

Guidance for registered pharmacies providing pharmacy services at a distance, including on the internet

April 2015

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

About this guidance

This guidance explains what you should consider before deciding whether any parts of your pharmacy service can be provided safely and effectively 'at a distance' (including on the internet), rather than in the 'traditional' way.

A 'traditional' pharmacy service is one where all parts of the pharmacy service, including the sale and supply of medicines, takes place in the same registered pharmacy. For example, the patient brings their prescription to the registered pharmacy, pharmacy staff dispense it and advise the patient in the same pharmacy.

Different ways of providing pharmacy services are becoming more common. We recognise that because of changes in society and advances in technology, pharmacy services will continue to adapt and change. However the pharmacy service is delivered, the legal principles and regulatory standards aimed at guaranteeing safe outcomes for patients and people who use pharmacy services must still be met. The sale and supply of Pharmacy (P) medicines and Prescription Only Medicines (POMs) must only happen at or from a registered pharmacy under the supervision of a pharmacist, even when the sale or supply is made on the internet.

To meet the needs of patients and people who use pharmacy services, some parts of the pharmacy service may not take place at the pharmacy itself. The authorisation to supply a P medicine or the clinical check of a prescription may take place off site. Examples of this would be at a clinic or care home, although the supply of medicines would still have to be from a registered pharmacy and supervised by a pharmacist.

We want this guidance to be useful for pharmacies wanting to innovate and introduce new ways of working. We also want it to support appropriate access to medicines and pharmaceutical care, which complies with the law and meets our standards.

You should read this guidance alongside the **standards for registered pharmacies**¹.

Following this guidance will help your pharmacy to:

- meet our standards, and
- provide assurances that the health, safety and wellbeing of patients and people who use pharmacy services are safeguarded

The pharmacy owner is responsible for making sure this guidance is followed. If the registered pharmacy is owned by a 'body corporate' (for example a company or an NHS organisation) the superintendent pharmacist also has that responsibility. Those responsible for the overall safe running of the pharmacy must take into account the nature of the pharmacy, the range of services provided and, most importantly, the needs of patients and people who use pharmacy services.

¹ www.pharmacyregulation.org/standards/standards-registered-pharmacies

As well as meeting our standards, the pharmacy owner and superintendent pharmacist must make sure they keep to all the laws that apply to pharmacies. This includes the law on supplying and advertising medicines², new consumer information for online sales³, and data protection⁴.

Pharmacy owners and superintendent pharmacists should make sure that all staff involved in providing pharmacy services at a distance – including on the internet – are familiar with this guidance. All staff have a responsibility to provide medicines safely to patients and to only do work they are competent to do.

We expect this guidance to be followed. However, we also recognise there are a number of ways to meet our standards and achieve the same outcomes for patients and people who use pharmacy services – that is, to provide safe treatment, care and services. If you do not follow this guidance you must be able to show how your own ways of working:

- safeguard patients and users of pharmacy services
- identify and manage any risks, and
- meet our standards.

In this document, when we use the term ‘staff’ this includes:

- employees (registrants and non-registrants)
- agency and contract workers, and
- any third party who helps the pharmacy provide any part of the pharmacy service, and deals with patients and people who use pharmacy services on behalf of the pharmacy owner

² www.gov.uk/advertise-your-medicines <https://www.gov.uk/government/publications/blue-guide-advertising-and-promoting-medicines>

³ www.gov.uk/government/policies/providing-better-information-and-protection-for-consumers

⁴ www.ico.org.uk/for_organisations/sector_guides/health

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

We will review this guidance from time to time, to make sure it stays relevant when there are changes in government policy or the law, or when new ways of working develop.

The scope of this guidance

This guidance covers pharmacy services that are not 'traditional' ones. In a 'traditional' pharmacy all parts of the service are provided at the same registered pharmacy, including:

- displaying medicines for sale
- receiving prescriptions for dispensing
- assessing whether Pharmacy (P) medicines and General Sale List (GSL) medicines, and prescriptions, are clinically appropriate
- advising patients and people who use pharmacy services and counselling them on how to take their medicines
- taking payments, prescription charges or notifications of exemption from patients
- selecting medicines for supply
- assembling, preparing and labelling medicines against prescriptions
- handing over medicines to patients or their carers and representatives

So this guidance applies to pharmacy services when any of the activities above are carried out at different registered pharmacies or places. It also applies in all cases when a member of staff or a third party providing any part of the pharmacy service, and the patient or person who uses the pharmacy service, are not both in the same registered pharmacy together.

Examples of the pharmacy services covered by this guidance include:

- a pharmacy service where prescriptions are not handed in by patients but collected by pharmacy staff, or received by post or electronically – such as in the electronic prescription service (EPS)⁵
- a delivery service from the registered pharmacy to patients in their own home or in a care home or nursing home
- a collection and delivery service⁶
- a ‘click and collect’ service
- a mail order service from a registered pharmacy
- an internet pharmacy service, including ones linked to an online prescribing service whether or not the prescribing service is owned and operated by you, or by a third-party business
- a ‘hub and spoke’⁷ pharmacy service, where medicines are prepared, assembled, dispensed and labelled for individual patients against prescriptions at a central ‘hub’ registered pharmacy

This is not a full list. You must consider how you will follow this guidance and meet our standards for registered pharmacies if you intend to provide any part of your pharmacy service at a distance, including on the internet. You need to make sure you identify and manage risks, and supply medicines and services safely to patients and people who use pharmacy services.

⁵ www.systems.hscic.gov.uk/eps

⁶ A collection and delivery service is defined in Regulation 248 of the Human Medicines Regulations 2012.

⁷ The dispensed medicines are supplied by the ‘hub’ to ‘spokes’ or delivered direct to patients in their homes or to care homes. The ‘spokes’ may be other registered pharmacies; or non-registered premises, where patients drop off their prescriptions and from where they collect their dispensed medicines.

Introduction

The law⁸ says 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. And this must be done by, or under the supervision of, a pharmacist.

The law⁹ also says 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 same law applies whether you provide pharmacy services in a ‘traditional’ way, at a distance or on the internet.

Even if you offer a delivery service, the handover to the delivery agent of a P or POM medicine must take place at a registered pharmacy under the supervision of a pharmacist.

If you sell or supply medicines to patients in other countries you must keep to any other laws that apply. This may include making sure the medicine you supply has the marketing authorisation needed for it in that country¹⁰.

If you sell or supply medicines for animal use, the parts of the law that apply, and the exemptions that allow this, are covered elsewhere¹¹. The Veterinary Medicines Directorate (VMD)¹² licenses and approves animal medicines and issues guidance on supplying medicines for animals.

The NHS Regulations in England¹³ include a number of specific situations that allow distance-selling pharmacies to open and operate. In Scotland and Wales the regulations are not the same. However, they do not prevent pharmacies that are already open from providing pharmacy services at a distance or on the internet.

⁸ Regulation 220 of the Human Medicines Regulations 2012. Supplies made by hospitals, and made by doctors or dentists to their patients, are exempt from this.

⁹ Section 10 Medicines Act 1968. There are exemptions when these activities take place under the supervision of a pharmacist in a hospital, a care home or a health centre.

¹⁰ Regulation 28 of the Human Medicines (Amendment) Regulations 2013

¹¹ Veterinary Medicines Regulations 2013

¹² www.gov.uk/government/organisations/veterinary-medicines-directorate

¹³ The National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013

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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.

1.1 Risk assessment

There are different risks with providing any pharmacy service at a distance, including on the internet. Before you start providing the service, you should gather evidence that you have identified and managed the risks, and checked that the arrangements you have in place meet the requirements of principle 1. This will show you can provide the service safely and effectively.

A risk assessment will help you identify and manage risks. It is a careful and thorough look at what in your work could cause harm to patients and people who use pharmacy services, and what you need to do to keep the risk as low as possible. You may want to make sure that risks are reduced 'as low as reasonably practicable'¹⁴, managing the risk against what you have to do to reduce it further.

Your risk assessment should say what risks you have identified, and include the different options you have for setting up your pharmacy service. Your staff should know the outcome of any risk assessment and contribute to it appropriately. If you keep a risk register, you are responsible for keeping it up to date and recording any actions you have taken.

¹⁴ www.hse.gov.uk

Risk assessments may be corporate wide but still need to take into account the circumstances of each individual pharmacy, including the staff working in it, and each individual part of the pharmacy service you intend to provide. It should cover the whole service.

If parts of your pharmacy service are the responsibility of several different pharmacies and staff, you should consider how the systems you use to provide your pharmacy service work together – including IT systems for exchanging information between different locations. You should also consider how you monitor the accuracy of these systems and manage any potential failures.

Areas of risk you should think about include:

- how staff tell patients and the public about the pharmacy services they will receive, and how they get their consent
- how staff communicate between different locations
- medicines supply, including counselling and delivery (see principle 4, page 20)
- your business's capacity to provide the proposed services, and
- business continuity plans, including website and data security

Not all risks can be foreseen and dealt with in advance. Some may only appear with time, as a result of:

- patient, user of pharmacy service or staff behaviour
- different technologies operating together, or
- an increase in the number, or scale, of services

You should therefore review your risk assessment regularly (see section 1.2), and when circumstances change – for example, when you make significant business or operational changes (see section 1.3).

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. You should also be able to show how your staff are involved in the audit. Regular audits may be corporate wide, but still need to be relevant to the circumstances of each individual pharmacy.

The audit should be part of the evidence which gives assurance and shows that your pharmacy continues to provide safe pharmacy services to patients and people who use those services. You should take action to sort out any issues you identify, and this may lead to your carrying out a 'reactive' review (see section 1.3).

This is not a full list of issues, but you should consider the following as part of your regular audit:

- staffing levels and the training and skills within the team
- suitability of communication methods with patients, and between staff and other healthcare providers, including between hubs and spokes and with collection and delivery points
- systems and processes for receiving prescriptions, including EPS
- records of decisions to make or refuse a sale
- systems and processes for secure delivery to patients
- any information about your pharmacy services on your website
- how you keep to your information security policy, Payment Card Industry Data Security Standard (PCI DSS) and data protection law
- feedback from patients and people who use pharmacy services
- concerns or complaints received, and
- activities of third parties, agents or contractors

You should consider whether your information security practices need to be audited by independent experts, depending on the type of service you provide.

1.3 Reactive review

You should carry out a review if a regular audit identifies a problem, or when any of the following happens:

- a change in the law affecting any part of your pharmacy service
- a significant change in any part of the pharmacy service you provide, for example an increase in the number of patients you provide services to, or an increase in the range of services you intend to provide
- a data security breach
- a change in the technology you use
- concerns or negative feedback are received from patients or people who use pharmacy services
- a review of near misses and error logs causes a concern about an activity

You should record this reactive review and say clearly when a new risk assessment needs to be carried out.

1.4 Accountability – staff

When parts of a pharmacy service take place at different locations (such as in a ‘hub and spoke’ or ‘click and collect’ service) you must be clear about which pharmacist is accountable and responsible for each part of the service, and which pharmacy technician and other staff are involved.

When medicines are not given to the patient in the registered pharmacy but are delivered by a member of staff or an agent to the patient’s home or workplace, there may be more risk of medicines being lost or delivered to the wrong person. You must make sure there are clear lines of accountability and responsibility in these circumstances.

If you contract out any part of your pharmacy service to a third party you are still responsible for providing it safely and effectively. You must carry out ‘due diligence’ in selecting any contractors.

1.5 Record keeping

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

When a patient has direct face-to-face contact with pharmacy staff in a pharmacy no records of the sale of P medicines are usually made. And when a product is unsafe or unsuitable and no supply is made, staff tell the patient, but no records are usually kept.

When there is no face-to-face contact, you should consider what information you and your staff record and keep to show that the pharmacy service you provide is safe. This may include the key points on which you made the decision to sell or not to sell a particular medicine. The records you keep are important evidence for the judgements you and your staff make, and can be a powerful tool for service improvement and quality management.

Although medicines law says how long you should keep certain records, you should keep other records for as long as you consider, and can show, to be appropriate.

The records should include:

- information on risk assessments, audits and reactive reviews
- details of the staff accountable and responsible for providing each part of your pharmacy service
- the information and advice you give patients and people who use pharmacy services on using medicines safely
- consent to use a particular delivery method, and the date of dispatch of the medicine
- information on complaints or concerns from patients or people who use pharmacy services and what you have done to deal with these; and
- IT records (see principle 5, page 23)

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

2.1: Trained and competent staff

You are responsible for creating a culture of patient-centred professionalism within your pharmacies. This should support pharmacists and pharmacy technicians in behaving and practising as professionals. You must make sure that all staff are properly trained and competent to provide medicines and other professional pharmacy services safely. This is vital to the safety and wellbeing of patients and the public.

You must be able to show you have considered the specific training staff will need to provide any part of your pharmacy service. You and your staff must do any relevant training needed before being involved in providing any pharmacy services at a distance, including on the internet. Staff may be involved in these services while they are doing this training, but their work in this area must be closely supervised until their training is finished.

You should consider extra training in the following areas:

- information security management – how patient data is protected, and cyber security
- communication skills¹⁵ to support staff in managing effective non-face-to-face communications with patients and prescribers, and
- using specialised equipment and new technology

You should document and keep evidence of the training done for as long as you consider, and can show, to be appropriate.

¹⁵ Support for professionals or employers wanting to develop communications skills of staff are available from a range of organisations referenced at the end of this guidance

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.

3.1 Your premises

You must make sure your pharmacy and the premises you use for any part of your pharmacy services meet the standards for registered pharmacies.

If you provide pharmacy services at a distance or on the internet, your registered pharmacy must be fit for purpose to reflect the scale of the work you do. If you automate certain activities, there must be enough space to use automated dispensing systems safely. You should make sure that you have suitable areas in your registered pharmacy to send medicines to patients safely.

3.2 Your website

If you sell and supply P medicines on the internet, you must make sure that these are only displayed for sale on a website that is associated with a registered pharmacy. This could be under a service level agreement or some other arrangement. The public may be able to access the site directly or through a third-party site.

People who use pharmacy services should be able to select a P medicine for purchase only on a website associated with a registered pharmacy.

You should consider the design and layout of your website and make sure that it works effectively and looks professional.

Your website must be secure and follow information security management guidelines and the law on data protection. This is particularly important when you ask patients for personal details. You must make sure that your website has secure facilities for collecting, using and storing patient details¹⁶ and a secure link for processing card payments.¹⁷

All information must be clear, accurate and updated regularly, and it must not be misleading in any way. Your site may include information about medicines, health advice and links to other information sources such as relevant healthcare services and other regulators. Your site must not mislead pharmacy service users about the identity or location of the pharmacies involved in providing your pharmacy services.

Links from your pharmacy website to an online prescribing service or another registered pharmacy website must be clearly shown as such. Some pharmacy businesses and online prescribing services are owned by the same company and operate together using the same website. If you allow a link to another business (either hosted on your website or reached by an external link) you are responsible for making sure the business is legitimate. And, if relevant, it must be registered with the appropriate regulator such as the Care Quality Commission, Healthcare Improvement Scotland or the Health Inspectorate Wales.

¹⁶ See www.ico.org.uk/for_organisations/sector_guides/health

¹⁷ For example a secure link that complies with the Payment Card Industry Data Security Standard (PCI DSS).

You should display prominently on your website:

- the GPhC pharmacy registration number
- your name as the owner of the registered pharmacy
- the name of the superintendent pharmacist, if there is one
- the name and address of the registered pharmacy that supplies the medicines
- details of the registered pharmacy where medicines are prepared, assembled, dispensed and labelled for individual patients against prescriptions (if any of these happen at a different pharmacy from that supplying the medicines)
- information about how to check the registration status of the pharmacy and the superintendent pharmacist (if there is one)
- the email address and phone number of the pharmacy
- details of how patients and users of pharmacy services can give feedback and raise concerns

Later this year the MHRA will launch the compulsory EU internet logo¹⁸. When this is available you must apply to the MHRA for this logo and display it on every page of your website if you sell any GSL or P medicines, or supply POM medicines, on the internet. (The EU internet logo will also be displayed on the websites of non-pharmacy retailers of GSL medicines.) You will need to meet all the conditions set out in the law¹⁹ before the MHRA will give you the EU internet logo for display.

You may also apply to use the **voluntary GPhC internet logo**²⁰ on your website, which links directly to the GPhC register entry for your pharmacy. You can only display it on your own website. You must not allow it to be used by a third-party, prescribing or other website.

¹⁸ www.gov.uk/government/organisations/medicines-and-healthcare-products-regulatory-agency

¹⁹ Regulation 28 of the Human Medicines (Amendment) Regulations 2013

²⁰ www.pharmacyregulation.org/registration/internet-pharmacy

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.

4.1 Transparency and patient choice

Patients have the right to make decisions about their care and medicines, and the services they want to receive, including being able to choose where they want their medicines supplied from. Pharmacy professionals must give the patient the information they need so they can make an informed decision about their medicines and the pharmacy services they use.

Your pharmacy service can be associated with a medical or non-medical prescribing service. The prescribing service may be:

- one where you order and collect prescriptions on behalf of patients from the doctor's surgery, or
- one where you receive prescriptions by post or electronically, or
- an online service that patients can access on your pharmacy website or by a link from your pharmacy website

In all cases, you and your staff must make sure patients consent to any pharmacy service you provide using these prescribing services.

You must be able to show that your arrangements with medical or non-medical prescribers are transparent, and do not:

- cause conflicts of interest
- restrict a patient's choice of pharmacy, or
- unduly influence or mislead patients deliberately or by mistake

If parts of your pharmacy services are provided at different locations you must explain clearly to patients and people who use pharmacy services where each part of the service is based. You must avoid any information that could mislead the patient or user of the pharmacy service about the identity or location of the pharmacy.

4.2 Managing medicines safely

Selling and supplying medicines at a distance, including on the internet, brings different risks than those of a 'traditional' pharmacy service. You should consider these as part of your initial risk assessment. (See also principle 1, page 11.)

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

- decide which medicines are appropriate for supplying at a distance, including on the internet
- make sure your pharmacy staff can:
 - check that the patient is who they claim to be, and
 - get all the information they need from patients to check that the supply is safe and appropriate, taking into account for example their age, gender, other medicines and other relevant issues
- make sure patients can ask questions about their medicines
- make sure patients know who to contact if they have any questions or want to discuss something with the pharmacy staff, and
- identify requests for medicines that are inappropriate, too large or too frequent

4.3 Supplying medicines safely

You should make sure the medicines are delivered safely to the correct person when they need them. You should 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 should include how you:

- assess the suitability and timescale of the method of supply, dispatch, and delivery²¹ (for example, for refrigerated medicines and controlled drugs)
- assess the suitability of packaging (for example, packaging that is tamper proof or temperature controlled)
- check the terms, conditions and restrictions of the carrier
- check the laws covering the export or import of medicines if the intended recipient is outside the UK
- train your staff, and
- monitor third-party providers

4.4 Patient information

When pharmacy staff do not see the patient face to face you should consider how staff can communicate any important information to patients clearly and effectively.

You must also tell patients about services that take place at different locations, and you must make sure you have their consent for this form of service.

You must give clear information to patients and people who use pharmacy services on how they can contact your pharmacy staff if they have any problems or need more advice. This should also include advice on when they should go back to their GP or local pharmacist.

²¹ Royal Pharmaceutical Society www.rpharms.com Delivery and posting of medicines to patients - Medicines, Ethics and Practice – The professional guide for pharmacists Edition 38 July 2014.

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

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, and your equipment is:

- of high specification, accuracy and security, and
- calibrated, maintained and serviced regularly in line with the manufacturer's specifications, and you keep maintenance logs for as long as you consider, and can show, to be appropriate.

Examples of specialist equipment include:

- automated dispensing systems and labelling equipment
- mobile devices used for remote access

Your software for providing services at a distance, including on the internet, should be robust enough to handle the volume of work.

You must make sure your IT equipment meets the latest security specifications. You must also make sure the security of data is protected when it is in transit, by either wired or wireless networks, inside your business and outside it. You must also control access to records and how you store, keep and remove records.

Other sources of information

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=-

Community Pharmacy Scotland

www.communitypharmacyscotland.org.uk

Community Pharmacy Wales

www.cpwales.org.uk/Home.aspx

Department for Business, Innovation & Skills

www.getsafeonline.org/shopping-banking/buying-medicines-online1/
www.cyberstreetwise.com/#!/protect-business/what-you-need-to-know

European Alliance for Access to Safe Medicines (ASOP EU)

www.asop.eu/

Health and Social Care Information Centre

www.systems.hscic.gov.uk/eps

Medicines and Healthcare products Regulatory Agency

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

www.gov.uk/government/organisations/medicines-and-healthcare-products-regulatory-agency

www.ec.europa.eu/health/human-use/eu-logo/index_en.htm

Risks of buying medicines over the internet

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

National Pharmacy Association (NPA)

www.npa.co.uk

NHS England

www.england.nhs.uk/

Pharmaceutical Services Negotiating Committee

www.psn.org.uk/

Distance selling pharmacies

www.psn.org.uk/contract-it/market-entry-regulations/distance-selling-pharmacies/

Electronic prescription service

www.psn.org.uk/dispensing-supply/eps/

Royal Pharmaceutical Society

www.rpharms.com

Veterinary Medicines Directorate

Internet retailers of veterinary medicines

www.vmd.defra.gov.uk/pharm/internetretailers.aspx

More information

If you would like copies of this document in Welsh, please go to www.pharmacyregulation.org/standards/guidance where you can download a PDF. If you would like this document in other formats, please contact our communications team at communications@pharmacyregulation.org.

If you have questions or comments about the content of this guidance, please contact our standards team:

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We have also produced guidance on other topics that you may find useful:

www.pharmacyregulation.org/standards/guidance

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