

Discussion paper on making sure patients and the public obtain medicines and other pharmacy services safely online

June 2018



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About the GPhC

Who we are

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.

Context

We have an important role in providing assurance to people that the pharmacy services they and their families use will be safe and effective. We also want to drive continuous improvement in the quality of care that people receive when using pharmacy services.

We regulate all registered pharmacies in Great Britain, including pharmacies that provide services on the internet to patients and the public. We inspect all registered pharmacies and will look for evidence that pharmacies providing services on the internet are meeting our **standards for registered pharmacies**.

In 2015, we published **guidance for pharmacy owners who provide pharmacy services at a distance, including on the internet**. The guidance is intended to cover a range of services, including services provided over the internet. It makes clear that, however the pharmacy service is delivered, the legal principles and regulatory standards aimed at guaranteeing safe outcomes for patients and people who use pharmacy services must still be met.

Advances in technology and the development of new service models have brought opportunities to deliver pharmacy services and other healthcare services in new ways. But providing pharmacy services at a distance, especially online, carries particular risks which need to be successfully managed.

We continue to support and encourage responsible innovation as long as people using pharmacy services receive safe, effective,

person-centred care. However, we are increasingly concerned about the way some services appear to undermine the important safeguards that are in place to protect patients from accessing medicines that are not clinically appropriate for them.

The way pharmacy services and the supply of medicines are delivered online varies. Some pharmacies operate alongside prescribing services, while others provide pharmacy services alone. Also, the nature of the internet, which has no physical boundaries, means that some patients will live abroad and some prescribing services are located abroad. This means that regulating healthcare services on the internet is complex, with different organisations and agencies responsible for different parts of the service.

We work closely with the other regulators involved in regulating online primary care services in Great Britain. We aim to make sure that people are receiving safe and effective care at each stage of the process, from when they first visit an online primary care service to when they receive their medicines from a pharmacy.

We are aware of situations where patients have been put at risk because of the inappropriate sale and supply of medicines on the internet. This includes through concerns raised with us and through our work with other regulators. Medicines are not ordinary items of commerce, and must not be treated as such.

We are therefore asking for views on changes to our guidance for pharmacy services provided on the internet or at a distance. We aim to strengthen our guidance to make clear what our expectations are of pharmacy owners who provide these services.

Examples of ways online healthcare services may be regulated

Example 1

A pharmacy provides medicines online and operates alongside a private online prescribing service. Both are based in Great Britain.

- 1. The GPhC is responsible for regulating the pharmacy and the pharmacy professionals.**
- 2. The GMC is responsible for regulating the doctor working for the prescribing service.**
- 3. The Care Quality Commission in England, Health Improvement Scotland or Healthcare Inspectorate in Wales are responsible for regulating the online prescribing service, depending on which country the prescribing service is based in.**
- 4. The MHRA is responsible for authorising the display of the EU common logo to show that the supplier is permitted to supply medicines online.**

Example 2

A pharmacy in Great Britain provides medicines online and operates alongside an online prescribing service located abroad with a prescriber who is not registered with the GMC.

- 1. The GPhC is responsible for regulating the pharmacy and the pharmacy professionals.**
- 2. The doctor will be regulated by the relevant organisation in the country from where they prescribe.**
- 3. The prescribing service may also be regulated by a relevant organisation in the country where the prescribing service is based.**

This discussion paper

This discussion paper focuses on the new areas that we are proposing to cover in the updated guidance for pharmacy owners who provide pharmacy services at a distance, including on the internet.

The discussion period will run for eight weeks, until 21 August 2018. During this time, we are keen to hear from individuals and organisations with an interest in how medicines and pharmacy services are provided on the internet or at a distance. This includes patients and the public, and people who own or work in these pharmacies.

We would like to hear what you think of our proposals, and whether they will provide additional safeguards to patients and the public. We are also keen to understand the impact of our proposals, both on patients and the public who may wish to use pharmacy services online and those who offer these services.

Our report on this consultation

Once the discussion period ends, we will analyse the responses we receive and publish a summary on our website of what we have heard.

We will take the responses into account when updating the guidance for pharmacy owners who provide pharmacy services at a distance, including on the internet. We plan to publish this in the second half of 2018.

How to respond

You can respond to this consultation by going to www.pharmacyregulation.org/online-pharmacy and filling in an online survey there.

Please contact us at communications@pharmacyregulation.org if you would like a copy of the discussion paper survey in another format (for example, in larger type or in a different language).

Comments on the consultation process itself

If you have concerns or comments about the consultation process itself, please send them to:

feedback@pharmacyregulation.org

or post them to us at:

Governance Team
General Pharmaceutical Council
25 Canada Square
London E14 5LQ

Please do not send consultation responses to this address.

Our proposals

We plan to include the following points in our updated guidance:

1. Transparency and patient choice

We believe it is vital for patients and members of the public to know:

- the name and physical address of the pharmacy
- the name of the responsible pharmacist, and supervising pharmacist if this is different to the responsible pharmacist
- the name and location of the prescriber if the patient is being prescribed medicines following an online consultation, and
- whether the prescriber is a doctor or a non-medical independent prescriber – for example a pharmacist, nurse or physiotherapist

We will therefore make it clear that however the pharmacy service is designed, we expect there to be transparency for patients. This is so patients have enough information about the clinical service, and who is providing it, to make an informed decision. They can also raise concerns about the quality of the service and about the health professionals who provided the service, if they need to.

We believe pharmacy owners have an important role to play in raising awareness among patients about what they should expect from a safe and effective pharmacy service. For example, a good pharmacy service will verify the patient's identity so that the medicines are right for the patient. Therefore we are proposing to include in our guidance more

advice on the types of information patients and the public should be given online.

Also, if a pharmacy owner works with a prescribing service based outside the UK, we expect the pharmacy owner to make sure patients are provided with clear information about these arrangements. This would include the indemnity and regulatory arrangements that apply to those prescribers, especially if they are not regulated by a healthcare regulator in the UK. The pharmacy owner must be able to show that patients, before they start using the service:

- have been given this information, and
- have provided explicit, informed consent to receiving medical advice and treatment from a prescriber not regulated by a UK healthcare regulator

Questions about these proposals

1. Do you think our proposals on transparency and patient choice should be included in our guidance?
2. Do you have any comments about our proposals on transparency and patient choice?

2. Making sure medicines are clinically appropriate for patients

We know that pharmacy owners can make non-promotional information available to patients about the range of treatment options available. We also recognise that this information is important for patients and the public who use pharmacy services online. We are also aware that some websites are set up in a way that allows patients to choose a prescription-only medicine before having a consultation with a prescriber.

We believe there is an important balance to be achieved. Patients should have a choice of where they go to obtain their medicines. They should also be empowered and encouraged to make decisions to maintain and improve their own health and well-being.

At the same time, medicines are not ordinary items of commerce. There are additional risks to patient safety when prescription-only medicines can be chosen before having an appropriate consultation with a prescriber. For example, if a patient simply has to answer questions before the healthcare professional makes their prescribing decision, they might fill in a number of questionnaires, learning what answers to give so they can get the medicine in question. This may result in medication being selected or later prescribed which may be inappropriate and lead to harm.

We want to explore, through this discussion paper, whether it is appropriate for pharmacy websites to be arranged in such a way that a patient can choose a prescription-only medicine, and its quantity, before having a consultation with a prescriber, and what the risks and benefits are. We are particularly keen

to hear the experiences of patients, and those who provide these services.

Also, our standards for registered pharmacies make it clear that pharmacy owners must make sure that pharmacy professionals are able to meet their own professional and legal obligations, and are able to exercise their professional judgement in the interests of patients and the public. Pharmacy professionals must be able to meet the **standards for pharmacy professionals**, and they must be satisfied that a prescription is clinically appropriate.

We expect pharmacy owners to have robust processes in place so that the pharmacy team are able to:

- make appropriate checks (for example, on the identity of patients), and
- identify possible risks to patients (for example, have systems to identify multiple orders to the same address or using the same payment details)

Questions about these proposals

3. a) Do you think it is appropriate for pharmacy websites to be arranged in such a way that a patient can choose a prescription-only medicine, and its quantity, before having a consultation with a prescriber?
- b) Please describe the circumstances when it would be appropriate for a patient to choose a prescription-only medicine, and its quantity, before having a consultation with a prescriber.

4. We want to explore the risks and benefits of patients being able to choose a prescription-only medicine, and its quantity, before having a consultation with a prescriber.

- Please describe any risks in this approach.
- Please describe any benefits of this approach.

3. Further safeguards for certain categories of prescription-only medicines

All prescription-only medicines must be reviewed regularly by the prescriber if they are prescribed on an ongoing basis. However, we know that the nature of the review and how often it happens will vary depending on the category of medicine. We believe that there are certain categories of medicines that may not be suitable to be prescribed and supplied online unless further action is taken to make sure that they are clinically appropriate for the patient. These include:

- a. antimicrobials (antibiotics):** where 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 usually only be prescribed and supplied:
- if physical examination or diagnostic testing shows that they are clinically appropriate, and

- in line with best practice guidance, taking into account antimicrobial stewardship guidelines relevant for the patient and their location

b. opiates and sedatives: where there is a risk of addiction, overuse or misuse, and ongoing monitoring is important. These should only be prescribed and supplied if:

- the patient has given consent for the prescriber to contact their GP, and
- the GP has confirmed to the prescriber that the prescription is appropriate for the patient and that appropriate monitoring is in place

We expect pharmacy owners to have systems in place so that the pharmacy team can clearly document the prescriber's decision to issue the prescription if there is either no GP or there is no consent to share this information.

c. medicines or medical products for chronic conditions (including asthma and diabetes) and mental health conditions: where ongoing monitoring is important. These should only be prescribed and supplied if:

- the patient has given consent for the prescriber to contact their GP, and
- the GP has confirmed to the prescriber that the prescription is appropriate for the patient and that appropriate monitoring is in place

We expect pharmacy owners to have systems in place so that the pharmacy team can clearly document the prescriber's decision to issue the prescription if there is either no GP or there is no consent to share this information.

d. non-surgical cosmetic medicinal products (such as Botox, Dysport or Vistabel): following GMC guidance, these should only be prescribed and supplied after the prescriber has carried out a physical examination of the patient.

We will therefore make clear that it is not appropriate for pharmacy owners to work with prescribing services unless they are assured that the above safeguards are in place for certain prescription-only medicines.

Questions about these proposals

5. Do you think our proposal to add further safeguards for certain categories of medicines should be included in our guidance?
6. Are there any other categories of medicine we should include in our guidance?
7. Do you have any comments about our proposal to add further safeguards for certain categories of medicines?

4. Regulatory oversight

It is not appropriate for pharmacy owners to work with online prescribing providers who may try to deliberately bypass the regulatory oversight which aims to ensure patient safety throughout the healthcare system. Working with prescribers who are not appropriately registered with the relevant professional regulator within the UK, and with prescribing services not based in the UK, could create significant additional risks for patients for a number of reasons. These risks include the fact

that both patients and prescribers may not be familiar with the legal and healthcare requirements in the UK and language barriers may prevent an appropriate consultation, which includes patients being able to ask questions. We plan to make it clear that if a pharmacy owner decides to work with prescribers or prescribing services operating lawfully outside the UK, we expect the pharmacy owner to make sure and be able to show that:

- they successfully manage the additional risks that this may create
- the prescribers are keeping to national prescribing guidelines for the UK, and
- the prescribers are keeping to their home country regulator's relevant legislation, ethical standards and guidance

Questions about these proposals

8. Do you think our proposals on regulatory oversight for services or prescribers not based in the UK should be included in our guidance?
9. Do you have any comments about our proposals on regulatory oversight for services or prescribers not based in the UK?

5. The impact of these proposals

Overall questions about these proposals

We want to understand the impact that these proposals would have on the key groups that may be affected.

10. What kind of impact do you think the proposals will have on people using pharmacy services?

Please give comments explaining your response.

11. What kind of impact do you think the proposals will have on the owners of registered pharmacies?

Please give comments explaining your response.

12. What kind of impact do you think the proposals will have on the pharmacy team?

Please give comments explaining your response.

We want to understand whether our proposals may discriminate against or unintentionally disadvantage any individuals or groups sharing any of the protected characteristics in the Equality Act 2010. These characteristics are:

- age
- disability
- gender reassignment
- marriage and civil partnership
- pregnancy and maternity
- race
- religion or belief

sex
sexual orientation

13. Do you think anything in the proposed changes would have an impact – positive or negative – on certain individuals or groups who share any of the protected characteristics listed above?

Please give comments explaining your response.

14. Do you think our proposals will have any other impact which you have not already mentioned?

How we will use your responses

After the discussion, we will publish a report summarising what we heard.

If you respond as a private individual, we will not use your name or publish individuals' responses. If you respond on behalf of an organisation, we will list your organisation's name and may publish your response in full unless you tell us not to.

If you want any part of your response to stay confidential, you should explain why you believe the information you have given is confidential. We may need to disclose information under the laws covering access to information (usually the Freedom of Information Act 2000). If you ask us to keep part or all of your response confidential, we will treat this request seriously and try to respect it. But we cannot guarantee that confidentiality can be maintained in all circumstances.

If you email a response to the consultation and this is covered by an automatic confidentiality disclaimer generated by your IT system this will not, in itself, be binding on the GPhC. Under data protection law, you may ask for a copy of your response to this consultation or other information we hold about you. You may also ask us to delete your response.

For more information about your rights and who to contact please read our privacy policy on our website.



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