



The Medicines (Pharmacies)(Responsible Pharmacist)Regulations 2008: Guidance

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INTRODUCTION

BACKGROUND

1. The four UK Health Departments have published plans for developing NHS pharmaceutical services. These, together with the introduction of changes to the NHS community pharmacy contractual arrangements in England, Scotland and Wales, are part of action to improve

- patients' and the public's access to and choice of services
- public health and help tackle inequalities in health
- support in the community for people with long term conditions
- the provision of professional advice, including support for self care.

2. The changes to the Medicines Act 1968 ("the Medicines Act") and related NHS legislation support delivery of these plans, whilst maintaining public safety in relation to the dispensing and sale of medicines. The Health Act 2006 (the Health Act") amends the Medicines Act in relation to the personal control requirement (sections 70 to 72) and pharmacist supervision of the preparation, dispensing, sale and supply of medicines from registered retail pharmacies (section 10 and section 52) and amends NHS legislation relating to *direct* pharmacist supervision of medicines supplied on an NHS prescription.

3. This guidance provides information on the amendments to the Medicines Act relating to the personal control requirement and the new responsible pharmacist requirements. **It does not concern the statutory changes relating to the requirements on pharmacists to supervise the preparation, sale and dispensing of medicines - which will be the subject of later Government public consultation (see below).**

THE MEDICINES ACT 1968: WHERE THERE IS NO CHANGE

4. Sections 70, 71 and 72 of the Medicines Act continue to require

- A pharmacist to be in charge of a registered pharmacy owned by an individual or a partnership (section 70), a body corporate (section 71) or a pharmacy business carried on by a representative of a pharmacist (section 72), where the pharmacy business relates to the sale and supply of medicines.
- Each registered pharmacy must have a pharmacist in charge of the pharmacy – the one pharmacy/one pharmacist "rule"
- That where a body corporate carries on the pharmacy business, a superintendent pharmacist must have management responsibility for the keeping, preparing and dispensing of medicines
- That where the superintendent pharmacist is not in charge of a registered pharmacy, it must be in the charge of another pharmacist who is subject to the directions of the superintendent pharmacist

CHANGES TO THE MEDICINES ACT 1968: SECTIONS 70 TO 72

5. The Health Act makes the following changes to sections 70 to 72 of the Medicines Act.

Removal of the Personal Control Requirement

6. Currently, sections 70 to 72 of the Medicines Act require each pharmacy business to be under the personal control of a pharmacist. The personal control requirement relates to the sale and supply of **all** medicines, including those on the general sale list (GSL medicines).

7. The Medicines Act does not define “personal control” nor does it set out how the pharmacist is to comply with this requirement. There is little case law. The common interpretation of “personal control” is that the pharmacist must be physically present in the pharmacy in order to comply with this requirement and to enable the sale or supply of **all** medicines to continue, including those on the general sale list (GSL medicines). This advice has created an anomaly in relation to the sale of GSL medicines from pharmacies, as there is no requirement on other retail outlets that sell only these medicines (eg a garage shop or newsagents) to have a pharmacist present to permit sale.

8. To define more clearly the role of the pharmacist in charge of the pharmacy, sections 27, 28 and 29 of the Health Act amend sections 70, 71 and 72 of the Medicines Act to remove the “personal control” requirement and to provide for a new requirement for a responsible pharmacist to be in charge of each registered pharmacy. Like “personal control”, the new requirement relates to all registered pharmacies in the community and in hospitals. If a pharmacy does not have a responsible pharmacist, it is operating illegally in relation to the retail sale and supply of all medicines.

The New Responsible Pharmacist Requirement

9. The new requirement makes clear that the responsible pharmacist is “*in charge of the business at the premises*” where this relates to the retail sale and supply (ie in circumstances corresponding to retail sale) of all medicinal products, including GSL medicines. This is a Medicines Act requirement that relates to the sale and supply of medicines. **It does not concern the provision of NHS pharmaceutical services that do not involve the sale or supply of medicinal products (eg screening or diagnostic testing) – which is a matter for separate NHS law.**

Display of Information relating to the Responsible Pharmacist

10. Sections 70 to 72 require the pharmacist in personal control to display, conspicuously in the pharmacy, his/her name and registration certificate. In practice, most pharmacists display their registration certificates when working in a registered pharmacy. Thus, where there is more than one pharmacist working in a pharmacy at the same time, it may be unclear to the public and others which pharmacist is in charge.

11. The Health Act 2006 amends these sections of the Medicines Act to require the responsible pharmacist to display a notice, conspicuously, in the pharmacy stating that s/he is the pharmacist in charge of the pharmacy on that date and at that time, together with details of his/her registration number. The notice will make clear to all those using the pharmacy who is the pharmacist in charge. It also means that pharmacists no longer have to carry their registration certificates around with them for display in each pharmacy in which they may be working.

CHANGES TO THE MEDICINES ACT 1968: THE NEW SECTION 72A

12. Section 30 of the Health Act inserts a new section 72A into the Medicines Act, placing a legal duty on the responsible pharmacist to secure the safe and effective running of the pharmacy in relation to the retail sale and supply of all medicines.

The Legal Duty on the Responsible Pharmacist

13. As with the responsible pharmacist requirement in sections 70, 71 and 72, the legal duty relates to the sale and supply of **all** medicinal products (including those on the general sale list) at the registered pharmacy premises.

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Again, it is important to be clear that the duty relates to the sale and supply of medicines - it does not concern the provision of NHS pharmaceutical services that do not involve the sale or supply of medicinal products (eg screening or diagnostic testing), which is a matter for separate NHS law.

The One Pharmacy/One Responsible Pharmacist “Rule”

14. Section 72A(2) states a pharmacist may be responsible for only one pharmacy at the same time - thus, the one pharmacy/one pharmacist “rule” continues. Where more than one pharmacist is working in a pharmacy at the same time, only one may be the responsible pharmacist in charge of the pharmacy.

15. However, section 72A (2) allows a pharmacist, **exceptionally**, to be responsible for more than one pharmacy at the same time but **only** in the circumstances set out in the regulations **and** in compliance with specified conditions set out in the regulations. The Government intends to bring forward these regulations later.

Complying with the Legal Duty

16. Section 72A sets out how the responsible pharmacist is to comply with the duty. S/he must

- Establish (where not already in place), maintain and review pharmacy procedures designed to secure the safe and effective running of the pharmacy – section 72A(3)
- Make a record (which must be available at the pharmacy premises) of the pharmacist responsible for the pharmacy on any date and at any time – section 72A(4)

The Legal Duty on the Pharmacy Owner

17. Section 72A also places a legal duty on the pharmacy owner to

- Ensure that for each registered pharmacy, the responsible pharmacist maintains the pharmacy record as required – section 72A(5)(a)
- Preserve the pharmacy record for the required period set out in the regulations –section 72A(5)(b)

Regulations under Section 72A

18. In addition, section 72A makes provision for regulations concerning

- The circumstances and conditions that allow a pharmacist, exceptionally, to be responsible for more than one pharmacy at the same time – section 72A(2)
- The preservation of the pharmacy record – section 72A(5)
- How the responsible pharmacist is to comply with the legal duty to secure the safe and effective running of the pharmacy - section 72A(6) and the matters that may be covered by the regulations (section 72A(7)) including the
 - Qualifications and experience needed to be a responsible pharmacist – subsection (7)(a)
 - Responsible pharmacist’s absence from the registered pharmacy premises – subsection (7)(b)

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- Ability of the responsible pharmacist to supervise the dispensing and sale of medicines in a location other than the pharmacy (known as “remote” supervision) – subsection (7)(c)
- Circumstances in which a responsible pharmacist may supervise the dispensing and sale of medicines in a pharmacy where s/he is not the responsible pharmacist –subsection (7)(d)
- Form in which the pharmacy procedures are to be kept and the matters to be covered by the procedures –subsection (7)(e)
- Form in which the pharmacy record is to be kept and the information to be included in the record – subsection (7)(f)

Section 72A: The Medicines (Pharmacies) (Responsible Pharmacist) Regulations 2008

19. The Medicines (Pharmacies)(Responsible Pharmacist) Regulations 2008 (“the Regulations”) set how the responsible pharmacist is to comply with the legal duty in relation to

- the pharmacy procedures
- the pharmacy record, and
- his/her absence from the pharmacy

The Regulations are available at

www.dh.gov.uk/publications/en/Publicationsandstatistics/Legislation/Statutoryinstruments/index

or

www.opsi.gov.uk/si/si2008/uksi_20082789_en_1

CHANGES TO THE MEDICINES ACT 1968: THE NEW SECTION 72B

20. Section 30 of the Health Act also inserts a new section 72B into the Medicines Act, which provides for the responsible pharmacist’s failure to comply with the requirements under section 72A and the Regulations to be a matter of professional misconduct, other than where failure relates to the keeping of the pharmacy record. Where the responsible pharmacist fails to keep the record as required in section 72A(4) and the Regulations, s/he will be guilty of an offence subject on conviction to the payment of a fine. The pharmacy owner will also be guilty of an offence where failing to ensure the responsible pharmacist keeps the pharmacy record or where the owner fails to preserve the record for at least the period set out in the Regulations – section 72A(5).

HEALTH ACT 2006: OTHER CHANGES TO THE MEDICINES ACT

21. Section 30 of the Health Act amends

- Section 77(b) of the Medicines Act (the annual return of premises to the registrar), which requires the pharmacy owner, in January each year, to inform the registrar of the name of the pharmacist in personal control of the registered pharmacy. Instead, the responsible pharmacist is required to make a record, which must be available at the pharmacy premises, of the pharmacist responsible for the pharmacy at any time and on any date

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- Section 84 of the Medicines Act to includes offences under the Act relating to the pharmacy record. (See paragraph 20 above).

22. Section 31 makes changes to sections 108,109 and 110 of the Medicines Act in relation to enforcement of the new provisions in sections 70 to 72A and the Regulations in relation to matters of professional misconduct. These reflect the current arrangements. In England, Scotland and Wales, the Royal Pharmaceutical Society of Great Britain (RPSGB) has statutory responsibilities relating to the professional regulation of pharmacists and the registration and inspection of registered pharmacies. In Northern Ireland, the Pharmaceutical Society of Northern Ireland (PSNI) is the professional regulatory body and has responsibilities for the registration of pharmacy premises with the Department of Health, Social Services and Public Safety (the DHSSPSNI), undertaking the inspection of registered pharmacies. In relation to the pharmacy record, section 30 amends sections 108,109 and 110 to provide for the professional regulatory bodies, together with the appropriate Minister, to enforce these requirements.

23. Currently, the Government is consulting on the draft Pharmacy Order 2009, which will establish a new General Pharmaceutical Council (GPhC) to replace the RPSGB as the professional regulator for pharmacists in 2010. The GPhC will provide an integrated regulatory framework for pharmacy covering professionals (pharmacists and pharmacy technicians) and the environment in which they practise (premises and pharmacy owners) in England, Scotland and Wales.

WHEN DO THESE LEGISLATIVE CHANGES COME INTO FORCE?

24. The Health Act changes to the Medicines Act relating to the responsible pharmacist will come into force at the same time as the Regulations – that is on **1 October 2009**.

25. These changes to the Medicines Act, together with the Regulations, make clear

- That the responsible pharmacist is the pharmacist in charge of the pharmacy
- What the responsible pharmacist must do to comply with the legal duty to secure the safe and effective running of the pharmacy.
- That the safe and effective running of the pharmacy is **not** solely dependent on the responsible pharmacist's physical presence in the pharmacy – **the responsible pharmacist must ensure that s/he complies with the legal requirements set out in section 72A and the Regulations. Therefore, pharmacy owners and pharmacists must be clear that, alone, the responsible pharmacist's mere physical presence in the pharmacy is not sufficient to indicate that s/he is meeting the legal duty to secure the safe and effective running of the pharmacy.**
- That the responsible pharmacist may be absent from the pharmacy whilst it is operational for the prescribed maximum period set out in the Regulations and where able to comply with the specified conditions for absence – See Chapter 2. **The responsible pharmacist is required to ensure the pharmacy is operating safely and effectively at all times that s/he is responsible for the pharmacy, including any periods during that time that s/he is not present on the registered pharmacy premises (ie absent).**
- That whilst the responsible pharmacist has a legal duty to secure the safe and effective running of the pharmacy in relation to **all** medicines, GSL medicines (where not part of an NHS prescription) may be sold when the responsible pharmacist is not present in the pharmacy. This will bring pharmacies more into line with other retail outlets that only sell these medicines, where there is no requirement for a pharmacist to be present at the time of sale.

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- How these legal requirements are to be enforced.

26. The changes also make clear the separate provisions in the Medicines Act relating to the safe and effective running of the pharmacy (sections 70,71,72 and 72A) and those relating to the requirements on pharmacists to supervise individual transactions involving the preparation, dispensing and sale of medicines (sections 10 and 52).

THE PHARMACIST SUPERVISION REQUIREMENTS

27. The Government has stated its intention to consult on proposals for the content of the supervision regulations later. That consultation will include proposals for the content of regulations under section 72A(7) of the Medicines Act on the pharmacist's ability to supervise the dispensing and sale of medicines from a location other than the pharmacy (known as "remote supervision") and supervision by the responsible pharmacist in a pharmacy where s/he is not the responsible pharmacist. The aim is to support consideration of these proposals within the context of wider consultation on pharmacist supervision. Thus, this guidance does not concern

- regulations to be made under section 72A(7)(c) and section 72A(7)(d) of the Medicines Act
- the Medicines Act requirements on the pharmacist to supervise the sale and supply of Pharmacy (P) medicines and Prescription Only Medicines (POMs)
- NHS legislation requiring *direct* pharmacist supervision of the dispensing, sale and supply of *all* medicines where part of an NHS prescription (ie General Sale List (GSL), POM and P medicines)

28. The current pharmacist supervision requirements will continue until the Health Act changes to the Medicines Act and NHS legislation and the regulations ("the supervision regulations") come into force at a future date. Therefore, pharmacists and the owners of pharmacy businesses must ensure there is compliance with the current supervision requirements in sections 10 and 52 of the Medicines Act in respect of each prescription dispensed and "P" (Pharmacy only) medicine supplied. Where a pharmacy dispenses NHS prescriptions, there is also a need to comply, as appropriate, with the requirements in the National Health Service (Pharmaceutical Services) Regulations 2005, the Pharmaceutical Services Regulations (Northern Ireland) 1997 and the National Health Services (Pharmaceutical Services)(Scotland)Regulations 1995.

CONTENT OF GUIDANCE

29. This guidance includes information on the changes to sections 70 to 72 of the Medicines Act, the new sections 72A and 72B inserted into the Act, and the regulatory requirements in the Regulations:

- **Chapter 1** looks at the legal duty on the responsible pharmacist and the role and responsibilities of the superintendent pharmacist in a body corporate, the NHS hospital trust chief pharmacist (in Scotland, the Health Board Director of Pharmacy) and the pharmacy owner
- **Chapter 2** looks at the ability of the responsible pharmacist to be absent from the pharmacy, including the maximum time s/he may be absent when the pharmacy is operational and the need to comply with certain conditions for absence
- **Chapter 3** concerns the pharmacy procedures and the legal requirement on the responsible pharmacist to establish, review and maintain the procedures
- **Chapter 4** looks at the legal requirements on the responsible pharmacist and the pharmacy owner in relation to the pharmacy record

STATUS OF GUIDANCE

30. **This is not statutory guidance and neither does it represent an authoritative statement on the law.** There is no substitute for reference to the law itself or for seeking professional legal advice as to what the law says or how it applies in particular circumstances. It is recommended that pharmacists, the owners of pharmacy businesses (as defined in Section 69 of the Medicines Act), which are registered under section 75 of that Act, superintendent pharmacists (as defined in section 71 of that Act) and pharmacy organisations ensure their actions and decisions are in accordance with the law. They should not place sole reliance on the advice contained in this guidance (or any other commentary on the law). Therefore, those consulting this guidance should do so with reference to the Acts of Parliament, the Responsible Pharmacist Regulations, and related regulations mentioned above.

31. In addition, there is professional guidance issued by the professional regulatory bodies - the Royal Pharmaceutical Society of Great Britain and the Pharmaceutical Society of Northern Ireland – including Codes of Ethics and associated papers setting out relevant professional requirements on pharmacists and standards of pharmacy practice. The RPSGB and the PSNI have prepared draft professional regulatory standards and good practice guidance relating to the responsible pharmacist requirements. The aim is publish these later in 2009.

CHAPTER 1: THE RESPONSIBLE PHARMACIST

Who is the responsible pharmacist?

1.1. **The responsible pharmacist is the pharmacist in charge of a registered pharmacy on any day and at any time.** Only one pharmacist may be responsible for a pharmacy at any one time.

1.2. For example, in many pharmacies, only one pharmacist will be working in the pharmacy and s/he will be meeting the legal requirement that each pharmacy has a responsible pharmacist and the requirement for a pharmacist to supervise the dispensing, sale and supply of medicines. However, where more than one pharmacist is working in a pharmacy at the same time, only one may be the responsible pharmacist but both may be meeting the separate supervision requirements. (The requirements for a pharmacist to supervise the dispensing, sale and supply of medicines are separate and distinct from the legal duty on the responsible pharmacist to secure the safe and effective running of the pharmacy. The supervision requirements are set out in sections 10 and section 52 of the Medicines Act and related NHS legislation. These will not change until the relevant provisions in the Health Act 2006 and the supporting regulations (“the supervision regulations”) come into force. The Government intends to consult with all interests on proposals for these changes later).

The Legal Duty on the Responsible Pharmacist

1.3. The new section 72A of the Medicines Act places a legal duty on the responsible pharmacist to secure the safe and effective running of the pharmacy. As with “personal control”, this requirement extends beyond the separate pharmacist supervision requirements in the Medicines Act and related NHS legislation. The pharmacist in charge of a pharmacy has wider responsibilities relating to the overall safe and effective operation of the pharmacy business where this concerns medicines. To comply with the legal duty, the responsible pharmacist must ensure there are procedures for safe working in the pharmacy and make a record of the pharmacist in charge of the pharmacy on any date and at any time. In addition, to comply with changes to sections 70 to 72 of the Act, the responsible pharmacist must display a notice in the pharmacy, stating s/he is the pharmacist in charge of the pharmacy on that date and at that time, together with details of his/her registration number.

The Responsible Pharmacist: Presence in the Pharmacy

1.4. **It is important to be clear that compliance with the legal duty is not solely dependent on the responsible pharmacist’s physical presence in the pharmacy.** The legal duty requires the responsible pharmacist to secure the safe and effective running of the pharmacy **at all times that s/he is in charge of the pharmacy**. This includes where the pharmacy is operating but not open to the public (eg out of hours and on-call arrangements) and whether or not the responsible pharmacist is present in the pharmacy – for example, where s/he

- is present on the registered pharmacy premises
- is working in an area adjacent to the registered premises (eg a consultation room within the pharmacy but outside the registered premises area)
- is absent from the pharmacy (eg working with another healthcare professional in a health centre or consulting with a patient in a clinic)

The Responsible Pharmacist: Absence from the Pharmacy

1.5. Section 72A(7)(b) of the Medicines Act allows the responsible pharmacist to be absent from the pharmacy. **Absence is not mandatory.** This provision enables the responsible pharmacist to be absent whilst remaining

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responsible for the safe and effective running of the pharmacy – but only where s/he complies with the specified conditions for absence in the Regulations. See Chapter 2.

Taking on responsibility for a pharmacy

1.6. On taking on responsibility for a pharmacy, a responsible pharmacist should

- Check that pharmacy procedures are in place and be satisfied that these support the safe and effective running of the pharmacy (see Chapter 3).
- Enter the required information in the pharmacy record (See Chapter 4)
- Display a notice, conspicuously, in the pharmacy stating s/he is the pharmacist in charge of the pharmacy on that date and at that time, together with details of his/her registration number.

Taking on Responsibility for More than One Pharmacy at the Same Time

1.7 The general “rule” continues to be that a pharmacist may only be responsible for one pharmacy at a time. However, section 72A(2) of the Medicines Act enables Ministers to set out in regulations the circumstances and conditions that will allow a pharmacist, exceptionally, to be responsible for more than one pharmacy at the same time. The Government intends to introduce these regulations later.

Locum Pharmacists

1.8. As with the “personal control” requirement, the pharmacy must have a responsible pharmacist to continue to operate legally in relation to the retail sale and supply of medicines. Therefore, if there is only one pharmacist working in the pharmacy, then s/he is in charge of the pharmacy - ie the responsible pharmacist - **whether working as a locum or as the pharmacist employed by a pharmacy owner to work each day in the same pharmacy.** As the responsible pharmacist, s/he must comply with the legal duty to secure the safe and effective running of the pharmacy and the legal requirements set out in section 72A of the Medicines Act and the Regulations.

1.9. Therefore, the owners of pharmacy businesses employing locum pharmacists and pharmacists working as locums must be clear as to the basis on which they are working in the pharmacy. For example, if a pharmacy owner employs a locum pharmacist only to supervise the dispensing, sale and supply of medicines, another pharmacist must be available to be the responsible pharmacist – otherwise the pharmacy is operating illegally.

The Pharmacy Owner

1.10. For each type of pharmacy business, there are a number of common legal requirements. All pharmacy owners should be clear as to their role and responsibilities and how this relates to the role of the responsible pharmacists they appoint to be in charge of each of their pharmacies. It is for the owner of a pharmacy business to

- Appoint the pharmacist who is to be responsible for a registered pharmacy.
- Enable each responsible pharmacist to comply with the legal duty – including allowing the responsible pharmacist to exercise his/her professional judgement, as appropriate, in relation to the safe and effective running of the pharmacy concerned.
- Ensure the responsible pharmacist keeps the pharmacy record as required

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- Preserve the record for at least the minimum time set out in the Regulations.

The Superintendent Pharmacist: Bodies Corporate

1.11. Where a body corporate carries on a pharmacy business, section 71 of the Medicines Act requires the business to be under the management of a superintendent pharmacist where this concerns the keeping, preparing, dispensing and sale of medicines. There is no change to the statutory role and responsibilities of the superintendent pharmacist. S/he continues to have an important, corporate, management responsibility to ensure the company carrying on the pharmacy business complies with the legal requirements for the retail sale and supply of medicines and the company's policies and governance framework reflect ethical and professional standards for pharmacists and pharmacy practice set down by the professional regulatory bodies.

1.12. Thus, the superintendent pharmacist has a wider legal role - separate but complementary to that of the responsible pharmacist. In carrying out his/her legal and professional responsibilities, the superintendent pharmacist provides the overarching operational framework for the company's pharmacies – and this should support each responsible pharmacist in complying with the legal duty to secure safe and effective running of the individual pharmacy.

1.13. A superintendent pharmacist may also be the responsible pharmacist for a particular pharmacy. However, where a company owns a large number of pharmacies, the superintendent pharmacist is unable to meet the legal requirements relating to the responsible pharmacist - the pharmacist in charge of the day-to-day running of an individual pharmacy. For example, the superintendent pharmacist is not in a position to secure the safe and effective running of each pharmacy or to comply with requirements relating to the responsible pharmacist's absence from the pharmacy. Therefore, where not also the responsible pharmacist, the superintendent pharmacist will need to ensure that another pharmacist is responsible for each pharmacy owned by the company. As now, these pharmacists remain subject to the directions of the superintendent pharmacist.

1.14. As the company manager of the pharmacy business where this relates to the keeping, preparing, dispensing, and sale of medicines, the superintendent pharmacist should

- Ensure arrangements are in place to appoint the responsible pharmacist in charge of each set of registered premises owned by the company
- Enable each responsible pharmacist to comply with the legal duty – including allowing the responsible pharmacist to exercise his/her professional judgement, as appropriate, in securing the safe and effective running of the pharmacy concerned.
- Ensure the responsible pharmacist keeps the pharmacy record as required
- Ensure preservation of the pharmacy record for at least the minimum time set out in the regulations.

Bodies Corporate: Area Managers

1.15. It is for an individual body corporate to decide on any internal arrangements for meeting the legal requirements on the pharmacy business. For example, some bodies corporate appoint "area managers" to support the superintendent pharmacist in carrying out his/her responsibilities. An area manager is not the pharmacist responsible for an individual pharmacy if s/he is unable to comply with the legal duty to secure the safe and effective running of that pharmacy and the Regulations.

NHS Hospital Trusts – The Chief Pharmacist (in Scotland, the Health Board Director of Pharmacy)

1.16. Each set of registered pharmacy premises owned and operated by an NHS hospital trust must have a responsible pharmacist. Like the superintendent pharmacist in a body corporate with a number of registered pharmacy premises, it is unlikely that the hospital trust chief pharmacist will be able to exercise the legal duty on the pharmacist in charge of each of the trust's registered pharmacies, together with his/her wider responsibilities within the trust. Neither will s/he be able to comply with regulatory requirements, such as absence. Therefore, like the superintendent pharmacist, the hospital trust chief pharmacist should

- Ensure each of the trust's registered pharmacies has a responsible pharmacist and there are arrangements in place to appoint the responsible pharmacist.
- Enable each responsible pharmacist to comply with the legal duty – including allowing the responsible pharmacist to exercise his/her professional judgement, as appropriate, in relation to securing the safe and effective running of the pharmacy concerned.
- Ensure the responsible pharmacist keeps the pharmacy record, as required
- Ensure the preservation of the pharmacy record for the minimum time set out in the regulations.

Roles and Responsibilities in Other Types of Pharmacy Business: Some Examples

1.17. It may also be helpful to look at roles and responsibilities in the context of pharmacy businesses not owned by a body corporate.

A pharmacist owner with one pharmacy

1.18. Where a pharmacist owns one pharmacy, s/he will also be the responsible pharmacist unless s/he appoints another pharmacist to be in charge of the pharmacy. As **the pharmacy owner**, he or she must

- Ensure the pharmacy has a responsible pharmacist, including when s/he is not the responsible pharmacist (for example, where ill or on holiday and unable to meet the absence requirements).
- Enable another pharmacist, appointed as the pharmacist responsible for the pharmacy, to comply with the legal duty - including that pharmacist's ability to exercise professional judgement, as appropriate, in securing the safe and effective running of the pharmacy.
- Ensure the responsible pharmacist maintains the pharmacy record, as required.
- Ensure preservation of the pharmacy record for the minimum time set out in the regulations

1.19. Where a pharmacy owner is also the **pharmacist responsible for the pharmacy**, s/he must comply with the legal duty to secure the safe and effective running of the pharmacy, including the requirements to

- Ensure pharmacy procedures are in place to support the safe and effective running of the pharmacy, and to maintain and keep these under review (see **Chapter 3**).
- Make and maintain the pharmacy record as required (see **Chapter 4**).
- Relating to any absence from the pharmacy (see **Chapter 2**).

A pharmacy business, owned by a pharmacist, with three registered pharmacies

1.20. A pharmacist owning a body corporate with three registered pharmacies may be the superintendent pharmacist and the responsible pharmacist for one of the pharmacies. S/he may not be responsible for more than one pharmacy at the same time unless s/he is able to comply with the circumstances **and** conditions set out in regulations (which are not yet in force). Therefore, the pharmacy owner must appoint another pharmacist to be in charge of the remaining two pharmacies. As **the pharmacy owner** (and superintendent pharmacist), s/he must

- Ensure that each set of registered pharmacy premises has a responsible pharmacist, including when s/he is not responsible for one of the pharmacies (eg when on holiday and unable to meet the absence requirements).
- Enable the pharmacists responsible for the other two pharmacies to comply with the legal duty - including allowing them to exercise their professional judgement, as appropriate, in securing the safe and effective running of the pharmacies concerned.
- Ensure the responsible pharmacists maintain the pharmacy records, as required.
- Ensure the preservation of the pharmacy record(s) in all three pharmacies for the minimum time set out in the Regulations.

1.21. As the **responsible pharmacist for one of the pharmacies**, s/he must comply with the legal duty to secure the safe and effective running of the pharmacy, including

- Ensuring pharmacy procedures are in place to secure the safe and effective running of the pharmacy, and to maintain and keep these under review (see Chapter 3)
- Make and maintain the pharmacy record as required (see Chapter 4)
- Meeting the requirements relating to absence from the pharmacy (see chapter 2)

A pharmacy business, carried on by a representative of a pharmacist, with four registered pharmacies

1.22. Where the representative is not a pharmacist, s/he may not be responsible for any of the four pharmacies owned by the business. However, in representing the pharmacist, s/he must carry out the pharmacy owner's legal responsibilities. S/he must

- Ensure that each set of registered pharmacy premises has a responsible pharmacist.
- Enable each responsible pharmacist to comply with the legal duty - including allowing the responsible pharmacists to exercise their professional judgement, as appropriate, in securing the safe and effective running of each pharmacy concerned.
- Ensure the responsible pharmacists maintain the pharmacy records, as required.
- Ensure the preservation of each pharmacy record for the minimum time set out in the Regulations.

The Responsible Pharmacist: Professional Accountability

1.23. Throughout the time s/he is in charge of the pharmacy, the responsible pharmacist is accountable for any failure to comply with the legal duty and the requirements set out in the Regulations. The pharmacy record will provide details of the pharmacist in charge of the pharmacy on any date and at any time, including when the pharmacist took on responsibility for the pharmacy, when s/he is absent from the pharmacy and when he or she ceased to have responsibility.

1.24. All pharmacists are professionally accountable for the exercise of their professional judgement and adherence to the professional Code of Ethics. Where a pharmacist is in charge of a pharmacy, s/he also has a legal responsibility to secure safe and effective working in the pharmacy. In complying with the legal duty, the responsible pharmacist is required to set out procedures for safe and effective working in the pharmacies. This supports the professional requirement on pharmacists to ensure there are Standard Operating Procedures (SOPs). Thus, the responsible pharmacist is legally and professionally accountable for the pharmacy procedures.

1.25. Pharmacy staff (including other pharmacists working in the pharmacy) should work within the procedures set down by the responsible pharmacist. If another registered pharmacist working in the pharmacy, who is not the responsible pharmacist, exercises his/her professional judgement as to divergence from the procedures set down by the responsible pharmacist, he or she will be professionally accountable for that decision and for working in that way. This also applies to registered pharmacy technicians.

The Responsible Pharmacist: Professional Regulatory Guidance

1.26. The changes to the Medicines Act, together with the responsible pharmacist Regulations, provide a legal framework to underpin professional and ethical responsibilities on pharmacists to ensure safe and effective working in the pharmacy. Therefore, those consulting this guidance should also consult the Code of Ethics and other professional guidance to be issued by the professional regulatory bodies (in England, Scotland and Wales, the Royal Pharmaceutical Society of Great Britain, and in Northern Ireland, the Pharmaceutical Society of Northern Ireland). In particular, that guidance draws attention to the professional standards set down for pharmacists and pharmacy technicians who are in positions of authority, including the responsible pharmacist, the superintendent pharmacist and those pharmacists who own pharmacy businesses.

CHAPTER 2: ABSENCE OF THE RESPONSIBLE PHARMACIST FROM THE PHARMACY: SECTION 72A OF THE MEDICINES ACT AND REGULATION 3

2.1. As the Medicines Act does not define “personal control” or how the pharmacist is to comply with this requirement, the commonly used interpretation is that the pharmacist is in control only where physically present on the registered pharmacy premises, thus allowing the sale and supply of medicines to continue. This interpretation is closely associated with the separate Medicines Act and NHS statutory requirements relating to pharmacist supervision of the dispensing, sale and supply of medicines. In addition, the provision of NHS pharmaceutical services (for example, the availability of services during contracted “core” hours), is also seen as coming within the “personal control” requirement, supporting the view that the pharmacist is required to be physically present in the pharmacy at all times when it is operational.

2.2. When the changes to sections 70 to 72 of the Medicines Act come into force on 1 October 2009, the “personal control” requirement will no longer apply. The interpretation of “personal control”, as requiring the pharmacist’s physical presence in the pharmacy to allow the sale and supply of medicines to continue, will also fall away.

2.3. Instead, the new section 72A in the Medicines Act places a statutory duty on the responsible pharmacist to secure the safe and effective running of the pharmacy. Compliance with the legal duty is **not** dependent on the responsible pharmacist’s physical presence in the pharmacy at all times. **The responsible pharmacist must comply with the requirements in section 72A and the Regulations throughout the time s/he is responsible for the pharmacy – that is, whether or not s/he is present on the registered pharmacy premises.**

The Responsible Pharmacist’s Absence from the Pharmacy

2.4. Section 72A(7)(b) allows regulations to be made concerning the responsible pharmacist’s absence from the premises – these are set out in **Regulation 3** of the Regulations. **This is an enabling, not a mandatory, provision. There is no statutory requirement or obligation on the responsible pharmacist to be absent from the pharmacy.**

2.5. However, in deciding that s/he may be absent from the pharmacy, the responsible pharmacist will need to be aware

- That throughout the time s/he is responsible for the pharmacy, the responsible pharmacist must comply with the legal duty to ensure the pharmacy is operating safely and effectively – including any period during that time s/he is absent from the registered pharmacy premises.
- There is also a need to comply with requirements in Regulation 3.

What is Absence?

2.6. **Absence refers to periods when the responsible pharmacist is away from the registered pharmacy premises whilst remaining responsible for the safe and effective running of the pharmacy.** During the time s/he is responsible for a pharmacy, the responsible pharmacist may be away 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
- participating in the commissioning and development of local health services

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- participating in continuing professional development (CPD)
- seeing patients in a consulting room in the non-registered area of the pharmacy

What amount of time, when responsible for the pharmacy, should the pharmacist be in the pharmacy?

2.7. The Medicines Act and the Regulations do not specify the amount of time the responsible pharmacist must spend in the pharmacy to comply with the legal duty. During passage of the legislative changes, the Government recognised the responsible pharmacist should be able to exercise professional judgment as to safe and effective working in the pharmacy when s/he is in and away from the pharmacy. However, the Government also made clear its view that, in order to exercise the legal duty fully and effectively, the responsible pharmacist needs to be in the pharmacy for the majority of the time s/he is responsible for the pharmacy.

The Responsible Pharmacist – the Maximum Time Allowed for Absence from the Pharmacy

2.8. Although the law does not specify the amount of time the responsible pharmacist should spend in the pharmacy, **Regulation 3** limits the responsible pharmacist's absence during the pharmacy's business hours. **Regulation 3(1)** states that **two hours** is the maximum time the responsible pharmacist may be absent during the pharmacy's business hours. **It is important to be clear that the maximum time allowed for absence includes the time needed to travel away from and return to the pharmacy.** **Regulation 3(7)** defines business hours as a 24-hour period during which the pharmacy is operational on any day, beginning and ending at midnight.

2.9. **Regulation 3(2)** makes clear that where more than one pharmacist is responsible for the pharmacy during the defined business hours, the total period of absence allowed for **all** the responsible pharmacists concerned must not exceed two hours. For example, the pharmacist responsible for a pharmacy may change during the day. If the first responsible pharmacist is absent for two hours during the time s/he is responsible for the pharmacy, no other pharmacist responsible for the pharmacy on that day may be absent from the pharmacy. However, if the first responsible pharmacist is absent for only one hour, there is scope for further absence during the day – bearing in mind that any absence must allow for the responsible pharmacist to return to the pharmacy without exceeding the permitted maximum two hours.

Conditions for Absence from the Pharmacy

2.10. To be absent from the pharmacy, the responsible pharmacist must comply with the conditions for absence set out in **Regulation 3**. **The responsible pharmacist may not be absent from the registered premises unless s/he has put the required arrangements in place – Regulation 3(3).** These are as follows.

Arrangements to remain in contact with pharmacy staff

2.11. **Regulation 3(4)(a)** requires the responsible pharmacist to remain in contact with pharmacy staff throughout any absence. This is to enable pharmacy staff to seek advice or to request the responsible pharmacist's return to the pharmacy, as necessary.

Arrangements to return to the pharmacy with reasonable promptness

2.12. In addition, **Regulation 3(4)(b)** requires the responsible pharmacist to make arrangements that enable him/her to return with "reasonable promptness" if, in his/her opinion, this is necessary to secure the safe and effective running of the pharmacy. **Regulation 3(4)(b)** does not define "reasonable promptness", as it is difficult to

do so in a way that meets all possible circumstances – allowing the responsible pharmacist to use his/her professional judgement in deciding there is a need to return to the pharmacy as soon as possible.

Absence: Some Examples

2.13. The following examples may help in looking at the maximum time permitted for absence, the arrangements that must be in place to ensure the responsible pharmacist remains in contact with pharmacy staff, and enables him/her return with reasonable promptness where s/he judges this is necessary to secure safe and effective working in the pharmacy.

- **Example:** The responsible pharmacist holds a weekly “clinic” for patients with diabetes, using a consultation room located in the same building as the pharmacy but which does not form part of the registered pharmacy premises. The responsible pharmacist is absent from the pharmacy during the clinic sessions. To comply with **Regulation 3(1)**, the duration of the clinic must not exceed the maximum two hours permitted for absence. Whilst s/he remains close to the registered area of the pharmacy, s/he will still need to ensure arrangements are in place to remain in contact with pharmacy staff (**Regulation 3(4)(a)**). S/he must also ensure that s/he is able to return to the registered premises with reasonable promptness (**Regulation 3(4)(b)**), where s/he decides this is necessary to ensure the pharmacy continues to operate safely and effectively.
- **Example:** The responsible pharmacist is working in a local clinic, held in a GP practice. To do so, s/he must ensure arrangements are in place to comply with the conditions that allow him/her to be absent from the pharmacy. S/he needs to take into account the clinic’s location – to ensure that s/he does not breach the maximum two hours allowed for absence (**Regulation 3(1)**). S/he also needs to judge whether the clinic is close enough to allow him/her to return to the pharmacy with reasonable promptness if s/he needs to do so – eg if there is a serious incident in the pharmacy (**Regulation 3(4)(b)**). In addition, s/he must ensure that pharmacy staff are able to contact him/her during his/her absence (**Regulation 3(4)(a)**).

What happens if the Responsible Pharmacist is unable to remain in contact with staff or return to the pharmacy with reasonable promptness?

2.14. **Regulation 3** recognises there may be circumstances in which the responsible pharmacist is unable to comply with the requirement to maintain contact with pharmacy staff during his/her absence from the pharmacy - for example, where it is difficult or inappropriate to interrupt a consultation with a patient. This means pharmacy staff will be unable to seek advice or alert the responsible pharmacist to any need to return to the pharmacy – and s/he will not be in a position to decide whether there is a need to do so with reasonable promptness.

Arranging for another pharmacist to be available to provide advice

2.15. The responsible pharmacist must first judge whether s/he is able to comply with the conditions for absence in **Regulation 3(4)** and then consider the need to comply with **Regulation 3(5)**. That is, to enable him/her, to be absent, the responsible pharmacist must arrange for another pharmacist to be available and contactable to provide advice throughout the period of absence, or any time during that absence that s/he will be unable to maintain contact with the pharmacy. There is no requirement in **Regulation 3(5)** for the other pharmacist to be a responsible pharmacist or to be present in the pharmacy in order to provide advice to pharmacy staff.

2.16. The responsible pharmacist continues to be responsible for the pharmacy throughout the time s/he is absent from the pharmacy in compliance with the legal duty. In making arrangements with another pharmacist to provide

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advice under **Regulation 3(5)**, that responsibility does not pass to the pharmacist who has agreed to be available and contactable to provide advice where the responsible pharmacist is unable to comply with **Regulation 3(4)**.

- **Example:** The responsible pharmacist is attending a meeting to discuss provision of specific local health services. S/he needs to travel through an area of very poor mobile phone reception and this means that for periods during his/her absence pharmacy staff will be unable to contact him/her. However, s/he also judges that it may be difficult to maintain contact with pharmacy staff during the meeting, Therefore, before attending the meeting, s/he arranges for another pharmacist to be available and contactable throughout the time s/he is absent from the pharmacy.

Making Arrangements for Absence from the Pharmacy

2.17. The Regulations do not specify what arrangements must be in place in order for the responsible pharmacist to comply with **Regulation 3(4) and Regulation 3(5)**. Again, this allows the responsible pharmacist to use his/her professional judgement in deciding the specific arrangements (as these may differ in relation to each pharmacy and differing circumstances) that need to be in place to comply with the conditions for absence. However, the responsible pharmacist may look to professional standards and guidance set out by the professional regulatory bodies and any guidelines set out by the superintendent pharmacist (for a body corporate) or the pharmacy owner on such arrangements.

Absence and the Sale of GSL medicines

2.18. **Regulation 3(6)** makes clear that GSL medicines may be sold where the pharmacist is absent from the pharmacy – as with retail outlets that only sell GSL medicines where there is no requirement for a pharmacist to be present to permit sale.

2.19. However, the legal duty on the responsible pharmacist relates to the sale and supply of **all** medicines, including those on the general sale list. Therefore, in complying with **Regulation 4(1)(b)** (which requires the pharmacy procedures to set out the circumstances in which a member of pharmacy staff, who is not a pharmacist, may give advice about medicines), the responsible pharmacist should set out arrangements for the safe sale of GSL medicines – including when s/he is absent from the pharmacy.

Absence and the Pharmacy Procedures

2.20. **Regulation 4(1)(e)** also requires the responsible pharmacist to set out in the procedures the arrangements relating to any absence from the pharmacy - see **Chapter 3**. These should include the arrangements for contacting the responsible pharmacist during his/her absence and the arrangements made with another pharmacist to be available and contactable in order to provide advice where the responsible pharmacist is unable to maintain contact with the pharmacy during or throughout any absence.

Absence and the Pharmacy Record

2.21. **Regulation 5(1)(e)** requires the responsible pharmacist to include details of the date and time of any absence from the pharmacy in the pharmacy record – see **Chapter 4**.

Absence and the Pharmacist Supervision Requirements

2.22. In judging when s/he may be absent from the pharmacy, the responsible pharmacist must take into account the pharmacist supervision requirements in the Medicines Act and related NHS legislation. Where the responsible

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pharmacist is the only pharmacist working in the pharmacy, s/he must remain available to meet these requirements – otherwise, the dispensing of prescriptions and the sale of P medicines may not continue.

2.23. Therefore, until the introduction of statutory changes relating to pharmacist supervision, the responsible pharmacist is limited in his/her ability to be absent from the pharmacy, unless another pharmacist is available in the pharmacy to meet the supervision requirements.

Provision of NHS Pharmaceutical Services that do not involve the dispensing and sale of medicines (eg diagnostic testing)

2.24. The Medicines Act concerns the sale and supply of medicines. The legal duty on the responsible pharmacist and the Regulations do not relate to the provision of NHS pharmaceutical services where these do not involve the dispensing and supply of medicines. This is a matter for separate NHS legislation. However, in deciding that s/he may be absent from the pharmacy, the responsible pharmacist will need to take into account the need to comply with other statutory and contractual requirements.

What happens where the Responsible Pharmacist is away on holiday or ill?

2.25. **Regulation 3** sets out the requirements relating to permitted absence by the responsible pharmacist during the time s/he is responsible for the pharmacy – that is a maximum period of two hours during defined business hours.

2.26. Section 72B(4) makes clear that a pharmacist is no longer considered to be responsible for a pharmacy where s/he is in breach of section 72B(3)(b) – that is, there is failure to comply with the requirements for absence in the Regulations. Therefore, for any time in which the responsible pharmacist exceeds the two hours permitted for absence in **Regulation 3(1)** or fails to meet the conditions for absence in **Regulation 3(4)** and **(5)**, s/he will not be the pharmacist responsible for the pharmacy.

2.27. Generally, if the responsible pharmacist is to be away from the pharmacy for more than the permitted two hours, s/he will need to note in the pharmacy record (see Chapter 4) the date and time that s/he ceases to be responsible for the pharmacy. The pharmacy owner will need to ensure that another pharmacist is available to be responsible for the pharmacy. Some examples:

- **Example:** The responsible pharmacist will be on holiday for two weeks. Before leaving the pharmacy, he enters the required information in the pharmacy record (the date and time s/he ceased to be responsible for the pharmacy). During his holiday, the pharmacy owner has arranged for another pharmacist to be responsible for the pharmacy. She notes in the pharmacy record the date and time that she became responsible for the pharmacy and when s/he ceased to be responsible. On return from holiday, the responsible pharmacist enters in the record, the date and time he resumes responsibility for the pharmacy.
- **Example:** A pharmacy owner employs a locum pharmacist to be responsible for a pharmacy for one day. The locum pharmacist notes in the record the date and time he becomes responsible for the pharmacy. However, later that morning, he becomes ill and decides he must return home. He notifies the pharmacy owner or superintendent pharmacist and, before leaving the pharmacy, he enters the required information in the record to make clear that he has ceased to be responsible for the pharmacy. The sale and supply of medicines may not continue until the pharmacy owner has arranged for another pharmacist to be responsible for the pharmacy. When the other pharmacist arrives, he notes in the record the date and time he became the pharmacist in charge of the pharmacy.

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2.28. Where absence exceeds the permitted two hours and/or there is failure to comply with the conditions for absence in Regulation 3, the responsible pharmacist will cease to be responsible for the pharmacy. This will include where s/he has been unable to complete the pharmacy record to this effect – for example, because s/he has failed to return to the pharmacy due to sudden illness or an accident.

2.29. If the responsible pharmacist has indicated in the pharmacy record that s/he is no longer responsible for the pharmacy, or where his/her absence is greater than the permitted maximum time specified in the regulations or s/he has failed to meet the conditions for absence, the pharmacy will be without a responsible pharmacist. As with the “personal control” requirement, the pharmacy owner will need to ensure another pharmacist is available to be responsible for the pharmacy. Otherwise, the pharmacy is operating illegally and the retail sale and supply of medicines may not continue.

CHAPTER 3: THE PHARMACY PROCEDURES: SECTION 72A OF THE MEDICINES ACT AND REGULATION 4

Standing Operating Procedures (SOPs): Professional Requirements

3.1. There are professional requirements on pharmacists to put in place written Standard Operating Procedures (SOPs) for safe working in pharmacies. In 2003, the Pharmaceutical Society of Northern Ireland (PSNI) made the use of SOPs a professional requirement and the Royal Pharmaceutical Society of Great Britain (RPSGB) introduced this requirement in 2005. Thus, pharmacists and pharmacy owners will already be familiar with developing and working to Standard Operating Procedures, which have been in use for some time in hospital and community pharmacies and in the pharmaceutical industry.

3.2. The Government's view is that regulations relating to pharmacy procedures should reflect professional requirements and guidance on SOPs provided by the professional regulatory bodies and others (for example, superintendent pharmacists).

Pharmacy Procedures: Legal Requirements

3.3. Section 72A(3) of the Medicines Act, requires the responsible pharmacist to establish (where these are not already in place) pharmacy procedures designed to secure the safe and effective running of the pharmacy and to maintain and review the procedures. Section 72A(7)(e) allows for regulations to set out the matters to be included in the pharmacy procedures and the format of the procedures. These legal requirements underpin the professional requirements on pharmacists, providing a statutory framework for the content of pharmacy procedures, for maintenance of the procedures and their regular review.

3.4. The legislation does not specify, in detail, how the responsible pharmacist is to comply with requirements for pharmacy procedures. This is because the responsible pharmacist's professional judgement and knowledge of the pharmacy and its staff play an important part in tailoring procedures to meet the needs of the individual pharmacy for which s/he is responsible. Similarly, the timing and extent of any review of procedures will need to take into account the circumstances within each pharmacy.

Establishing Pharmacy Procedures – The Responsible Pharmacist

3.5. It is important to be clear that

- The legal duty on the responsible pharmacist extends to the safe sale and supply of **all** medicines from the pharmacy – ie the sale of pharmacy (P) medicines and those on the general sale list (GSL) as well as the dispensing and supply of prescribed medicines (POMs).
- The pharmacy procedures must cover, as a minimum, **all** the matters set out in **Regulation 4** (see below).

Thus, if SOPs are already in place, there may be a need to review these to ensure the procedures comply with **Regulation 4**.

Matters to be covered in the Pharmacy Procedures

3.6. The responsible pharmacist is professionally and legally accountable for the pharmacy procedures and, in establishing procedures. **Regulation 4(1)(a)** requires the responsible pharmacist to ensure the procedures cover, as a minimum, all the following specified areas:

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- Arrangements for the safe, secure, and effective ordering, storage, preparation, dispensing, sale or supply, delivery (including the handing over of a medicine(s) to a patient or carer either in the pharmacy or as part of the pharmacy's arrangements for delivery of medicines to, for example, the patient's home) and the disposal of medicinal products.
- The required training, competencies and experience of the pharmacy staff who may undertake specified tasks or activities in the pharmacy.
- The arrangements that support record keeping – that is, records relating to the ordering, receipt, storage, sale, supply, delivery and disposal of medicinal products.
- Which pharmacy staff may provide advice to patients and the public on the use of medicines (including where this supports the sale of a GSL medicine) and when they must seek the further advice or involvement of the responsible pharmacist or another pharmacist who may be working in the pharmacy.
- Arrangements when the responsible pharmacist is absent from the pharmacy - pharmacy staff must adhere to the pharmacy procedures set down by the responsible pharmacist whether or not s/he is present in the pharmacy. These arrangements will need to take into account the regulations relating to absence – see **Chapter 2**.
- Arrangements relating to a change in the pharmacist responsible for the pharmacy
- Procedures following a complaint about the pharmacy business relating to the sale and supply of medicines
- Procedures following an incident that appears to suggest that the pharmacy is not operating safely and effectively
- Arrangements to ensure that all pharmacy staff are aware of the content of the procedures and of any changes to the procedures

3.7. In establishing the pharmacy procedures, the responsible pharmacist should also bear in mind the need to comply with other relevant statutory requirements relating to safe and effective working in the pharmacy where this concerns medicines. For example, the separate legal requirements in regulations relating to the Misuse of Drugs Act 1971 and, where the pharmacy is involved in the sale and supply of veterinary medicines, the Veterinary Medicines Regulations. In addition, in securing safe and effective working in the pharmacy, the responsible pharmacist will need to take into account legislation on health and safety at work, the Safeguarding Vulnerable Groups Act 2006 and, in Scotland, the Protection of Vulnerable Groups (Scotland) Act 2007 and the Adults support and Protection (Scotland) Act 2007. (From, October 2009, employers of pharmacists and other pharmacy staff who provide assistance, advice or guidance to patients and the public will be required to check registration of these staff with the Independent Safeguarding Authority (ISA). Further information is available on the ISA's website at www.isa-gov.org.uk. In Scotland, checks should be made through Disclosure Scotland – www.disclosurescotland.co.uk.)

3.8. **Regulation 4(1)** does not prevent the responsible pharmacist from including other matters in the pharmacy procedures where, in his/her professional judgement, s/he considers this is necessary to secure the safe and effective running of the pharmacy. **However, there is a need to bear in mind that matters covered in the procedures relate to the safe and effective sale and supply of medicines. (There is no requirement to include in the pharmacy procedures arrangements relating to the provision of NHS pharmaceutical services that do not involve the sale or supply of medicines).**

Setting Out the Pharmacy Procedures

3.9. The Regulations do not require the responsible pharmacist to set out the procedures in a prescribed format – thus, allowing the responsible pharmacist flexibility to tailor the procedures to meet the needs of the pharmacy. However, **Regulation 4(2)** requires the pharmacy to have **written** procedures, which may be set out on paper or in electronic form.

3.10. The pharmacy owner (in the case of a body corporate, the superintendent pharmacist and for hospital trust, the chief pharmacist – in Scotland, the Health Board Director of Pharmacy) has an important role in ensuring that the pharmacy business supports the responsible pharmacist in complying with the legal requirements to establish, maintain and review pharmacy procedures. For example, where kept electronically, systems will need to be secure to prevent unauthorised overwriting.

Availability of the Pharmacy Procedures at the Pharmacy Premises

3.11. Whether the pharmacy procedures are set out on paper or electronically (or both), **Regulation 4(3)** requires the procedures to be readily available, at the pharmacy premises, to all those who need to consult them, including

- the pharmacy owner and/or the superintendent pharmacist/hospital trust chief pharmacist, who have legal responsibilities in relation to the pharmacy business
- the responsible pharmacist who will need to consult the procedures on taking responsibility for the pharmacy
- pharmacy staff, who will need to consult the procedures on arrangements for safe and effective working in the pharmacy

3.12. **Regulation 4(3)** does not specify that the pharmacy procedures should be available for inspection by pharmacy inspectors. Section 112(3) of the Medicines Act already allows inspectors access to all pharmacy documents they may require in carrying out their enforcement responsibilities.

Establishing the Pharmacy Procedures: The Pharmacy Owner

3.13. Section 72A(3) of the Medicines Act is clear that it is for **the responsible pharmacist** to establish pharmacy procedures (where these are not already in place) as part of the legal duty to secure the safe and effective running of the pharmacy. In some circumstances (eg an independent pharmacy owned and operated by an individual pharmacist), the pharmacy owner is also the responsible pharmacist.

3.14. The pharmacy owner's role is to ensure that pharmacy procedures are in place in each of the registered pharmacy premises owned by the business and that these meet with the regulatory requirements.

3.15. The responsible pharmacist is legally responsible and accountable for the procedures and must be able to use his/her professional judgement in deciding that procedures will secure the safe and effective running of the pharmacy for which s/he is responsible. The pharmacy owner should support and enable the responsible pharmacist to exercise the legal duty in relation to the pharmacy procedures and should not seek to impose procedures that the pharmacist responsible for a pharmacy considers s/he is unable to support or accept. Rather, the pharmacy owner and the responsible pharmacist should be able to discuss how the procedures will secure safe and effective working in the pharmacy concerned.

Establishing the Pharmacy Procedures: Bodies Corporate – The Superintendent Pharmacist

3.16. The legal duty to secure the safe and effective running of the pharmacy falls on the pharmacist in charge of the pharmacy – the responsible pharmacist - not the superintendent pharmacist.

3.17. However, the superintendent pharmacist has a legal responsibility, within a body corporate owning a pharmacy business, to manage the “keeping, preparing and dispensing of medicinal products” and may direct the pharmacist responsible for a registered pharmacy owned by a body corporate. In exercising his/her legal responsibility, the superintendent pharmacist may, for example, provide guidance as to the standards for pharmacy procedures for the company’s pharmacies – in compliance with the regulations. The guidance might include the provision of model procedures to support and enable the responsible pharmacist to establish procedures for the pharmacy for which s/he is responsible. However, like the pharmacy owner, the superintendent pharmacist should not seek to impose procedures on the responsible pharmacist but allow sufficient flexibility, within any overall company policies and guidance, to allow the responsible pharmacist to tailor procedures to the specific operational needs of the pharmacy and to discuss any need for local variations to model procedures with the superintendent pharmacist.

Establishing Pharmacy Procedures – the hospital trust chief pharmacist (in Scotland, the Health Board Director of Pharmacy)

3.18. The hospital chief pharmacist has professional leadership and accountability for the use of medicines in the hospital. Where the hospital trust has one or more registered pharmacies, the chief pharmacist has a role similar to that of the superintendent pharmacist in a body corporate. S/he must ensure that each of the hospital’s registered pharmacies has a responsible pharmacist and that each of these pharmacies has procedures in place. Like the superintendent pharmacist, the chief pharmacist/Health Board Director of Pharmacy should support and enable the responsible pharmacist to carry out the legal duty, including allowing the responsible pharmacist to exercise professional judgement as to the procedures needed to secure the safe and effective running of the pharmacy for which s/he is responsible.

Is the responsible pharmacist required to establish pharmacy procedures when becoming responsible for a pharmacy?

3.19. Section 72A(3) of the Medicines Act requires the responsible pharmacist to establish procedures for the safe and effective running of the pharmacy *where these are not already established*. Therefore, it is clearly not the intention to require a new set of pharmacy procedures each time there is a change in the pharmacist responsible for the pharmacy. The procedures are an essential and important part of safe working in the pharmacy. Frequent changes can result in unsafe working with uncertainty about requirements as to the way pharmacy staff work (particularly where there is failure to communicate any changes in a timely and comprehensive way or there is a need to take account of additional training needs).

3.20. However, when becoming responsible for a pharmacy, in exercising the legal duty the responsible pharmacist should

- check pharmacy procedures are available in the pharmacy and these cover the minimum required areas
- be satisfied that the procedures support the safe and effective running of the pharmacy

In some circumstances, on becoming responsible for the pharmacy, the responsible pharmacist may need to consider whether there needs to be a change in the procedures. For example, s/he may need to amend the

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procedures where a member of staff who undertakes specified tasks in the pharmacy is on holiday or absent due to illness– adjusting the procedures, as appropriate, until the member of staff returns.

Maintaining the Pharmacy Procedures

3.21. Section 72A(3) of the Medicines Act also requires the responsible pharmacist to maintain the pharmacy procedures. That is, to ensure the pharmacy procedures are up to date and relevant to the safe and effective running of the pharmacy at all times – reflecting current professional pharmacy practice and any changes in the pharmacy itself (eg new staff or training completed by existing staff).

Review of Pharmacy Procedures

3.22. In addition, section 72A(3) of the Medicines Act requires the responsible pharmacist to keep the procedures under review. The timing and frequency of review of the procedures will vary in the light of circumstances within the individual pharmacy. For example, significant changes in the pharmacy (eg a number of new staff or an increase in the volume of business) or a serious incident or complaint will prompt a review of procedures to assess the need for changes. Where there has been a recent review of procedures, it may be inappropriate to undertake a further review. There needs to be a balance. There is a need to avoid frequent review and changes in the procedures that can result in uncertainty by pharmacy staff on how they are required to work in the pharmacy. At the same time, regular review of procedures is important to ensure compliance with the requirement in section 72A(3) of the Medicines Act for procedures “*designed to secure the safe and effective running of the business.*”

3.23. **Regulation 4(4)** requires regular review of the pharmacy procedures but does not set out a period within which the responsible pharmacist must undertake a review. This allows for differences in the timing and extent of any review in relation to an individual pharmacy. It also allows the responsible pharmacist some flexibility in using his/her professional judgement in assessing the need for review.

3.24. Neither does **Regulation 4(4)** specify how the responsible pharmacist is to undertake a review of the pharmacy procedures. Again, this is because the extent and timing of any review of the procedures will differ from pharmacy to pharmacy and there is a need for flexibility to ensure pharmacy procedures continue to reflect professional regulatory guidance and standards of pharmacy practice. Therefore, the responsible pharmacist will need to consult guidance provided by the professional regulatory bodies and others (eg that provided by the superintendent pharmacist or hospital chief pharmacist (in Scotland, the Health Board Director of Pharmacy) for advice on the review of pharmacy procedures - including the timing of regular and other reviews (such as those triggered by changes in the pharmacy or a significant incident, complaint, or error).

Failure to establish, maintain and review procedures

3.25. Section 72B of the Medicines Act provides for the professional regulatory bodies (the Royal Pharmaceutical Society of Great Britain and the Pharmaceutical Society of Northern Ireland) to deal with any failure, to establish, maintain or review the pharmacy procedures as required under section 72A of the Medicines Act and the Responsible Pharmacist Regulations, as a matter of professional misconduct.

CHAPTER 4: THE PHARMACY RECORD: SECTION 72A OF THE MEDICINES ACT AND REGULATION 5

The Pharmacy Record and the Responsible Pharmacist

4.1. Section 72A(4) of the Medicines Act requires the responsible pharmacist to make a record, which must be available at the pharmacy premises, of the pharmacist responsible for the pharmacy on any date and at any time. This replaces the requirement in Section 77 of the Act on the pharmacy owner, in January each year, to inform the registrar of the name of the pharmacist in personal control of each pharmacy included on the list of premises submitted. Section 72A(7)(f) provides for regulations on the format and content of the pharmacy record.

Information to be included in the Record

4.2. **Regulation 5(1)** sets out the information that must be included in the pharmacy record. That is

- The name and registration number of the responsible pharmacist
- The date and time s/he became responsible for the pharmacy
- The date and time s/he ceased to have responsibility for the pharmacy
- The date and time, s/he commenced any absence from the pharmacy
- The date and time, s/he returned to the pharmacy following any absence.

4.3. **Regulation 5(1)** does not require the responsible pharmacist to include in the pharmacy record the reason(s) for his/her absence from the pharmacy. The legal duty on the responsible pharmacist requires him/her to secure safe and effective running of the pharmacy at all times that s/he is responsible for the pharmacy. This includes any time, when responsible for the pharmacy, that the responsible pharmacist is absent from the premises. The test will be whether the responsible pharmacist has complied with the duty – ie whether the pharmacy continued to operate safely and effectively during any absence.

4.4. **Regulation 5(1)** does not prevent the responsible pharmacist from including information, other than that specified, in the pharmacy record. However, given the importance of the record, those consulting the record must be able to find quickly the required information. **The record provides information on the pharmacist responsible for the pharmacy.** Therefore, the responsible pharmacist (and the pharmacy owner, superintendent pharmacist, or hospital chief pharmacist – in Scotland, the Health Board Director of Pharmacy) should avoid including other information in the pharmacy record, particularly where this more appropriately forms part of other records. For example, noting amendments or the date of review of the pharmacy procedures in the pharmacy record rather than in the procedures themselves or details of staff working in the pharmacy.

Making the Pharmacy Record and its Availability

4.5. **Regulation 5(2)** does not prescribe the format of the pharmacy record and the written record may be set out on paper or electronically (or both). However, whether kept on paper or electronically, Section 72A(4) requires the pharmacy record to be available at the pharmacy premises. **Regulation 5(3)** makes clear that the pharmacy record must be available to specified persons, that is

- The pharmacy owner who has legal responsibilities relating to the pharmacy record (see paragraph 4.6. below)

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- The superintendent pharmacist/hospital chief pharmacist (in Scotland, the Health Board Director of Pharmacy), who will need to check that the pharmacy record is made and maintained as required
- The responsible pharmacist who also has legal responsibilities relating to the pharmacy record and is required to include the specified information in the record

Regulation 5(3) does not specify that the pharmacy record must be available to pharmacy inspectors as there is already provision, under section 112(3) of the Medicines Act, for inspectors to access documents that support them in carrying out their enforcement responsibilities.

The Pharmacy Record and the Pharmacy Owner

4.6. Section 72A(5) places a legal duty on the pharmacy owner in relation to the pharmacy record. The pharmacy owner must

- Ensure the pharmacist responsible for the pharmacy on any date and at any time makes and maintains the pharmacy record as required in **Regulation 5(1)**.
- Preserve the pharmacy record for the period specified in the **Regulation 5(4)**.

4.7. **Regulation 5(4)** requires the pharmacy owner to ensure preservation of the pharmacy record for a minimum of five years. In the case of an electronic record, this period commences on the date that the record is created – **Regulation 5(4)(a)**. Where the responsible pharmacist makes the pharmacy record in paper form, the five-year period commences on the last date on which the record is completed – **Regulation 5(4)(b)**.

4.8. In complying with this legal duty, the pharmacy owner (the superintendent pharmacist where the business is a body corporate and the chief pharmacist where the business is owned by a hospital trust) should ensure there are robust systems in each pharmacy to support the responsible pharmacist in making and maintaining the record as required. For example, these should help ensure the pharmacy record is up to date, accurate, secure, and readily available for inspection as required – including inspection within the five-year period that the pharmacy owner is required to preserve the record.

Failure to Keep and Preserve the Pharmacy Record as Required

4.9. The pharmacy record is an important, legal, document. It

- Confirms the pharmacy is operating legally – a responsible pharmacist is in charge of the pharmacy
- Provides information relating to the pharmacist legally accountable for the safe and effective running of the pharmacy on any date and at any time
- Supports professional audit and accountability
- Supports the investigation of complaints, errors or incidents and
- Provides evidence of any professional misconduct

4.10. Changes to section 84 of the Medicines Act – which relates to offences under Part IV of the Act – reflect the importance of the pharmacy record as a legal document. Section 30(3) of the Health Act amends section 84 to include the following additional offences that, on conviction, are subject to the payment of a fine:

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- Failure by a pharmacist responsible for a registered pharmacy to make and maintain the pharmacy record as required by section 72A (4) of the Medicines Act and Regulation 5 of the Regulations.
- Failure by the owner of a pharmacy business to ensure that the responsible pharmacist makes and maintains the pharmacy record as required by section 72A(4) of the Medicines Act and Regulation 5 of the Regulations – in breach of the legal duty on the pharmacy owner under section 72A(5)(a) of the Medicines Act.
- Failure by the owner of a pharmacy business to preserve the pharmacy record – in breach of the legal duty under section 72A(5)(b) of the Medicines Act and the requirements in Regulation 5.