

Online Pharmacies: Guidance for Registered Pharmacies providing Pharmacy Services at a Distance including on the Internet

On 16 April 2019, the General Pharmaceutical Council ('GPhC') published further safeguards in relation to online pharmacies with the aim of protecting patients and other members of the public ('the public') when obtaining medicines online. The guidance is entitled 'Guidance for Registered Pharmacies providing Pharmacy Services at a Distance including on the Internet' ('Guidance').

All highlighted areas in this article have been extracted from the Guidance published by the GPhC and the GPhC is the owner of the copyright in such extracted material.

Because of changes in society and advances in technology, different ways of providing pharmacy services are becoming more common.

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-to-face way.

... 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.

...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.

According to the GPhC, the major issue concerning the public is the safety of online pharmacies. There are risks with providing and obtaining **pharmacy services** online including the provision of medicines, medical devices and pharmaceutical 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 Guidance comprises four main **safeguards** as follows:

- Ensuring medicines are clinically appropriate for patients
- Specific safeguards in connection with certain categories of prescription only medicines
- Transparency and patient choice

- Regulatory oversight

Responsibility for Implementing the Guidance

The responsibility for implementing the Guidance falls on the pharmacy owner.

Meaning of Pharmacy services

Pharmacy services include one or more of the following:

- Where prescriptions are collected or received by post or electronically
- Delivery of goods or medicine to the public in their homes or in care homes
- Hub and spoke
- A collection or delivery service

➤ **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**

➤ **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**

means an arrangement whereby a person may—

(a) take or send a prescription given by a doctor, dentist, nurse independent prescriber, pharmacist independent prescriber or optometrist independent prescriber to premises other than a registered pharmacy and which are capable of being closed by the occupier to exclude the public; and

(b) collect or have collected on his or her behalf from such premises a medicinal product prepared or dispensed in accordance with such a prescription at a registered pharmacy by or under the supervision of a pharmacist.

➤ **a 'click and collect' service**

This usually refers to the service where a customer can buy or order goods from a store's website and collect them from a local branch.

➤ **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 third party 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

Hub and spoke

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

Which Laws apply to an Online Pharmacy?

The laws are the same whether it's a pharmacy providing pharmacy services to the public face to face or via an online pharmacy:

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

... It is your responsibility to make sure the medicine you supply has the marketing authorisation needed for it in the country of destination...

The Five Principles Governing the Standards for Registered Pharmacies are

The Guidance is set out in accordance with the five Principles governing the standards for registered Pharmacies:

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

❖ Risk assessments

Under the Guidance a pharmacy owner, is required as a registered pharmacy, to conduct **risk assessments** to meet the standards under Principle I by identifying and managing the risks associated with providing pharmacy services online:

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.

...You should review your risk assessment regularly and whenever circumstances change

The risk assessments have to be conducted for each pharmacy service, medicine and medical device that is sold at a distance, including via the internet. The Guidance states that a pharmacy owner must ensure that **any cross-border arrangements are lawful under UK law**:

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
- your risk assessment includes considering:
 - ...the risks you have identified and how these will be managed
 - ...how medicines are supplied, including counselling and delivery (see section 4)
 - ...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; and
 - ...changes in the number or scale of services
- We expect you to make sure that any cross-border arrangements in your service design are lawful under UK law

❖ Regular audits

The pharmacy owner **must review and monitor** the **safety and quality** of the pharmacy services being provided by conducting **regular audits**:

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...

The pharmacy owner must conduct **regular audits** to ensure staffing levels, training and skills, the rights systems and processes are in place for receiving prescriptions and the information about your **pharmacy services on your website is compliant with the law**:

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

- your regular audit includes:
 - ...systems and processes for receiving prescriptions, including the electronic prescription service (EPS)
 - ...systems and processes for secure delivery to people receiving care
 - ...any information about your pharmacy services on your website...

❖ Accountability – staff

There has to be delineation of responsibilities for each pharmacists or technician in particular where the pharmacy services (like for example the delivery of medicines) include 'hub and spoke' or 'click

and collect' services. A major concern is **patient safety** such as the **failure to deliver the right medicines to the right persons**:

...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.

❖ **Record keeping**

There is an obligation to maintain records to show that the pharmacy services are safe, for instance, there is a requirement to maintain a daily log of the responsible pharmacist. This begs the question, how long the records should be retained for? The answer in the Guidance is vague 'for as long as you consider, and can show, to be appropriate':

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.

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

❖ **Trained and competent staff**

All members of staff must be properly trained and competent to provide medicines and other professional pharmacy services safely.

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.

❖ **Your premises**

The premises from which the pharmacy services are run must 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.

❖ **Your website**

The sale or supply of prescription medicines should be carried out by a registered pharmacy. There has to be compliance with data protection laws:

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...

To meet the standards under Principle 3, as the pharmacy owner:

- We expect you to be able to show how you are assured that all prescribers, whether medical or non-medical, follow the relevant remote consultation, assessment and prescribing guidance.
- Under the good practice guidance, prescribers must prescribe drugs only when they:
 - have adequate knowledge of the person's health, and
 - are satisfied that the drugs serve the person's needs.
- We expect you to make sure that your website and the websites of companies you work with are arranged so that a person cannot choose a POM and its quantity 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 jointly consider during the consultation. However, the final decision will always be the prescriber's.
- We expect you to make sure your website prominently displays:
 - ...the pharmacy's GPhC registration number
 - ...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..

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.

❖ **Transparency and choice**

Pharmacy owners are required to state the location of each pharmacy and obtain the requisite consents in accordance with data protection laws:

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.

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 **as set out in the ICO's guidance on consent**. 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
2. 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
3. you provide information about the indemnity and regulatory arrangements for those prescribers who are not based in the UK, especially if they are not regulated by a UK health professional regulator

❖ **Managing medicines safely**

In conducting your initial risk assessments you should include the sale and supply of medicines at a distance, including on the internet. The risks are different risks to those of a 'traditional' pharmacy service.

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 appropriate identity check (for example by keeping to the Identity Verification and

Authentication Standard for Digital Health and Care Services, which provides a consistent approach to identity checking across online digital health and care services)

Online prescribing services or prescribers should be made of categories of medicines are not suitable to be supplied online unless further safeguards:

- **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 opiates, sedatives, laxatives, pregabalin, gabapentin
- **Medicines that require ongoing monitoring or management.** For example medicines with a narrow therapeutic index, 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

- **Non-surgical cosmetic medicinal products (such as Botox, Dysport or Vistabel).** In line with good practice guidelines, these should be prescribed and supplied only after a physical examination of the person.

The Guidance recommends a number of safeguards to be 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 the safeguards below have been put in place:

- the prescriber has robust processes in place to ensure that the medicines prescribed go to the right persons
- obtain consent
- be able to share all relevant information about the prescription with other health professionals involved in the care of the persons
- to avoid misuse of medicines
- record keeping
- working within national prescribing guidelines for the UK and good practice guidance.

❖ **Supplying medicines safely**

The Guidance requires medicines to be delivered safely and effectively (include as part of your initial risk assessment). In order to meet the standards laid down in Principle 4, the pharmacy owner must ensure:

1. 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 (for example, for refrigerated medicines and controlled drugs)
- assess the suitability of packaging (for example, packaging that is tamperproof and/or temperature controlled) 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

❖ **Information for pharmacy users**

Staff members are required to communicate any important information to users of the pharmacy clearly and effectively when dealing remotely with the persons.

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

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

❖ **Specialist equipment and facilities**

You must ensure that your pharmacy has the equipment and facilities needed to provide pharmacy services fit for purpose:

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

3. 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

Please visit our website at www.rtcoopers.com/onlinepharmacy.php or you may contact us by email enquiries@rtcooperssolicitors.com.

Contact us.

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