

# **Draft guidance for registered pharmacies providing pharmacy services at a distance, including on the internet**

**September 2024**



# Contents

<b>About this guidance .....</b>	<b>1</b>
<b>Services covered by this guidance.....</b>	<b>2</b>
<b>Introduction .....</b>	<b>3</b>
<b>The legal duties of pharmacy owners and Superintendent Pharmacists .....</b>	<b>3</b>
<b>Guidance for registered pharmacies providing pharmacy services at a distance, including on the internet .....</b>	<b>4</b>
<b>Other useful sources of information .....</b>	<b>23</b>

# About this guidance

**This guidance explains what the pharmacy owner and Superintendent Pharmacist should consider before deciding whether any parts of their pharmacy service can be provided safely and effectively at a distance (including on the internet), rather than in the traditional face-to-face way.**

The pharmacy owner and Superintendent Pharmacist are responsible for making sure this guidance is followed. Everyone in the pharmacy team should understand the guidance and be aware of their responsibilities to follow it. This includes managers with delegated responsibility, the Responsible Pharmacist and any pharmacists prescribing 'at a distance'. When we use the word 'you' in this guidance, as well as meaning the pharmacy owner and the Superintendent Pharmacist (if there is one), this may also include someone to whom they have delegated responsibility for an action.

This guidance should be read alongside the [Standards for registered pharmacies](#), our [Inspection decision making framework](#), and the [Standards for pharmacy professionals](#) and any supporting guidance.

The standards for registered pharmacies, which pharmacy owners must meet, are designed to create and maintain the right environment – both organisational and physical – for the safe and effective practice of pharmacy.

The standards for pharmacy professionals describe how safe and effective care is delivered through 'person-centred' professionalism. The supporting guidance helps pharmacy professionals apply our standards and meet their professional responsibilities. The standards are essential in making sure that patients and the public receive safe and effective care, and these should be considered before deciding whether any parts of the pharmacy service can be provided safely and effectively at a distance (including on the internet).

Pharmacy owners and Superintendent Pharmacists must also make sure they keep to all the laws that apply to pharmacies. These include the law on supplying and advertising medicines, new consumer information for online sales, and data protection.

Following this guidance is an important part of making sure that our standards for registered pharmacies are met. The standards are grouped under five principles, and we refer to these throughout this guidance.

Not following this guidance, or not taking the appropriate steps to meet our standards, may result in us taking enforcement action. This could be against the pharmacy, or the pharmacy owner, or the Superintendent Pharmacist (or all three). We may also investigate the fitness to practise of all the pharmacy professionals involved.

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

- employees (both pharmacy professionals and other pharmacy staff)
- agency and contract workers, and
- any third parties who help the pharmacy provide any part of the pharmacy service

In some limited circumstances (for example following the death or bankruptcy of a pharmacy owner), a representative may take the role of the pharmacy owner. In these cases, the representative will be responsible for making sure these standards are met.

## Services covered by this guidance

Examples of the pharmacy services covered by this guidance include:

- a pharmacy service where prescriptions are not handed in by people using pharmacy services but are collected by pharmacy staff, received by post or electronically including by a digital platform hosted by a third party
- a delivery service from the registered pharmacy to people in their own homes, a care home or a nursing home
- a collection and delivery service. This is defined in **Regulation 248 of the Human Medicines Regulations 2012**. Prescription collection units usually involve a service where a person can get their dispensed medicines from a collection point such as an automated prescription collection machine or a locker
- a ‘click and collect’ service. This is usually a service where a person can buy or order goods from a pharmacy’s website and then collect them from one of their branches
- a mail-order service from a registered pharmacy
- an internet pharmacy service, including one linked to an online prescribing service, whether or not the prescribing service is owned and operated by a third-party business
- a ‘hub and spoke’ pharmacy service. This is where dispensed medicines are supplied by the ‘hub’ pharmacy to the ‘spoke’ pharmacy. Or the hub may deliver them direct to people in their homes, or to care homes; or they may be collected from another secure location, such as a locker or other collection point, if the person asks for this. At the moment, the law says that the ‘spoke’ must be a registered pharmacy forming part of the same legal entity as the hub pharmacy

# Introduction

**Changes in society and advances in technology have led to different ways of providing pharmacy services. Pharmacy services will keep adapting and changing, bringing opportunities to deliver pharmacy and other healthcare services in new ways. We support and encourage these changes, as long as people using these services receive safe, effective and person-centred care.**

Providing pharmacy services at a distance, especially online, carries particular risks – and these need to be managed. We want this guidance to support pharmacy owners, Superintendent Pharmacists and pharmacy professionals in safely providing medicines, medical devices and other pharmaceutical care to patients and the public. At the same time, the guidance is in place to make sure that they follow the law and meet our standards.

## The legal duties of pharmacy owners and Superintendent Pharmacists

The same laws apply whether pharmacy services are being provided in a traditional face-to-face way, at a distance, or on the internet.

If medicines are sold or supplied to people who are outside the UK, the laws that apply in the countries the medicines are being sent to must be followed. This includes making sure any medicines supplied are appropriate for use in the country of destination.

If medicines are sold or supplied for animal use, the legal requirements that apply are covered elsewhere<sup>1</sup>. The **Veterinary Medicines Directorate (VMD)** license and approve animal medicines and issue guidance on supplying medicines for animals. Under the updated veterinary medicines regulations, all online retailers of veterinary medicinal products must register with the VMD. (This does not apply to retailers selling only veterinary medicines in the AVM-GSL category.)

A new Register of Online Suppliers of veterinary medicines is replacing the VMD's present Accredited Internet Retailer Scheme (AIRS), and AIRS is closed for new applications. To find out more about the regulations, and registering with the VMD, please go to the VMD's website: **Sell veterinary medicines on the internet**.

The NHS regulations that allow distance-selling pharmacies to open and operate in England<sup>2</sup>, Scotland<sup>3</sup> and Wales<sup>4</sup> are not the same for each country. For more information on how to run a distance-selling pharmacy, please get independent legal advice or support from the local pharmaceutical committee or representative body (**Community Pharmacy England**, **Community Pharmacy Scotland** or **Community Pharmacy Wales**).

---

<sup>1</sup> Veterinary Medicines Regulations 2013, as amended

<sup>2</sup> The National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013, as amended

<sup>3</sup> The National Health Service (Pharmaceutical Services) (Scotland) Regulations 2009, as amended

<sup>4</sup> The NHS (Wales) Act 2006

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

The standards for registered pharmacies are grouped under five principles. This guidance follows the same five principles.

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

## 1.1 Risk assessment

Providing pharmacy services at a distance, particularly online, carries different risks to those in face-to-face settings.

A risk assessment will help with identify and managing risks that apply to the pharmacy's operating model. A risk assessment is a careful and thorough look at the ways pharmacy services could cause harm to people who use them. It will help in deciding what measures need to be put in place to keep the amount of risk as low as reasonably practicable.

Risk assessments may apply across whole organisations but still need to take into account the unique circumstances of each individual pharmacy. These include:

- the staff working at each pharmacy
- the activities of third parties, agents or contractors, and
- each individual part of the pharmacy service being provided, including how to use and securely store confidential and sensitive information

The risk assessment should cover the whole service, including the medicines and treatments which are provided.

Any risk assessments should be reviewed and updated regularly and whenever circumstances change – for example, when there are significant business or operational changes or when incidents happen (also see section 1.2). Staff should know the outcome of any risk assessment, contribute to it appropriately, and know who is responsible for managing the risk.

We expect clear, written, service-level agreements to be in place between the pharmacy and any third-party provider(s). This is to make sure that:

- the roles and responsibilities of each organisation are clear
- the pharmacy team are able to contact relevant team members of the third-party service if they need to, and
- patients and members of the public know who to contact when they need to speak to someone

***To meet the standards under Principle 1 we expect the pharmacy owner and the Superintendent Pharmacist, if there is one, to do the following:***

### **a. Gather evidence about the risks**

We expect you to do this for each individual service, medicine and medical device that is provided at a distance, including on the internet, before the service, medicine or medical device is provided.

As part of the risk assessment, you should consider:

- national guidance, when it is available, and
- the 'exclusion criteria' and cautions for medicines and medical devices, and any situations in which supplies may need to be limited to maintain safety

### **b. Produce a comprehensive risk assessment, make sure staff are aware of it, and review it regularly**

The risk assessment should include (but is not limited to):

- identified risks and how they will be managed
- the training, knowledge and skills staff need to provide services safely. When prescribing services are involved, this includes considering:
  - the prescriber's area(s) of competency
  - staff recognising their limitations
  - how staff tell people about the pharmacy services they will receive, and
  - how they get users' consent
- how staff communicate, including how they communicate between different parts of the service and between different locations
- how medicines are supplied, including advice or counselling on their use, and delivery (see section 4)
- the consultation method chosen for online prescribing services (see section 4)
- how prescribing and dispensing will be managed when the Responsible Pharmacist or Superintendent Pharmacist is also the prescriber
- the business's capacity to provide the proposed services
- business continuity plans, including for websites, data security and equipment
- what records will be kept – depending on the nature of the pharmacy services being provided – and how records, risk assessments and relevant policies and procedures will be easily accessible to staff
- the behaviour of people using pharmacy services, and the behaviour of staff
- different technologies operating together, and
- changes in the number or scale of services

Any risk register should be kept up to date and reviewed at least once a year or when processes or systems are changed, making sure any actions taken are recorded.

### **c. Consider specific issues if parts of the pharmacy service are carried out outside the pharmacy, or by other pharmacies or organisations**

If parts of the pharmacy service (including a prescribing service) are the responsibility of several different pharmacies and staff – or the responsibility of a third party, agent or contractor – consider the following (this list is not exhaustive):

- how the systems providing the pharmacy service work together. This includes information flow and the systems used for exchanging information between different locations
- how the accuracy of these systems is monitored and maintained, and how any potential failures are managed
- making sure the provider of the systems is assured and has risk assessments in place to cover all aspects of their service, including:
  - the medicines and treatments they provide
  - how consent is obtained, and
  - how any follow-up and monitoring will take place
- whether the provider has appropriate indemnity arrangements in place for the business, the services they provide and the staff they employ
- making sure the provider has policies, procedures and safeguards in place that protect and maintain patient safety
- making sure staff are properly trained and competent for the roles they carry out, and are registered with the relevant professional regulator
- making sure that the provider is registered with the appropriate regulator, in the country where they are based, for the activities they carry out. This may include registration with:
  - the Care Quality Commission (CQC)
  - Healthcare Improvement Scotland (HIS)
  - the Regulation and Quality Improvement Authority (RQIA), or
  - Health Inspectorate Wales (HIW)

In these circumstances, the relevant regulator has responsibility for regulating the third-party service's activities

- whether they have adequate business continuity measures in place
- whether they have risk-assessed the consultation methods they use

Pharmacies should not work with online providers who avoid, or try to avoid, keeping to the regulatory system put in place within the UK to ensure patient safety throughout the healthcare system.

### **d. Consider the extra risks of working with prescribers who are not based in the UK or appropriately registered**

There are significant extra risks for patients and the public by working with:

- prescribers who are not registered with the relevant UK professional regulator, or



- prescribing services not based in the UK

If the service involves working lawfully with prescribers or prescribing services operating outside the UK, you should make sure that:

- the extra risks this may create are actively managed, and you can show that this is the case
- there is sufficient indemnity insurance in place to cover:
  - the services that use prescribers or prescribing services based outside the UK, and
  - pharmacy staff supplying medicines against prescriptions issued by prescribers or prescribing services based outside the UK
- the prescriber is registered with the relevant professional regulator in the country they are based in (that is, where the prescription is issued), and they can lawfully issue prescriptions online to people in the UK
- the prescriber is working within national prescribing guidelines for the UK
- any cross-border arrangements in the service design meet the legal requirements that apply in all parts of the UK the business operates in

## 1.2 Regular audit

The safety and quality of pharmacy services must be regularly reviewed and monitored. Audits should be carried out at intervals that are appropriate for the pharmacy services. Audits should be part of the evidence which gives assurance that the pharmacy continues to provide safe pharmacy services. Regular audits may be corporate-wide, but still need to be relevant to the circumstances of each individual pharmacy.

For example, if working with a third-party provider that offers a prescribing service, it is important to make sure the prescriber carries out regular prescribing audits, which helps to assure the safety and quality of the treatments provided.

If any issues are identified, especially if they affect patient safety, take action to put them right. This may include putting in place extra safeguards. This may include carrying out a 'reactive' review as a result of identifying the issue. This should be documented, and include a risk assessment.

***To meet the standards under Principle 1 we expect the pharmacy owner and the Superintendent Pharmacist, if there is one, to do the following:***

### **e. Carry out a regular audit and make sure staff are involved**

A regular audit should include reviewing (but is not limited to):

- standard operating procedures (SOPs), which must cover all services provided and be specific to the pharmacy
- staffing levels, the training and skills within the team, and any extra training needed so that all staff have the appropriate skills and competence for the tasks they carry out
- the suitability of communication methods with people using pharmacy services
- the suitability of communication methods used to provide services. This should include, for example, communications:

- between staff
- with third parties, agents, contractors and other healthcare providers
- between hubs and spokes, and
- with collection and delivery points
- systems and processes for receiving prescriptions, including electronic prescription services
- clinical decisions (including the reasons for prescribing decisions). This should include, for example, records of decisions to:
  - make or refuse a sale, or
  - supply or refuse to supply a medicine against a prescription in line with national and good practice guidance

For more information, please see ‘Other useful sources of information’ at the end of this guidance

- systems and processes for secure delivery to people receiving care
- any information about the pharmacy services on any associated website
- how you keep to your information security policy, the Payment Card Industry Data Security Standard (PCI DSS) and data protection laws. Information security policies should be relevant to the type of service being provided and independent experts should be used to carry out this audit
- feedback from people who use pharmacy services, including any concerns or complaints you receive
- the activities of third parties, agents or contractors. You must also get assurance that the provider is carrying out regular audits relevant to the services they provide and that they are making any improvements needed

Make sure staff are involved in the audit and that anything relevant that is learnt is shared with the team. It may be helpful to use the audit as an educational activity with the pharmacy team.

#### **f. Carry out a reactive review when there are changes or when issues are identified**

Make sure a reactive review is carried out when any of the following happen:

- issues are identified during audits
- there is a change in the law or national guidance affecting any part of the pharmacy service
- there is a significant change in any part of the pharmacy service, such as:
  - the number of people services are provided to goes up
  - the range of services being provided increases, or
  - there is a change in a third party, agent or contractor being used
- there is a data security breach
- there is a change in the technology being used
- concerns or negative feedback are received from people who use pharmacy services
- a review of near misses and error logs identifies concerns about an activity or service being provided

### 1.3 Accountability – staff

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

If the same person could be acting as the owner, Superintendent Pharmacist, Responsible Pharmacist or the prescriber, consider getting assurances from outside the pharmacy that the service is running safely. This could involve, for example, using another clinician to carry out audits of safety and quality.

When medicines are not given to the person or their representative in the registered pharmacy, but instead are delivered to the person’s home or workplace, there may be a bigger risk of medicines being lost or delivered to the wrong person. In these circumstances, there should be clear lines of accountability and responsibility.

Due diligence in selecting all contractors is important. The pharmacy owner and the Superintendent Pharmacist, if there is one, is still responsible for providing the pharmacy service safely and effectively, even if there are arrangements with a third party, or if part of the pharmacy service is sub-contracted to a third party.

### 1.4 Record keeping

Necessary records must be kept and maintained, depending on the nature of the pharmacy services being provided.

When selling P medicines, and there is no face-to-face contact with the person receiving them, consider what information is being recorded to show that the pharmacy service is safe. Record this in the risk assessment. The records are important evidence for the judgements that staff make. They can also be a powerful tool for service improvement and quality management.

Keep clinical records for consultations and prescribing decisions in a way that makes the history of, and reasons for, prescribing decisions for the individual easily available. This will help with future decisions around the appropriateness of treatment. The records should include monitoring and follow-up plans. Records for prescribing services must be available to relevant members of the team and all relevant information should be shared with other healthcare professionals involved in the care of the person, for example their GP. Records must also be available for inspection and audit purposes.

All applicable laws covering how long records need to be kept must be followed. Good practice guidance will provide useful support.

***To meet the standards under Principle 1 we expect the pharmacy owner and the Superintendent Pharmacist, if there is one, to do the following:***

#### **g. Keep and maintain accurate records**

Make sure records include (but are not limited to):

- details of the staff who are accountable and responsible for providing each part of the pharmacy service
- the information and advice on using medicines safely given to people who use pharmacy services

- clinical records. For example, provide the key points on which the decision is made to make or refuse a sale or supply of a particular medicine against a prescription, or to prescribe a particular medicine
- information about the safeguards needed to be put in place by the online prescribing service(s) used for supplying certain medicines (see section 4.2)
- the person's consent to use a particular delivery method, the delivery method used, the date of dispatch of the medicine and the record of successful delivery
- information on complaints or concerns raised by people who use the pharmacy services and the steps taken to put things right
- information technology (IT) records (see section 5)

## **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**

The pharmacy team are vital to the safe and effective practice of the pharmacy.

All the team are responsible for creating a culture of person-centred professionalism within the pharmacy. Incentives or targets must not put the health, safety and wellbeing of patients and the public at risk, or affect the professional judgement of staff. Staff should be able to use their professional judgement so they can act in the best interests of the person receiving the services.

The pharmacy owner and the Superintendent Pharmacist, if there is one, must make sure that all staff are properly trained and competent to provide medicines and other professional pharmacy services safely. This includes staff who work remotely and are not in the pharmacy itself. The GPhC has produced **guidance to ensure a safe and effective team**. The guidance explains how to meet the standards under Principle 2 of the standards for registered pharmacies.

***To meet the standards under Principle 2 we expect the pharmacy owner and the Superintendent Pharmacist, if there is one, to do the following:***

#### **a. Provide appropriate training**

We expect the pharmacy owner and the Superintendent Pharmacist, if there is one, to provide, when appropriate, extra training in:

- information security management – for example, on how data is protected and on maintaining and improving cyber security
- communication skills to support staff in managing effective non-face-to-face communications with pharmacy users and prescribers. For more information on communications training, please see ‘Other useful sources of information’ at the end of this document
- using specialised equipment and new technology
- developing and helping maintain clinical skills for prescribers employed by the pharmacy. This should also include the provision of clinical supervision

**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 Premises**

The pharmacy and the premises used for any part of the pharmacy services must meet the standards for registered pharmacies.

The registered pharmacy must be fit for purpose in terms of the scale of the work being carried out. This includes making sure there is enough space to safely and securely operate any automated dispensing systems, and to transport medicines.

### **3.2 Website**

If P medicines are sold or supplied on the internet, through an app or digital platform, these may only be displayed for sale on a website, app or digital platform that is associated with the registered pharmacy. This could be under a service-level agreement or some other arrangement. The public may be able to access the pharmacy website directly or through a third-party site, for example eBay, but it must be clear which pharmacy is supplying the medicine.

***To meet the standards under Principle 3, we expect the pharmacy owner and the Superintendent Pharmacist, if there is one, to do the following:***

**a. Make sure the website is clear, accurate and updated regularly, and that the design and layout of the site works effectively and looks professional**

The website should not be misleading in any way. It may include information about medicines, health advice and links to other information sources such as relevant healthcare services and other regulators. However, the site should not mislead pharmacy service users about the identity of the pharmacies involved in providing the pharmacy services, or where they are located. This includes the identity and location of any online prescribing service(s).

Make sure the website prominently displays:

- the pharmacy's GPhC registration number
- the name of the owner of the registered pharmacy
- the name of the Superintendent Pharmacist, if there is one
- the name and physical address of the registered pharmacy or pharmacies that supply the medicines, with relevant phone numbers and email addresses
- details of the registered pharmacy where medicines are prepared, assembled, dispensed and labelled for individuals against prescriptions (if any of these things happen at a pharmacy different from that supplying the medicines)
- information about how to check the registration status of the pharmacy, the Responsible Pharmacist and the Superintendent Pharmacist, if there is one
- details of how users of pharmacy services can give feedback and raise concerns
- information by way of a privacy policy which clearly sets out how information gathered will be used

If the person is prescribed medicines following an online consultation, the website should also prominently display:

- the name of the prescriber, the address of the prescribing service and their contact details
- the prescriber's registration number and the country they are registered in
- whether the prescriber is a doctor or a non-medical independent prescriber – for example a pharmacist, nurse or physiotherapist
- information about how to check the registration status of the prescriber and if the service is regulated

#### **b. Make sure the website is secure and follows data protection laws**

The website must have secure facilities for collecting, using and storing pharmacy users' details. It must also have a secure link for processing card payments – for example, a secure link that meets the Payment Card Industry Data Security Standard (PCI DSS). More information, as well as advice and guidance on building a secure online service, can be found on the **National Cyber Security Centre's** website.

Your website must also meet data protection law, and include a privacy notice which tells people how their information will be used. This is especially important when asking people using pharmacy services for personal details. Any personal data that you collect via your website should be stored on servers which are hosted in the UK or in another jurisdiction which has equivalent levels of data protection in place. For the most up-to-date information on international data transfers, see the website of the **Information Commissioner's Office (ICO)**.

#### **c. Make sure that linked businesses are legitimate and registered with the relevant regulator**

Make sure that any business that is either hosted on the website, or reached by a link from it, is legitimate. This includes any online prescribing service(s). Businesses that are linked to (if located in the UK) must be registered with the appropriate regulator, such as:

- the Care Quality Commission (CQC)
- Healthcare Improvement Scotland (HIS)
- the Regulation and Quality Improvement Authority (RQIA), or
- the Health Inspectorate Wales (HIW)

The business must also meet the relevant national regulatory standards and requirements.

#### **d. Follow the Medicines and Healthcare products Regulatory Agency's (MHRA) guidance on advertising and promoting medicines**

The MHRA's guidance on advertising and promoting medicines<sup>5</sup> says:

- The website content should not promote Prescription Only Medicines (POMs) to the public. The home page should focus on medical conditions and the services the website provides. It should not include any reference to named POMs, including price information. Special offers on prices of medicines should not be highlighted on the homepage. The homepage should not use icons or

---

<sup>5</sup> MHRA Blue Guide: advertising and promoting medicines in the UK, November 2020

other features encouraging the purchase of POMs: for example, 'Buy Now', 'Buy XXX', 'Add to Basket'.

- an advertisement must not promote a medicine outside the therapeutic indications listed in the summaries of product characteristics (SPC) for that medicine. This means an advertisement cannot promote a medicine for use in treating or preventing conditions or illness for which it has not been licensed.
- Medicinal products which do not have a valid licence – that is, a marketing authorisation, traditional herbal registration or homeopathic registration – may not be advertised for medicinal purposes.

#### **e. Arrange the website so there is an appropriate consultation with the prescriber before any supply of a POM is made**

We expect the pharmacy website and the websites of associated companies to be arranged so that a person has an appropriate consultation with a prescriber before any supply of a POM is made. The website can allow people to give their preferred choice of medicine, for example a preferred brand or formulation, before the consultation. However, it should be made clear that the decisions about treatment are for both the prescriber and the person to consider together during the consultation.

There should be a means to allow two-way communication between the prescriber and the person. This is so the prescriber can ask for more information from the person if they need it. If the operating model involves prescribing decisions being made remotely, based just on answers given to a questionnaire, there must be careful consideration of whether it is safe to prescribe and supply medicines. A record should be made of:

- all the decisions taken, for example by way of risk assessments, and
- how it is decided that a specific medicine is safe and suitable for a particular person

#### **GPhC internet pharmacy logo**

The GPhC has a voluntary internet pharmacy logo scheme to reassure patients and the public that they are buying medicines online from registered pharmacies who have to meet the GPhC standards.

The logo links directly to the GPhC online register entry for each pharmacy, and it must be displayed only on the pharmacy website. It must not be used by a third-party, prescribing or other website.

To apply to use our voluntary internet pharmacy logo on the pharmacy website please read the conditions for use before applying.

#### **Distance selling logo**

From 1 January 2021, online sellers who are based in Great Britain (England, Wales and Scotland) can no longer display the EU common logo (in the UK, this was known as the 'Distance Selling Logo').

With the full implementation of the Windsor Framework by 1 January 2025, the Distance Selling Logo will be disappplied in Northern Ireland on 31 December 2024.

Should a replacement for the Distance Selling Logo be implemented in the future, this will be notified by the relevant responsible authority.



## **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 choice**

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

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

- one where the pharmacy orders or collects prescriptions from the doctor's surgery on behalf of people, or
- one where the pharmacy receives prescriptions by post or electronically, or
- an online service that people can access on the pharmacy website, via an app or by a link from the pharmacy website

If parts of the pharmacy services are provided at different locations, there should be a clear explanation to users of where each part of the service is based. There should be no information that could mislead the user of the pharmacy service about the identity or location of the pharmacy, or of any online prescribing service. This includes information on the website and information used to promote the pharmacy services.

In all cases, the pharmacy team must make sure people receiving care consent to the actual pharmacy service being provided to them, including using any associated prescribing services. This includes services lawfully provided by a prescriber not regulated by a UK health professional regulator. There is more information **set out in the ICO's [guidance on consent](#)**.

***To meet the standards under Principle 4 we expect the pharmacy owner and the Superintendent Pharmacist, if there is one, to do the following:***

#### **a. Provide transparent pharmacy services**

Make sure it is clear how the pharmacy provides services and care to people using the pharmacy services, so that they:

- know who is responsible for the supply of their medicines or medical devices. This information can be provided in various ways, including on the website, or it can be communicated to people when medicines are supplied
- have enough information about the service to make an informed decision, and
- can raise concerns, if they need to, about the quality of the service

Be able to show that arrangements with medical or non-medical prescribers are lawful, ethical and transparent, and do not:

- cause conflicts of interest, for example by giving incentives to prescribers to issue prescriptions, or
- restrict a person's choice of pharmacy, or

- unduly influence or mislead people needing services, deliberately or by mistake

#### **b. Have appropriate indemnity arrangements in place**

Make sure people receiving pharmacy services get information about the indemnity and regulatory arrangements for associated prescribers. This includes ones who are not based in the UK, especially if the prescriber is not regulated by a UK health professional regulator.

### **4.2 Managing medicines safely**

Selling and supplying medicines at a distance, including on the internet, brings different risks to those of a ‘traditional’ community pharmacy service. These should be identified and included in risk assessments (see section 1.1).

***To meet the standards under Principle 4 we expect the pharmacy owner and the Superintendent Pharmacist, if there is one, to do the following:***

#### **a. Show the steps taken to keep identified risk as low as possible**

This should include how you decide which medicines are appropriate for supplying at a distance, including on the internet. This should also include the extra safeguards you have put in place to help make sure these medicines are supplied safely at a distance.

#### **b. Select the appropriate method of consultation**

Decide which method of consultation is best suited to get the information needed to deliver safe and effective care. This includes deciding which method is best suited to deal with any specific requirements, or concerns. Examples include (but are not limited to):

- if the person has a potentially serious, high-risk condition where there is a need for a physical examination or other assessments
- if there was a need for a diagnostic test before prescribing a medication
- whether two-way communication can be established, if needed. That is, decide whether the consultation method:
  - meets the communication needs of the person, and
  - gives the pharmacy professional and the person the chance to ask questions to get the information they both need

A system where prescriptions are issued remotely based on a questionnaire, and there is no built-in way of having a conversation with people, is unlikely to meet these principles

- whether the method allows the pharmacy professional to make a proper assessment of the person’s needs
- whether the pharmacy professional can provide advice or counselling to the person if needed, as well as directing them to other support services if they need them
- whether consent for treatment can be obtained. For more information on consent please see our guidance, ***In practice: Guidance on consent***
- if the pharmacy professional is uncertain about the person’s capacity to make decisions about their own treatment. The method of consultation chosen should allow the pharmacy professional to get the information they need to make an informed decision on the person’s capacity. For example, this

is especially important when prescribing a high-risk medicine or one linked to treating mental health conditions

- whether the method of consultation will maintain the person's confidentiality and privacy. For more information on confidentiality please see our guidance, ***In practice: Guidance on confidentiality***
- when the prescriber is not the person's usual prescriber, and they have not been given consent to share information with the usual prescriber or GP if the person has one. Before deciding whether it is safe and appropriate to prescribe, the professional needs to get as much information as possible from the person to determine the method of consultation used. An appropriate method of consultation will help the prescriber to decide whether it is safe to prescribe

Choosing the appropriate consultation method is especially important when dealing with the following:

- when treatment may need follow-up or ongoing monitoring, and the prescriber needs to verify with the person how this will be done. (Some monitoring can be 'self-reported', for example, checks on weight and blood pressure. But there may be clinical reasons for considering whether readings should be verified in some way)
- when prescribing medicines that are liable to misuse, or medicines that need extra safeguards
- when the person would be at risk of death or serious harm if they are also getting medicines from another source

#### **c. Confirm the person's identity**

For sales or supplies of P and POM medicines, make sure pharmacy staff can check that the person receiving pharmacy services is who they claim to be by carrying out an identity check appropriate for the medicine being supplied.

There are a number of different ways to check a person's identity. This can include using an outside credit reference database, or a specific identity-checking service using photo ID verification.

Standard Operating Procedures (SOPs) may cover the use of different ways of verifying a person's identity, depending on the risks associated with the medicine to be supplied. Or the SOP may tell staff to use **the Identity Verification and Authentication Standard for Digital Health and Care Services**. This provides a consistent approach to identity checking across online digital health and care services.

#### **d. Get all the information needed to make a safe and appropriate supply**

Make sure the pharmacist or pharmacy staff get all the information needed so they can check that the supply is safe and appropriate. This may be from the person receiving pharmacy services and from access to a person's medical records. However, access may not be possible or may be limited, and there are potential risks in supplying without these records.

They should also give the person – and carer' – whenever appropriate – all the relevant information in a way they can understand, so that they can make an informed decision and choice and come to a shared decision about the care they provide.

They will need to take into account, for example, their age, gender and other medicines.

They should also take into account other relevant issues, for example:

- if there are concerns about domestic abuse (and there is a need for a confidential space), or
- if they feel that a person may be under duress to obtain particular medicines

They should assess if the person receiving pharmacy services has capacity to decide about their medicines.

**e. Make sure people know who to contact to ask questions and provide feedback**

Make sure the person receiving pharmacy services:

- has the chance to ask questions about their medicines, and
- knows who to contact if they have any questions or want to discuss something with the pharmacist or pharmacy staff

**f. Be able to identify inappropriate requests**

Use automated systems to warn staff about requests for medicines that are inappropriate. For example, the systems should be able to identify and flag up:

- multiple orders to the same address
- a person using multiple accounts to make orders
- orders that seem to be from different people but are using the same payment details
- inappropriate combinations of medicines, or
- requests that are too large or made too often

**g. Make sure all associated medical and non-medical prescribers are following good practice**

Make sure all associated prescribers follow the relevant remote consultation, assessment and prescribing guidance. This applies to both medical and non-medical prescribers. They should also be following good practice guidance and working in line with guidance issued by their regulator(s) Pharmacist Independent Prescribers (PIPs) should follow:

- the GPhC guidance ***In practice: Guidance for Pharmacist Prescribers***, and
- the Royal Pharmaceutical Society's (RPS) *Competency Framework for all Prescribers*

When PIPs widen or change their scope of practice they should also follow the RPS professional guidance on expanding scope of prescribing practice.

For more information on prescribing, please see the 'Other useful sources of information' section at the end of this document.

Make sure that medical and non-medical prescribers are following The General Medical Council's *Good practice in prescribing and managing medicines and devices*<sup>6</sup>, which says:

'In providing care [prescribers] must propose, provide or prescribe drugs or treatment (including repeat prescriptions) only when you have adequate knowledge of the person's health and are satisfied that the drugs or treatment will meet their needs.

It is especially important to ensure that the latest clinical guidelines and best practice guidance is followed when considering the sale/supply of medicines which are known to be liable to misuse. In such situations, it is essential to ensure appropriate monitoring, communication with other

---

<sup>6</sup> General Medical Council, *Good practice in prescribing and managing medicines and devices*, 2021

members of the person's healthcare team, thorough documentation of all decision making, and that access to their medical records is sought prior to supplies being made.'

#### **h. Be aware that some medicines are not suitable to be prescribed by a questionnaire model alone, and some should not be supplied unless further safeguards have been put in place**

Some medicines are not suitable to be prescribed by a questionnaire model alone. Also some medicines should not be supplied unless extra safeguards have been put in place to make sure they are clinically appropriate. Examples include but are not limited to:

- **Antimicrobials** (such as antibiotics), which must take into account antimicrobial stewardship guidelines relevant for the person and their setting
- **Medicines liable to misuse**, such as opioids, sedatives, laxatives, gabapentinoids, stimulants and nootropics
- **Medicines which have a higher risk of fatality or serious harm if taken in overdose.** For example, amitriptyline, propranolol, colchicine and carbamazepine
- **Medicines and long-term conditions that require ongoing monitoring or management.** For example:
  - medicines with a narrow therapeutic index<sup>7</sup> such as lithium and warfarin
  - medicines used for diabetes, asthma, epilepsy, heart conditions and mental health conditions
  - medicines which are part of a pregnancy prevention programme (PPP) – for example sodium valproate and oral retinoids – because they carry a high risk of causing damage to the unborn baby and developmental problems
- **Medicines where there needs to be a physical examination of the person to support a safe prescribing decision.** For example, non-surgical cosmetic medicinal products
- **Medicines used for weight management and those known to be misused to achieve weight loss**
- **Medicines labelled with a black triangle (▼ or ▼\*).** These need additional monitoring and are examples of medicines where suspected drug reactions should be reported through the **MHRA yellow card scheme**

#### **i. The safeguards to put in place if the above medicines are to be supplied online**

If working with an online prescribing service or prescriber, the above medicines should not be prescribed unless there is evidence that at least the safeguards below have been put in place:

- the prescriber has robust processes to check the identity of the person to make sure the medicines prescribed go to the right person. For example, they keep to the Identity Verification and Authentication Standard for Digital Health and Care Services, which provides a consistent approach to identity checking across online digital health and care services
- the prescriber does not base prescribing decisions just on the information provided in a questionnaire. Instead, they use a system that allows for two-way communication between the prescriber and the person, so that both have the opportunity to ask questions to get the

---

<sup>7</sup> Drugs with a narrow therapeutic index are drugs with small differences between therapeutic and toxic doses

information they need to deliver safe care. Examples include face-to-face, video-chat and end-to-end encrypted online platforms. If this is not possible, the prescriber should consider whether it is safe and appropriate to prescribe in the circumstances, and raise concerns if that is appropriate

- the prescriber independently verifies the information that the person provides. This may be through a phone call or video consultation, in person or by contacting another healthcare provider such as the person's GP. For example, if they are being asked to provide medication for weight loss, it is important that prescribers independently verify the person's weight, height and/or body mass index. This helps to safeguard vulnerable people who may misuse the medication. It also helps to confirm adequate weight-loss before continuing any supply
- for medicines where ongoing monitoring is important to ensure safety, you should take appropriate steps to confirm it is suitable to supply the medicine. This could include contacting the person's GP, their regular prescriber or a third-party provider, or checking the person's clinical records before making a supply. The prescriber must take responsibility for making sure the necessary monitoring arrangements are in place before prescribing
- for medicines which are liable to misuse, and/or ongoing monitoring is needed, the pharmacist dispensing the medicine should have confirmed, before supplying against the prescription, that the prescriber has contacted the person's regular GP or prescriber. The regular GP or prescriber must confirm that the prescription is appropriate for the person and that appropriate monitoring is in place
- the person has provided the contact details of their regular prescriber, such as their GP, and their consent to contact them about the prescription
- the prescriber actively shares all relevant information about the prescription with other health professionals involved in the care of the person (for example their GP)
- if the person does not have a regular prescriber, such as a GP, or if there is no consent to share information, the prescriber must then decide whether it is safe to prescribe. They will need to think about the person's best interests and carry out an individual risk-based assessment about whether they can prescribe safely. They should consider whether supplying treatment outweighs the risks, taking into account whether the person would be at risk of death or serious harm if they were also getting medicines from other sources. If there are exceptional circumstances and treatment needs to be provided, they must make sure they verify the information that is provided to them. If the decision is made not to prescribe, the person should be directed to an appropriate care provider so that they can be appropriately assessed. Examples include, but are not limited to, an out-of-hours service, a local walk-in centre or an urgent-care centre. The prescriber must make a clear, comprehensive record, at the time they make the decision, setting out their justification for prescribing, or not prescribing
- the prescriber is working within national prescribing guidelines for the UK and good practice guidance. This would include following the relevant guidance on prescribing a licensed medicine for an unlicensed purpose (known as 'off-label' use). For more information, please see the 'Other useful sources of information' at the end of this document

### 4.3 Supplying medicines safely

Make sure all medicines are delivered safely and effectively, which should be outlined in the associated risk assessments (see section 1.1).

**To meet the standards under Principle 4 we expect the pharmacy owner and the Superintendent Pharmacist, if there is one, to do the following:**

**j. Manage the identified risks**

Show the steps taken to manage the risks identified. This should include how:

- the suitability and timescale of the method of supply, dispatch, and delivery<sup>8</sup> are assessed (for example, for refrigerated medicines and controlled drugs)
- the suitability of packaging is assessed (for example, testing or auditing packaging that is tamper-proof and/or temperature controlled)
- the method of storing and accessing medicines is made secure. For example, when using a prescription collection unit, there must be a secure means of access, such as a secure code or password which is only made available to the right person
- the package is tracked and monitored to make sure it reaches the right person, and to monitor any unexpected interruptions in delivery
- the terms, conditions and restrictions of the carrier are checked
- the legal requirements that apply in the UK and abroad on the export or import of medicines are identified and understood, if the pharmacy intends to supply medicines to people located outside the UK
- staff are trained and their competence is assessed
- third-party providers are monitored

#### **4.4 Information for pharmacy users**

When pharmacy staff do not see the person receiving care face-to-face, consider using methods of communication that encourage discussion between the person and pharmacy staff, including the pharmacist.

**To meet the standards under Principle 4 we expect the pharmacy owner and the Superintendent Pharmacist, if there is one, to do the following:**

Consider how staff can communicate any important information to the person clearly and effectively.

Provide clear information to people who use the pharmacy services about how they can contact the pharmacist, pharmacy staff or prescriber, (if applicable) if they have any problems or need more advice. This should also include advice on when they should go back to their regular prescriber, GP or pharmacist.

---

<sup>8</sup> For more information about supplying medicines, see the Royal Pharmaceutical Society's Delivery and posting of medicines to patients (including abroad); Medicines, Ethics and Practice – The professional guide for pharmacists, Edition 47, July 2024; or get advice from the **National Pharmacy Association** (NPA) or your professional indemnity provider

## **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**

Make sure that the pharmacy has the equipment and facilities needed to provide pharmacy services, and that they are fit for purpose. Examples of specialist equipment include automated dispensing systems, labelling equipment, and prescription collection units used for remote access.

***To meet the standards under Principle 5 we expect the pharmacy owner and the Superintendent Pharmacist, if there is one, to do the following:***

#### **a. Make sure equipment and operating systems are fit for purpose**

Equipment should be:

- of high specification, accuracy and security. IT equipment should meet the latest security specifications and the security of data should be protected when it is in transit, by either wired or wireless networks, inside the business and outside it. Access to records should also be controlled, including how they are stored, kept and removed
- calibrated, maintained and serviced regularly in line with the manufacturer's specifications

Software and operating systems should:

- be robust enough to handle the volume of work, and be regularly backed-up
- have control systems built in to help manage the risk
- be accessible so that they can be regularly audited
- be understood – for example, how the software and operating systems work, what control systems are built in and whether there are any vulnerabilities

Make sure maintenance logs are kept for as long as appropriate.

Make sure business continuity plans include:

- how to manage the risk of equipment failure, including disruptions in IT, and
- how patients and members of the public are made aware of any potential delay or disruption to the supply of medicines or medical devices



## Other useful sources of information

- Advertising Standards Authority (ASA)
- Alliance for Safe Online Pharmacies (ASOP Global)
- Centre for Postgraduate Pharmacy Education (CPPE) – Consultation skills: face-to-face and remote
- Care Quality Commission – Online primary care: information for providers
- Community Pharmacy Scotland
- Community Pharmacy Wales
- Department for Business, Energy and Industrial Strategy
- Faculty of Reproductive Sexual Health (FRSH) and British Association for Sexual Health and HIV (BASHH) – Standards for Online and Remote Providers of Sexual and Reproductive Health Services
- General Medical Council – Good practice in prescribing and managing medicines and devices
- General Pharmaceutical Council
  - Guidance for employers on the education and training requirements of pharmacy support staff
  - Guidance for registered pharmacies preparing unlicensed medicines
  - High level principles for good practice in remote consultations and prescribing
  - In practice: Guidance for pharmacist prescribers
  - In practice: Guidance on consent
  - In practice: Guidance on confidentiality
- Government.UK
  - Consumer protection
  - Antimicrobial prescribing and stewardship competencies
- Health and Safety Executive – Risk Management Resource
- Health Improvement Scotland – Learning from adverse events through reporting and review
- Medicines and Healthcare products Regulatory Agency
  - Advertise your medicines
  - Blue guide: Advertising and promoting medicines
- Risks of buying medicines over the internet
- Valproate banned without the pregnancy prevention programme
- Monitor: Risk Assessment Framework
- National Cyber Security Centre
- National Institute for Health and Care Excellence (NICE) Guidance

- **National Pharmacy Association (NPA)**
- **NHS Digital**
- **NHS England**
- **Community Pharmacy England**
  - **Distance-selling pharmacies**
  - **Electronic prescription service**
- **Pharmacy Voice – Community Pharmacy Medication Safety Risk Assessment Tool**
- **Royal Pharmaceutical Society**
  - **Clinical Governance – a quick reference guide**
  - **Prescribing competency framework**
  - **Expanding Prescribing Scope of Practice**
- **Veterinary Medicines Directorate – Internet retailers of veterinary medicines**



