General Pharmaceutical Council

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

February 2025

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About this guidance

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

This guidance should be applied alongside our regulatory standards: the **Standards for registered pharmacies** and the **Standards for pharmacy professionals**. The standards are legal requirements that must be met to make sure that patients and the public receive safe and effective care.

The standards for registered pharmacies 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.

This guidance sets out our expectations about the actions that need to be taken to meet our standards and deliver safe and effective pharmacy services 'at a distance'. We have designed it mainly to support pharmacy owners

About us

We regulate pharmacists, pharmacy technicians and pharmacies in Great Britain.

We work to assure and improve standards of care for people using pharmacy services.

What we do

Our role is to protect the public and give them assurance that they will receive safe and effective care when using pharmacy services.

We set standards for pharmacy professionals and pharmacies to enter and remain on our register.

We ask pharmacy professionals and pharmacies for evidence that they are continuing to meet our standards, and this includes inspecting pharmacies.

We act to protect the public and to uphold public confidence in pharmacy if there are concerns about a pharmacy professional or pharmacy on our register.

Through our work we help to promote professionalism, support continuous improvement and assure the quality and safety of pharmacy.

and Superintendent Pharmacists in understanding and meeting our standards and their professional responsibilities. But it also applies to everyone in the team including:

- managers with delegated responsibility

- the Responsible Pharmacist, and

- any pharmacists prescribing 'at a distance'

This guidance cannot cover every situation and does not give legal advice. Pharmacy owners and Superintendent Pharmacists must 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.

The standards are grouped under five principles, and we refer to these throughout this guidance.

Not meeting our standards could result in us taking enforcement action. This could be against the pharmacy, the pharmacy owner, the Superintendent Pharmacist, or all three. We could also investigate the fitness to practise of all the pharmacy professionals involved.

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

- the pharmacy owner

- the Superintendent Pharmacist (if there is one), and

- anyone who has been delegated responsibility for an action in relation to this guidance

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 by a digital platform hosted by the pharmacy or a third party

- a delivery service from the registered pharmacy to people in their own homes or to their place of residence

- a collection and delivery service. This is defined in **Regulation 248 of the Human Medicines Act**. 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 from an online pharmacy, including one linked to an online prescribing service, whether or not the prescribing service is owned and operated by a third-party business. An 'online pharmacy' is a registered pharmacy with a digital portal through which transactions with users can take place without any in-person contact before the delivery of medicines or pharmacy services. Those transactions can include the sale or supply of pharmacy (P) medicines and prescription-only medicines (POMs)

- 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

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, which 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, our 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 in-person 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[1]. 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 authorised veterinary medicinal product – general sales list 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[2], Scotland[3] and Wales[4] 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**).

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[1] Veterinary Medicines Regulations 2013, as amended
[2] The National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013, as amended

[3] The National Health Service (Pharmaceutical Services) (Scotland) Regulations 2009, as amended
[4] 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 identifying 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 can apply across whole organisations but still need to consider 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.

Risk assessments need to 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.

To reduce risks we expect clear, written, service-level agreements between the pharmacy and any third-party provider(s) to be in place. 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, consider:

- national guidance, when it is available, and

- the 'exclusion criteria' and cautions for medicines and medical devices, and any situations in which services or supplies of medicines 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

A comprehensive risk assessment will, as a minimum, include the following:

- 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 the diverse needs of people using pharmacy services are identified, and

how staff get users' valid consent (for example, how staff assess the mental capacity of users)

- 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

Keep any risk register up to date and review it 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, including 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

    - Healthcare Inspectorate Wales (HIW)

    If the provider is registered with a regulator, that regulator has responsibility for regulating the third-party service's activities.

- whether they have adequate business continuity measures in place, and

- whether they have risk-assessed the consultation methods they use

Do 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, 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 and following good practice guidance

- 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. Carry out audits at intervals that are appropriate for the pharmacy services and use these audits to assure yourself, and provide evidence, that the pharmacy continues to provide safe pharmacy services. Regular audits can be corporate-wide, but still need to be relevant to the circumstances of each individual pharmacy.

If you identify any issues, especially if they affect patient safety, take action to put them right. This can include putting in place extra safeguards or carrying out a 'reactive' review as a result of identifying the issue. Document these, and do 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

As a minimum, make sure your regular audit reviews the following:

- 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 digital platform

- 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 should 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 can be helpful to use the audit as an educational activity with the pharmacy team, to support continuous improvement and learning.

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 should 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, make sure there are 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, whether on paper or electronic, 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. 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, including 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 Digital platform

If P medicines are sold or supplied on a digital platform like a website or app, these can only be displayed for sale on the 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 digital platform directly or through a third-party site. But make it 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 digital platform is clear, accurate and updated regularly, and that the design and layout of the site works effectively and looks professional

The digital platform needs to be structured in such a way that it cannot mislead the public in any way. It can include information about medicines, health advice and links to other information sources such as relevant healthcare services and other regulators. However, design and set out the site contents so that pharmacy service users are not at risk of being misled 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 digital platform 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, make sure the digital platform prominently displays:

- 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 the service, if the service is regulated

b Make sure the digital platform is secure and follows data protection laws

The digital platform 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 digital platform 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 digital platform 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 digital platform, or reached by a link from it, is legitimate. This includes any online prescribing service(s). If any business is hosted on a digital platform by a third party, you should have satisfied yourself that the necessary safeguards are in place. 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 Healthcare Inspectorate Wales (HIW)

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

d Follow the law and guidance on the advertising and promotion of medicines

For more information, please see the **MHRA's Blue Guide: advertising and promoting medicines in the UK**, and the rules and guidance provided by the **Advertising Standards Authority (ASA).**

e Arrange the digital platform so there is an appropriate consultation with the prescriber before any supply of a POM is made

We expect the pharmacy's digital platform and the platforms 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 digital platform can allow people to give their preferred choice of medicine, for example a preferred brand or formulation, before the consultation. However, make it clear that the decisions about treatment are for both the prescriber and the person to consider together during the consultation. Before medication is provided, the prescriber is required to carefully consider the safety and suitability of the treatment for the person, making sure that they have all the necessary information.

Make sure there is a means to allow timely 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.

Distance Selling Logo

From 1 January 2021, online sellers who are based in Great Britain (England, Wales and Scotland) could 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 on 1 January 2025, the last day the Distance Selling Logo applied in Northern Ireland was 31 December 2024.

If a replacement for the Distance Selling Logo is 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 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 using a digital platform like a website or app, or by a link from the pharmacy website

If parts of the pharmacy services are provided at different locations, give users a clear explanation to 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 any digital platform 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 digital platform associated with the pharmacy, 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 prescribers are transparent, and do not:

- cause conflicts of interest, for example by giving incentives to prescribers to issue prescriptions, or

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

If there are arrangements in place that restrict a person's choice of supplying pharmacy, make these arrangements clear to the person before any consultation or prescribing takes place.

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. Identify these and include them 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:

c   Show the steps taken to keep identified risk as low as possible

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

d   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 is a need for a diagnostic test before prescribing a medication

- whether timely two-way communication can be established. That is, decide whether the consultation method:

    - meets the communication needs of the person

    - gives the pharmacy professional the chance to ask questions to get the information they need to make a proper assessment of the person, and

    - gives the person the chance to ask any questions that they have

- a method to make sure that if timely two-way communication is not available to both the prescriber and the person, the person is directed to an appropriate care provider so that they can be appropriately assessed. You can, for example, direct them to their regular prescriber, an out-of-hours service, a local walk-in centre, or urgent care

- 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**

- whether the pharmacy professional can be certain 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. 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.

In summary, an appropriate method of consultation will mean that the prescriber can decide whether it is safe to prescribe. If there is any doubt about this, the person may be put at risk.

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

- treatment that 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 blood pressure. But there may be clinical reasons for considering whether readings should be independently verified in some way

- 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

e   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 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.

f   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, for example their NHS national care record. However, access may not be possible or may be limited, and there are potential risks in supplying without these records.

They need to 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 consider, for example, their age, gender and other medicines.

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

g   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

h   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

- repeated requests for medicines to manage infection symptoms, or

- requests that are too large or made too often

i   Make sure all associated prescribers are following good practice

Make sure all associated prescribers follow the relevant remote consultation, assessment and prescribing guidance. Ensure they follow good practice guidance and work 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 prescribers are following the **General Medical Council's** *Good medical practice*[5], 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.'

Make sure that prescribers are following the General Medical Council's more detailed guidance, *Good practice in proposing, prescribing, providing and managing medicines and devices.*

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 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.'

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[5] **General Medical Council, Good medical practice**, 2024

j Be aware that some medicines are not suitable to be prescribed by a questionnaire model alone, and some medicines 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. Some medicines are not suitable to 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**, which must take into account antimicrobial prescribing and 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[6] 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 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**

- **medicines labelled with a black triangle (▼ or ▼*)**. These need additional monitoring and are medicines where suspected drug reactions are required be reported through the **MHRA yellow card scheme**

k 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 require the safeguards below to be in place before they can be prescribed.

- The prescriber has robust processes to check the identity[7] 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

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[6] Drugs with a narrow therapeutic index are drugs with small differences between therapeutic and toxic doses

[7] For guidance on appropriate identity checks for online and remote provision of sexual health services please see 'Other sources of information' at the end of this document.

approach to identity checking across online digital health and care services.

- The prescriber does not base prescribing decisions on the information provided in a questionnaire alone. Instead, the prescriber independently verifies the information the person provides, and gets the information they need to support their prescribing decisions. This could be through timely two-way communication with the person, accessing the person's clinical records, or contacting the person's GP, their regular prescriber, or a third-party provider. If the prescriber chooses not to use two-way communication with the person to support their prescribing decision, they should make a record, specific to the individual person's circumstances, justifying their reasons.

  If the prescriber cannot independently verify the information the person provides or get the information they need, 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 urgent care.

- 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. If the person does not have a regular prescriber, such as a GP, or if there is no consent to share information, the prescriber should 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. The prescriber should make a clear, comprehensive record, at the time they make the decision, setting out their justification for prescribing, or not prescribing. 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 urgent care.

- The prescriber is working within national prescribing guidelines for the UK and good practice guidance. This would include following national patient safety alerts and the relevant guidance on prescribing, such as when using 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.

l **The extra safeguards that need to be in place for some medicines**

- When supplying **medicines liable to misuse, or medicines which have a higher risk of fatality or serious harm if taken in overdose,** take appropriate steps to confirm that the medicine is appropriate for the person, before making a supply. For example, contact the person's GP, their regular prescriber, or a third-party provider,

or check the person's clinical records, with their consent, before making a supply. Be aware that the prescriber (including where appropriate, the GP) takes responsibility for making sure the necessary monitoring arrangements are in place before prescribing.

- When supplying **medicines liable to misuse, or medicines which have a higher risk of fatality or serious harm if taken in overdose,** the pharmacist dispensing the medicine should have assurance that any prescribing service they are working with has the above systems in place and that you are able to confirm that the medicine is appropriate for the person and appropriate monitoring is in place.

- When supplying **medicines for long-term conditions or conditions that require ongoing monitoring or management**, the prescriber independently verifies the medical history provided by the person to make sure the supply is appropriate. By 'independently' we mean that the prescriber uses a different way to verify the information provided to them by the person. This should be through contacting the person's GP, their regular prescriber, or a third-party provider, or checking the person's clinical records, with the person's consent, before making a supply. In addition, the prescriber takes responsibility for making sure the necessary monitoring arrangements are in place before prescribing. These arrangements may be put

in place by the prescriber, the GP or other healthcare provider.

- When supplying **medicines used for weight management**, the prescriber independently verifies the person's weight, height and/or body mass index. By 'independently' we mean that the prescriber uses a different way to verify the information provided to them by the person. This could be through a video consultation, in person, from the person's clinical records or by contacting another healthcare provider such as the person's GP. Verifying information helps to confirm that any continued supply is clinically suitable and helps to safeguard vulnerable people. Verifying information through a phone call would not be appropriate when supplying medication for weight loss.

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:

m   Manage the identified risks

Show the steps taken to manage the risks identified. As a minimum, include how:

- the suitability and timescale of the method of supply, dispatch, and delivery[8] are

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[8] 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

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.

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from the **National Pharmacy Association** (NPA) or your professional indemnity provider

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.

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 UKCA (UK Conformity Assessed) or CE marked

- 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

Make sure you understand how the software and operating systems work, what control systems are built in and whether there are any vulnerabilities. Keep maintenance logs 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 proposing, prescribing, providing 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**
  - **Drug safety update: GLP-1 receptor agonists: reminder of the potential side effects and to be aware of the potential for misuse**
- **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**

  - **Patient Safety Professional Standards: Responding to Patient Safety Incidents**

- **Veterinary Medicines Directorate** – **Internet retailers of veterinary medicines**