

Draft guidance for registered pharmacies providing internet and distance sale, supply or service provision

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The General Pharmaceutical Council is the regulator for pharmacists, pharmacy technicians and registered pharmacies in England, Scotland and Wales.

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About this guidance

The aim of this guidance is to describe the factors that should be considered before deciding whether any parts of a pharmacy service can be safely and effectively provided in a different way to the traditional manner normally found in a registered pharmacy. Our standards refer to services provided 'at or from' a registered pharmacy. This guidance focuses on those services provided at or from registered pharmacies either through the internet or other forms of distance sale, supply or service provision.

In the traditional way of service delivery all the parts of the pharmacy service described below, take place in the registered pharmacy:

- the display of medicines for sale - whether on a shelf in your registered pharmacy or on a website that belongs to your registered pharmacy
- receipt of prescriptions for dispensing
- the assessment of clinical appropriateness of Pharmacy (P) medicines or the clinical appropriateness of prescriptions for patients
- providing advice to patients or the public and counselling them on how to take their medicines
- receipt of payment from purchasers, prescription tax or notification of exemptions from patients
- selection of medicines for supply
- assembly, preparation and labelling of medicines against prescriptions
- handing over medicines to patients.

This guidance applies in all cases where one or more parts of the sale or supply of medicines or pharmacy services are provided over the internet or in other forms of distance service provision. In particular it applies in all cases when pharmacy staff providing any part of the service, and the patient, carer or member of the public receiving that service, are not both present together in the registered pharmacy.

Alternative ways of providing pharmacy services are becoming increasingly common. This guidance supports current models of such pharmacy service

delivery for example as in ‘hub and spoke’ services¹, distance selling and internet pharmacy services. We recognise that due to socio-economic changes and advances in technology, pharmacy services will continue to adapt and change. We want this guidance to be useful in enabling innovation and the development of services which increase patient access to medicines and benefit their health and wellbeing. However there remain consistent legal principles and regulatory standards which focus on safe outcomes for patients that must be met in any pharmacy service development, regardless of the context of pharmacy service delivery.

This guidance should be read alongside the standards for registered pharmacies² which aim to create and maintain the right environment, both organisational and physical, for the safe and effective practice of pharmacy.

Following this guidance will help the pharmacy to:

- meet our standards, and
- provide assurances that the health, safety and wellbeing of patients and the public are safeguarded.

Responsibility for making sure this guidance is followed lies with the pharmacy owner. If the registered pharmacy is owned by a ‘body corporate’ (for example a company or an NHS organisation) the superintendent pharmacist also has responsibility. Those responsible for the overall safe running of the pharmacy need to take into account the nature of the pharmacy and the range of services provided and, most importantly, the needs of patients.

As well as meeting our standards, the pharmacy owner and superintendent pharmacist must make sure they keep to all legal requirements, including medicines legislation, the advertising of medicines, new consumer information regulations for online sales, data protection, health and safety, and equalities legislation.

¹ ‘Hub and spoke’ is a term used to describe a pharmacy service where certain activities such as the assembly, dispensing and labelling of medicines against prescriptions for individual patients occur in a central ‘hub’. The dispensed medicines are supplied by the ‘hub’ to ‘spokes’. The ‘spokes’ may be other registered pharmacies, or non-registered premises, where patients had dropped off their prescriptions and from where they collect their dispensed medicines.

² [Standards for registered pharmacies](#)

Pharmacy owners and superintendent pharmacists should make sure that all staff involved in providing these pharmacy services are familiar with this guidance. All staff have a responsibility to provide medicines safely to patients and work within their scope of competence.

We expect this guidance to be followed. However we also recognise that there are a number of ways to meet our standards and achieve the same outcomes for patients, of providing safe treatment, care and services. If you do not follow this guidance you should be able to show how your alternative ways of working safeguard patients, identify and manage any risks and meet our standards.

In this document when we use the term 'staff' this includes registrant and non-registrant agency and contract workers, as well as employees and other people who are involved in providing any part of your pharmacy service.

In this document, when we use the term '**you**' this means:

- a pharmacist who owns a pharmacy as a sole trader, and
- a pharmacist who owns a pharmacy as a partner in a partnership, and
- a pharmacist who is the appointed superintendent pharmacist for a body corporate, and
- the body corporate itself.

The scope of this guidance

Pharmacy services covered by this guidance include:

- a pharmacy service where prescriptions are not handed in by patients but collected by pharmacy staff, received by post or electronically;
- a delivery service from the registered pharmacy to patients in their own home or in a care/nursing home;
- a collection and delivery service³;
- a 'click & collect' service;
- a mail order service from a registered pharmacy;
- an internet pharmacy service, including those that have an NHS 'distance selling contract', or linked to an on-line prescribing service

³ A collection and delivery service is defined in Regulation 248 of the Human Medicines Regulations 2012.

whether or not the prescribing service is owned and operated by you, or a third party business;

- a 'hub and spoke' pharmacy service where the preparation, assembly, dispensing and labelling of medicines for individual patients against prescriptions, takes place at a central 'hub' registered pharmacy and then either delivered directly to the patient or to a 'spoke' for collection by the patient.

This is not an exhaustive list as advances in technology and innovations in pharmacy service delivery are constantly changing. You should consider how you will meet our standards for registered pharmacies and this guidance when you are developing any new pharmacy service, to make sure risks are managed and medicines are supplied safely to patients.

Introduction

The law⁴ sets out that pharmacy (P) medicines and prescription only medicines (POMs) can only be sold or supplied, or offered for sale or supply from a registered pharmacy by or under the supervision of a pharmacist. This applies in the same way to the sale, supply or offer of such from both the traditional face to face registered pharmacy and also to any new pharmacy service models.

The law⁵ also sets out that medicines can only be prepared, assembled, labelled and supplied for individual patients against prescriptions at a registered pharmacy under the supervision of a pharmacist. This applies in the same way to pharmacy services provided from both the traditional face to face registered pharmacy and also to any new pharmacy service models.

If you sell or supply medicines to patients who live in other countries you must make sure that the medicine you supply has the relevant marketing authorisation in that country and that you comply with all legal requirements.

⁴ Regulation 220 Human Medicines Regulations 2012. There are exemptions from this requirement for hospitals and also for supplies made by doctors or dentists to their patients.

⁵ Section 10 Medicines Act 1968. There are exemptions where these activities take place under the supervision of a pharmacist but in a hospital, a care home service or a health centre.

If you sell or supply medicines for animal use, the parts of the law that apply, and the exemptions that allow this are found elsewhere⁶. The body that regulates animal medicines is the Veterinary Medicines Directorate ([VMD](http://www.vmd.defra.gov.uk/))⁷.

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⁶ Veterinary Medicines Regulations 2013

⁷ <http://www.vmd.defra.gov.uk/>

Guidance for registered pharmacies providing internet and distance sale, supply or service provision

The standards for registered pharmacies are grouped under five principles, and this guidance is set out under each of the five principles.

Principle 1: The governance arrangements safeguard the health, safety and wellbeing of patients and the public.

The following areas relate to this principle in the standards for registered pharmacies.

Although the same legal framework and the standards for registered pharmacies apply, different risks are associated with internet and distance sale, supply or service provision. These risks can be managed but you will need to provide evidence that you have done so and that you can provide pharmacy services safely and effectively.

1.1 Risk assessment

A risk assessment is a careful and thorough look at what in your work could cause harm to patients and what you need to do to prevent this. Risk assessments should be specific to your individual pharmacy, the staff working in it and each part of the pharmacy service you provide over the internet or by other forms of distance sale, supply or service provision.

You should consider the risks before deciding whether your pharmacy should provide internet or other forms of distance sale or supply to ensure safe outcomes for patients. This is particularly important as the risks will be very different and potentially much greater if proper controls are not in place.

You should carry out a risk assessment and carry out the necessary checks to satisfy yourself that any arrangements you have in place to manage the risks involved meet the requirements of principle 1 and be able to produce evidence to show that you have done this.

The areas you should consider in your risk assessment are similar to those that you would consider in the traditional pharmacy service model but the risks you identify, assess and need to manage are likely to be very different.

This is because the different parts of your pharmacy service may not always take place in one registered pharmacy where both the pharmacy staff and patient are physically present, but may take place at different locations and be the responsibility of several different parties. In such cases, for example, you should consider how the systems you use to provide your pharmacy service, including ICT systems for the exchange of information between different locations, connect and interact. You should also consider how you would monitor the accuracy of these systems and manage any potential failures.

Also as patients may not have to physically come to your registered pharmacy to receive all parts of your pharmacy service, you may be providing pharmacy services to many more patients. In your risk assessment you should consider including evidence of your capacity to provide pharmacy services to a larger number of patients safely and the impact of any business decisions you make.

The risk assessment should be reviewed regularly (see section 1.2) and should also be reviewed when circumstances change (see section 1.3).

The risk assessment should state what the risks are and may include looking at different options available to you for setting up your pharmacy service.

1.2 Regular audit

You should carry out a regular audit, at an interval that you can show to be appropriate, for your pharmacy services.

The audit should form part of the evidence which provides assurance and shows that your pharmacy continues to provide pharmacy services that are safe for patients although one or more parts of your service maybe provided over the internet or other form of distance sale, supply or service provision.

While this is not a full list of issues that need to be considered, the audit should, if applicable look at the:

- staff training and skills
- suitability of communication methods with patients
- records of decisions to make or refuse a sale
- systems and process for secure delivery to patients

- the information about your pharmacy services on your website, (where relevant)
- compliance with your information security policy, Payment Card Industry Data Security Standard (PCI DSS) and data protection legislation.

While the above also apply to all registered pharmacies, there will be different issues to consider in internet and distance sale, supply or service provision.

Also depending on the nature of the services you provide, we would expect you to consider whether your information security practices need to be audited by external, independent auditors.

1.3 Reactive review

A review should for example, take place when any of the following happens:

- a change in regulations affecting any part of your pharmacy services
- any change in any part of the pharmacy service you provide
- a data security breach
- any change in the technology you use
- concerns or feedback received
- a review of near misses and error logs indicates a concern about an activity.

You should document this reactive review and say when a new risk assessment is needed. It can form part of that new assessment, when one needs to be carried out.

1.4 Accountability – staff

In internet, distance sale, supply or service provision some of the activities needed to safely make a sale and supply of a medicine may not take place in one registered pharmacy as in the traditional pharmacy service, but may be done safely and legally in different places. For example if you use a delivery service, although medicines are supplied from your registered pharmacy they may be delivered by an agent and received by the patient at their home or place of employment. As the hand over to the patient does not take place in the registered pharmacy there is increased risk of medicines being lost or

delivered to the wrong patient. There must be clear lines of responsibility and accountability for staff providing parts of the pharmacy service where there may be no pharmacist present to direct and supervise. Where you contract any part of your pharmacy service you continue to be responsible for its safe and effective provision.

It must be clear which pharmacist is accountable and responsible for any part of the pharmacy service.

It must be clear which pharmacy technician and other staff are involved in providing any part of the pharmacy service.

1.5 Record keeping

Where the patient has direct face to face contact with pharmacy staff in a traditional community pharmacy no records of the sale of P medicines are made. And where a product is unsafe or unsuitable and no supply is made this is communicated appropriately to the patient but no records are usually kept.

Where there is no face to face contact you should consider what extra checks are necessary and what information you should record and keep to show that the pharmacy service you provide is safe. The records you keep are an important evidence base for the judgements you and your staff make and are potentially a powerful tool for service improvement and quality management.

You should decide as part of your risk assessment the records you keep depending on the nature of the pharmacy services you provide.

You should keep the records for as long as you consider, and can show, to be appropriate. Ask the pharmacy's professional indemnity or insurance provider for advice about how long records should be kept.

The records may include information on the following:

- details of the staff accountable and responsible for providing that part of your pharmacy service
- information and advice provided on safe use of medicines
- consent to a mode of delivery and date of dispatch

- complaints or concerns from patients or their carers.

Principle 2: Staff are empowered and competent to safeguard the health, safety and wellbeing of patients and the public.

The following areas relate to this principle in the standards for registered pharmacies.

2.1 Trained and competent staff

Staff involved in providing any part of your pharmacy service must be properly trained and competent. You should be able to show that you have considered the specific development needs required by staff to provide any part of your pharmacy service in this way.

You and your staff must have done relevant training before being involved in providing any pharmacy services over the internet or other forms of distance sale, supply or service provision. Staff may also be involved in these services if they are doing such training, but their work in this area must be closely supervised until their training is complete. You should consider the training staff need to effectively communicate with patients to confirm that medicines are safe and help patients in their decision making when patients are not in the registered pharmacy.

Additional training in the following areas should be considered:

- information security management, the Data Protection Act and cyber security;
- communication skills to support staff in managing non-face to face patient communications;
- use of specialised equipment.

You should keep records of any training done.

Principle 3: The environment and condition of the premises from which pharmacy services are provided, and any associated premises, safeguard the health, safety and wellbeing of patients and the public.

The following areas relate to this principle in the standards for registered pharmacies.

3.1 Your premises

You must make sure that, apart from the limited exemptions in legislation:

- the sale, supply or offer for sale or supply of P medicines or POMs
- the preparation, assembly, labelling and supply of medicines against prescriptions for individual patients

take place under the supervision of a pharmacist at or from a registered pharmacy.

You must also make sure that the physical premises you use for any part of the pharmacy service you provide meet the same standards required for pharmacy services provided in the traditional way.

You may sell and supply medicines to more patients than a traditional pharmacy would. Therefore your pharmacy premises must be fit for purpose to reflect the scale of work you do. If you consider automating certain activities, there must be adequate space to accommodate robot technology safely. You may also need to make sure that you have suitable areas within your registered pharmacy to safely dispatch medicines to patients.

3.2 Your website

You should consider the design and layout of your website and make sure it is appropriate for the safe supply of medicines to patients.

If you sell and supply P medicines over the internet, you must make sure that the P medicines are only displayed for sale on a website that belongs to a registered pharmacy.

You should make sure that your website is secure and complies with information security management guidelines.

All information on your website should be clear, accurate and up to date. This may include information about medicines, health advice and links to other information sources such as relevant healthcare services and other regulatory authorities.

You should also consider what information you display on your pharmacy website. This should include your GPhC registration number and may also include:

- the name of the owner of the registered pharmacy
- where applicable, the name of the superintendent pharmacist
- the name and address of the registered pharmacy that supplies the medicines
- details of the registered pharmacy responsible for preparing, assembling, dispensing and labelling medicines for individual patients against prescriptions, if these activities take place at a different pharmacy from that supplying the medicines
- information about how to check the registration status of the pharmacy and the superintendent pharmacist (where applicable)
- the contact details of the pharmacy
- details of how patients can provide feedback and raise concerns.

This information should be available to patients in a prominent way.

You must make sure that you comply with data protection legislation when you ask patients for personal details. You must make sure that your website has secure facilities for collecting, using and storing patient details⁸ obtained via the internet and a secure link for processing card payments.⁹

Some registered pharmacies providing internet services have direct links to or from other websites, for example an on-line prescribing service or to another

⁸ See http://ico.org.uk/for_organisations/sector_guides/health

⁹ For example a secure link that complies with the Payment Card Industry Data Security Standard (PCI DSS).

registered pharmacy website. If you do allow a link to another business you are responsible for making sure that that business is legitimate and, where relevant, registered with the appropriate regulator.

Patients must be clear who is responsible for providing which service. Links from your pharmacy website to an on-line prescribing service or another registered pharmacy website should be clearly indicated.

You should consider how you can dispense medicines to patients safely if your pharmacy is responsible for supplying medicines against prescriptions following an on-line consultation.

You may also consider applying to use the [voluntary GPhC internet logo](#)¹⁰ on your website. The logo links directly to the GPhC register entry for your pharmacy. It may only be used on the website of the registered pharmacy for whom it was issued and cannot be used by a third party, prescribing or other websites.

In the future the EU is introducing a compulsory internet logo for all organisations selling prescription and non-prescription medicines (including General Sales List Medicines) over the internet which will have to be displayed on every page of your website. This legislation will come into force in July 2015.¹¹

¹⁰ <http://www.pharmacyregulation.org/registration/internet-pharmacy>

¹¹ Regulation 28 of the Human Medicines (Amendment) Regulations 2013

Principle 4: The way in which pharmacy services, including the management of medicines and medical devices, are delivered safeguards the health, safety and wellbeing of patients and the public.

The following areas relate to this principle in the standards for registered pharmacies.

4.1 Transparency and patients' choice

Your pharmacy service may be associated with a medical or non-medical prescribing service. The prescribing service may be an on-line service that patients can access by a link from your pharmacy website, or one where prescriptions are ordered and collected by you on behalf of patients from a local surgery or received by your pharmacy by post or electronically.

In all cases you must ensure that patients are aware of and consent to the pharmacy service you provide in association with these prescribing services.

You will need to be able to show that your arrangements with medical or non-medical prescribers do not give rise to conflicts of interest or restrict a patient's choice of pharmacy.

4.2 Managing medicines safely

The sale or supply of medicines in an internet or distance pharmacy service presents different risks that you should consider as part of your initial risk assessment.

You should be able to show the steps you have taken to minimise the risks you identify. This may include how you:

- identify that the patient is who he/she claims to be
- assess which medicines are or are not appropriate for supply in a non-face to face pharmacy service
- make sure your pharmacy staff can get all relevant information from patients to check the supply is safe and appropriate, taking into account for example their age, gender and other relevant factors

- make sure patients can ask questions about their medicines
- monitor orders for medicines to identify ones that are large or inappropriate.

4.3 Supplying medicines safely

In your pharmacy service the supply of medicines to the patient from a registered pharmacy can occur via a delivery agent at a destination selected by the patient. More recent models of distance sale and supply use automated collection machines.

You should make sure the medicines are delivered safely to the correct person when they need them and consider how to do this as part of the initial risk assessment.

You should be able to show the steps you have taken to manage the risks you identify. This may include how you:

- assess the suitability of the mode of dispatch;
- check the terms, conditions or restrictions of the carrier;
- check the legal requirements for export or import of medicines if the intended recipient is outside the UK.

4.4 Patient information

Where pharmacy staff do not see the patient face to face you should consider how staff can give the patient any important information they need to use the medicine safely and give clear information on how the patient can contact a pharmacist.

Where parts of your pharmacy service take place at different locations you should consider how you inform patients of the services that take place at different locations and ensure consent is given for this form of service provision.

Principle 5: The equipment and facilities used in the provision of pharmacy services safeguard the health, safety and wellbeing of patients and the public.

The following areas relate to this principle in the standards for registered pharmacies.

5.1 Specialist equipment and facilities

You should make sure that your pharmacy service has equipment and facilities which are specifically designed for the intended purpose. Equipment should be of sufficiently high specification, accuracy and security.

Examples of specialist equipment include, but are not limited to the following:

- automated dispensing and labelling equipment
- automated collection points
- mobile devices used for remote access.

You should make sure that you have a maintenance contract with the specialist equipment supplier and keep maintenance logs for as long as you consider and can show to be appropriate.

Other useful sources of information

Medicines and Healthcare products Regulatory Agency

Falsified medicines directive: Sales of medicines at a distance to the public

www.mhra.gov.uk/Howweregulate/Medicines/Overviewofmedicineslegislationandguidance/TheFalsifiedMedicinesDirective/Salesofmedicinesatadistancetothepublic/index.htm

Advertising of medicines

www.mhra.gov.uk/home/groups/pl-a/documents/publication/con2022589.pdf

Risks of buying medicines over the internet

www.nidirect.gov.uk/risks-of-buying-medicines-over-the-internet

NHS England

NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013

www.legislation.gov.uk/uksi/2013/349/contents/made

The Veterinary Medicines Directorate

Internet retailers of veterinary medicines

<http://www.vmd.defra.gov.uk/pharm/internetretailers.aspx>

Department for Business, Innovation & Skills

www.getsafeonline.org/shopping-banking/buying-medicines-online1/

<https://www.cyberstreetwise.com/#!/protect-business/what-you-need-to-know>

The Information Commissioner's Office

Data protection advice for NHS and health professionals

www.ico.org.uk/for_organisations/sector_guides/health

Centre for Postgraduate pharmacy education (CPPE)

Confidence in consultation skills

www.cppe.ac.uk/learning/Details.asp?TemplateID=Consult-W-02&Format=W&ID=115&EventID=-