



HOSPITAL PHARMACY PRACTICE IN THE UK AND THE RESPONSIBLE PHARMACIST REQUIREMENTS

ROYAL PHARMACEUTICAL SOCIETY OF GREAT BRITAIN AND THE PHARMACEUTICAL SOCIETY OF NORTHERN IRELAND

STATUS OF THIS DOCUMENT

This guidance is intended to assist hospital pharmacists in implementing the responsible pharmacist requirements within their hospitals.¹

This guidance has been developed in conjunction with the UK Departments of Health, the Medicines and Healthcare products Regulatory Agency (MHRA) and the Guild of Healthcare Pharmacists.

Where this document refers to ‘the Act’ this is the Medicines Act 1968, as amended by the Health Act 2006. Where this document refers to “the regulations”, these are the Medicines (Pharmacies) (Responsible Pharmacist) Regulations 2008. This document does not detail all the requirements of the Act or the regulations, but will reference these where appropriate. Further information on these legal requirements is available in the document titled *The Medicines (Pharmacies) (Responsible Pharmacist) Regulations 2008: guidance*, available at www.dh.gov.uk/publicationsandstatistics.

Those reading this document should also be aware of the project that is underway to strengthen the medicines’ supply chain. MLX 357 can be viewed on the MHRA website: <http://www.mhra.gov.uk/Publications/Consultations/Medicinesconsultations/MLXs/CON033660>.

The professional regulatory bodies, Royal Pharmaceutical Society of Great Britain (RPSGB) and Pharmaceutical Society of Northern Ireland (PSNI), have also developed mandatory professional standards for responsible pharmacists, which supplement the Code of Ethics. These are titled *Professional standards and guidance for responsible pharmacists and Professional standards and guidance on the responsible pharmacist regulations* and are available at www.rpsgb.org and www.psni.org.uk, respectively.

¹ This guidance is intended to assist in understanding the requirements of the Medicines Act 1968. However, it does not 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. If any queries arise that are not covered by this guidance then Health Boards and Trusts should seek advice from their own legal team.

PURPOSE OF THIS DOCUMENT

The overall aim of this guidance is to support hospital pharmacists in their ongoing sale and supply of medicines from hospital pharmacies because the care of many patients is dependent upon these activities.

This document is intended for pharmacists working in the hospital sector, including those in positions of authority, for example superintendent and chief pharmacists of Health Boards and Trusts, and responsible pharmacists in charge of hospital pharmacies that are registered with the RPSGB or the PSNI.

This document provides guidance on the legal framework that underpins the manufacture, preparation, assembly, sale/supply and wholesale of medicines from hospital pharmacies that are registered as a pharmacy premises with the RPSGB or the PSNI. This guidance does not just cover hospital pharmacies registered with RPSGB or the PSNI, it enables those that are not registered to confirm they do not need to do so.

THE OBJECTIVES OF THIS GUIDANCE ARE TO:

- briefly outline the new responsible pharmacist requirements;
- identify hospital activities that can only take place from pharmacy premises registered with the RPSGB or the PSNI and therefore require a responsible pharmacist to be in charge of the pharmacy;
- identify hospital activities that can take place in the hospital without the need for pharmacy premises to be registered with the RPSGB or the PSNI and therefore do not require a responsible pharmacist to be in charge of the pharmacy;
- identify hospital activities that require an appropriate licence (e.g. wholesale dealer's licence or manufacturing licence);

Appendix 1 of this document includes some Frequently Asked Questions, and Appendix 2 includes definitions that are used throughout the document. The flow chart in Appendix 3 diagrammatically illustrates these objectives.

BACKGROUND

The responsible pharmacist requirements

The Health Act 2006 amends the Medicines Act 1968 in relation to the sale and supply of *all* medicines from pharmacy premises registered with the RPSGB or the PSNI. These changes

- replace the current ill-defined “personal control” requirement and the common interpretation that this requires the physical presence of the pharmacist in the pharmacy at all times when it is open for business;
- place a legal duty on the pharmacist in charge of pharmacy premises registered with the RPSGB or the PSNI – the responsible pharmacist – to secure the safe and effective running of the pharmacy throughout the time s/he is responsible for the pharmacy;
- make clear what the responsible pharmacist must do to exercise the duty – i.e. this is not wholly dependent on physical presence. The responsible pharmacist must meet the legal and professional requirements.

From 1 October 2009, those individuals in positions of authority, for example superintendent and chief pharmacists of Health Boards and Trusts, must ensure that each pharmacy premises registered with the RPSGB or the PSNI has a responsible pharmacist. The responsible pharmacist has a clear role in implementing a legal framework for the safe and effective running of the pharmacy, where activities concern the sale and supply of all medicines.

There must be a responsible pharmacist in charge of each pharmacy premises registered with the RPSGB or the PSNI when that pharmacy is operational. A pharmacy may be considered operational when an activity that requires registration with the RPSGB or PSNI takes place. This may include times when the pharmacy premises registered with the RPSGB or the PSNI is closed to the public. The responsible pharmacist requirements only apply when those hospital activities that require a pharmacy premises to be registered with the RPSGB or the PSNI take place.

To comply with the legal duty to secure the safe and effective running of the pharmacy, the responsible pharmacist is required to:

- conspicuously display a notice stating that they are the pharmacist in charge of that premises on that date and at that time;
- ensure procedures that secure safe working (SOPs) are in place, and;
- keep a record, in the pharmacy, setting out who is the pharmacist responsible for that pharmacy on any date and at any time.

Further information on how the responsible pharmacist must meet these requirements is set out in the regulations and the Professional Standards and Guidance for Responsible Pharmacists document: www.rpsgb.org or www.psn.org.uk. Department of Health guidance is also available in the document titled *The Medicines (Pharmacies) (Responsible Pharmacist) Regulations 2008: guidance*, available at: www.dh.gov.uk/publicationsandstatistics.

Activities involving the manufacture, preparation, assembly, sale/supply and wholesale of medicines

The Act provides the legal framework for the manufacture, preparation, assembly, sale/supply and wholesale of medicines in the UK.

The sale or supply of medicines

The Act requires that (subject to certain exemptions - see below) prescription-only medicines (POM) and pharmacy (P) medicines are only sold or supplied from pharmacy premises registered with the RPSGB or the PSNI and that the sale or supply is made by or under the supervision of a registered pharmacist.²

General sale list (GSL) medicines may be sold by pharmacy premises registered with the RPSGB or the PSNI and other retail outlets (such as a hospital pharmacy that is not registered with the RPSGB or PSNI) provided these meet the legal conditions for the sale/supply of these medicines. The conditions are that:

- The premises must be occupied by the owner of the business who must be able to close the premises to exclude the public

² Section 52(1) of the Medicines Act 1968.

- Where sale is via an automatic machine, this must be located on premises which the owner of the business can close to exclude the public
- The medicine must be made up for sale in a container elsewhere and unopened since made up for sale³

Where GSL medicines are sold/supplied from pharmacy premises registered with the RPSGB or the PSNI there must be a responsible pharmacist in charge of the pharmacy.⁴

The Act provides an exemption from these requirements when the sale or supply of a medicine (GSL, P or POM) is;

- in the course of the business of a hospital or health centre and
- where the medicine is sold or supplied for the purpose of being administered (whether in the hospital or elsewhere) in accordance with the directions of a doctor or dentist.⁵

The wholesale of medicines

The Act requires that in order to wholesale medicines a wholesale dealer's licence is required⁶. The wholesale of medicines is the supply of stock to a person who is legally permitted to receive it for the purposes of either selling or supplying it, or administering it to another person. The wholesale of medicines is not supply to a patient (i.e. it is not the supply of medicines labelled for a specific patient against a prescription).

The Act provides an exemption for pharmacy premises registered with the RPSGB or PSNI to wholesale medicines without a wholesale dealer's licence⁷.

It should be noted that registration of a pharmacy premises with RPSGB or PSNI should not be undertaken to circumvent the wholesale licensing requirements. The intention of the Act is to allow pharmacy premises registered with RPSGB and PSNI to undertake some wholesale transactions within the UK where it is clear this is ancillary to the main activity of a retail pharmacy business.

The conditions that apply to this exemption are that:

- the wholesale supply is made from a pharmacy premises registered with the RPSGB or PSNI;
- the transaction is under the supervision of a registered pharmacist; and,
- wholesale dealing constitutes no more than an inconsiderable part of the business carried on at that pharmacy.

The term "inconsiderable part of the business" is not defined in legislation. Advice from the MHRA is that in order to comply with the exemption, wholesale dealing of licensed medicinal products by a registered pharmacy should, in any 12 month period, amount to no more than 5% of the total financial value of sales or supplies of licensed medicinal products made by that registered pharmacy." This is commonly known as the 'de minimis' rule.

This exemption only allows licensed medicines to be wholesaled. Unlicensed medicines cannot be wholesaled using this exemption⁸.

³ Section 53 of the Medicines Act 1968

⁴ Section 70(2)/71(2) of the Medicines Act 1968

⁵ Section 55(1)(b) of the Medicines Act 1968

⁶ Section 8(3) of the Medicines Act 1968

⁷ Section 10(7) of the Medicines Act 1968

⁸ Schedule 1 of the Medicines for Human Use (Marketing Authorisation Etc) Regulations 1994

A hospital pharmacy that does not have a pharmacy premises registered with the RPSGB or PSNI cannot use this exemption to wholesale licensed medicines – a wholesale dealer’s licence is required.

The manufacture, assembly and preparation of medicines

Licensed medicinal products and medicinal products for export may only be manufactured by the holder of a (‘full’) manufacturer’s licence issued by the MHRA.⁹

The holder of a manufacturer’s licence may wholesale the medicinal products manufactured or assembled under that licence without the need also to hold a wholesale dealer licence.

The Act provides an exemption for pharmacy premises registered with the RPSGB or PSNI to prepare medicinal products with a view to retail sale or to supply that product from that pharmacy.¹⁰

HOSPITAL ACTIVITIES

Using the above background information, this document identifies hospital activities and explains where these:

- must take place from a pharmacy premises registered with the RPSGB or the PSNI;
- can take place from the hospital without the need for a pharmacy premises that is registered with the RPSGB or the PSNI
- require an appropriate MHRA licence.

HOSPITAL ACTIVITIES INVOLVING THE SUPPLY OF INDIVIDUALLY DISPENSED MEDICINES

Scenario A: Supply of licensed or unlicensed medicines to a patient of the hospital

The Act allows the sale or supply of medicines in the course of the business of a hospital.¹¹ Supplies of dispensed medicines to a patient of a hospital are likely to be regarded as in the course of the business of the hospital and therefore this does not require a pharmacy premises to be registered with the RPSGB or PSNI. As this activity does not require the pharmacy premises to be registered with the RPSGB or PSNI the responsible pharmacist requirements do not apply.

In modern day healthcare, Trusts/Health Boards may include several different hospitals on different sites. In such cases all the hospitals within a Trust/Health Board are viewed as being part of a single legal entity. Therefore, the supply of medicines from one hospital to a patient in another hospital within the same Trust/Health Board would be regarded as a supply within the same legal entity. As such the pharmacy would not be required to be registered with the RPSGB or PSNI.

Example: A hospital pharmacy supplies medicines for patients on the hospital wards. This can be regarded as being in the course of the business of the hospital and therefore this does not require a pharmacy premises to be registered with the RPSGB or PSNI.

Example: A hospital pharmacy supplies medicines against a prescription for outpatients of the hospital. This can be regarded as being in the course of the business of the hospital and therefore this does not require a pharmacy premises to be registered with the RPSGB or PSNI.

⁹ Section 8(2) of the Medicines Act 1968

¹⁰ Section 10(6) of the Medicines Act 1968

¹¹ Section 55(1)(b) of the Medicines Act 1968

Example: A Trust/Health Board has two hospitals on different sites but only one hospital has a pharmacy. The pharmacy is not registered with the RPSGB or PSNI. The pharmacy can make supplies of medicines to patients of the same Trust/Health Board (i.e. to patients of either hospital within the Trust/Health Board). Registration of pharmacy premises with the RPSGB or PSNI is not required.

Example: Under homecare arrangements, a hospital pharmacy supplies medicines to patients of the Trust/Health Board. This activity does not require registration of pharmacy premises with the RPSGB or PSNI.

Example: A hospital pharmacy supplies medicines for patients on the hospital wards or against a prescription for outpatients of the hospital. The medicine is collected by a nurse who will either take the medicines to the ward or give it to the outpatient. This is regarded as being in the course of the business of the hospital and therefore does not require a pharmacy premises to be registered with the RPSGB or PSNI. The medicines do not have to be delivered to the wards by pharmacy staff or collected personally by the outpatient.

Scenario B: Supply of licensed medicines to a patient who is not a patient of the same legal entity.

Trusts/Health Boards may be asked to provide medicines sale or supply services to patients in a separate organisation (such as a private cancer service provider). The separate organisation may be on the same site as the Trust / Health Board or may be co-located (for example in the same building but on a separate floor). Although the services to patients are co-located, the organisations responsible for the care of the patients are separate legal entities.

The Act requires that (subject to certain exemptions) POM and P medicines are only sold or supplied from pharmacy premises registered with the RPSGB or the PSNI.¹² The exemption provided for by the Act only applies when medicines are sold or supplied in the course of the business of a hospital.¹³ In these circumstances, if a hospital does not have a pharmacy premises registered with the RPSGB or the PSNI, it may only supply to patients who are patients of the same legal entity.

However, if the hospital has a pharmacy premises that are registered with the RPSGB or the PSNI then supplies of a licensed medicine to a patient who is not a patient of the legal entity may lawfully be made against a legally valid prescription.¹⁴

If the hospital does not have a pharmacy premises registered with the RPSGB or the PSNI, it would not be lawful for licensed medicines to be supplied to a patient who is not the patient of that same legal entity.

Example: A hospital pharmacy supplies a POM in accordance with a legally valid prescription for a patient of another Trust or Health Board. This would not be regarded as being in the course of the business of the hospital (as the patient is under the care of another Trust/Health Board, which is a separate legal entity) and therefore this would require a pharmacy premises to be registered with the RPSGB or PSNI.

¹² Section 52 (1) of the Medicines Act 1968

¹³ Section 55(1)(b) of the Medicines Act 1968

¹⁴ See definition of “legally valid prescription” on page of this guidance

Example: An individual presents at the hospital pharmacy with a private prescription issued by his GP. If the hospital pharmacy is not a pharmacy premises registered with the RPSGB or the PSNI, the pharmacy cannot make this supply.

Example: A private patient is under the care of separate legal entity (e.g. private IVF unit or private chemotherapy unit) located in the premises of Trust/Health Board A. As the patient is not a patient of Trust/Health Board A, the hospital pharmacy must be registered with the RPSGB or PSNI to supply licensed medicines to these private patients.

Example: A hospital pharmacy supplies individually dispensed medicines for administration to inpatients in a ward. The ward is part of a separate legal entity which is part of a separate Trust/Health Board. As the patient is not a patient of the hospital, the pharmacy must be registered with the RPSGB or PSNI to supply licensed medicines to these patients.

Scenario C: Supply of licensed medicines to a patient under a service level agreement or contract with a separate legal entity

As detailed in Scenario B, the Act does not allow the supply of licensed medicines from a hospital to patients of a separate legal entity (i.e. the patient of another Trust or Health Board). The existence of a service level agreement or a contract does not alter this fact.

Therefore for a hospital to make a supply of licensed medicines to a patient of another legal entity, the hospital must have a pharmacy premises which is registered with the RPSGB or the PSNI.

Example: A hospital in Trust/Health Board A has a service level agreement (SLA) to supply medicines to patients of a local prison. However, as the prison is not part of the same legal entity as Trust/Health Board A, supply of licensed medicines cannot be made unless the pharmacy premises are registered with the RPSGB or the PSNI. An SLA does not override the legal requirements of the Act.

Example: A Trust has a contract with the local PCT clinic to supply patients of the clinic with their medicines. The Trust cannot supply the licensed medicines unless the pharmacy premises are registered with the RPSGB or the PSNI. This is because the PCT clinic is not part of the same legal entity as the Trust. As above, a contract does not override the legal requirements of the Act.

Scenario D: Preparation, assembly and dispensing of unlicensed medicines for a patient of another legal entity

The Act allows hospitals to prepare/assemble, and/or, dispense unlicensed medicines (e.g. aseptically prepared medicines) against a prescription for a named patient¹⁵ and for those medicines to be supplied to another Trust/ Health Board's hospital, normally via that hospital's pharmacy, for dispensing to its patients even it is not part of the same legal entity. This does not require the hospital preparing the product for a named patient in another hospital to have a pharmacy premises that is registered with the RPSGB or PSNI.

Example: The aseptic dispensing pharmacy in hospital A prepares parenteral nutrition against prescriptions for a named patient, who is under the care of hospital B, which is part of a different Trust/Health Board. Hospital A does not require a pharmacy premises that is registered with the RPSGB or PSNI providing that the products are supplied to hospital B for

¹⁵ Section 10 (1) (a) of the Medicines Act 1968

supply to the named patient. Hospital A cannot supply the products direct to patients in hospital B.

Example: A hospital pharmacy in Trust/Health Board A imports an unlicensed medicine through an importation company. Hospital pharmacy A dispenses this product for a patient of Trust/Health Board B. The hospital in Trust/Health Board A does not require a pharmacy premises that is registered with the RPSGB or PSNI providing that the products are supplied to the hospital in Trust/Health Board B for supply to the named patient. The medicinal product cannot be supplied direct to the patient in Trust/Health Board B.

Example: The hospital pharmacy in Trust/Health Board Y buys 10 bags of 1000ml sodium chloride 0.9% containing 80mmol of potassium chloride, as an unlicensed “special” from a supplier with a manufacturing licence. The hospital pharmacy at Trust/Health Board Y can supply this unlicensed “special” against a legally valid prescription for a patient in hospital Z which is part of a different Trust/Health Board. The hospital at Trust/Health Board Y does not require a pharmacy premises that is registered with the RPSGB or PSNI providing that the products are supplied to hospital Z for supply to the named patient. The medicinal product cannot be supplied direct to the patient in hospital Z.

Example: Pharmacy X in Trust/Health Board A is contacted by a consultant in ITU in Trust/Health Board B. The consultant in ITU is requesting the supply of unlicensed medicines for their named patients. ITU is requesting that pharmacy X supplies these direct to ITU. Pharmacy X does not require a pharmacy premises registered with the RPSGB or PSNI provided the products are supplied to Trust/Health Board B for supply to the named patient. The medicinal product cannot be supplied direct to the patient in Trust B.

HOSPITAL ACTIVITIES INVOLVING THE WHOLESALING OF MEDICINES

Scenario E: Supply of stock of licensed medicines to a separate legal entity

The Act provides an exemption that allows a pharmacy premises registered with the RPSGB or the PSNI to wholesale licensed medicines.

If the hospital has a pharmacy premises registered with the RPSGB or the PSNI it may wholesale medicines if this activity constitutes no more than an inconsiderable part of the business carried on at that pharmacy. As outlined on page 4, in order to comply with the exemption for pharmacy premises registered with the RPSGB or PSNI, wholesale dealing of licensed medicinal products by a registered pharmacy should, in any 12 month period, amount to no more than 5% of the total financial value of sales or supplies of licensed medicinal products made by that registered pharmacy.

A hospital that does not have a pharmacy premises that are registered with the RPSGB or the PSNI cannot lawfully wholesale medicines unless it has a wholesale dealer’s licence.

Example: A community pharmacy requests a supply of 20 boxes of amoxicillin 500mg capsules from a hospital pharmacy. Unless the hospital has a pharmacy premises that is registered with the RPSGB or the PSNI or holds a wholesale dealer’s licence, it cannot lawfully wholesale the medicine.

Example: A prison requests 10 boxes of atenolol 50mg tablets from a hospital pharmacy. A hospital pharmacy that is registered with the RPSGB or PSNI can make the wholesale supply provided that the, wholesale dealing of licensed medicinal products in any 12 month

period, amounts to no more than 5% of the total financial value of sales or supplies of licensed medicinal products made by that registered pharmacy.

Example: A Mental Health Trust requests ward stock from a hospital pharmacy. Unless the hospital has a pharmacy premises that is registered with the RPSGB or the PSNI or holds a wholesale dealer's licence, it cannot lawfully wholesale the medicine.

Scenario F: Supply of assembled packs to another legal entity (includes supply of over-labelled original packs)

The assembly of medicines for supply to another legal entity requires a manufacturer's licence. This licence would enable one legal entity to prepare pre-packs and wholesale these to a separate legal entity.

Example: Hospital A is asked to assemble and supply pre-packs of an antibiotic to a GP within the primary care setting. A manufacturer's licence is required to make this supply.

Example: A hospital has pharmacy premises registered with the RPSGB or PSNI. The pharmacy is asked to assemble pre packs for supply to a care home. The pharmacy must obtain a manufacturer's licence from the MHRA in order to undertake this activity.

Example: A hospital pharmacy assembles over-labelled original packs or pre-packs for supply from a clinic in another Trust/Health Board. A manufacturer's licence is required to make this supply.

Scenario G: Supply of stock of an unlicensed medicine to another legal entity

The Act allows pharmacy premises registered with the RPSGB or the PSNI to wholesale medicines; however, as outlined earlier, this only applies to licensed medicines.¹⁶

A manufacturer's ("specials") licence (MS) entitles the holder to both manufacture unlicensed medicinal products and wholesale these unlicensed medicinal products. If an organisation has not manufactured the unlicensed medicines but wants to wholesale unlicensed medicines, a wholesale dealer's licence is required.

Example: Hospital A reconstitutes flucloxacillin injection 1g in 100ml of 0.9% sodium chloride. The hospital pharmacy sells these reconstituted injections to hospitals B, C and D. Hospital B sells these to Hospital E, which is part of a separate Trust. A manufacturer's ("specials") licence (MS) would be required by Hospital A, which would authorise both their manufacture of unlicensed medicinal products and the wholesale distribution of those unlicensed medicinal products to Hospitals B, C and D. Hospital B, having procured unlicensed medicinal products from an MS holder (Hospital A) would require a wholesale dealer licence to wholesale distribute these medicines.

Example: Hospital pharmacy A, which holds a MS licence, prepares parenteral nutrition bags to sell to Hospital B. The pharmacy in Hospital B dispenses the bags to named patients in Hospital B. Hospital A is preparing the nutrition bags under its manufacturer's licence. Hospital pharmacy B uses Section 55 of the Act in making supplies to patients of the hospital.

¹⁶ Section 10(7) of the Medicines Act 1968, Schedule 1 of The Medicines for Human Use (Marketing Authorisation Etc) Regulations 1994

Remember: the supply of stock within the same legal entity for example between two hospitals within the same Trust/Health Board, is not classed as a wholesale supply, but is instead a distribution activity. Therefore this activity can take place regardless of whether the hospital has a pharmacy premises registered with the RPSGB or the PSNI and a wholesale dealer's licence is not required.

EXERCISING PROFESSIONAL JUDGEMENT

Pharmacists must make the care of patients their first concern. There may be exceptional circumstances where you may be faced with conflicting professional obligations or legal requirements. In these circumstances you must consider fully the options available to you, evaluate the risks and benefits associated with possible courses of action and determine what is most appropriate in the interests of patients and the public.

NEXT STEPS FOR PHARMACISTS WHO WORK IN THE HOSPITAL SECTOR

In the light of this guidance, pharmacists working in the hospital sector, including those in positions of authority, for example superintendent and chief pharmacists of Health Boards and Trusts, should review the activities being undertaken by the hospital pharmacy that relate to the manufacture, preparation, assembly, sale/supply and wholesale of medicines and decide whether these activities:

- must take place from a pharmacy premises registered with the RPSGB or the PSNI;
- can take place from the hospital without the need for a pharmacy premises that is registered with the RPSGB or the PSNI
- require an appropriate MHRA licence;

Where a decision is made to register pharmacy premises with the RPSGB or PSNI or to obtain an appropriate licence from the MHRA, pharmacists in a position of authority in Trusts and Health Board must be clear as to the legal requirements on owners of registered pharmacy businesses in the Act and the regulations. That is the

- requirement on bodies corporate owning registered pharmacies to appoint a superintendent pharmacist to have responsibility for the management of the keeping, preparing and dispensing of medicines for all pharmacies owned by that body;
- requirement on the pharmacy owner to appoint a responsible pharmacist for each pharmacy premises registered with the RPSGB/PSNI;
- requirement on the pharmacy owner to ensure the responsible pharmacist keeps the record as required;
- requirement on the pharmacy owner to ensure the pharmacy record is preserved for a minimum of 5 years.

REGISTERING A PHARMACY PREMISES WITH THE RPSGB/PSNI AND/OR OBTAINING AN APPROPRIATE LICENCE FROM THE MHRA

As stated previously, registration of a pharmacy premises with RPSGB or PSNI should not be undertaken to circumvent the wholesale licensing requirements. The intention of the Act is to allow pharmacy premises registered with RPSGB and PSNI to undertake some wholesale transactions where it is clear this is ancillary to the main activity of a retail pharmacy business.

The RPSGB and PSNI would not be supportive of an application to register a pharmacy premises where the business to be conducted is entirely or predominantly wholesale dealing and registration is intended as a means to circumnavigate the requirement under the Act to obtain the appropriate licence.

Remember: A hospital undertaking minimal sale and supplies of medicinal products from the pharmacy premises they have registered with the RPSGB or PSNI may still have to obtain a wholesale dealers licence as the amount of wholesale dealing allowed under the exemption within the Act is unlikely to be sufficient. Please refer to the explanation on page 4.

FREQUENTLY ASKED QUESTIONS

1. *A hospital pharmacy has registered their dispensary as registered pharmacy premises with the RPSGB/PSNI, because some of the activities that take place require registration. Is a responsible pharmacist needed at all times within the registered premises?*

No, a responsible pharmacist is not necessarily needed at all times within the registered premises. A responsible pharmacist must be in charge of the registered pharmacy when any activities which require pharmacy premises registration with the RPSGB or PSNI take place.

2. *The responsible pharmacist regulations limit absence from a pharmacy to a maximum period of two hours, provided other specified conditions are also met. How does this apply to hospital pharmacy?*

The responsible pharmacist requirements apply to pharmacy premises registered with the RPSGB or PSNI in exactly the same way – whether located in the community or hospital.

If the hospital has a pharmacy premises registered with the RPSGB or PSNI, the responsible pharmacist requirements apply where and when an activity that requires registration as a pharmacy premises takes place.

It is important that those in positions of authority (for example superintendent and chief pharmacists of Health Boards and Trusts) consider how best to enable those they appoint to be responsible for registered pharmacies owned by their organisations to meet the responsible pharmacist requirements.

3. *What skills and experience does a responsible pharmacist need?*

There are no statutory requirements relating to the additional training and qualifications required to take on the role of responsible pharmacist. However, you must only work within areas in which you are competent and must be able to comply with the legal and ethical responsibilities of a responsible pharmacist.

4. *Does an on call pharmacist who is appointed as the responsible pharmacist have to display the notice containing their details?*

Yes, if the on call pharmacist is the pharmacist in charge of the pharmacy and is undertaking an activity that requires pharmacy premises registration with the RPSGB or the PSNI, he is the responsible pharmacist and must display the notice with the required information.

5. *Hospital Z operates an on call out-of-hours service and the hospital pharmacy is registered with the RPSGB or PSNI. A pharmacist working in that pharmacy needs to supply stock for a ward and is also asked to supply a prescribed licensed medicine to a named patient of another hospital in a separate Trust/Health Board. When are the responsible pharmacist requirements applicable, if at all?*

It is helpful to consider the activities that are taking place separately. The first activity involves the pharmacist making a supply of ward stock within hospital Z; this is regarded as within the 'course of the business of the hospital'¹⁷ and the distribution of stock. Therefore the supply does not need to take place from registered pharmacy premises and the responsible pharmacist requirements do not apply.

¹⁷ Section 55 of the Medicines Act 1968.

The second activity involves the pharmacist making a supply to a patient of another Trust/Health Board. Supply of licensed medicines can only lawfully take place from a pharmacy premises which is registered with the RPSGB or the PSNI against a legally valid prescription. Therefore, the responsible pharmacist requirements apply.

This scenario shows that whilst the premises may be registered, the responsible pharmacist requirements only apply when those activities requiring a pharmacy premises to be registered with the RPSGB or the PSNI takes place.

6. *A hospital pharmacy is registered with the RPSGB or the PSNI. It has calculated that it has wholesaled approx 10% of its turnover in licensed medicinal products. Does the hospital need a wholesale dealer's licence?*

Yes, this hospital would require a wholesale dealer's licence if it continued to wholesale medicines at this level. A pharmacy premises registered with the RPSGB/PSNI is able to wholesale medicines provided that wholesale dealing constitutes no more than an inconsiderable part of the business carried on at that pharmacy.

The term "inconsiderable part of the business" is not defined in legislation. Advice from the MHRA is that in order to comply with the exemption, wholesale dealing of licensed medicinal products by a registered pharmacy should, in any 12 month period, amount to no more than 5% of the total financial value of sales or supplies of licensed medicinal products made by that registered pharmacy." This is commonly known as the 'de minimis' rule.

7. *How much of a pharmacy should a chief pharmacist register?*

There are no guidelines in relation to this. The chief pharmacist should consider which activities undertaken within the pharmacy would require the premises to be registered with the RPSGB or PSNI and where those activities take place.

Currently there are very few statutory standards for inclusion of pharmacies registered with the RPSGB or PSNI in the Register. When the new pharmacy regulator, the General Pharmaceutical Council, is established (which is expected in 2010) and takes over the regulation of pharmacy premises that are currently registered with the RPSGB, it will be required to establish and promote standards for the safe and effective practice of pharmacy at registered premises. The draft Pharmacy Order 2009 gives the General Pharmaceutical Council the power to set standards in Rules. These are new powers and have been incorporated in order to ensure entry and retention on the Register of only those pharmacies that comply with the relevant standards. Standards will cover requirements to be met by superintendent pharmacists and owners of registered pharmacies.

8. *Does a technician led dispensary need to have a responsible pharmacist?*

Where a technician led dispensary is part of unregistered premises or does not form part of premises registered with the RPSGB or the PSNI, there is no requirement for a responsible pharmacist to be in charge. However, if the dispensary is included in the registered premises, a responsible pharmacist must be in charge of the pharmacy when activities that require registration take place.

9. *Where can I find out how to register a pharmacy premises?*

Further details about how to register pharmacy premises can be found at www.rpsgb.org or alternatively the Society registration department can be contacted on: 0207 572 2322 or e-

mailed at registration@rpsgb.org or in Northern Ireland contact the PSNI by email at registration@psni.org.uk or by telephoning 028 90326927.

*10. What are the implications of holding a manufacturer's or wholesale dealer's licence?
How do I obtain a licence?*

Further details about how to apply for a manufacturer's licence are contained in MHRA Guidance Note No. 5 "Notes for applicants and holders of a manufacturer's licence" available on the MHRA website at:
www.mhra.gov.uk/home/groups/commsic/documents/publication/con007542.pdf.

Further details about how to apply for a wholesale dealer's licence are contained in MHRA Guidance Note No. 6 "Notes for applicants and holders of a wholesale dealer's licence" available on the MHRA website at:
www.mhra.gov.uk/home/groups/comms-ic/documents/publication/con007543.pdf.

11. Can a pharmacist qualified in Europe be a responsible pharmacist?

A pharmacist qualified in an EU member state may be the responsible pharmacist of a pharmacy which has been registered with the RPSGB or the PSNI 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; however they cannot be appointed as the responsible pharmacist.

12. A hospital pharmacy has two pharmacies on different floors of the same hospital; would this constitute one registered pharmacy premises?

If a premises is on 2 floors it would be considered to be a single premises if there is a direct link between the two floors, i.e. stairs which appear on the plans (and therefore form part of the registered area). If you have to leave the registered area on floor 1 to get to the registered area on floor 2, i.e. through a public area, then this would require 2 registrations.

13. What determines which legal entity is caring for a patient?

Hospitals themselves will need to determine which patients are considered to be under their care.

14. What is the definition of a single legal entity in respect of a company i.e. BMI or General Healthcare Group?

The company will need to determine what constitutes the same legal entity for the purpose of providing pharmacy services.

DEFINITIONS

These definitions are listed here for information within the context of this guidance document and are not legal definitions and/or interpretations.

Absence of the responsible pharmacist

A responsible pharmacist can be absent from the pharmacy for a maximum of two hours during the business hours of the pharmacy when the pharmacy is operational. The responsible pharmacist continues to be responsible for the safe and effective running of the pharmacy throughout their absence. A responsible pharmacist must comply with the conditions for absence, these are:

- that they remain contactable throughout their absence
- return with reasonable promptness
- in the event that they cannot remain contactable, they must arrange for another pharmacist to provide advice during their absence.

Assemble¹⁸

In relation to a medicinal product, this means enclosing the product (with or without other medicinal products of the same description) in a container which is labelled before the product is sold or supplied, or, where the product (with or without other medicinal products of the same description) is already enclosed in the container in which it is to be sold or supplied, labelling the container before the product is sold or supplied in it, and "assembly" has a corresponding meaning;

The term assembly includes the over-labelling and pre-packing of medicines (see definitions contained in this section)

Course of business

This is not defined in legislation. The working group has interpreted this to mean supply of medicines made within the same legal entity.

Hospital

Section 132 of the Act includes in the definition of a hospital a clinic, nursing home or other similar institution. The MHRA has taken the view that hospices fall within this definition. In Northern Ireland the RQIA (Regulation and Quality Improvement Authority) registers independent hospitals, which include hospices. The Care Quality Commission also publishes guidance on registration – for example the CQC registers independent treatment centres as hospitals.

Other organisations wishing to operate under the hospital exemption would need to demonstrate a claim to the exemption available under the Medicines Act (i.e. the hospital/health centre exemption).

Legally valid prescription (not including Controlled Drugs)

To be valid, a prescription issued by an appropriate practitioner:

- (a) shall be signed in ink with his own name by the appropriate practitioner giving it;
- (b) shall be written in indelible ink (this includes typewriting and computer generated prescriptions). A health prescription, which is not for a Controlled Drug specified in Schedule 1, 2 or 3 to the Misuse of Drugs Regulations, can be written by means of carbon paper or similar material but must be signed in indelible ink by the practitioner giving it;
- (c) shall contain the following particulars:
 - (i) the address of the appropriate practitioner giving it,
 - (ii) the appropriate date,

¹⁸ Section 132 of the Medicines Act 1968

- (iii) such particulars as indicate whether the appropriate practitioner giving it is a doctor, dentist, supplementary prescriber, community practitioner nurse prescriber, nurse independent prescriber, optometrist independent prescriber, pharmacist independent prescriber, EEA or Swiss doctor or an EEA or Swiss dentist,
- (iv) where the appropriate practitioner giving it is a doctor, dentist, supplementary prescriber, community practitioner nurse prescriber, nurse independent prescriber, optometrist independent prescriber, pharmacist independent prescriber, EEA or Swiss doctor or an EEA or Swiss dentist, the name, address and the age, if under 12, of the person for whose treatment it is given;
- (d) shall not be dispensed after the end of the period of six months from the appropriate date, unless it is a repeatable prescription in which case it shall not be dispensed for the first time after the end of that period nor otherwise than in accordance with the direction contained in the repeatable prescription;
- (e) in the case of a repeatable prescription that does not specify the number of times it may be dispensed, shall not be repeated on more than one occasion unless it is a prescription for oral contraceptives in which case it may be dispensed a total of six times (i.e., five repeats) before the end of the period of six months from the appropriate date.

The legislation¹⁹ allows a hospital to sell or supply a prescription-only medicine in the course of its business, against a patient specific "written direction" of a person (other than a veterinary surgeon or veterinary practitioner) who is an appropriate practitioner in relation to that medicine, instead of a prescription. The written direction does not need to comply with the requirements specified for prescriptions, but does need to relate to a specific patient.

Licensed medicines

These are medicines granted a product licence by the MHRA or a marketing authorisation by the European Commission.

Manufacture²⁰

In relation to a medicinal product, includes any process carried out in the course of making the product, but does not include dissolving or dispersing the product in, or diluting or mixing it with, some other substance used as a vehicle for the purpose of administering it

Notice: the responsible pharmacist requirements

A notice must be displayed conspicuously and must contain the following information:

- The name of the responsible pharmacist
- The registration number of the responsible pharmacist
- The fact that they are in charge of the pharmacy at that time.

Operational

A registered pharmacy premise is considered to be operational when an activity covered by the responsible pharmacist requirements takes place; see pharmacy procedures.

Over-labelling

This is generally understood to relate to the application of additional labelling to original packs of medicines, without any further changes or interventions to the packs.

Patient of a Hospital

Where a patient of a hospital is being treated and/or prescribed medicines by a practitioner or other appropriate healthcare professional who is employed by the hospital, that patient is deemed to be a patient of the hospital. This may include inpatients, outpatients, outreach patients and homecare patients.

¹⁹ Article 12 of the Prescription Only Medicines (Human use) Order 1997

²⁰ Section 132 of the Medicines Act 1968

Pharmacy

A department in a hospital or health centre can use the title 'pharmacy' without the need for the pharmacy to be registered with the RPSGB/PSNI.²¹

Pharmacy Procedures: the responsible pharmacist requirements

As a minimum, the procedures must set out

- 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.
- 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

Pharmacy record: the responsible pharmacist requirements

The pharmacy record must be available at the premises and the responsible pharmacist must record the:

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

Pre-packing

This is generally understood to relate to breaking bulk packs and filling the dosage forms (e.g. capsules or tablets) into smaller containers, which will require labelling.

²¹ Section 78(4) of the Act

Retail sale

A retail sale, selling by way of retail and circumstances corresponding to a retail sale are defined as sales or supplies that are not wholesale transactions. The dispensing of a prescription is considered to be a circumstance corresponding to a retail sale.

Registered Pharmacy

Section 74 defines this as premises for the time being entered in the register required under section 75 of the Act; the premises being registered with either the RPSGB or the PSNI.

Unlicensed medicines

A medicine which falls within the definition of a medicinal product but does not have a product licence or marketing authorisation within the UK.

Wholesale dealing

This takes place when a medicinal product is sold to a purchaser in a separate legal entity who purchases it with the purpose of

- Selling or supplying that medicinal product to another person
- Administering, or causing, the medicinal product to be administered to one or more human beings;

the sale, supply or administration of the medicinal product being in the course of the business carried on by the purchaser.

The Act requires those who engage in wholesale dealing to possess a licence. This wholesale dealer's licence is issued by the MHRA.

APPENDIX 3

FLOW CHART TO SUPPORT HOSPITAL PHARMACY PRACTICE IN THE UK

