

General Pharmaceutical Council: Discussion paper on making sure patients and the public obtain medicines and other pharmacy services safely online
Royal Pharmaceutical Society response

1. Do you think our proposals on transparency and patient choice should be included in our guidance?

Yes, we agree that the GPhC proposals on transparency and patient choice should be included in the GPhC guidance. The Royal Pharmaceutical Society expects pharmacists to provide patients with the same high standards of care wherever they are practicing.

2. Do you have any comments about our proposals on transparency and patient choice?

These proposals should help to reassure members of the public and patients that the services provided by online pharmacies are professional, safe and effectively regulated. People using the online services should know exactly who is delivering the service, where they are located and what the qualifications of the professionals involved are. However, there are some practical considerations, so depending upon the model it might be difficult to identify the prescriber in advance, for example there could be a team of prescribers, fronted by a GMC registered practitioner. The identity of the responsible pharmacist should also be clear and visible to the patient.

It is also important for healthcare professionals providing prescription medicines via an online service to be able to verify the person's identity to ensure the medicines and advice they are providing are appropriate for that individual and their needs. For sale and supply of P medicines this requirement is not necessary. This is in line with the purchase of P medicines in a bricks and mortar pharmacy where patients' anonymity can be preserved.

We know that there have been a number of actual deaths in the past few years associated with online prescribing and / or online pharmacy services; sometimes involving EEA prescribing from Europe and sometimes involving medicines which can be misused. These situations have arisen where contact between the patients and prescriber or pharmacy is remote and limited. We are broadly supportive of GPhC and CQC actions in relation to their responsibilities to prevent future similar deaths, as this is an outcome that we all desire.

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?

The design of the website should be such that a patient cannot purchase prescription only medicines without some decision support, either a PGD-based or a real time remote prescriber consultation, with or without decision support algorithms. With algorithm based systems, the decision process should not be obvious to the end user, to avoid the risk of people 'gaming the system' to obtain the medicine they feel they need. The use of algorithms has the ability to apply

consistency to prescribing decisions. It would be appropriate for a patient to indicate the treatment they are seeking to obtain as long as it is clear to them that the actual supply of the product is dependent on a clinician reviewing their suitability for the medicine as part of a consultation. It is also important that patients are given enough information up front in order for them to be able to make an informed decision, particularly where there are a number of treatment options available.

A prescriber who is providing online prescriptions should ensure they are competent to elicit the required information from the patient before prescribing any medicines.

Websites should not take a ‘product led’ approach and enable patients to order large or inappropriate quantities of prescription only medicines without having an appropriate consultation to gather all the necessary safety information. This is an unacceptable risk to the public. Stockpiling of medicines should also not be promoted. Any online consultation should meet the same standard as a face-to-face consultation.

These proposals should also apply to providers of online prescribing services and not just internet pharmacies. The remit of GPhC only covers registered premises i.e. internet pharmacies which are associated with online prescribing services. There are also many online prescribing services which are set up to be separate to an associated pharmacy, or are truly independent of pharmacy. The proposals about websites allowing self-selection of POMs should also apply to these (via CQC / MHRA) otherwise businesses will re-arrange themselves so that the pharmacy business is legally independent to the prescribing business.

We think that the GPhC use of the term “clinical appropriateness” to describe the website arrangement is likely to cause confusion because the profession uses the term in a different way such as assessing if items prescribed are clinically appropriate i.e. the clinical check.

3. 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

Individuals taking medicines for long term conditions are precisely the people who will benefit from the convenience of an ongoing supply as long as their conditions or circumstances remain the same. There should be appropriate monitoring support in terms of the condition and potential side effects but such supplies should not be too restricted. However, appropriate risk assessments should be carried out when designing an online service and ongoing supplies and type of medicine being prescribed, along with the condition, should be considered as part of this and used to inform selection of a medicine up front and the quantities permitted to be prescribed. Access to electronic patient records, such as the Summary Care Record in England, must be included as part of the online service.

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.

The risks are that the patient may be able to navigate an online questionnaire to ensure they get the outcome that they want i.e. access to the medicine, by providing false information.

The obvious risks are that the patient receives a medicine that has a detrimental effect on their health, or they abuse the medicine which could have fatal consequences. However, patient evasion of this nature could also occur in a face-to-face consultation and this needs to be considered as part of the online service design through risk assessment.

A patient may be able to select the medicine they would like along with the quantity prior to entering a consultation with a clinician. However, it should be made clear to them that the actual supply of the product is dependent on a clinician reviewing their suitability for the medicine as part of a consultation.

• Please describe any benefits of this approach.

People who have a long term condition and are stable on their medicine(s), or people who choose this method of supply in terms of convenience, discretion and cost effectiveness, may benefit from being able to obtain their medicines online. However, there should always be an element of checking that nothing has changed in their medical history, checking for allergies and development of side effects. Also, if they are on medicines that require monitoring there should be a requirement to have access to the latest test results,

There could be a fraction of patients, who use private services, who find the shopping-around approach useful to them and they might appropriately use this for long-term-conditions, stable conditions, repeat order following initial consultation e.g. sildenafil or oral contraceptives. So there may be circumstances where this is appropriate in-line with any national prescribing guidelines for that particular condition or indication.

5. Do you think our proposal to add further safeguards for certain categories of medicines should be included in our guidance?

Yes, we think the proposal to add further safeguards for certain categories of medicines should be included in the guidance. But this need to also be taken on a case to case basis, backed up by robust risk assessment and mitigation when the online service is developed. There could be legitimate circumstances, for example, where an opiate is prescribed for a patient in their best interests and it should be the responsibility of the prescriber to make this decision.

Physical examination for a) would not always occur in a face to face consultation, so it should not be any different for an online consultation. There are now a variety of methods to assess and diagnose via an online consultation including video chat and photo analysis. However, if patients are taking medicines that require certain tests to be undertaken then there should be access to the latest test results.

In relation to category c) for chronic conditions consideration needs to be given to patient self-monitoring. With the use of technology it is possible that many patients with chronic conditions such as asthma and diabetes monitor themselves and they could potentially share their results with the prescriber online.

The responsibilities of the pharmacist and the prescriber need to be clarified as it would be the prescriber's responsibility to undertake a variety of checks and ensure the medicine is appropriate for the individual patient.

6. Are there any other categories of medicine we should include in our guidance?

We have been made aware that there has been an increase in the supply of performance enhancing medicines and GPhC may wish to also consider these. Slimming pills should also be considered.

7. Do you have any comments about our proposal to add further safeguards for certain categories of medicines?

We believe it is necessary to add these additional safeguards in relation to the fact that providers of online services are considering the appropriate and additional safeguards that need to be in place if they prescribe any of these categories of medicines. However, the liaison required by the pharmacists between the prescribing clinician and the patient's GP is unfounded, unless deemed necessary by the pharmacist for that individual patient.

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

We think the proposals on regulatory oversight as outlined in the discussion document should be included in the guidance.

9. Do you have any comments about our proposals on regulatory oversight for services or prescribers not based in the UK?

It is important that patients accessing the service in the UK are aware that the services are provided from outside of the UK. It is also important that they feel reassured that the services meet the UK legal and regulatory requirements. If pharmacies decide to work with overseas providers then they have a responsibility to ensure the providers they are working with are providing high quality, safe and effective services.

Some countries do not have the same categories of medicines as those in the UK e.g. the United States does not have a pharmacy only category, so medicines that are available to purchase in one country may not be available in the UK and this should be flagged.

We would also recommend that any prescriber prescribing for a UK citizen via an online service needs to be qualified to practice in the UK as is the current legal requirement for all prescriptions dispensed in the UK.

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.

As more online services are available for obtaining medicines it is likely that more people using pharmacy services will access them in this way. However, care needs to be taken that medicines are not seen or treated as ordinary items of commerce and that people only get the medicines that are safe and appropriate for them as an individual. These proposals will ensure that the services that are provided online are safe for the people accessing them. GPhC needs to describe how it will monitor, investigate and enforce this guidance in the future.

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

Please give comments explaining your response.

These proposals may make it more difficult for pharmacies to provide online services but they are needed in the interest of patient safety. However, online registered pharmacies and individual pharmacists working for these organisations have the same obligations as any other pharmacy to comply with regulatory standards and our professional guidance in order to ensure the safety of the public. The requirements of an online service should not require additional workload over and above that of a bricks and mortar pharmacy and this needs to be clarified by GPhC. For example, the requirement for liaison between the patient's GP and the prescribing clinician is an additional burden for an online service.

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

Please give comments explaining your response.

An online prescription service can potentially increase the workload for the pharmacy team if the prescriptions are directed via a UK registered pharmacy. Currently the prescription is sometimes faxed to the pharmacy and then the original copy sent in the post and these need to be reconciled. However, this practice is not encouraged and we would recommend the use of electronic prescribing systems.

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.

Yes. The proposals may have a negative impact on those under 18 accessing online services as there are no options for verifying identity in under 18s. Gender is relevant for many treatments and gender at birth needs to be declared so this may have some impact on those people undergoing, or who have undertaken, gender reassignment, as this group may be unable to access a particular service.

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

It is important that medicines are not seen and treated as ordinary items of commerce so whilst many patients may prefer to obtain their medicines online there needs to be clear guidance for online providers to ensure that people only receive medicines that are safe and appropriate for them as individuals.

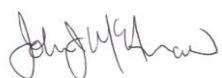
In order to ensure patient safety and a full audit trail of supply from the pharmacy to the person purchasing the medicines it is essential that medicines are signed for at the receiving end i.e. by the person purchasing the medicines.

The scope of the guidance needs to be better articulated and clarified. There are many distinct areas that could be placed under the term s of obtaining medicines and other pharmacy services safely online including Pharmacy Medicines (P meds), online doctor led services, online other clinician led services, online pharmacy / internet pharmacy and bricks and mortar pharmacy who may dispense prescriptions from an online service. Some of these will be under the remit of the Care Quality Commission so GPhC will need to work closely with other regulators to ensure they are not imposing guidance on online services outside their remit.

Safeguarding also needs to be considered as part of the online service development.



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About us

The Royal Pharmaceutical Society (RPS) is the professional body for every pharmacist in Great Britain. We are the only body that represents all sectors and specialisms of pharmacy in Great Britain.

The RPS leads and supports the development of the pharmacy profession to deliver excellence of care and service to patients and the public. This includes the advancement of science, practice, education and knowledge in pharmacy and the provision of professional standards and guidance to promote and deliver excellence. In addition, it promotes the profession's policies and views to a range of external stakeholders in a number of different forums.

Its functions and services include:

Leadership, representation and advocacy: Ensuring the expertise of the pharmacist is heard by governments, the media and the public.

Professional development, education and support: helping pharmacists deliver excellent care and also to advance their careers through professional advancement, career advice and guidance on good practice.

Professional networking and publications: hosting and facilitating a series of communication channels to enable pharmacists to discuss areas of common interest, develop and learn.