharmacist remains present in the pharmacy, the maximum time might vary – allowing a longer time for absence. However, the responsible pharmacist must still take into account the specified maximum time for absence, which will include journey times from and to the pharmacy and, in doing so, the requirement to return to the pharmacy with reasonable promptness if required to do. Again, the responsible pharmacist must also set out arrangements for pharmacy staff to contact him/her during that absence (eg to request return) taking into account any time within that period when s/he is not contactable.

CHAPTER 6

THE CONDITIONS APPLYING TO THE RESPONSIBLE PHARMACIST: QUALIFICATIONS AND EXPERIENCE

- 6.1 The Government recognises that pharmacy owners and pharmacists may need more time to prepare for introduction of certain of the responsible pharmacist regulations. For example, the timing of introduction of regulations relating to qualifications and experience will need to take into account the need to ensure there are sufficient pharmacists available to fulfil the role of the responsible pharmacist, whilst maintaining the public's ready access to pharmacist advice and the medicines they need. In Chapter 9, the Government is seeking views, more generally, on the introduction of the responsible regulations, including the time needed to prepare for changes and the possibility of taking a phased approach to introducing these regulations.
- 6.2 The Health Act inserts a new section 72A into the Medicines Act that allows Health Ministers to set out in regulations further provisions on how the responsible pharmacist is to exercise the duty to secure safe and effective running of the pharmacy. These will apply to all registered pharmacies, within hospitals and in the community. These regulations may include requirements as to the qualifications and experience needed to be a responsible pharmacist.
- 6.3 In this chapter, therefore, the Government puts forward and welcomes views on proposals for regulatory requirements relating to the qualifications and experience needed to be a responsible pharmacist.

Qualifications to be a Responsible Pharmacist

- 6.4 During passage of the Health Act, and during informal consultation in early 2007, the Government confirmed there is no intention to introduce any significant, additional, formal or academic qualification over and above registration as a pharmacist.
- 6.5 Nevertheless, the Government believes the pharmacist's qualifications and experience to be an important safeguard. These legislative changes will allow the responsible pharmacist greater flexibility in how s/he makes use of pharmacy staff and modern technology. The responsible pharmacist will be able to determine when s/he may be absent from the pharmacy and the use of remote supervision arrangements, provided the circumstances and conditions specified in regulations are met. The responsible pharmacist will also be able to decide, subject to requirements in the regulations, whether supervision of certain aspects of the sale and supply of pharmacy and prescription only medicines may be safely delegated to other registered and suitably trained health professionals, taking into account the particular circumstances of the pharmacy. The responsible pharmacist must be able to fulfil these responsibilities effectively to maintain patient safety and safeguard the public - the key principle underpinning the Medicines Act. Therefore, the Government also believes that the responsible pharmacist should have adequate preparation to take on this role before assuming responsibilities for all activities within the pharmacy and for pharmacy staff

The Responsible Pharmacist

6.6 As a matter of European law, the United Kingdom must recognise the qualifications of pharmacists qualified in other European Community Member States. The Government does not intend that anything in these regulations should be inconsistent with that legal requirement. To qualify to practise as a pharmacist in the UK, it will be sufficient to have undertaken a period of registration as a pharmacist in another Member State in the same way as a period of registration in the UK. For example, working in a community pharmacy in another member state for the specified period would satisfy the “experience” part of the requirement in these regulations. That is, to become a responsible pharmacist someone has to have been qualified as a registered pharmacist for a number of years and – for a community pharmacy – have experience of working in a registered pharmacy in that setting.

An Annotation to the Register

6.7 During passage of the Health Act, and informal consultation, the Government outlined a possible option in relation to qualifications and experience. That is, the Royal Pharmaceutical Society of Great Britain and the Pharmaceutical Society of Northern Ireland might include on the register of pharmacists an annotation against the names of those pharmacists who have the necessary length of registration and the appropriate experience to take on the role of a responsible pharmacist. For example, this could provide transparency for both pharmacy owners and pharmacists when considering appointment as a responsible pharmacist. Such an approach requires the legislation to provide for both the qualifications and the experience required to be a responsible pharmacist.

6.8 In early 2007, the majority view emerging from informal consultation on this option was that any requirement to annotate the register would need careful consideration, including, for example

- that newly qualified pharmacists or those gaining experience to become a responsible pharmacist were not placed at a disadvantage in seeking or gaining posts in the community or hospital pharmacy sectors
- the purpose of the annotation – the majority felt this should make clear a pharmacist was competent to take on the role of a responsible pharmacist rather than just indicating that he or she had undertaken that role in a registered pharmacy in the community or in a hospital.
- Any maintenance arrangements to ensure such information (and the register) remained accurate and up to date
- Use of this information - the majority considered that pharmacy owners should not rely on any annotation to the register alone when considering the appointment of a pharmacist to be responsible for a pharmacy

The Responsible Pharmacist

6.9 The Government is now seeking views, more widely, on whether the Royal Pharmaceutical Society of Great Britain and the Pharmaceutical Society of Northern Ireland might include on the register an annotation against the names of those pharmacists with the necessary experience to be a responsible pharmacist.

Q. *What is your view of an option to annotate the register indicating a pharmacist has experience to be a responsible pharmacist? What are your reasons for your view?*

Q. *Do you think other matters need to be considered, in addition to those outlined above? If so, what are these and what are your reasons for putting them forward?*

Pharmacist Experience

6.10 The Government recognises that the Royal Pharmaceutical Society of Great Britain makes clear in the revised Code of Ethics, issued in August 2007, that pharmacists have a professional responsibility to ensure continuing competence and up-to-date knowledge relevant to their field of practice. The Pharmaceutical Society of Northern Ireland Code of Ethics and Practice also makes clear this responsibility on pharmacists. The RPSGB has also issued supporting standards for pharmacists and pharmacy technicians in positions of authority. These include a requirement to ensure that pharmacists and other pharmacy staff are competent to take on their specific role and a requirement to report any concerns relating to professional competence or fitness to practice to the Society.⁴

6.11 The statutory requirements on the responsible pharmacist are distinct from the requirement on a pharmacist to supervise individual transactions involving the sale and supply of medicines. These requirements extend beyond supervision – the responsible pharmacist has a legal responsibility to ensure that all aspects of the pharmacy's operation are safe and effective where these concern medicines.

⁴ Royal Pharmaceutical Society of Great Britain Code of Ethics for Pharmacists and Pharmacy Technicians and Professional Standards for Pharmacists and Pharmacy Technicians in Positions of Authority (August 2007). Pharmaceutical Society of Northern Ireland Code of Ethics and guidance on ethics and practice (2006)

The Responsible Pharmacist

6.12 A number of different views on the experience needed to be a responsible pharmacist emerged from informal consultation, including

- The regulations should not specify that a pharmacist must have acquired a period of experience, beyond registration, before taking on the role of a responsible pharmacist. The view is that there is already lengthy and extensive training to qualify as a pharmacist and pharmacists are under a professional obligation to ensure that they, and the pharmacists they may employ, are competent to carry out their responsibilities.
- A view that pre-registration trainee pharmacist training could be developed to provide more relevant experience
- Wide ranging views on any requirement that a pharmacist needs a minimum period of experience, beyond registration, before taking on the role of the responsible pharmacist. For example – these ranged from a requirement of 6 months post registration experience to a requirement on a pharmacist to acquire between two and four years experience to demonstrate competency in this role, undertaken as part of the pharmacist's continuing professional development
- A proposal that any required minimum period of experience might vary. For example, the regulations might specify a requirement for a period of experience where the responsible pharmacist wished to offer services away from the pharmacy (ie to be absent from the pharmacy) and take up his/her ability to permit another suitably trained, registered, healthcare professional working in the pharmacy (eg a registered pharmacy technician) to supervise aspects of the sale and supply of medicines
- A majority view was that any requirement relating to experience should focus on competency to take on the responsibilities of a pharmacist in charge of a pharmacy - not the extent of time a pharmacist may have spent undertaking this role

6.13 The Government welcomes views on the issues raised and discussed during informal consultation. Proposals in relation to a minimum period of experience are set out in the following paragraphs.

Q. What is your view on the issues outlined above and do you think there is also a need to consider other issues? If so, what are these?

A minimum period of experience following registration as a pharmacist

6.14 To allow time for a pharmacist to gain sufficient experience to be a responsible pharmacist, one option might be to include a requirement in these regulations that a pharmacist has a minimum period of experience following registration before he or she may take on this role. For example, this could underpin professional Code of Ethics requirements and pharmacy owners' arrangements (and, as appropriate, those of the superintendent pharmacist) for the assessment of pharmacists wishing to take on this role in their pharmacies. The Government welcomes views on this option, including what the minimum period of experience might be.

Q. *Do you think there should be a minimum period of experience, following registration, before a pharmacist may become a responsible pharmacist? If so, what should that minimum period be and what are your reasons for putting this forward?*

Q. *If you do not agree with this proposal, what do you propose?*

Variations to the minimum period of experience

6.15 During informal consultation, one view put forward was that any requirement relating to a minimum period of experience could be an additional condition, for example, for absence from the pharmacy. That is, where a responsible pharmacist wished to be able to be absent from the pharmacy, s/he must comply with a condition that requires him/her to have the minimum period of experience set out in regulations. This approach would allow a recently qualified pharmacist to take on the role of the responsible pharmacist but s/he would need to have a minimum period of experience in that role to meet all the conditions that would allow him/her to be absent from the pharmacy. The ability of the responsible pharmacist to meet his/her statutory requirement to secure the safe and effective running of the pharmacy is not dependent on his or her physical presence in the pharmacy at all times. However, the responsible pharmacist will need to have 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 Government welcomes further views on whether the minimum period specified might vary as an additional condition supporting the responsible pharmacist's absence from the pharmacy. Other proposals on conditions relating to absence from the pharmacy are set out in chapter 5.

Q. *Do you think a requirement relating to a minimum period of experience might vary? For example, what is your view on the proposal that any minimum period of experience requirement could be an additional condition supporting, for example, the responsible pharmacist's ability to be absent from the pharmacy? What are your reasons for supporting your view?*

Recent Experience in the Relevant Pharmacy Sector

6.16 The Government has also sought views, informally, on whether the regulations should specify that a responsible pharmacist should have a minimum period of experience in the relevant pharmacy sector. Overall, the majority view emerging from informal consultation supported the need for a pharmacist to have relevant experience before taking on the role of the responsible pharmacist in a specific pharmacy sector. However, there were a number of views put forward, including:

- That the regulations should not specify a minimum period, including recent experience in the relevant pharmacy sector
- A pharmacist did need recent experience in the relevant pharmacy sector before becoming a responsible pharmacist. For example, a pharmacist who had been responsible for a hospital pharmacy would need time to adapt to the operational needs of a community sector pharmacy (eg volumes of dispensing activity and the sale of medicines) and vice versa. Or a pharmacist who had been working within the pharmaceutical industry, in taking on responsibility for a community pharmacy, would need to be aware of requirements relating to the sale and supply of medicines.
- Where a pharmacist has not practised as a pharmacist for some time (for example, a career break), on return, before taking on the role of the responsible pharmacist s/he should gain experience of working in the relevant pharmacy sector. Different views were put forward on a minimum period of experience – from 3 months to a lengthier period of up to a year where a pharmacist had not practised as a pharmacist for more than three years

Q. *What is your view and are there other issues in relation to recent experience in the relevant pharmacy sector? If so, what are these and your reasons for putting them forward?*

6.17 In the light of the majority view expressed during informal consultation, the Government proposes that the regulations specify that a responsible pharmacist must have a minimum period of *recent*, relevant, experience in the pharmacy sector to which he/she wishes to become a responsible pharmacist. For example, the regulations might define the minimum period of experience as “x” period of experience within the last “y” years and might include relevant experience of a specific pharmacy sector gained during pre-registration training. The Government welcomes views on this proposal and, in particular, what the minimum period of recent, relevant, experience might be.

Q. *Do you agree with this approach? If so, what are your reasons for supporting this proposal? What do you think should be the minimum period of recent experience in the relevant pharmacy sector and how should this be defined?*

Q. *If you do not agree, what do you propose instead and what are the reasons supporting your proposals?*

A minimum period of relevant experience, where a pharmacist has not practised as a pharmacist for three years or more

6.18 Following informal consultation, the Government also proposes that the regulations specify a minimum period of experience in the relevant pharmacy sector for pharmacists wishing to become a responsible pharmacist where they have not practised as a pharmacist for three years or more. The Government welcomes further views on this proposal and, in particular, what the minimum period might be.

- Q. Do you agree that the minimum period of experience might differ where a pharmacist is returning to practise after an absence of three years or more? If so, what should this be?**
- Q. If you do not agree with this approach, what do you propose instead and what are the reasons for supporting your proposals?**

CHAPTER 7

ONE PHARMACY/ONE RESPONSIBLE PHARMACIST

- 7.1 Sections 27, 28 and 29 of the Health Act amend section 70, 71 and 72 of the Medicines Act, replacing personal control with a requirement that each pharmacy is to have a responsible pharmacist. During passage of the Health Act through Parliament, the Government made clear its view that to discharge fully and effectively the statutory duty on the responsible pharmacist to secure safe and effective running of the pharmacy, the general “rule” remains that each pharmacy is to have a responsible pharmacist. Thus, a registered pharmacy must have a responsible pharmacist if it is to remain open for the sale and supply of medicines to the public and that pharmacist may only be responsible for one registered pharmacy at any one time. If there are two pharmacists working in a pharmacy at the same time, only one will be the responsible pharmacist. However, one or both of them may be the pharmacist supervising individual transactions involving the sale and supply of pharmacy and prescription only medicines.
- 7.2 If a registered pharmacy does not have a responsible pharmacist (as now with the personal control requirement), the pharmacy may not remain open for the sale and supply of medicines to the public. This applies to registered pharmacy premises within hospitals and in the community.

Exceptional Circumstances Permitting a Responsible Pharmacist to be Responsible for more than One Pharmacy at the Same Time

- 7.3 However, during passage of the Act, the Government also made clear its view that it was sensible for the legislation to allow sufficient flexibility to make exceptions to this general “rule” where there was a need to give a considered response to any exceptional circumstances that may arise in the future. The new section 72A, inserted into the Medicines Act, allows Health Ministers to specify such circumstances in regulations. The Government is seeking views on what circumstances might be considered to be exceptional and thus set out in the regulations.

Conditions Permitting a Responsible Pharmacist to be Responsible for more than One Pharmacy at the Same Time

- 7.4 As an added safeguard, section 72A also requires compliance with certain specified conditions before a pharmacist may be responsible for more than one pharmacy at the same time. The Government believes the need to comply with requirements relating to exceptional circumstances and specified conditions will ensure the responsible pharmacist is able to fulfil his/her responsibilities for the safe sale and supply of medicines in each of the pharmacies for which s/he is responsible. Public safety is paramount. The Government’s view is that the responsible pharmacist will need to be sure that s/he does not overstretch both his/her capacity and ability to exercise the statutory duty in relation to each pharmacy.
- 7.5 Therefore, in this chapter, the Government is seeking views on proposals relating to the specific circumstances and conditions that will permit a pharmacist to be responsible for more than one pharmacy at the same time.

The Responsible Pharmacist

- 7.6 Before a responsible pharmacist may take on responsibility for more than one pharmacy, s/he will need to comply with the specified circumstances and conditions, with the regulations relating to absence from the pharmacy (see Chapter 5) and with the pharmacist supervision regulations (on which the Government is consulting later). Therefore, the Government recognises that it may be appropriate to take a phased approach to the introduction of regulations relating to the ability of a pharmacist to be responsible for more than one pharmacy at the same time. In chapter 9, the Government welcomes views on this possible approach.

Possible Exceptional Circumstances

- 7.7 The Government believes that, by their nature, exceptional circumstances will be unusual and will require careful consideration when deciding if these require making an exception to the general “rule” of one pharmacy/one responsible pharmacist.
- 7.8 The Government does not believe that circumstances such as sickness, holidays, and “emergencies” (eg an accident, problems at home, and disruption to travel) should be included in the regulations as exceptional circumstances. For example, where a responsible pharmacist plans to be away on holiday for two weeks, this would not be an exceptional circumstance prompting consideration of an exception to the one pharmacy/one responsible pharmacist “rule”. As now, with the personal control requirement, where a pharmacy is without a responsible pharmacist, the pharmacy owner must appoint another pharmacist to be in charge of the pharmacy until the usual responsible pharmacist returns from his/her holiday. This will also be the case where the responsible pharmacist’s holiday involves only a short period, as there will need to be compliance with regulations relating to absence from the pharmacy (see Chapter 5).
- 7.9 During passage of the Health Act and as part of informal consultation in early 2007, the Government put forward two possible examples of circumstances for consideration as exceptions to the one pharmacy/one responsible pharmacist “rule”. These are set out below. The Government is now seeking wider views on the examples given.

Example 1: A temporary pharmacy

- 7.10 Possible exceptional circumstances might be where a large number of people attend an event (such as a festival or agricultural show) held over a several days, with a temporary pharmacy available at the site to meet their needs during this period. Trained pharmacy staff (such as registered pharmacy technicians) would be available at the pharmacy with the pharmacist responsible for the main pharmacy in a nearby town or village also becoming responsible for the safe running of the temporary pharmacy. The pharmacist responsible for the main pharmacy would set out the temporary pharmacy’s procedures, and decide which staff may undertake certain activities in that pharmacy. Such arrangements would also need to comply with the pharmacist supervision regulations on which the Government is consulting later.
- 7.11 The majority view emerging from informal consultation was this scenario did not present a strong enough case for consideration as an exception to the general “rule”. However, the Government welcomes any further views.

Example 2: Pharmacist operated dispensing machine located in separate registered pharmacy premises

- 7.12 Developing technologies are already making available machines, controlled and operated by a pharmacist, to dispense medicines to patients who are unable to visit the pharmacy where the pharmacist is located. Although located in separate registered pharmacy premises, the machine supports “tele-link” face-to-face interaction between the pharmacist and the patient to provide advice, the pharmacist can see and receive the prescription, choose and label the medicine required and deliver this to the patient via the machine. As the pace of developing technologies continues to advance, such circumstances are likely to arise in the near future – the technology described is already under development in countries such as Australia.
- 7.13 As an exception to the general “rule”, the same pharmacist would be responsible for the registered premises where the machine is located as well as the main pharmacy. A pharmacist undertakes extensive clinical training. Therefore, the Government does not believe it is sensible or appropriate to require him/her to be responsible for a registered pharmacy where s/he only stands guard over a machine operated by a pharmacist from another pharmacy. In such circumstances, the Government’s view is that it is more appropriate for the pharmacist responsible for the main pharmacy, who also controls the dispensing machine, to be responsible for the safe and effective operation of such technology and the registered pharmacy premises where the machine is located.
- 7.14 Whilst those responding to informal consultation recognised that such a scenario may already be possible (and increasingly so in the future), no firm view emerged on this as a possible exception to the general “rule” that each pharmacy is to have a responsible pharmacist. Therefore, the Government welcomes wider views on whether the increasing availability of such technologies might support consideration of these circumstances as exceptional, thus allowing a pharmacist to be responsible for more than one pharmacy at the same time.
- Q. *What is your view of the two examples in providing a possible case for an exception to the one pharmacy/one responsible pharmacist “rule”?***
- Q. *Are there other exceptional circumstances where you think a pharmacist might be responsible for more than one pharmacy at the same time?***
- 7.15 Subject to receipt of further views on the examples given, and any other examples of possible exceptional circumstances that might be put forward, the Government recognises that it may be more appropriate to seek views on the second example in the wider context of consultation on the regulations relating to pharmacist supervision (see Chapter 9). The Government is consulting on the content of these regulations later, including the ability of the responsible pharmacist to supervise individual transactions remotely, using appropriate technologies.

Compliance with conditions that will allow a pharmacist to be responsible for more than one pharmacy at the same time

- 7.16 In addition to specifying exceptional circumstances that will allow a pharmacist to be responsible for more than one pharmacy at the same time, there will also be a need to comply with conditions specified in the regulations. During informal consultation, the Government put forward proposals on what these conditions might be. These proposals, together with initial views emerging from informal consultation, are set out below.

Capacity to Exercise the Statutory Duty

- 7.17 The Government believes that the responsible pharmacist must be able to meet his/her statutory responsibilities fully and effectively in each of the pharmacies for which s/he is responsible. For example, the responsible pharmacist will need to assess his/her capacity to ensure the safe and effective sale and supply of medicines and his/her capacity in relation to other services provided in each of the pharmacies (for example, medicines use reviews, advice on self-care). During informal consultation, the majority view was that this was an important condition and should be included in the responsible pharmacist regulations. As part of this consultation, the Government is seeking further views on this proposal.

Q. Do you agree the regulations should include, as a condition, the responsible pharmacist's capacity to be in charge of more than one pharmacy at the same time?

Staff employed in the pharmacies

- 7.18 This proposed condition supports the condition set out above. For example, the responsible pharmacist's capacity and ability to ensure the safe and effective running of each pharmacy for which s/he is responsible will depend, to some extent, on the availability of suitably trained, competent and experienced pharmacy staff (eg a registered pharmacy technician). Thus, the regulations might specify the employment of certain pharmacy staff where a pharmacist is to be responsible for more than one pharmacy at the same time. Informal consultation in early 2007 supported this view but, as part of this consultation, the Government welcomes further views, including whether certain specified staff should be available in one or all of the pharmacies for which a pharmacist is responsible.

Q. Do you agree with the proposal to include in the regulations, as a condition, that certain staff should be available in the pharmacy? What are your reasons for your views?

Q. If you agree, which trained pharmacy staff (eg a registered pharmacy technician) do you think will need to be available in the pharmacy where the pharmacist is responsible for more than one pharmacy at the same time? What are the reasons supporting your view?

Q. Should this be all the pharmacies concerned or, for example, as a minimum one of the pharmacies? What are the reasons supporting your view?

The period for which a responsible pharmacist may be responsible for more than one pharmacy at the same time

7.19 Depending on the nature of the exceptional circumstances involved, the Government proposes a limit to the period during which a pharmacist might be responsible for more than one pharmacy at the same time. For example, such a limit could support re-assessment of the need for such arrangements and if these continue to comply with the regulations.

Q. Do you agree that, subject to the exceptional circumstances, the regulations should specify a limit to the period for which a pharmacist may be responsible for more than one pharmacy at the same time? If so, what are your reasons for supporting this?

Q. What do you suggest that period might be and what are your reasons for this?

Notification that a pharmacist is responsible for more than one pharmacy at the same time

7.20 The Government is seeking views on a proposal that the pharmacy owner or the responsible pharmacist notifies the Royal Pharmaceutical Society of Great Britain or the Pharmaceutical Society of Northern Ireland where the responsible pharmacist is to be in charge of more than one pharmacy at any one time. Such a notification would not require the professional regulatory bodies' agreement before a pharmacist became responsible for more than one pharmacy at the same time. The Government recognises that such an arrangement will need to fit with the programme of routine visits to pharmacies by the RPSGB pharmacy inspectors and, in Northern Ireland, the Department of Health, Social Services and Public Safety (DHSSPSNI) inspectors. However, notification would enable pharmacy inspectors to plan their visits to pharmacies in order to check compliance with the circumstances and conditions specified in the regulations.

7.21 A majority view on this proposal did not emerge during informal consultation. For example, one view is that the responsible pharmacist should be required to note the pharmacy record of each pharmacy concerned when s/he takes on responsibility for the pharmacies at the same time. Another related view put forward is that, as pharmacy inspectors are able to check the pharmacy record when visiting the pharmacies concerned, there should be no requirement to notify the professional regulatory bodies. As no clear view has emerged on this proposal, the Government welcomes further views.

Q. What is your view on the proposal that the professional regulatory bodies are notified of any arrangements where a responsible pharmacist takes on responsibility for more than one pharmacy at the same time? If you agree, who should be required to notify the arrangements – the responsible pharmacist or the pharmacy owner?

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

Each pharmacy concerned should be owned and managed by the same company, partnership or individual

- 7.22 The RPSGB and the PSNI Code of Ethics place a professional requirement on pharmacists to comply with their legal and professional obligations. For example, that the pharmacist's workload or working conditions do not compromise patient care or public safety or prevent others from meeting their legal or professional requirements, particularly in relation to safeguarding patients and the public. In addition, where a pharmacist is employed (ie not under locum pharmacist arrangements) by a pharmacy business to be responsible for a pharmacy, the contract of employment agreed between the pharmacist and the pharmacy owner may set out that s/he may not be employed as a responsible pharmacist for a pharmacy owned by another business.
- 7.23 However, the Government welcomes views on a proposal that, as an added safeguard, that the regulations specify that the same body corporate, partnership or individual must own each pharmacy concerned where a pharmacist is responsible for more than one pharmacy at the same time. Possibly, such a condition might further support the responsible pharmacist in his/her capacity to exercise the statutory duty in respect of each pharmacy for which s/he is responsible, as the responsible pharmacist will be working within the same governance framework for that pharmacy business.

Q. *Do you think the regulations should include a condition that the same company, partnership or individual should own each pharmacy where a pharmacist is responsible for more than one pharmacy at the same time? What are your reasons for taking your view?*

The number of pharmacies for which a pharmacist may be responsible at the same time

- 7.24 The Government proposes that the regulations specify, as one of the conditions, the maximum number of pharmacies for which a pharmacist might be responsible at the same time. The Government believes that such a condition will further support the important condition that the responsible pharmacist must have the capacity and the ability to meet his/her statutory duty in each of the pharmacies for which s/he is responsible. During informal consultation, the majority view was, given the need to meet the exceptional circumstances requirement and the additional need to comply with other specified conditions (eg absence from the pharmacy), the maximum number should be set at two pharmacies.

Q. *Do you agree that the regulations specify the maximum number of pharmacies for which a pharmacist may be responsible at the same time? If so, what are your views on the number of pharmacies (eg two)?*

- 7.25 In addition to views on the proposals for the individual conditions set out above, the Government also welcomes views on whether all or only some of these should be included in regulations. The Government also welcome views on whether there is a need to include further conditions and, if so, what these might be.

Q. *Do you think the regulations need to include all or only some of the conditions outlined above? What are your reasons for this?*

Q. *Are there any gaps – for example, do you propose that other or further conditions need to be set out in the regulations? If so, what are your reasons for this?*

CHAPTER 8

CONDITIONS RELATING TO THE RESPONSIBLE PHARMACIST: SUPERVISION BY THE RESPONSIBLE PHARMACIST OF ACTIVITIES IN A PHARMACY WHERE HE OR SHE IS NOT THE RESPONSIBLE PHARMACIST

- 8.1 The new section 72A inserted in the Medicines Act by the Health Act makes provision for regulations setting out the circumstances in which a pharmacist responsible for one pharmacy may supervise individual transactions relating to the preparation, assembly, sale and supply of medicines in a pharmacy where s/he is not the responsible pharmacist.
- 8.2 For example, such circumstances might include where a pharmacist responsible for pharmacy A asks the pharmacist responsible for pharmacy B to supervise relevant activities in pharmacy A during his/her absence from the pharmacy. Thus, the pharmacist responsible for pharmacy B will continue to exercise his/her statutory duty in relation to pharmacy B whilst s/he is acting as a supervising pharmacist in pharmacy A. The responsible pharmacist for Pharmacy A will also continue to be responsible for safe working in Pharmacy A whilst s/he is absent from Pharmacy A. Both responsible pharmacists will need to comply with the regulations relating to absence from the pharmacy.
- 8.3 In addition, a pharmacist may only supervise the preparation, assembly, sale and supply of medicines in a pharmacy where s/he is not the responsible pharmacist, where s/he complies with the supervision requirements in the pharmacy where s/he is the responsible pharmacist. Currently, this may only be where another pharmacist is present in pharmacy B to supervise individual transactions involving the sale and supply of medicines in that pharmacy or the pharmacy must close for the sale and supply of medicines. In future, with the introduction of the pharmacist supervision regulations, the responsible pharmacist will need to comply with conditions set out in these regulations before being able to agree to supervise in pharmacy A. The Government is consulting on the content of the pharmacist supervision regulations later.

The Responsible Pharmacist

8.4 Meanwhile, the Government welcomes views on whether there is a need for the responsible pharmacist regulations to specify conditions, other than those allowing the responsible pharmacist's absence from the pharmacy, as an additional safeguard where the responsible pharmacist for one pharmacy is supervising individual transactions in another pharmacy where s/he is not the responsible pharmacist. For example, such conditions might include:

- That one or both pharmacies should have suitably trained staff working in the pharmacy(eg a registered pharmacy technician)
- That a pharmacist responsible for one pharmacy (pharmacy B) may supervise individual transactions in another pharmacy where s/he is not the responsible pharmacist (pharmacy A) where the pharmacies concerned have the same pharmacy owner. This, for example, would help ensure that the responsible pharmacists in both pharmacy A and pharmacy B are aware of the pharmacy business's operational policies and activity in both pharmacies. It may also help address any potential conflicts of interest presented to a responsible pharmacist in agreeing to supervise in another pharmacy with a different responsible pharmacist and a different owner.

Q. *Do you think regulations should specify the need to meet certain other conditions (in addition to those allowing absence from the pharmacy) before a pharmacist responsible for one pharmacy is able to supervise transactions in a pharmacy where he is not the responsible pharmacist? If so, what are your reasons for this?*

Q. *What are your views on the conditions identified? Are there others that you consider might be included in the regulations and what are your reasons for suggesting these?*

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

CHAPTER 9

OTHER MATTERS RELATING TO THE RESPONSIBLE PHARMACIST REGULATIONS

- 9.1 In addition to proposals on the content of the responsible regulations, this paper sets out a number of related matters. These are
- - enforcement of the responsible pharmacist regulations
 - the timing of introduction of these regulations – for example, the time needed by pharmacists, pharmacy owners and others to prepare for change
 - the availability of guidance to support introduction of the regulations

Enforcement of the Responsible Pharmacist Regulations

- 9.2 The Health Act inserts a new section 72B into the Medicines Act and amends other sections relating to enforcement of Medicines Act requirements. These amendments place a specific duty on the Royal Pharmaceutical Society of Great Britain (RPSGB) and the Pharmaceutical Society of Northern Ireland (PSNI) to enforce statutory requirements relating to the responsible pharmacist where failure to comply is a matter of professional misconduct. For example, the requirement that pharmacy procedures include matters specified in the regulations. The duty on the RPSGB and the PSNI extends to registered pharmacies located in hospitals or in the community.
- 9.3 The amendments also give the appropriate Health Minister a right of entry to inspect and investigate in relation to provisions in section 72A of the Medicines Act. This reflects current arrangements in Northern Ireland, where the PSNI works with the Department of Health, Social Services and Public Security, Northern Ireland (the DHSSPSNI), which has responsibility for the inspection of pharmacies and action to ensure compliance with statutory requirements.
- 9.4 The new Section 72B in the Medicines Act makes clear that breach of certain provisions in relation to the responsible pharmacist is an offence, subject to the payment of a fine on conviction. This includes failure by the responsible pharmacist to keep and maintain the pharmacy record as required, failure of the pharmacy owner to ensure the responsible pharmacist properly keeps the record and failure of the pharmacy owner to preserve the record for the period set out in the regulations.

Introduction of the Responsible Pharmacist Regulations: Preparing for Change

- 9.5 In relation to enforcement, it will be important to ensure there is a consistent approach to the implementation of the statutory changes with adequate time allowed for pharmacists, pharmacy owners and pharmacy organisations – such as the professional regulatory bodies and others – to prepare for change. In addition, the Government recognises that, at this time, the professional regulatory bodies and others are engaged in a challenging work programme to establish a General Pharmaceutical Council. Therefore, the Government is consulting on the time needed to prepare for the introduction of the responsible pharmacist regulations.

Introduction of the Majority of the Responsible Pharmacist Regulations

9.6 Given the responsible pharmacist requirements replace and clarify the current personal control requirement, and that pharmacists and pharmacy owners are already operating under systems supporting safe operation of the pharmacy (eg Standard Operating Procedures), the Government believes there is scope to introduce the majority of the responsible pharmacist regulations at the same time. These are the regulations providing the statutory framework that underpins the safe and effective running of the pharmacy – the professional and other quality assurance systems that safeguard pharmacy operations and the delivery of safe services to the public. That is regulations in relation to

- the pharmacy procedures
- the pharmacy record
- the ability of the responsible pharmacist to be absent from the pharmacy – recognising that this will be limited to where another pharmacist is present in the pharmacy until introduction of the pharmacist supervision regulations at a later date
- requirements relating to *recent* experience in the relevant pharmacy sector for a pharmacist wishing to be responsible for a pharmacy in that sector (eg hospital or community) or where a pharmacist has not practised as a pharmacist for a period of, for example, three years

9.7 The Government welcomes views on the proposal to introduce the majority of the responsible pharmacy regulations at the same time and what might be a reasonable time period to allow pharmacists, the professional regulatory bodies and others to prepare. During informal consultation, the general view was that it would be unhelpful to have a prolonged preparatory period but that at least 12 months was required to prepare for change. Others thought there was a need for more time to support implementation of change.

Q. *How long do you think pharmacy owners, pharmacists, and others need to prepare for the introduction of the majority of the responsible pharmacist regulations? What are your reasons for putting forward your view?*

A phased approach to the Introduction of other Responsible Pharmacist Regulations

9.8 A view emerging from informal consultation is a need for more time to prepare for introduction of some of the responsible pharmacist regulations – for example, those closely linked to the pharmacist supervision regulations. Therefore, in response to views expressed during informal consultation, the Government is consulting more widely on whether it may be more appropriate to consult on the introduction of certain of the responsible pharmacist regulations in the context of the later consultation on the pharmacist supervision regulations.

The Responsible Pharmacist

- 9.9 The Government has made clear its intention to consult on remote supervision as part of that later consultation. However, the Government also welcomes views on whether consultation on introduction of regulations relating to the ability of a responsible pharmacist to supervise activities in a pharmacy where s/he is not the responsible pharmacist (see chapter 8) should also be part of the later consultation, given the link to the pharmacist supervision regulations.
- 9.10 Section 72A of the Medicines Act provides for regulations specifying the exceptional circumstances and conditions that will allow a pharmacist to be responsible for more than one pharmacy at the same time. In addition to compliance with exceptional circumstances and specified conditions, the responsible pharmacist will need to comply with conditions relating to the pharmacist's ability to be absent from the pharmacy and the pharmacist supervision requirements. The responsible pharmacist must be able to meet his/her statutory duty for safe and effective running of the pharmacy and ensure that s/he is meeting all the conditions that will allow him/her to be responsible for more than one pharmacy at the same time.
- 9.11 At this stage, the Government is seeking views on two possible examples of exceptional circumstances that may prompt consideration of an exception to the one pharmacy/one responsible pharmacist "rule" (see Chapter 7). One example is dependent on the responsible pharmacist's ability to supervise transactions remotely using appropriate new technologies. Therefore, subject to other examples being put forward in response to this consultation, the Government welcomes views on whether it may be more appropriate to seek views on these again (and other examples that may be put forward) in the context of the later consultation on the pharmacist supervision regulations, in particular remote supervision. For example, it may be more appropriate to look at the timing of introduction of these regulations at the same time or following the introduction of the pharmacist supervision regulations.
- 9.12 During informal consultation, the Government sought views on the time needed to prepare for introduction of the regulatory requirements relating to the qualifications and experience needed to be a responsible pharmacist. As made clear in chapter 6, the Government recognises that the timing of introduction of these regulations must take into account the need to ensure there are sufficient pharmacists available to fulfil the role of the responsible pharmacist, whilst maintaining the public's ready access to pharmacist advice and the medicines they need.
- 9.13 The response indicated that it may take some time to develop arrangements to meet some of the proposed requirements but any firmer view on a timetable for change depended on the outcome of public consultation on the proposed content of these regulations and the approach adopted. Therefore, subject to the outcome of consultation on the proposals outlined in chapter 6, the Government welcomes further views on the time needed to prepare for the introduction of regulations relating to the qualifications and experience to be a responsible pharmacist. In particular, the Government is seeking views on the possibility of introducing some of these regulations before others – for example, those relating to the minimum period of recent experience in the relevant pharmacy sector.

The Responsible Pharmacist

9.14 Given views expressed during informal consultation, and subject to the response to consultation on proposals set out in this paper, the Government welcomes views on whether it may be more sensible and appropriate to introduce some of the responsible pharmacist regulations either following or at the same time as introduction of the pharmacist supervision regulations. For example, this may allow pharmacists and pharmacy owners more time to ensure that key responsible pharmacist requirements are in place to enable the responsible pharmacist to exercise the statutory duty (eg pharmacy procedures and the pharmacy record). It will also allow them further time to consider how the specific regulations, for example those relating to the one pharmacy/one responsible pharmacist “rule”, fit with other regulations relating to absence and pharmacist supervision, including remote supervision.

Q. *Do you think it would be helpful to take a phased approach to introduction of other responsible pharmacist regulations?*

Q. *If so, what are your views on the proposal that an option might be to*

i) Consult on the timing of introduction of regulations relating to the circumstances and conditions that will allow a pharmacist to be responsible for more than one pharmacy at the same time as part of later consultation on the pharmacist supervision regulations

ii) Consult on the timing of regulations, relating to the ability of a pharmacist responsible for one pharmacy to supervise activities in a pharmacy where s/he is not the responsible pharmacist, as part of later consultation on the pharmacist supervision regulations

iii) Introduce some of the regulations, relating to the qualifications and experience needed to be a responsible, with the majority of the responsible pharmacist regulations (see chapter 6) – for example, those relating to recent, relevant, experience

Q. *What are the reasons supporting your view?*

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

Guidance Supporting the Introduction of the Responsible Pharmacist Regulations

9.15 During informal consultation, many felt that it would be more appropriate to look to guidance rather than the regulations to provide further details on meeting the responsible pharmacist requirements. For example, earlier in this consultation paper, there are views outlined on a possible need for guidance providing detailed information and advice on developing pharmacy procedures and how the responsible pharmacist is to maintain contact and provide advice to pharmacy staff when absent from the pharmacy.

The Responsible Pharmacist

- 9.16 Some guidance is already available from the professional regulatory bodies, other pharmacy organisations, pharmacy owners (and superintendent pharmacists) on professional and ethical standards and operational systems that need to be in place to assure safe working in the pharmacy (eg Standard Operating Procedures). The Government's view is that, wherever possible, pharmacists and pharmacy owners, should continue to use current guidance and best practice in preparing for the introduction of the responsible pharmacist regulations.
- 9.17 However, the Government welcomes views on the need for further guidance to support introduction of the responsible pharmacist regulations. In particular, the Government is seeking views on the matters that should be included in guidance and who should develop and publish such guidance. For example, for some matters it may be more appropriate for the professional regulatory bodies to provide further guidance or to update current guidance available where these concern professional standards and requirements.
- Q. *Do you think there is a need for specific guidance to support introduction of the responsible pharmacist regulations? If so, what should this cover and what are your reasons for proposing this?***
- Q. *Do you think, for example that the professional regulatory bodies should provide guidance on certain matters? Or is there scope for a joint approach to developing guidance by, for example, the Health Departments and the regulatory bodies? What are your reasons for supporting your view?***

APPENDIX A: SUMMARY OF CONSULTATION QUESTIONS

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?*

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?*

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

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?

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 Responsible Pharmacist

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 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 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 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?*

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 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 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?

ABSENCE FROM THE PHARMACY: Chapter 5

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?***

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? Eg 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 Responsible Pharmacist

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 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 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?

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?

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?

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?

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?***

The proposal is that regulations could specify a minimum period of experience in the *relevant* pharmacy sector and this, eg, 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?***

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?***

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

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?***

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 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?***

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?***
- 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?***

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?***

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?***

APPENDIX B: THE RESPONSIBLE PHARMACIST: FREQUENTLY ASKED QUESTIONS

WHY CHANGE?

A. The current legislation in the Medicines Act 1968 (the Medicines Act) is unclear. There is a requirement that each registered pharmacy must be under the “personal control” of a pharmacist. However, the Medicines Act does not define “personal control” nor does it specify how the pharmacist is to exercise “personal control”.

The Medicines Act requires the sale and supply of medicines, other than general sales list (GSL) medicines, to be under the supervision of a pharmacist. Further, NHS legislation requires the supply of all prescribed medicines to be under the direct supervision of a pharmacist.

The uncertainty about the personal control requirement and the different provisions in the Medicines Act and NHS legislation on pharmacist supervision have resulted in a common interpretation of the law as

- the pharmacist is only exercising personal control if he/she is physically present in the pharmacy at all times just as pharmacist supervision requires the physical presence of the pharmacist
- GSL medicines (where not supplied as part of an NHS prescription) may only be sold from a pharmacy when the pharmacist is present – although there is no requirement for a pharmacist to be present when these medicines are sold from other retail outlets such as a garage shop or newsagents
- If a pharmacy does not have a pharmacist in personal control, (i.e. because the pharmacist is not present in the pharmacy) nothing requiring the presence of the pharmacist (ie the sale or supply of POM and P) may take place.

The uncertainties arising from current legislation

- constrain pharmacists from using their extensive clinical training and expertise to provide a range of other services to patients, other than the dispensing of medicines, both in and away from the pharmacy
- prevent the pharmacist from working with other healthcare professionals away from the pharmacy or providing services to patients in clinics or their own homes
- make it difficult for the pharmacist to engage in continuous professional development or to participate in local health services planning
- hamper better use of the skills and training of other staff working in pharmacies (eg pharmacy technicians)
- prevent the pharmacist from leaving the pharmacy when it is open to the public
- restrict people’s access to medicines - if the pharmacist is not present, they must await his/her return before they may collect prescriptions or purchase GSL medicines or travel to another pharmacy where the pharmacist is present

The Responsible Pharmacist

- highlight the need for change to keep pace with modern pharmacy practice and to enhance the ability of pharmacists to contribute to health strategies that increasingly focus on patient choice, improving public health and the provision of patient care and treatment in the community

There was strong and clear support for legislative change in response to the 2005 consultation on improving pharmacy skill mix. Around 75% of respondents wanted to see clarification of the “personal control” requirement and 80% wanted to see changes to the pharmacist supervision requirements to allow pharmacists to make better use of their skills and training and those of pharmacy staff.

THE PHARMACY

Q. What is the definition of “pharmacy” in relation to the responsible pharmacist?

A. In relation to the responsible pharmacist, “pharmacy” relates to registered pharmacy premises in hospitals and in the community.

The Medicines Act states a pharmacy business is one that concerns the retail sale of medicinal products or the supply of such products in circumstances corresponding to retail sale, excluding those businesses that sell only GSL medicines.

Pharmacy businesses can be carried on by individual pharmacists, partnerships of pharmacists (in Scotland where one or more of the partners is a pharmacist), bodies corporate or a representative of a pharmacist. In all circumstances, lawful conduct of the pharmacy insofar as it concerns the retail sale of medicines at the premises must be under the personal control of someone who is a pharmacist.

The Health Act 2006 (the Health Act) amends the Medicines Act to replace the “personal control” requirement with a requirement that each pharmacy is to have a responsible pharmacist.

THE RESPONSIBLE PHARMACIST

Q. Who will be the responsible pharmacist?

A. Under current legislation, sections 70, 71 and 72 of the Medicines Act require each pharmacy to be under the “personal control” of a pharmacist insofar as this concerns the retail sale of medicines from the pharmacy. The pharmacist “in personal control” is the pharmacist in day-to-day charge of an individual pharmacy.

The Health Act amends sections 70, 71 and 72 to replace the “personal control” requirement with a requirement that each pharmacy is to have a responsible pharmacist. The Health Act also inserts a new section 72A into the Medicines Act to place a statutory duty on the responsible pharmacist to secure the safe and effective running of the pharmacy and sets out a framework of how the responsible pharmacist – the pharmacist in charge of the pharmacy – is to exercise that duty.

The pharmacist in charge of a pharmacy on any day and at any time is the responsible pharmacist.

The Responsible Pharmacist

If a locum pharmacist is the only pharmacist working in the pharmacy, he or she will be the responsible pharmacist – as under current legislation the locum pharmacist is the pharmacist in personal control of the pharmacy if he/she is the only pharmacist in the pharmacy. As now with the “personal control” requirement, if a pharmacy does not have a responsible pharmacist it may not remain open for business involving the sale or supply of medicines. However, changes to the Medicines Act now make clear that the exercise of the statutory duty is not dependent on the responsible pharmacist’s physical presence in the pharmacy at all times. Regulations may provide for the responsible pharmacist’s absence from the pharmacy, whilst s/he remains responsible for the safe running of the pharmacy.

Currently, the Medicines Act makes separate provisions in relation to the pharmacist in “personal control” of the pharmacy insofar as this concerns the retail sale of medicines from the pharmacy (sections 70 to 72) and in relation to the requirement for a pharmacist to supervise the preparation, assembly, sale and supply of medicines (section 10 and section 52). The Health Act 2006 amends the Medicines Act to replace the “personal control” requirement with a requirement that each pharmacy is to have a responsible pharmacist. There continue to be separate provisions in the Medicines Act in relation to the responsible pharmacist (sections 70, 71, 72 and 72A) and the supervision requirements (sections 10 and 52).

In many cases, where there is only one pharmacist working in the pharmacy, he or she will be the pharmacist responsible for the safe operation of the pharmacy and the pharmacist meeting the statutory requirement to supervise individual transactions involving the preparation, assembly, sale and supply of medicines. However, where there are two pharmacists working in the pharmacy, only one of them may be the responsible pharmacist at any one time.

It is for the owner of a pharmacy business, or where the pharmacy business is part of a body corporate the superintendent pharmacist, to ensure that each pharmacy has a responsible pharmacist and to appoint the responsible pharmacist. Where there is more than one pharmacist working in the pharmacy at the same time, one will be the responsible pharmacist although all may be fulfilling the supervision requirements.

Q. When does the responsible pharmacist take on responsibility for the pharmacy?

A. It is a statutory requirement that each pharmacy must have a responsible pharmacist when the pharmacy is operational – ie carrying out activities relating to the retail sale of medicines and their supply in circumstances corresponding to retail sale – ie dispensing.

This will include carrying out some of these activities on the premises when the pharmacy is not open to the public – for example, out of hours and on-call arrangements. If the on-call or out of hours pharmacist is the pharmacist recorded as the pharmacist in charge of the pharmacy on that date and at that time, he or she is the responsible pharmacist. S/he may also be supervising transactions. Only one pharmacist may be responsible for a pharmacy at any one time. Therefore, if another pharmacist is also supervising transactions as part of on-call or out of hours arrangements in the pharmacy, s/he will not be the responsible pharmacist.

The expectation is that such arrangements will be included in pharmacy procedures set down by the responsible pharmacist, who is responsible for ensuring that pharmacy staff (including a supervising pharmacist) work within those procedures.

The pharmacy record will also provide details of the pharmacist responsible for the pharmacy on any date and at any time.

The Responsible Pharmacist

Q. Do these responsibilities include pharmacy staff training?

A. The responsible pharmacist has a statutory duty to secure the safe and effective running of the pharmacy. We would expect the responsible pharmacist to set out in the procedures the required skills, training and experience to undertake specified activities in the pharmacy and the pharmacy staff able to take on these responsibilities.

Thus, the responsible pharmacist will need to ensure the availability of suitably trained pharmacy staff to support the safe and effective preparation, assembly, sale and supply of medicines.

Where a pharmacy has a series of locums as the responsible pharmacist, the Government believes that the pharmacy owner (or in the case of a business carried on by a corporate body, the superintendent pharmacist) will have a significant part to play. For example, they can support pharmacy staff in developing their skills and competencies to ensure the delivery of a safe and effective dispensing service and other pharmacy services.

THE SUPERINTENDENT PHARMACIST

Q. What is the difference between the responsible pharmacist and the superintendent pharmacist?

A. Currently, section 71 of the Medicines Act requires that, where a body corporate carries on a pharmacy business, the business must be under the management of a superintendent pharmacist. Where the superintendent pharmacist is not the pharmacist in personal control of pharmacy, it must be under the personal control of a manager or assistant who is a pharmacist and who is subject to the directions of the superintendent pharmacist.

The Health Act amends the Medicines Act to replace the “personal control” requirement with a requirement that each pharmacy is to have a responsible pharmacist. However, there is no change in the responsibilities of the superintendent pharmacist. As now, the responsible pharmacist remains subject to the directions of the superintendent pharmacist.

It may be that in some circumstances, someone is both the superintendent pharmacist and the pharmacist responsible for the pharmacy. However, it is unlikely that a pharmacist taking on the superintendent pharmacist’s role in relation to a large number of pharmacies owned by a company would be in a position to secure the safe and effective running of each pharmacy. Neither is it likely that the superintendent pharmacist would be able to meet any requirements relating to absence from the pharmacy which may be set out in regulations under the new section 72A of the Act. Therefore, the Government’s view is that the superintendent pharmacist has a wider, corporate, management responsibility to ensure that each pharmacy has a pharmacist in charge and the company carrying on the pharmacy business meets statutory, professional and ethical requirements and standards for the retail sale and supply of medicines. The responsible pharmacist is in charge of the day-to-day running of an individual pharmacy.

Some bodies corporate have appointed area managers to support the superintendent pharmacist in carrying out his/her responsibilities. An “area manager” is not the responsible pharmacist. However, it is for bodies corporate to decide on internal arrangements supporting the superintendent pharmacist in carrying out his/her responsibilities.

The Responsible Pharmacist

Q. When will the role of the superintendent pharmacist be reviewed?

A. The 2005 public consultation paper, *Making the Best Use of the Pharmacy Workforce*, sought views on the role of the superintendent pharmacist. The majority of respondents did not put forward a view. However, those who did so felt that this issue should be the subject of a separate consultation following detailed discussion with interested parties. Therefore, at this time, there is no change to the Medicines Act in relation to the responsibilities of the superintendent pharmacist.

PROFESSIONAL ACCOUNTABILITY

Q. Where does the professional accountability lie between the responsible pharmacist and other pharmacists working in the pharmacy?

A. Both the responsible pharmacist and other pharmacists working in a pharmacy are professionally accountable when exercising their professional judgement and in adhering to the professional code of ethics.

In addition, the new section 72A inserted into the Medicines Act requires the responsible pharmacist to secure the safe and effective running of the pharmacy. In exercising that duty, he or she is required to set out procedures for safe working in the pharmacy and is professionally accountable for those procedures. The new section 72B in the Medicines Act sets out that failure to comply with the provisions in section 72A, and any regulations made under section 72A, may constitute professional misconduct. A responsible pharmacist would only be accountable for any failure to comply with these statutory requirements during the period for which s/he is in charge of the pharmacy. The pharmacy record will set out who is the pharmacist responsible for the pharmacy on any date and at any time.

Pharmacy staff, including other pharmacists working in the pharmacy, will be working within the written pharmacy procedures set down by the responsible pharmacist – ie under his/her authority. For example if, in addition to employing a responsible pharmacist for the pharmacy, a pharmacy owner (or the superintendent pharmacist acting on behalf of a pharmacy owner) employs a locum pharmacist to supervise the preparation, assembly, sale and supply of medicines from the pharmacy, the locum pharmacist is required to adhere to procedures for safe working set down by the responsible pharmacist.

If a pharmacist working in the pharmacy, who is not the responsible pharmacist, exercises his/her professional judgement as to divergence from the procedures, he or she is professionally accountable for that decision and for working in that way.

For a pharmacy owned by a body corporate, the superintendent pharmacist has a wider, corporate, responsibility to ensure that each pharmacy has a responsible pharmacist and that the company carrying on the pharmacy business meets statutory, professional and ethical requirements and standards for the retail sale and supply of medicines. Where a body corporate employs a pharmacist as the pharmacist responsible for a pharmacy, the pharmacist is under a statutory duty to secure the safe and effective running of the pharmacy. He or she is also subject to the directions of the superintendent pharmacist.

ONE PHARMACY/ONE RESPONSIBLE PHARMACIST

Q. Can a pharmacist be responsible for more than one pharmacy at the same time?

A. The general “rule” continues to be that each registered pharmacy is to have a responsible pharmacist and that a pharmacist may not be responsible for more than one pharmacy at the same time. Where a number of pharmacists are working in the same pharmacy, only one may be the responsible pharmacist at any one time.

However, the Government’s view is there should be sufficient flexibility to support consideration of exceptions to this general “rule” that may arise in the future. For example, there is already technology available that enables a pharmacist located in one pharmacy to operate a dispensing machine located in another set of registered pharmacy premises in a way that allows him/her to interact with the patient, see and assess the prescription and dispense the medicine(s) required. In such circumstances, it would not be sensible or practical to require a qualified pharmacist to stand by a machine located in one set of premises when another pharmacist controls and operates the machine from elsewhere. Therefore, the Government’s view is that the pharmacist operating the machine could be responsible for two registered pharmacies, the main pharmacy and those premises housing the dispensing machine.

Thus, changes to the Medicines Act include a new provision to allow Health Ministers to specify in regulations the exceptional circumstances in which a pharmacist might be responsible for more than one pharmacy at the same time – and then only subject to compliance with certain conditions set out in the regulations.

Q. What happens if a pharmacy is open for 24 hours?

A. It is unlikely that a single responsible pharmacist will be able to exercise fully and effectively the statutory duty to secure safe and effective working in the pharmacy over a continuous 24-hour period in which a pharmacy is open to the public. Therefore, a pharmacy open for long periods might operate a pattern of shift working involving, for example, three responsible pharmacists. In these circumstances, each pharmacist would assume and hand over responsibility for the pharmacy at given times over the 24-hour period, with this information recorded in the pharmacy record.

The Responsible Pharmacist

Q. Will there be safeguards to ensure that each pharmacy has a responsible pharmacist?

A. There are a number of safeguards – for example

- Sections 70, 71 and 72 of the Medicines Act require each pharmacy to have a responsible pharmacist
- Section 72A(2) states that a pharmacist may not be responsible for more than one pharmacy at the same time, except in circumstances specified by Health Ministers in regulations and then only where there is compliance with certain conditions set out in regulations.
- The statutory duty on the responsible pharmacist includes a requirement to keep a record, in the pharmacy, which provides details of the responsible pharmacist for that pharmacy on any date and at any time. If the record shows that a responsible pharmacist has not handed over to another responsible pharmacist, then the pharmacy will be operating without a responsible pharmacist. This is illegal and the pharmacy must close to the public until another pharmacist takes on responsibility for that pharmacy. It is an offence for the responsible pharmacist to fail to maintain the pharmacy record as required
- The pharmacy owner is under a statutory duty to ensure the pharmacy record is kept properly and to preserve the record for as long as set out in the regulations. Failure to comply with these requirements is an offence
- The responsible pharmacist is required to display a notice, conspicuously in the pharmacy, stating that he or she is pharmacist in charge on that date and at that time, together with his/her registration number

PHARMACY PROCEDURES

Q. Who has responsibility for pharmacy procedures?

A. In exercising his/her statutory duty, the responsible pharmacist is required to establish (if these are not already established), maintain and review procedures that support safe and effective working in the pharmacy. It is important that the responsible pharmacist is able to exercise his/her professional judgement in assessing whether or not comprehensive systems are in place to support safe and effective working in that pharmacy.

Where a body corporate owns the pharmacy, the pharmacy owner is required to have a pharmacist in charge of each pharmacy – a responsible pharmacist. Within a body corporate, the superintendent pharmacist will have an important role in ensuring that the company meets statutory requirements and professional and other standards. Where the superintendent pharmacist is not also the responsible pharmacist for a pharmacy, the responsible pharmacist remains subject to the directions of the superintendent pharmacist. In exercising his/her responsibility, the superintendent pharmacist, for example, may wish to develop model procedures to support the responsible pharmacist in putting in place procedures tailored to the needs of the individual pharmacy.

The Responsible Pharmacist

Q. Will pharmacy procedures need review each time the responsible pharmacist changes – including where the responsible pharmacist is a locum pharmacist?

A. There is no intention to require a major review of procedures each time the pharmacy has a new responsible pharmacist. This is unlikely to be necessary unless there are also other significant staff changes. Frequent changes may also be unsafe if these constantly require staff to work differently.

However, the Government's view is that an incoming responsible pharmacist (including a locum taking on responsibility for the pharmacy) will need to be satisfied there are comprehensive procedures supporting safe working in that pharmacy. If there is a need to make changes, an incoming responsible pharmacist can discuss and agree these with the superintendent pharmacist or the pharmacy owner. The Government is seeking views on the review of pharmacy procedures, including the role of guidance.

Q. Will the requirement on the responsible pharmacist to establish, maintain and review pharmacy procedures supersede SOPs?

A. The pharmacy procedures may include a wide range of matters supporting safe operation of the pharmacy – in addition to those relating to the sale and supply of medicines. However, it is important to be clear that these regulations relate to the Medicines Act and the sale and supply of medicines – the provision of NHS pharmaceutical services is a matter for NHS legislation.

Therefore, for the purposes of these regulations, the Government is proposing that the procedures should include the minimum areas that it would expect to see pharmacy procedures cover in relation to the sale and supply of medicines. The Government is also seeking views on any additional areas that might need to be included – again in relation to the sale and supply of medicines.

Subject to including in the procedures those areas specified in the regulations, in developing pharmacy procedures the Government would expect pharmacists to build on experience and good practice provided by existing SOPs and to take into account guidance available from the professional regulatory bodies and the superintendent pharmacist.

The key difference is that there is now a statutory requirement for each pharmacy to have comprehensive procedures that support safe working in the pharmacy. The Government is proposing that regulations set out that the procedures should be readily accessible to staff and others who need to consult them.

THE PHARMACY RECORD

Q. Who has responsibility for the pharmacy record?

A. The new section 72A inserted into the Medicines Act requires the responsible pharmacist to keep a record, in the pharmacy, of the pharmacist responsible for that pharmacy on any day and at any time. The Government proposes that regulations allow the responsible pharmacist to keep the record in paper or electronic form, provided it is readily accessible to those who need to consult the record.

There is also a statutory duty on the pharmacy owner to ensure the responsible pharmacist keeps the record properly and to preserve the record for the period set out in regulations. It is for the pharmacy owner to fund any arrangements for keeping the record.

Failure to comply with the statutory requirements relating to the pharmacy record is an offence, subject to payment of a fine on conviction.

Those wishing to consult the pharmacy record will include an incoming responsible pharmacist, the pharmacy owner or the superintendent pharmacist in order to exercise the statutory duty to ensure it is properly maintained by the responsible pharmacist, and others such as pharmacy inspectors.

Q. What information must be included in the pharmacy record?

A. The Government proposes that regulations require the responsible pharmacist to record the following information, as a minimum, in the record

- Name and registration number of the responsible pharmacist
- Date and time at which the responsible pharmacist assumes responsibility for the pharmacy
- Date and time(s) the responsible pharmacist is absent from the pharmacy
- Date and time at which the responsible pharmacist ceases to have responsibility for the pharmacy

Thus, the responsible pharmacist will “sign in” and “sign off” the record to indicate when s/he became the responsible pharmacist and when s/he ceased to have responsibility or handed over responsibility to another responsible pharmacist.

As part of consultation on the content of the responsible pharmacist regulations, the Government is also seeking views on what other information might be included.

QUALIFICATIONS AND EXPERIENCE

Q. Will all registered pharmacists be able to be a responsible pharmacist on introduction of these regulations?

A. The Government is consulting on the content of the regulations relating to the qualifications and experience needed to become a responsible pharmacist.

The Government does not propose to introduce any formal, academic, qualification over and above the required training to become a qualified, registered, pharmacist.

Given the primary aim of the Medicines Act is to safeguard the public, the responsible pharmacist's ability to exercise his/her duty effectively is essential if public safety in relation to the preparation, assembly, sale and supply of medicines is to be maintained. The Government's view is that a pharmacist wishing to take on this important role will need some preparation and experience of the relevant pharmacy sector where he/she wishes to be a responsible pharmacist in order to exercise his/her statutory duty.

The responsible pharmacist is required to fulfil a number of requirements. These include responsibility for procedures for safe working, keeping a record of the responsible pharmacist, and compliance with any regulations relating to absence from the pharmacy and the pharmacist's ability to supervise activities from another location (ie remote supervision).

In addition, the Health Act 2006, together with existing provisions in the Medicines Act, provides for changes in the pharmacist supervision requirements. The Government proposes to consult on the content of these regulations later.

Subject to the outcome of consultation on the pharmacist supervision regulations, the responsible pharmacist – in certain circumstances and subject to conditions – will be allowed to permit another suitably trained registered healthcare professional working in the pharmacy (eg a pharmacy technician) to supervise certain aspects of the preparation, assembly, sale and supply of medicines. The responsible pharmacist will also determine whether another suitably trained, registered healthcare professional, and other pharmacy staff, are competent to undertake allocated tasks when the responsible pharmacist is absent from the pharmacy.

The Government recognises that pharmacists, pharmacy owners and others need time to prepare and develop training programmes (pre and post registration). Therefore, it may be that introduction of the regulations relating to qualifications and experience should follow later – for example, following the introduction of the majority of regulations relating to the responsible pharmacist. The Government is consulting on the time needed by pharmacists, pharmacy owners and others to prepare for changes relating to the responsible pharmacist.

Q. Where a responsible pharmacist takes a career break, on return will s/he need to practise for a minimum period before s/he is able to be a responsible pharmacist again?

A. During consultation on these regulations, the Government is seeking views on the minimum period of experience required by a pharmacist before taking on the role of the responsible pharmacist. For example, experience of the relevant sector (eg community or hospital) in which he or she wishes to become a responsible pharmacist, including how recent that experience should be. The Government is also seeking views on a requirement that a pharmacist returning to practise should have a minimum period of experience before taking on the role of the responsible pharmacist.

Q. What about pharmacists who have trained in Europe?

A. The Health Act inserts a new section 72A into the Medicines Act, which makes provision for Ministers to set out in more detail in regulations the qualifications and experience that a pharmacist must have if s/he is to be a responsible pharmacist. During passage of the Health Act, the Government made clear there was no intention to introduce any requirement for significant, additional, qualification over and above registration of a pharmacist. As a matter of European law, the United Kingdom recognises the qualifications of a pharmacist who has qualified in another member state. The Government does not intend that anything in the responsible pharmacist regulations should be inconsistent with that legal requirement. To qualify to practise as a responsible pharmacist in the UK, it will be sufficient to have undertaken a period of registration as a pharmacist in another member state – in the same way as in the UK. For example, working in a community pharmacy in another member state for a required period would satisfy the proposed “experience” requirement in these regulations.

Q. But what about pharmacists trained in Europe being unable to be in personal control of a pharmacy registered for less than 3 years?

A. The provisions of the Medicines Act are based on article 2(2) of EC Directive 85/433 - the Council Directive on the Mutual Recognition of Qualifications in the Field of Pharmacy. This states “.....member states need not give effect to [European] diplomas with respect to the establishment of new pharmacies open to the public. For the purposes of applying this Directive, pharmacies which have been in operation for less than three years shall also be regarded as new.” From October 2007, Directive 2005/36/EC repeals and replaces EC Directive 85/433 but, in article 21(4), it contains an almost identical provision to article 2(2).

This article provides a derogation from the general rule that, as a matter of European law, the qualifications of a pharmacist who has qualified in another member state must be recognised. The Government’s view is that member states may choose or may not choose to take up this discretionary derogation. However, having implemented it in the Medicines Act 1968, further legislation would be required to change the current position.

The derogation for which the Directives provide was originally sought by a UK Member of the European Parliament because pharmacy owners in the UK felt they were not in a comparable position to those in other parts of Europe. In a number of EU countries, the owners of pharmacy businesses are required to be pharmacists. In the UK, this is not the case although each registered pharmacy must have a pharmacist in charge. Therefore, UK pharmacy owners would be unable to develop their businesses within Europe unless they were qualified pharmacists, whereas European trained pharmacists would have the freedom to establish pharmacy businesses in the UK.

In recent years, the number of new pharmacies that have opened has increased. Therefore, there may need to be a fresh look at the provision in the Medicines Act relating to pharmacists who may be in charge of a pharmacy open for less than three years. In doing so, the Government will need to assess support for any change from all pharmacy interests in the UK and is prepared to listen and receive views from all concerned on this issue.

Meanwhile, a pharmacist qualified in an EU member state may be in charge of a pharmacy registered for three years or more. Where the pharmacy has operated for less than three years, a pharmacist qualified in the EU may be employed as a pharmacist *supervising* the sale and supply of medicines from the pharmacy.

ABSENCE FROM THE PHARMACY

Q. What is the definition of absence?

A. Absence refers to periods when the responsible pharmacist is away from the registered pharmacy premises for which he/she is responsible. This may be for a number of reasons. For example

- a session working with other healthcare professionals in a local clinic
- visiting patients at home, or in a residential care home, to monitor and provide advice on the effective use of prescribed medicines
- where a pharmacist is a member of the clinical team working with the PCT on the commissioning and development of local health services
- training as part of continuing professional development
- seeing patients in a consulting room in the non-registered area of the pharmacy

The consultation on the content of the responsible pharmacist regulations seeks views on the responsible pharmacist's absence from the pharmacy in relation to sale and supply of medicines from the pharmacy. It is important to look at these requirements in the context of the Medicines Act, which concerns the safe sale and supply of medicines. Any requirements on a pharmacist to be present in the pharmacy to provide pharmacy services other than the dispensing and sale of medicines do not come within the Medicines Act. This is a matter for NHS legislation on the provision of NHS pharmaceutical services.

Q. How can the responsible pharmacist be absent?

A. In relation to regulations on the ability of the responsible pharmacist to be absent from the pharmacy, the Government proposes that these set out the minimum proportion of time that a responsible pharmacist should spend in the pharmacy. During passage of the Health Act, the Government gave a commitment to Parliament that this should be the majority of the responsible pharmacist's time (ie greater than 50%).

The Government also proposes that regulations set out the maximum time that the responsible pharmacist may be away from the pharmacy during any one period of absence. Thus, where the responsible pharmacist is absent for more prolonged periods (such as sickness or holidays), the pharmacy owner is required (as now) to ensure another pharmacist is available to act as responsible pharmacist or to close the pharmacy.

Other proposals include specifying conditions such as the need to remain contactable so that pharmacy staff can seek advice or request return to the pharmacy and for the responsible pharmacist to be able to return to the pharmacy with reasonable promptness.

Where another pharmacist (who is not the responsible pharmacist) is in the pharmacy supervising dispensing activities, the Government is seeking views on whether this might vary the conditions supporting the responsible pharmacist's absence.

The Responsible Pharmacist

The responsible pharmacist must ensure there is safe and effective working in the pharmacy insofar as this relates to the retail sale of medicinal products and the supply of medicinal products (including GSL medicines) in circumstances corresponding to retail sale – ie dispensing. In exercising that responsibility, he/she must ensure suitably trained, experienced and competent pharmacy staff are available to undertake activities involving the preparation, assembly, sale and supply of medicines to the public. It will be for the responsible pharmacist to specify which pharmacy staff can take on specified activities in the pharmacy and we would expect him/her to make this clear in the pharmacy procedures.

Thus, pharmacy staff will continue to work under the authority of the responsible pharmacist when he/she is absent from the pharmacy, adhering to pharmacy procedures set down by the responsible pharmacist.

Until the pharmacist supervision regulations are introduced, the responsible pharmacist will be limited in his/her ability to be absent from the pharmacy, unless another pharmacist is working in the pharmacy to meet the supervision requirements.

In the future, the expectation is that where there is compliance with the pharmacist supervision regulations, the responsible pharmacist may permit another registered and suitably trained healthcare professional (eg a pharmacy technician) to supervise certain aspects of the sale and supply of medicines, including where the responsible pharmacist is absent from the pharmacy. The Government is not consulting on the pharmacist supervision regulations until later.

Q. Will services be able to continue where the responsible pharmacist is absent?

A. If the responsible pharmacist is absent and there is no other pharmacist in the pharmacy to comply with the current supervision requirements no transactions involving the sale or supply of P or POM medicines (or GSL medicines where part of an NHS prescription) can be made.

On introduction of the pharmacist supervision regulations, the responsible pharmacist, subject to compliance with the regulations, may be absent from the pharmacy where there is no other pharmacist in the pharmacy to supervise individual transactions. These regulations are expected to permit the responsible pharmacist to allow another suitably trained registered healthcare professional (eg a pharmacy technician) to supervise aspects of the sale and supply of medicines provided that the responsible pharmacist is satisfied that he/she is competent to take on this role.

The Government is not consulting on the content of the pharmacist supervision regulations until later.

The Responsible Pharmacist

Q. Will there always be a supervising pharmacist in the pharmacy?

A. In many pharmacies, the pharmacist will be the responsible pharmacist and the pharmacist supervising individual transactions involving the preparation, assembly, sale and supply of medicine.

Therefore, unless the pharmacy has another pharmacist to supervise transactions in his/her absence, the responsible pharmacist must be available to meet the supervision requirement. Otherwise, individual transactions involving the sale and supply of P and POM medicines may not continue. This also applies to GSL medicines where these are part of an NHS prescription.

On introduction of the pharmacist supervision regulations, subject to compliance with these regulations, the responsible pharmacist will have the ability to permit another suitably trained, registered healthcare professional (eg a pharmacy technician) to supervise aspects of the sale and supply of medicines. This includes where the responsible pharmacist is absent from the pharmacy. However, it is expected that certain activities – such as clinical checking of a new prescription – will always need to be undertaken by a pharmacist.

REMOTE SUPERVISION

Q. How is remote supervision different from absence?

A. “Remote supervision” describes circumstances where the responsible pharmacist is away from the pharmacy but is using appropriate technologies to supervise the sale and supply of medicines in the pharmacy from another location. For example, the responsible pharmacist may be located in Pharmacy A and supervising activity in this pharmacy. He/she may also be supervising activities in Pharmacy B by means of appropriate technologies (such as a video link).

During passage of the Health Act through Parliament, the Government made clear its view that telephone links alone would probably be insufficient to support remote supervision. The Government proposes to consult on conditions and circumstances supporting remote supervision as part of wider later consultation on the pharmacist supervision regulations. This will be in the next consultation stage, following that on the responsible pharmacist regulations.

SUPERVISION BY THE RESPONSIBLE PHARMACIST OF TRANSACTIONS INVOLVING THE SALE AND SUPPLY OF MEDICINES IN A PHARMACY WHERE HE/SHE IS NOT THE RESPONSIBLE PHARMACIST

Q. Will a responsible pharmacist be able to supervise individual transactions involving the sale and supply of medicines in another pharmacy, where s/he is not the responsible pharmacist?

A. There may be circumstances where the pharmacist responsible for pharmacy A asks the pharmacist responsible for pharmacy B to supervise transactions in pharmacy A. For example, where the pharmacist responsible for pharmacy A needs to be absent from the pharmacy and expects to be away for the proposed maximum time allowed under the absence regulations and there is no other pharmacist working in pharmacy A.

Subject to meeting the requirements for absence from the pharmacy, if there is another pharmacist working in pharmacy B to meet the current pharmacist supervision requirements, the pharmacist responsible for pharmacy B will be able to meet this request to supervise in pharmacy A. In doing so, the pharmacist responsible for pharmacy B will meet the supervision requirements in pharmacy A but will not take on responsibility for pharmacy A.

Following introduction of the pharmacist supervision regulations (on which the Government is consulting later), it is expected that responsible pharmacist B will be able to meet this request where s/he meets the proposed conditions for absence from pharmacy B and complies with certain conditions set out in these regulations. That is, if s/he is able to permit another suitably trained registered healthcare professional (eg a pharmacy technician) to supervise certain aspects of the sale and supply of medicines in pharmacy B whilst s/he is absent in pharmacy A.

In the meantime, the Government is consulting on possible specified conditions in the responsible pharmacist regulations, in relation to the ability of a pharmacist responsible for one pharmacy to supervise activities in a pharmacy where he/she is not the responsible pharmacist. For example, that the pharmacies concerned have adequate staffing and the same pharmacy owner.

PHARMACY TECHNICIANS

Q. Will a registered pharmacy technician be able to take on a supervisory role?

A. This will be subject to the introduction of the pharmacist supervision regulations. The Government's intention is that these regulations will specify compliance with certain conditions with the responsible pharmacist being satisfied that the registered pharmacy technician is suitably trained and competent to take on this role.

The Government has taken powers in the Health Act, which together with existing powers in the Medicines Act, will allow the responsible pharmacist to permit another suitably trained and registered healthcare professionals (eg pharmacy technicians and, possibly others) working in the pharmacy to supervise certain aspects of the sale and supply of medicines.

However, this will be subject to certain conditions. For example, it is expected the pharmacist will retain the responsibility for clinical assessment of new prescriptions and any changes in a repeat prescription. Other pharmacy staff taking on a supervisory role must be a registered healthcare professional (other than a pharmacist) with the training to do this competently and safely.

The availability of a suitably trained and registered pharmacy technician who is competent to take on a supervisory role will allow the responsible pharmacist to develop and offer a wider range of services in the pharmacy. For example, the responsible pharmacist will be able to maintain a safe and efficient dispensing service whilst he/she is engaged in providing services that make use of the pharmacist's clinical training and expertise in the use of medicines. This will allow the pharmacist to deliver these services elsewhere in the pharmacy (eg in a consulting room that is not part of the registered pharmacy premises) or to be absent from the pharmacy where providing these services in clinics or patients' homes

The Government is not consulting on the pharmacist supervision regulations until later.

DISPENSING DOCTORS

Q. Does this affect dispensing doctors?

A. No, this legislation relates to pharmacists and pharmacies.

HOSPITAL PHARMACIES

Q. How do these changes affect hospital pharmacies?

A. The responsible pharmacist regulations apply to all pharmacies registered with the registrar of the Royal Pharmaceutical Society of Great Britain (in Northern Ireland, the Pharmaceutical Society of Northern Ireland). Therefore, this will include registered pharmacies in hospitals.

Section 52 of the Medicines Act 1968 provides for POM and P medicines to be sold or supplied by a person lawfully conducting a retail pharmacy business, on registered pharmacy premises, under the supervision of a pharmacist. However, section 55 provides a specific exemption for hospitals, such that POM and P medicines can be sold or supplied in the course of the business of a hospital, where that medicine is to be administered (whether in the hospital or elsewhere) in accordance with the directions (or written directions for a POM medicine) of a doctor. This exemption would include the dispensing of a private prescription for a patient receiving treatment privately in the course of the business of that hospital.

Hospitals may choose to have registered pharmacy premises to:

- i) operate a retail pharmacy dispensing prescriptions generated out with the hospital and selling P or GSL medicines to visitors or staff;
- ii) utilise the provision where a registered pharmacy can undertake a de minimis level of wholesale dealing, without a wholesale dealers licence.

ENFORCEMENT

Q. Who is responsible for monitoring compliance?

A. The Health Act inserts a new section 72B into the Medicines Act, in relation to compliance with requirements in the responsible pharmacist regulations. The Health Act also amends sections of the Medicines Act relating to enforcement of the Medicines Act.

In relation to England and Wales, section 108 of the Medicines Act places a duty on the Royal Pharmaceutical Society of Great Britain (RPSGB) to enforce provisions made under section 72A, with corresponding provision for Scotland in section 109 of the Act. The duty on the RPSGB includes matters relating to professional misconduct or an offence (eg the keeping of the pharmacy record). For Northern Ireland, provision is made in section 110 of the Medicines Act.

These amendments also give the appropriate Minister a right of entry to inspect and investigate in relation to provisions in section 72A. This reflects current arrangements in Northern Ireland, where the DHSSPSNI Inspectorate inspects and investigates matters in pharmacies rather than the Pharmaceutical Society of Northern Ireland (PSNI).

The duty on the RPSGB and the PSNI extends to registered pharmacies located in hospitals and the community.

These amendments ensure full and proper enforcement of the responsible pharmacist provisions.

INTRODUCTION OF THE RESPONSIBLE PHARMACIST REGULATIONS

Q. Will pharmacists and pharmacy owners be given time to ensure they are meeting these requirements?

A. Yes. The aim is to introduce the regulations at a pace that will ensure continuing patient safety and public access to medicines and other pharmacy services and allow pharmacists and pharmacy owners enough time to prepare for change.

The Government is consulting on the time needed to introduce these changes and on the need to introduce some regulations before others. For example, further time to support introduction of regulations relating to the qualifications and experience needed to be a responsible pharmacist.

NHS PHARMACY SERVICES

Q. How do these changes fit with the pharmacy contract?

A. The Health Act amends the Medicines Act in relation to the safe and effective running of the pharmacy and both the Medicines Act and NHS legislation relating to pharmacist supervision of the preparation, assembly, sale and supply of medicines. The Medicines Act provisions relate to the sale and supply of medicines. NHS legislation, through the new contractual frameworks for community pharmacy services in England, Wales and Scotland, goes beyond the sale and supply of medicines. For example, these services include health promotion campaigns, sign-posting to other NHS services and stop smoking advice. The new contract for community pharmacy services in Northern Ireland is still being negotiated.

COMMUNICATIONS

Q. What plans are there to communicate these changes to the public and others?

A. The responsible pharmacist requirement clarifies how the pharmacist in charge of a pharmacy is to secure the safe and effective running of the pharmacy insofar as this relates to the safe sale and supply of medicines to the public. These changes to the Medicines Act do not affect the Act's primary aim to safeguard the public but remove uncertainties for pharmacists and pharmacy owners on meeting requirements relating to safe operation of the pharmacy.

Pharmacists and pharmacy owners will wish to ensure that those using their pharmacies understand these changes. For example, that they

- May identify the pharmacist in charge of the pharmacy on that day and at that time – through display of a notice in the pharmacy
- May buy GSL medicines from the pharmacy (where not part of an NHS prescription) when the pharmacist is not present in the pharmacy and that advice on the use of these medicines is available. The Government recognises the public will continue to choose to purchase these medicines from a pharmacy in order to be able to access professional advice unavailable in other retail outlets. Therefore, the expectation is that pharmacy procedures will include arrangements for the sale of GSL medicines, which staff are competent to provide advice on the use of these medicines when the pharmacist is away from the pharmacy, and when staff must seek the further advice or involvement of a pharmacist prior to sale.
- Know the times when the pharmacist is available for consultation and advice