General Pharmaceutical Council

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

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The General Pharmaceutical Council (GPhC) is the regulator for pharmacists, pharmacy technicians and registered pharmacies in England, Scotland and Wales. As part of our role, we set the standards that pharmacy professionals have to meet throughout their careers.

# About this guidance

This guidance explains what pharmacy owners 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-toface way.

As the pharmacy owner, you are responsible for making sure this guidance is followed. Everyone in the pharmacy team, including managers with delegated responsibility and the responsible pharmacist, should understand the guidance and be aware of their responsibilities to follow it. If the registered pharmacy is owned by a 'body corporate' (for example a company or an NHS organisation) you should make sure the superintendent pharmacist understands it should be followed.

You should read this guidance alongside the **standards for registered pharmacies**, which pharmacy owners must meet, our **inspection decision making framework**, and the **standards for pharmacy professionals**, and supporting guidance.

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. The guidance which supports the standards will help pharmacy professionals apply our standards and meet their professional obligations.

The standards are essential in making sure that patients and the public receive safe and effective care and you should consider them before deciding whether any parts of your pharmacy service can be provided safely and effectively at a distance (including on the internet). Therefore, you must be familiar with those standards, as well as the guidance we have published on our website.

Pharmacy owners must also make sure they keep to all the laws that apply to pharmacies. This includes 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 you meet our standards for registered pharmacies. These are grouped under five principles, which we refer to throughout this guidance. We therefore expect this guidance to be followed.

Not following this guidance, or not taking the appropriate steps to achieve a desired outcome under our standards, could mean that you fail to meet one or more of the standards for registered pharmacies. This could result in our taking enforcement action.

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

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

In this document, the term 'you' means the pharmacy owner.

In some limited circumstances (for example following death or bankruptcy), 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.

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, or received by post or electronically
- 2. a delivery service from the registered pharmacy to people in their own home, a care home or a nursing home

- a 'collection and delivery service'. This includes the use of prescription collection units (PCUs): for example automated prescription collection machines and lockers
- 4. a 'click and collect' service
- 5. 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 you or by a thirdparty business
- a 'hub and spoke' pharmacy service where medicines are prepared, assembled, dispensed and labelled for individuals against prescriptions at a central 'hub' registered pharmacy

#### Types of pharmacy services

Collection and delivery service, including the use of prescription collection units (PCUs)

A collection and delivery service is defined in <u>Regulation 248 of the Human Medicines</u> <u>Regulations 2012</u>. 'PCUs' usually means a type of service where a customer can get their dispensed medicines from a collection point such as an automated prescription collection machine or locker.

#### Click and collect

This is usually a service where a customer can buy or order goods from a pharmacy's website and then collect them from one of their branches.

#### Hub and spoke

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



### Introduction

Because of changes in society and advances in technology, different ways of providing pharmacy services are becoming more common. Pharmacy services will continue to adapt and change, bringing opportunities to deliver pharmacy and other healthcare services in new ways. We support and encourage responsible innovation as long as people using these services receive safe, effective and person-centred care.

But providing pharmacy services at a distance, especially online, carries particular risks which need to be managed. We want this guidance to support appropriate provision of medicines, medical devices and pharmaceutical care, which keeps to the law and meets our standards.

The same laws apply whether you provide pharmacy services in a traditional face-to-face way, at a distance, or on the internet. For example: if you offer a delivery service, the handover to the delivery agent of a pharmacy (P) or prescription-only medicine (POM) must take place at a registered pharmacy under the supervision of a pharmacist.

If you sell or supply medicines to people in other countries you must keep to any other

laws that apply. Countries have different restrictions, and some do not allow the online supply of medicines at all. It is your responsibility to make sure the medicine you supply has the marketing authorisation needed for it in the country of destination<sup>1</sup>.

If you sell or supply medicines for animal use, the parts of the law that apply – and the exemptions that allow this – are covered elsewhere<sup>2</sup>. The <u>Veterinary Medicines</u> <u>Directorate (VMD)</u> licenses and approves animal medicines and issues guidance on supplying medicines for animals. The VMD also operates a <u>voluntary accredited internet</u> <u>retailer scheme (AIRS)</u> for online retailers of veterinary medicinal products. The aim of the scheme is to provide assurance to the public that they are buying veterinary medicinal products from a reputable UK-based retailer.

The NHS Regulations that allow distance-selling pharmacies to open and operate in England<sup>3</sup>, Scotland<sup>4</sup> and Wales<sup>5</sup> are not the same. For more information on how to run a distanceselling pharmacy in the area you intend to operate in, please get independent legal advice.

<sup>4</sup> The National Health Service (Pharmaceutical Services) (Scotland) Regulations 2009, as amended

<sup>5</sup> The NHS (Wales) Act 2006

<sup>&</sup>lt;sup>1</sup> The Human Medicines Regulations 2012, as amended

<sup>&</sup>lt;sup>2</sup> Veterinary Medicines Regulations 2013, as amended

<sup>&</sup>lt;sup>3</sup> The National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013, as amended

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

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

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

#### 1.1 Risk assessment

The provision of pharmacy services at a distance, particularly online, carries particular risks by its nature.

A risk assessment will help you identify and manage risks. It is a careful and thorough look at what in your work could cause harm to people who use pharmacy services, and what you need to do to keep the risk as low as reasonably practicable.

Risk assessments may apply across whole organisations but still need to take into account the circumstances of each individual pharmacy. This includes the staff working in it; the activities of third parties, agents or contractors; and each individual part of the pharmacy service you intend to provide. It should cover the whole service. You should review your risk assessment regularly and whenever circumstances change – for example, when you make significant business or operational changes (also see section 1.2).

## To meet the standards under Principle 1, we expect you as the pharmacy owner to make sure:

- you gather evidence about the risks for each individual service, medicine and medical device that you provide at a distance, including on the internet, before you start providing the service
- 2. your risk assessment includes: (but is not limited to):
  - the risks you have identified and how these will be managed
  - how staff tell people about the pharmacy services they will receive, and how they get their consent
  - how staff communicate, including how they communicate between different parts of the service and between different locations
  - how medicines are supplied, including counselling and delivery (see section 4)
  - your business's capacity to provide the proposed services



- business continuity plans, including for your website, data security, and equipment
- what records you will keep, depending on the nature of the pharmacy services you provide
- the behaviour of people using pharmacy services or of staff
- different technologies operating together, and
- changes in the number or scale of services
- 3. your staff know the outcome of any risk assessment and contribute to it appropriately
- 4. any risk register you keep is kept up to date, and any actions you have taken are recorded
- 5. if parts of your pharmacy service are the responsibility of several different pharmacies and staff or the responsibility of a third party, agent or contractor you have considered how the systems you use to provide your pharmacy service work together. This includes information flow and the IT systems you use for exchanging information between different locations. You should also consider how you monitor and maintain the accuracy of these systems and manage any potential failures
- 6. you do not work with online providers who circumvent, or try to circumvent, the regulatory oversight put in place within the UK to ensure patient safety

throughout the healthcare system. Working with prescribers who are not appropriately registered with the relevant UK professional regulator, and with prescribing services not based in the UK, could create significant extra risks for patients and the public. If your service lawfully involves working with prescribers or prescribing services operating outside the UK, you should make sure that:

- you successfully manage the extra risks that this may create
- you have sufficient indemnity insurance in place to cover:
  - your service that uses prescribers or prescribing services based outside the UK, and
  - pharmacy staff supplying medicines against prescriptions issued by these prescribers or prescribing services
- the prescriber is registered in their home country where the prescription is issued and can lawfully issue prescriptions online to people in the UK
- the prescriber is working within national prescribing guidelines for the UK
- 7. any cross-border arrangements in your service design are lawful under UK law

#### 1.2 Regular audit

The safety and quality of pharmacy services must be reviewed and monitored. You should carry out a regular audit, at an interval that you

can show to be appropriate for your pharmacy services. The audit should be part of the evidence which gives assurance to people who use your pharmacy that it 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.

If you identify any issues, you should take action to put them right. This may lead to you carrying out a 'reactive' review. You should record this reactive review and say clearly when a new risk assessment needs to be carried out.

## To meet the standards under Principle 1, we expect you as the pharmacy owner to make sure:

- 1. your regular audit includes (but is not limited to):
  - reviewing your standard operating procedures (SOPs), which must cover all your services and be specific to your pharmacy
  - staffing levels, the training and skills within the team, and any additional training needed so that all staff have the appropriate skills and competence for the tasks they carry out
  - suitability of communication methods with people using pharmacy services
  - suitability of communication methods used to provide your services – for example: between staff, and with third parties, agents or contractors and other healthcare providers, including between hubs and spokes and with collection and delivery points

- systems and processes for receiving prescriptions, including the electronic prescription service (EPS)
- clinical decisions. For example: records of decisions to make or refuse a sale, or make or refuse a supply of a medicine against a prescription
- systems and processes for secure delivery to people receiving care
- any information about your pharmacy services on your website
- how you keep to your information security policy, to the Payment Card Industry Data Security Standard (PCI DSS) and to data protection law
- feedback from people who use pharmacy services, including any concerns or complaints received
- activities of third parties, agents or contractors
- 2. you show how your staff are involved in the audit
- 3. a reactive review is carried out when any of the following happens:
  - you identify any issues during your regular audit
  - there is a change in the law affecting any part of your pharmacy service
  - there is a significant change in any part of the pharmacy service you provide, such as an increase in the number of people you provide services to; or an increase in the range of services you



intend to provide; or a change in a third party, agent or contractor you use

- there is a data security breach
- there is a change in the technology you use
- concerns or negative feedback are received from people who use pharmacy services
- a review of near misses and error logs identifies a concern about an activity
- your information security practices are audited by independent experts, depending on the type of service you provide

#### 1.3 Accountability – staff

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

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

If you have an arrangement with, or contract out any part of your pharmacy service to, a third party, you are still responsible for providing the pharmacy service safely and effectively. You should carry out 'due diligence' in selecting any contractors.

#### 1.4 Record keeping

You must keep and maintain the necessary records depending on the nature of the pharmacy services you provide. This includes maintaining a daily log of the responsible pharmacist.

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

When there is no face-to-face contact, you should consider what information you and your staff record and keep to show that the pharmacy service you provide is safe. The records you keep are important evidence for the judgements you and your staff make. They can also be a powerful tool for service improvement and quality management.

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

#### To meet the standards under Principle 1, we expect you as the pharmacy owner to make sure:

- 1. your records include (but are not limited to):
  - details of the staff who are accountable and responsible for providing each part of your pharmacy service

- the information and advice on using medicines safely that you give people who use pharmacy services
- clinical records. For example, provide the key points on which you made the decision to make or refuse a sale of a particular medicine against a prescription. You should also provide the key points on which you made the decision to make or refuse a supply of a particular medicine.
- information about the required safeguards put in place by the online prescribing service you use for supplying certain categories of 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 record of successful delivery
- information on complaints or concerns from people who use pharmacy services and what you have done to deal with these
- 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 staff you employ, and the people you work with, are key to the safe and effective practice of pharmacy.

You are responsible for creating a culture of person-centred professionalism within your pharmacy. Incentives or targets must not compromise the health, safety and wellbeing of patients and the public, or the professional judgement of staff. Staff should be empowered to use their professional judgement so that they can act in the best interests of the person receiving your services.

You must make sure that all staff are properly trained and competent to provide medicines and other professional pharmacy services safely. The GPhC has produced **guidance to ensure a safe and effective team**. The guidance explains what you should do to make sure you are meeting the standards under Principle 2 of the standards for registered pharmacies.

## To meet the standards under Principle 2, we expect you as the pharmacy owner to make sure:

- 1. you provide, where appropriate, extra training in the following areas:
  - information security management how data is protected; and 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 the 'Other useful sources of information' section at the end of this document
- using specialised equipment and new technology

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

#### 3.1 Your premises

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

Your registered pharmacy must be fit for purpose to reflect the scale of the work you do. If you automate certain activities, there must be enough space to use automated dispensing systems safely. You must have suitable areas in your registered pharmacy to send medicines to people safely.

#### 3.2 Your website

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

Your website should be secure and follow information security management guidelines and the law on data protection. This is particularly important when you ask people using pharmacy services for personal details. You should make sure that your website has

secure facilities for collecting, using and storing pharmacy users' details and a secure link for processing card payments, for example, a secure link that meets the Payment Card Industry Data Security Standard (PCI DSS). For more information on the use and storage of data, **see the ICO website**.

### To meet the standards under Principle 3, we expect you as the pharmacy owner to:

- make sure your website is clear, accurate and updated regularly. It should not be misleading in any way. Your site may include information about medicines, health advice and links to other information sources such as relevant healthcare services and other regulators. However, your site should not mislead pharmacy service users about the identity or location of the pharmacies involved in providing your pharmacy services. This includes the identity and location of any online prescribing service
- 2. make sure that any business that is either hosted on your website, or reached by an external link, is legitimate. This includes any online prescribing service. Businesses you link to 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) and meet the relevant national regulatory standards and requirements

3. follow the MHRA's guidance on the advertising and promotion of medicines<sup>6</sup>, which states that your website content should not promote prescription only medicines (POMs) to the public. The home page should focus on medical conditions and the services your 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 website as they are likely to promote the specific POM.

You should not use inappropriate wording such as 'start order', 'express checkout' or 'add to cart'. Your website should not use icons or other features encouraging the purchase of POMs: for example, 'Buy Now', 'Buy XXX', 'Add to Basket'. For more information on the advertising and promotion of medicines, please see the MHRA Blue Guide.

- 4. make sure that your website and the websites of companies you work with are arranged so that a person cannot choose a POM before there has been an appropriate consultation with a prescriber. It should be made clear that the decisions about treatment are for both the prescriber and the person to consider together during the consultation
- 5. make sure your website prominently displays:

<sup>&</sup>lt;sup>6</sup> MHRA Blue Guide: advertising and promoting medicines in the UK, November 2020



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

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

- the name of the prescriber and the address of the prescribing service
- 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
- make sure you consider the design and layout of your website and make sure that it works effectively and looks professional

#### The 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 your pharmacy, and it must be displayed only on your own website. You must not allow it to be used by a third-party, prescribing or other website.

If you would like to apply to use our voluntary internet pharmacy logo on your website, **<u>please read the conditions for use</u>** before applying.

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

Because of the Northern Ireland Protocol, anyone in Northern Ireland who sells medicines to the public via a website must still meet the requirement of the EU common logo. This means they must be registered with the MHRA and display a Distance Selling Logo on every page of the website that offers medicines for sale.

For Great Britain, the MHRA will be considering an alternative to the use of the Distance Selling Logo in the future.

Voluntary GPhC internet logo



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.

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

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

If parts of your pharmacy services are provided at different locations you should explain clearly to people who use pharmacy services where each part of the service is based. You should avoid any 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 your website or information used to promote your pharmacy services.

In all cases, you and your staff must make sure people receiving care explicitly consent to any pharmacy service you provide using these prescribing services <u>as set out in the ICO's</u> <u>guidance on consent</u>. This includes services lawfully provided by a prescriber not regulated by a UK health professional regulator.

## To meet the standards under Principle 4, we expect you as the pharmacy owner to make sure:

- 1. you provide transparency to the people using your pharmacy services, so that they:
  - know who the responsible pharmacist is when their medicines or medical devices are supplied. 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
- you are able to show that your arrangements with medical or nonmedical prescribers are transparent, and do not:
  - cause conflicts of interest, or

- restrict a person's choice of pharmacy, or
- unduly influence or mislead people needing services, deliberately or by mistake
- 3. you provide information to the person about the indemnity and regulatory arrangements for those prescribers 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' pharmacy service. You should include these in your initial risk assessment (see section 1.1).

## To meet the standards under Principle 4, we expect you as the pharmacy owner to make sure:

- 1. you show the steps you have taken to minimise the risks you identify. This should include how you:
  - decide which medicines are appropriate for supplying at a distance, including on the internet
  - make sure your pharmacy staff can:
    - check that the 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 external credit

reference database, or a specific identity-checking service using photo ID verification. Your 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 your SOP may refer to the use of <u>the Identity</u> <u>Verification and Authentication</u> <u>Standard for Digital Health and</u> <u>Care Services</u>. This provides a consistent approach to identity checking across online digital health and care services

- get all the information they need from the person receiving pharmacy services so they can check that the supply is safe and appropriate, taking 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
- assess if the person receiving pharmacy services has capacity to decide about their medicines

- make sure the person receiving pharmacy services has the opportunity to ask questions about their medicines
- make sure people receiving pharmacy services know who to contact if they have any questions or want to discuss something with the pharmacist or pharmacy staff, and
- identify requests for medicines that are inappropriate – for example, by being able to identify multiple orders to the same address, a person using multiple accounts to make orders, or orders using the same payment details. This includes inappropriate combinations of medicines and requests that are too large or too frequent
- you are assured that all prescribers, whether medical or non-medical, follow the relevant remote consultation, assessment and prescribing guidance. For more information on prescribing, please see the 'Other useful sources of information' at the end of this document
- prescribers are following good practice guidance. For example, the General Medical Council's 'Good practice in prescribing and managing medicines and devices' 7 says:
  - prescribers must prescribe medicines only when they have adequate

<sup>&</sup>lt;sup>7</sup> General Medical Council, Good practice in prescribing and managing medicines and devices, 2021



knowledge of the person's health, and are satisfied that the medicines serve the person's needs

- they must not prescribe controlled drugs or medicines that are liable to abuse, overuse or misuse or when there is a risk of addiction and monitoring is important, if they don't have access to relevant information from the patient's medical records.
   For more information on prescribing, please see the 'Other useful sources of information' at the end of this document
- 4. that an online prescribing service, or a prescriber, that you choose to work with is aware that some categories of medicines are not suitable to be supplied online (for example non-surgical cosmetic products). Also, that they are aware that some categories of medicines should not be supplied unless further safeguards have been put in place to make sure they are clinically appropriate (see below for more details). The categories include:
  - Antimicrobials (antibiotics), when it is important to effectively manage their use to help slow the emergence of antimicrobial resistance and make sure that antimicrobials remain an effective treatment for infection. These should be supplied only in line with good practice guidance, taking

into account antimicrobial stewardship guidelines relevant for the person and their location

- Medicines liable to abuse, overuse or misuse, or when there is a risk of addiction and ongoing monitoring is important. For example, opioids, sedatives, laxatives, gabapentin, modafinil
- Medicines that require ongoing monitoring or management. For example, medicines with a narrow therapeutic index<sup>8</sup>, such as lithium and warfarin, as well as medicines used to treat diabetes, asthma, epilepsy and mental health conditions. A particular example of a medicine that requires ongoing monitoring and management is sodium valproate, which is used for the treatment of epilepsy and bipolar disorder, but which puts babies in the womb at a high risk of malformations and developmental problems

## Safeguards to put in place if the above categories of medicines are to be supplied online

 If you decide to work with an online prescribing service or prescriber, the above categories of medicines should not be prescribed unless you have evidence to assure yourself that the safeguards below have been put in place:

<sup>&</sup>lt;sup>8</sup> Drugs with a narrow therapeutic index are drugs with small differences between therapeutic and toxic doses.

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- 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, by keeping to <u>the Identity Verification</u> <u>and Authentication Standard for</u> <u>Digital Health and Care Services</u>, which provides a consistent approach to identity checking across online digital health and care services
- 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 will proactively share all relevant information about the prescription with other health professionals involved in the care of the person (for example their GP)
- for medicines which are liable to abuse, overuse or misuse, or when there is a risk of addiction and ongoing monitoring is important, you have confirmed before supplying against the prescription that the prescriber has contacted the person's regular prescriber, who has confirmed that the prescription is appropriate for the person and that appropriate monitoring is in place
- if there are circumstances where 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 or not to prescribe. They will need to think about the person's best interests and

make a risk-based assessment about whether they can prescribe safely, 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 must make a clear record 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 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

You must make sure medicines are delivered safely and effectively. You should consider how to do this as part of the initial risk assessment (see section 1.1).

### To meet the standards under Principle 4, we expect you as the pharmacy owner to make sure:

- you show the steps you have taken to manage the risks you identify. This should include how you:
  - assess the suitability and timescale of the method of supply, dispatch, and



delivery<sup>9</sup> (for example, for refrigerated medicines and controlled drugs)

- assess the suitability of packaging (for example, packaging that is tamperproof and/or temperature controlled)
- make sure that the method of storing and accessing medicines is 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
- track and monitor the package to make sure that it reaches the right person, and to monitor any unexpected interruptions in delivery
- check the terms, conditions and restrictions of the carrier
- check the laws covering the export or import of medicines if the intended recipient is outside the UK
- train your staff
- monitor third-party providers

#### 4.4 Information for pharmacy users

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

*Practice – The professional guide for pharmacists,* Edition 43, July 2019; or seek advice from the **National Pharmacy Association** (NPA) or your

professional indemnity provider.

You should consider how staff can communicate any important information to the person clearly and effectively.

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

<sup>&</sup>lt;sup>9</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* 

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

#### 5.1 Specialist equipment and facilities

You must make sure that your 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 you as the pharmacy owner to make sure:

- 1. your equipment is:
  - of high specification, accuracy and security. Your 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 your business and outside it. You should also control access to records and how you store, keep and remove records
  - calibrated, maintained and serviced regularly in line with the manufacturer's specifications
- 2. your software and operating systems:
  - are robust enough to handle the volume of work
  - have control systems built in to help manage the risk

- are accessible so that you can regularly audit your systems
- you understand your software and the operating systems you use – for example, how the software and operating systems work, what control systems are built in and whether there are any vulnerabilities
- 4. you keep maintenance logs for as long as you consider, and can show, to be appropriate
- 5. your business continuity plans include how you manage the risk of equipment failure, including disruptions in IT, and how you ensure 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

Alliance for Safe Online Pharmacies (ASOP Global)
 <u>buysaferx.pharmacy</u>

• Centre for Pharmacy Postgraduate Education

Consultation skills: <u>cppe.ac.uk/gateway/consultfound</u>

 Care Quality Commission <u>cqc.org.uk/</u>

Online primary care: Information for providers:

cqc.org.uk/guidance-providers/onlineprimary-care#care-standards

- Community Pharmacy Scotland <u>cps.scot/</u>
- Community Pharmacy Wales <u>cpwales.org.uk</u>
- Faculty of Reproductive Sexual Health and British Association for Sexual Health and HIV <u>fsrh.org</u>

Standards for Online and Remote Providers of Sexual and Reproductive Health Services for guidance on safe and appropriate online and remote provision of sexual health services:

#### fsrh.org/standards-andguidance/documents/fsrhbashhstandards-for-online-and-remoteproviders-of-sexual/

• General Medical Council

Good practice in prescribing and managing medicines and devices

gmc-uk.org/ethical-guidance/ethicalguidance-for-doctors/good-practice-inprescribing-and-managing-medicinesand-devices

Sharing information with colleagues gmc-uk.org/ethical-guidance/ethicalguidance-for-doctors/good-practice-inprescribing-and-managing-medicinesand-devices/shared-care

General Pharmaceutical Council

Guidance for employers on the education and training requirements of pharmacy support staff

pharmacyregulation.org/education/educa tion-and-training-requirementspharmacy-team/unregistered-staffsupport-staff

Guidance for registered pharmacies preparing unlicensed medicines pharmacyregulation.org/standards/guida nce/guidance-support-standardsregistered-pharmacies

High level principles for good practice in remote consultations and prescribing pharmacyregulation.org/news/principles-good-practice-issued-protect-patients-online-0

In practice: guidance for pharmacist prescribers

#### pharmacyregulation.org/guidance/guidan ce-support-standards-pharmacyprofessionals#prescribing

• Get Safe Online

Buying Medicines Online getsafeonline.org/shoppingbanking/buying-medicines-online1/

Health and Safety Executive
 Risk management: Expert guidance

hse.gov.uk/managing/theory/index.htm

Healthcare Improvement Scotland

Learning from adverse events through reporting and review <u>healthcareimprovementscotland.org/our</u><u>work/governance\_and\_assurance/manage</u> <u>ment\_of\_adverse\_events/national\_framew</u> <u>ork.aspx</u>

• Information Commissioner's Office (ICO)

Health sector resources ico.org.uk/for-organisations/healthsector-resources/

 Medicines and Healthcare products Regulatory Agency gov.uk/government/organisations/medici nes-and-healthcare-products-regulatoryagency

Advertise your medicines gov.uk/advertise-your-medicines Blue guide: Advertising and promoting medicines

#### gov.uk/government/publications/blueguide-advertising-and-promotingmedicines

Valproate banned without the pregnancy prevention programme gov.uk/government/news/valproatebanned-without-the-pregnancyprevention-programme

- National Cyber Security Centre <u>ncsc.gov.uk/cyberaware/home</u>
- National Institute for health and care excellence (NICE)

NICE Guidance nice.org.uk/guidance

- National Pharmacy Association (NPA)
  <u>npa.co.uk</u>
- NHS Digital <u>digital.nhs.uk</u>
- NHS England
  england.nhs.uk
- NHS Improvement

Risk assessment framework and reporting manual for independent sector providers of NHS services

<u>england.nhs.uk/wp-</u> <u>content/uploads/2020/12/B0106 b Update</u> <u>d-IPRAF-FINAL.pdf</u>

 Pharmaceutical Services Negotiating Committee
 psnc.org.uk



Distance-selling pharmacies psnc.org.uk/contract-it/market-entryregulations/distance-selling-pharmacies/

Electronic prescription service psnc.org.uk/dispensing-supply/eps/

• Royal Pharmaceutical Society <u>rpharms.com</u>

Clinical governance <u>rpharms.com/resources/pharmacy-</u> <u>guides/clinical-governance</u>

Prescribing competency framework <u>rpharms.com/resources/frameworks/pres</u> <u>cribers-competency-framework</u>

UK Government

Consumer protection gov.uk/government/policies/providingbetter-information-and-protection-forconsumers

Antimicrobial prescribing and stewardship competencies

gov.uk/government/publications/antimicr obial-prescribing-and-stewardshipcompetencies

• Veterinary Medicines Directorate

Internet retailers of veterinary medicines gov.uk/guidance/sell-veterinarymedicines-on-the-internet

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 /company/general-pharmaceutical-council www.pharmacyregulation.org