

General
Pharmaceutical
Council

Consultation on guidance for pharmacist prescribers

March 2019



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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.



Overview

We are consulting from **29 March** to **21 June 2019** on our draft guidance for pharmacist prescribers.

This consultation is about draft guidance to support pharmacist prescribers in meeting our standards for pharmacy professionals, and to ensure they provide safe and effective care when prescribing.

The draft guidance sets out the key areas pharmacist prescribers should consider when prescribing. The guidance applies to pharmacist prescribers working within the NHS or privately – including primary care and secondary care – and in healthcare roles within the armed forces and prisons.

This consultation asks for views on our draft guidance. More specifically we are asking for views on:

- the key areas for safe and effective prescribing
- what pharmacist prescribers must do in order to prescribe safely
- prescribing and supplying
- safeguards when remotely prescribing certain categories of medicines, and
- the impact this guidance may have on various stakeholder groups

We welcome responses from anyone with an interest in pharmacist prescribing. We are particularly interested to hear views about the impact of our proposals on patients, the public, pharmacist prescribers, pharmacy professionals, pharmacy owners and employers.

The consultation process

The consultation will run for 12 weeks and will close on **21 June 2019**. During this time, we welcome feedback from individuals and organisations. We will send this document to a range of stakeholders, including pharmacy professionals, pharmacist prescribers, pharmacy owners, patients' representative bodies and others with an interest in this matter.

Responding to the consultation

After the consultation, 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.

The GPhC may need to disclose information under the laws covering access to information (the General Data Protection Regulation 2016/679). 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.

How to respond

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

Please contact us at communications@pharmacyregulation.org if you would like a copy of the consultation 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.

Background

Pharmacist prescribers play a vital role in the delivery of high-quality healthcare services. They are responsible for creating a culture of person-centred professionalism wherever they work and for making sure prescribing services are delivered safely and effectively.

Government policies and the changing demands from health services and patients across Great Britain have significantly influenced and developed the role and use of pharmacist prescribers over the last few years. At the same time, the number of annotated pharmacist prescribers has significantly increased. At the moment, we have over 8000 annotated pharmacist prescribers on our register. National pharmacy strategies may vary across the countries in Great Britain, but it is recognised everywhere that employing pharmacist prescribers across healthcare settings:

- makes the best use of pharmacists' prescribing knowledge and skills, and
- complements the skills of other members of the healthcare team

Our ***Strategic plan 2017-20*** sets out our aim to use our regulatory powers to support and

improve the delivery of safe, effective care and to uphold trust in pharmacy. One of the ways we do this is by making sure that pharmacist prescribers have the necessary knowledge and skills.

We have carried out research over the past three years. From this – and from information received through our prescribers' survey (2016), the enquiries we received, fitness to practise cases, our discussion paper and consultations^{1,2} – we have better understood the issues affecting patient safety. These include:

- the question of pharmacist prescribers having access to relevant medical records
- the development of remote and online prescribing, and
- the prescribing of certain categories of medicine

We have also taken account of other prescriber guidance, including that of the GMC and the Joint Council of Cosmetic Practice (JCCP).

We are working with other regulatory agencies, for example the Medicines and Healthcare Regulatory Authority (MHRA) and health

¹ ***Discussion paper on making sure patients and the public obtain medicines and other pharmacy services safely online***, GPhC, June 2018

² ***Consultation on education and training standards for pharmacist independent prescribers***, GPhC, March 2018

systems regulators across Great Britain, to help identify issues that affect patient safety, and to make sure pharmacist prescribers provide safe and effective care.

Our **standards for pharmacy professionals** apply to all pharmacy professionals in Great Britain, including pharmacist prescribers. Given the increase in the number of pharmacist prescribers and the development of remote and online prescribing, we believe it is necessary to issue guidance to help make sure pharmacist prescribers are meeting our standards.

Who are pharmacist prescribers?

A **pharmacist independent prescriber** (PIP) is a pharmacist who has completed the relevant approved education and training to add an annotation to their entry in the register. A PIP may prescribe all medicines independently for any condition within their scope of practice and clinical competence. The exceptions to this are the three controlled drugs used to manage addiction (cocaine, dipipanone and diamorphine) and unlicensed cannabis-based medicinal products (CBMPs).

A **pharmacist supplementary prescriber** (PSP) works with a medical or dental practitioner within a specific clinical management plan (CMP). The law sets out what the CMP must include, and the limitations on what the PSP can prescribe and under what circumstances. A PSP may become a PIP through further training and by converting their qualification, and can then work as both a PSP and a PIP.



The draft guidance

The guidance sets out nine key areas that relate to the provision of safe and effective prescribing. Pharmacist prescribers should consider the first eight areas when prescribing, to ensure safe and effective care. These are:

1. taking responsibility for prescribing safely
2. keeping up to date and prescribing within your level of competence
3. working in partnership with other healthcare professionals and people seeking care
4. prescribing in certain circumstances
5. prescribing non-surgical cosmetic medicinal products
6. remote prescribing
7. safeguards for the remote prescribing of certain medicines
8. raising concerns

Section 9 contains information for pharmacy owners and the employers of pharmacist prescribers.

Please read the draft guidance in the next section for more information on how to apply the standards for pharmacy professionals.

In practice: Guidance for pharmacist prescribers

About this guidance

This guidance should be read alongside the **standards for pharmacy professionals**, which all pharmacy professionals must meet.

It should also be read alongside our **standards for registered pharmacies**. All pharmacy owners are responsible for meeting these, to ensure the safe and effective provision of pharmacy services from the registered pharmacy.

This guidance cannot cover every situation and does not give legal advice, as all pharmacy professionals must keep to the relevant laws.

It gives guidance to pharmacist prescribers in applying the standards when prescribing. The guidance applies whether they work privately or within the NHS, and sets out the key areas pharmacist prescribers should consider when applying the standards to their prescribing practice. It also applies to pharmacist prescribers who work remotely, including those who prescribe online, and where pharmacy owners employ or make a contract with a

pharmacist prescriber or service provider to provide online prescribing services.

We want this guidance to support appropriate and effective provision of pharmaceutical care and medicines, which keeps to the law³ and meets our standards. We believe this guidance will be helpful for other organisations who employ pharmacist prescribers or provide pharmacy prescribing services across a range of settings.

Pharmacist prescribers should be able to justify their decisions and use their professional judgement in applying this guidance in practice.⁴

All pharmacy professionals should be familiar with the matters covered in this guidance, and understand their own responsibilities in relation to prescribers.

This guidance should also be read alongside any relevant regulatory and NHS documents for England, Scotland and Wales, and any relevant guidance published by other organisations⁵,

³ For information on writing prescriptions and using electronic prescriptions, see the Royal Pharmaceutical Society's ***Practical guide to prescribing*** and the ***British National Formulary***

⁴ The GPhC sets **standards for the education and training of pharmacists to become PIPs**

⁵ ***A competency framework for all prescribers***, Royal Pharmaceutical Society, July 2016. The single competency framework for all prescribers sets out a common set of competencies that all prescribers should follow.



including professional leadership bodies and other regulators.

Pharmacist prescribers should also keep to the other relevant standards and guidance that apply to their place of work and role. These may be, for example, from the Care Quality Commission, Healthcare Inspectorate Wales, Healthcare Improvement Scotland and the Advertising Standards Authority⁶.

We have **a range of guidance on our website to help pharmacy professionals apply our standards.**

Pharmacist prescribing

Pharmacist prescribers play a vital role in the delivery of high-quality healthcare services, and the variety of their roles is increasing.

Pharmacist prescribers are responsible for creating a culture of person-centred professionalism wherever they work, and for ensuring prescribing services are delivered safely and effectively.

A pharmacist prescriber may be a pharmacist supplementary prescriber (PSP) or a pharmacist independent prescriber (PIP). Both can prescribe, supply and administer medicines.

A pharmacist independent prescriber (PIP) is responsible for and accountable for the clinical assessment and management of people with undiagnosed or diagnosed conditions, without needing to consult another prescriber. They are also responsible for the prescribing decisions they make, and for the appropriateness of the prescriptions they sign.

Prescribing can take place in different ways and in different contexts. It may involve the supply of a prescription for a prescription-only medicine or medical device, but can also include advising people on the supply of an over-the-counter medicine and giving advice or information.

⁶ The CQC publishes **guidance on care standards on their website**

Cosmetic interventions, Advertising Standards Authority, January 2016, and **online advice**, February 2015

The GPhC sets standards for the education and training of pharmacists to become PIPs.

A supplementary prescriber works with a medical or dental practitioner within a specific clinical management plan (CMP), but does not prescribe independently.

In this guidance we use the term 'pharmacist prescriber' to include both, as they can both work in the same settings.

What do we mean by 'supplementary prescriber'?

A supplementary prescriber works with a medical or dental practitioner within a specific clinical management plan (CMP). The law sets out what the CMP must include, and the limitations of what the PSP can prescribe and under what circumstances. A PSP may become a PIP through further training and by converting their qualification, and can then work as both a PSP and a PIP.

What do we mean by 'pharmacist independent prescriber'?

A pharmacist independent prescriber is a pharmacist who has completed the relevant approved education and training to add an annotation to their entry in the register. A PIP may prescribe all medicines autonomously for any condition within their scope of practice and clinical competence. The exceptions to this are the three controlled drugs for the treatment of addiction (cocaine, dipipanone and diamorphine), and unlicensed cannabis based medicinal products (CBMPs).

A change in the law in November 2018 made cannabis and certain cannabis-based medicinal products (CBMPs) schedule 2 drugs under the Misuse of Drugs Regulations 2001. However, CBMPs can only be prescribed by a specialist doctor registered on the General Medical Council (GMC) Specialist Register. Once a substance receives a marketing authorisation, this prescribing restriction will no longer apply and the product will be available for patient use as are other schedule 2 drugs. Pharmacist prescribers can also prescribe veterinary medicines classified as prescription-only medicines, in line with the current Veterinary Medicines Regulations



1. Taking responsibility for prescribing safely

People receive safe, effective and person-centred care when pharmacy professionals treat every person as an individual with their own values, needs and concerns.

Pharmacist prescribers are responsible and accountable for their decisions and actions. This will include when they prescribe and for the prescriptions they sign. To minimise patient risk and improve patient safety, pharmacist prescribers must make sure prescribing is evidence-based, safe and appropriate. Any prescribing decision must be made in partnership with the person being assessed, to make sure the care meets their needs and the pharmacist prescriber has obtained their consent⁷ to prescribe. Pharmacist prescribers should use their professional judgement, so that they act in the person's best interests and prescribe only the medicines they know to be safe and effective for the condition they are treating.

Pharmacist prescribers must communicate effectively with the person to:

- understand their needs
- make sure there is a genuine clinical need for treatment, and
- come to a shared decision about the care they provide

This includes getting all the relevant information from the person, and giving them all the relevant information in a way they can understand so that the person can make an informed decision and choice. Pharmacy professionals must take responsibility for ensuring person-centred care is not compromised by their own personal values and beliefs. They must understand that people receive safe and effective care when professionals recognise and value diversity and respect cultural differences.

To safeguard people, particularly children and vulnerable adults, it is important that pharmacist prescribers know who to refer to, and act when necessary. This is particularly important when prescribing remotely.

Pharmacist prescribers must manage incentives⁸ or targets. They must make sure the care they provide reflects the needs of the person and does not compromise the health, safety and wellbeing of patients and the public.

To prescribe safely, it is important to be able to access a person's medical records. However, access is variable and there are potential risks in prescribing without such records.

When prescribing, pharmacy professionals should consider the following three areas:

⁷ ***In practice – guidance on consent***, GPhC, June 2018

⁸ ***Joint statement from the Chief Executives of statutory regulators of***

health and care: conflict of interest and ***Focus on conflicts of interest***, *Regulate*, August 2017 (the article includes case studies on prescription direction)

Have all the necessary information to prescribe safely

They should consider whether they have sufficient information and knowledge of the person's health and medical history⁹, including using medical records such as the summary care record (SCR) (in England), or the **emergency care summary (in Scotland)** when these are available.

They should consider the risks of:

- prescribing for different groups of patients (for example babies, children, young people, women and girls able to have children, pregnant and lactating women, and older people)
- prescribing certain categories of medicines (for example, controlled drugs) and in certain circumstances
- inappropriate medicines-seeking behaviour
- requests for large quantities of medicines
- frequent requests
- prescribing in different contexts

and do everything they can to keep those risks as low as possible.

Prescribe safely


They should:

- prescribe in line with clinical¹⁰, national and local guidelines – which are evidence-based – whenever possible
- when they consider prescribing to be inappropriate, explain their reasons to the person and explain any other options available to them
- prescribe only within the limits of their knowledge, skills and area of competence
- fully assess the person, and carry out an examination in cases when it is necessary, in an appropriate environment which ensures the person's privacy and confidentiality
- refer the person to an appropriate healthcare professional when further examination or assessment is needed
- be able to show that all prescribing arrangements are transparent, and do not cause conflicts of interest such as: prescription direction (directing people to a certain pharmacy for commercial reasons);

⁹ This may include finding out about: any previous adverse reactions or allergies to medicines; allergies to flavouring and food products; recent use of other medicines, including regular medicines, acute medicines (for example, short-course antibiotics), OTC medicines, herbal medicines, alternative medicines and others bought online; and other medical conditions. They should encourage the person to be open about the

way they take their medicines, and about their adherence to the medicines they have been prescribed.

¹⁰ NICE (England), Scottish Medicines Consortium and Health Improvement Scotland, Department for Health, Social Services and Public Safety (Northern Ireland), All Wales Medicines Strategy Group (Wales) and medical colleges and other authoritative sources



restricting a person's choice; or unduly influencing or misleading, deliberately or by mistake, people requesting prescribing services

- prescribe and review the person's medicines, and promptly communicate and document any changes to the person's medical record, when possible. So that there is a complete audit trail, this should include: a record of discussions, particularly when prescribing is outside the national guidelines or is for an unlicensed medicine¹¹; the reasons for their prescribing decisions; and arrangements for follow-up and monitoring.
- make prescribing decisions based on the needs of the individual person and not on commercial interests or pressure from people, colleagues or pharmaceutical companies
- consider the impact of their prescribing on the person they are prescribing for
- consider when it may be appropriate to withdraw medicines, stop prescribing a medicine or alter the prescribed dose of a medicine
- review repeat prescriptions as part of the NHS repeat prescribing service¹² or **the chronic medication service**, or when

reviewing a person's medicines; checking whether there have been any changes in their circumstances, such as a hospital stay, or changes to their medicines following a hospital or home visit

- make sure repeat prescriptions are securely and safely generated by staff who are competent to prepare the repeat prescription authorisation
- in the case of an unlicensed medicine, or one licensed but used for an unlicensed purpose, make sure there is no licensed medicine available to meet the needs of the person
- have enough evidence of the safety, effectiveness and the appropriateness of the use of the unlicensed or off-label medicine. Some medicines are routinely used outside the terms of their licence, for example in paediatrics

¹¹ See **guidance for registered pharmacies preparing unlicensed medicines**, GPhC, August 2018

¹² The NHS repeat prescribing service is a process where a succession of prescriptions is issued without the need for referral back to the prescriber. This only applies in England and Wales.

What do we mean by 'unlicensed medicine'?

The term 'unlicensed medicine' is used to describe medicines that are used outside the terms of their UK licence or which have no licence for use in the UK. They are commonly used in paediatrics and palliative care. Prescribing unlicensed medicines may be necessary if there is no suitably licensed medicine that will meet the patient's need. This could be, for example, when there is no licensed medicine applicable to the particular patient, or when only an adult formulation is licensed and the patient is a child, or when the suitably licensed medicine is not available due to medicines shortages. In emergencies it may not always be appropriate to explain that the medicine is unlicensed, if this is likely to cause distress to the patient or the carer.

Follow up

They should:

- provide information – including patient information leaflets – in a way the person can understand, and check they have understood them
- use reporting mechanisms for suspected adverse drug reactions (ADRs), and take action when there is a need for urgent referral to another healthcare professional
- make sure the person seeking care knows how to report ADRs, and knows who to contact if they have any questions or concerns

2. Keeping up to date and prescribing within your level of competence

Pharmacist prescribers can prescribe in many different clinical and therapeutic areas, either as a specialist or generalist. These roles continue to develop and expand. So pharmacist prescribers must maintain, develop and use the professional knowledge and skills relevant to their role and prescribing area. They should use the **GPhC standards of initial education and training for pharmacist prescribers** and the learning outcomes, as well as the various reference sources¹³, to help identify any gaps in their knowledge.

With regards to the patient's condition and the medicines available to manage their health care, pharmacist prescribers must prescribe only within the limits of their knowledge, skills and clinical competence. They must maintain the competencies specific to their role as a prescriber and the scope of their practice, and reflect on the application of their knowledge and skills to keep themselves up to date. When prescribing in a new area, they should undertake any additional training they need, and be familiar with the relevant resources, to make sure that they are competent. When a person's condition is outside a prescribing pharmacist's scope of competence, they must refer the person to another appropriate prescriber.

Pharmacist prescribers should make sure that some of their revalidation records directly address their role as a pharmacist prescriber. This includes keeping up to date with relevant changes in the law, as well as in the therapeutic areas in which they prescribe. Pharmacist prescribers should use **the GPhC's revalidation framework** to plan and to demonstrate that they remain up to date when prescribing.

To continually improve their prescribing skills and the care they give, pharmacist prescribers should regularly audit and monitor their prescribing. If they work outside NHS settings where clinical governance systems may be different, or not be applied in the same way, pharmacist prescribers must make sure they are competent to practise. They must show how they:

- audit their practice
- keep up to date with current guidelines, and
- safeguard the people in their care

Pharmacist prescribers must regularly check that they are covered by their professional indemnity insurer for any additional or different prescribing roles they undertake, and review their cover as appropriate.

¹³ MHRA drug safety updates, NHS Central Alerting System, National Electronic Library for Medicines, the National Institute for Health and Clinical Excellence (NICE), medicines and

prescribing community, the electronic Medicines Compendium, patient information leaflets (PILs), British National Formulary (BNF) and British National Formulary for Children (BNFC)

3. Working in partnership with other healthcare professionals and people seeking care

Pharmacist prescribers must communicate effectively, and work in partnership with other health professionals and people seeking care, to deliver safe and effective care.

They must be open and honest with the person seeking care and those they prescribe for. They should make sure people know they are prescribing as a pharmacist prescriber, either as part of an NHS or private arrangement, and about any charges that apply.

Pharmacist prescribers must make sure they maintain a person's confidentiality¹⁴ and privacy, as this is a vital part of the relationship between the pharmacist prescriber and the person seeking care.

3.1 Working with people seeking care and sharing information with their prescribing doctor

Having all the relevant medical information about a person and their medicines is vital to ensure safe prescribing. This information may be obtained by communicating with the person's regular prescriber or by having access to the person's medical record. Pharmacist prescribers must ask the person for consent to access their medical records, or to get other reliable information about the person's health and medicines from their regular prescriber if they have one. To ensure person-centred care, they must give the person receiving care clear

information so they can make an informed decision, and must discuss other available options when it is not appropriate to prescribe. They should make a record of all decisions, including when they decide not to issue a prescription and the reasons why.

Pharmacist prescribers must decide whether they can prescribe safely when:

- they do not have access to the person's medical records
- the person refuses to give consent to contact their prescriber for more information
- the person has not been referred to the pharmacist prescriber by their prescriber, or
- the person does not have a regular prescriber (such as a GP)

Prescribing information should be shared with the person's regular prescriber, or others involved in their care, so the person receives safe and effective care. The pharmacist prescriber should give the other prescriber all relevant information (for example, information on all medicines prescribed, the reasons for any changes, and any further monitoring requirements) accurately and in a timely manner. This information should be clearly recorded.

¹⁴ ***In practice: Guidance on confidentiality***, GPhC, June 2018



When carers ask for information about medicines on behalf of a person, pharmacist prescribers should make sure they have the person's consent to disclose this information. If the person lacks capacity to give consent, they must decide whether it is in their best interests to share it.

3.2 Working in partnership with other healthcare professionals

Pharmacist prescribers must take responsibility for their practice and provide leadership to the people they work with.

Pharmacist prescribers who prescribe for people in environments such as a care home, nursing home or a hospice should communicate with the person or their carer and give the necessary information and advice. They must make sure any information is understood by the person and carer.

When a pharmacist prescriber prescribes on the recommendation of another healthcare professional, they are still professionally accountable and responsible for all the prescriptions they sign. They must make sure the prescription is appropriate, meets the

person's needs, and allows continuity of care for them.

When a person transfers¹⁵ between care settings, pharmacist prescribers should check the information provided. They should make sure all the necessary information about the person's medicines is accurately recorded and transferred with them.

When they share responsibility for a person's care with a colleague, they must make sure there are clear lines of accountability and that they are competent to share their part of the clinical responsibility. If they are responsible for the initial diagnosis or assessment of a person, they must find out all the information they need to be able to prescribe. Any decisions made about responsibility for follow up and monitoring should be in the person's best interests, and clearly communicated to everyone involved in the arrangement.

If a pharmacist prescriber is supervising another prescriber in training, as a designated prescribing practitioner (DPP), they must demonstrate leadership and exercise proper oversight¹⁶ to make sure safe and effective care is provided.

¹⁵ ***Keeping patients safe when they transfer between care providers - getting the medicines right***, Royal Pharmaceutical Society, 2012

¹⁶ ***The GPhC Council paper from the meeting held in December 2018*** notes that the Royal Pharmaceutical Society (RPS) will develop a competency framework for DPPs. ***This is also stated on the RPS' website***

4. Prescribing in certain circumstances

4.1 Prescribing for themselves, family and friends

Pharmacist prescribers should not prescribe for themselves or anyone with whom they have a close personal relationship (such as family members, friends or colleagues), other than in exceptional circumstances. This is particularly important when controlled drugs and drugs of abuse are prescribed.

Pharmacist prescribers may, in exceptional circumstances, prescribe when:

- there is no other prescriber available to assess the person's clinical condition, and to delay prescribing would put the person's life or health at risk or cause unacceptable pain or distress, or
- the treatment is immediately necessary to:
 - save a life
 - avoid serious deterioration in the person's health and wellbeing, or
 - alleviate otherwise uncontrollable pain or distress

Pharmacist prescribers, when prescribing for themselves or anyone they have a close relationship with, must:

- be able to justify their decision to prescribe, and
- make a clear record, including the nature of their relationship with the person and the reasons it was necessary to prescribe, so there is a robust audit trail

They should also consider whether the person needs an independent clinical assessment by another prescriber. This is to make sure their professional judgement is not influenced or impaired by the person they are prescribing for.

4.2 Prescribing and supplying

Pharmacist prescribers should usually keep the initial prescribing separate from the supply of medicines prescribed, to protect the person's safety. There may be circumstances when the person needs the medicine urgently, and person-centred care or the safety of the person would be compromised if the medicine were not supplied at that point. Other options, such as referring to another pharmacy, may not be available.

If a pharmacist prescriber both prescribes and supplies a prescription it must be within their scope of practice, and the pharmacist prescriber should have robust governance arrangements in place. When possible, a second suitably competent person should be involved in carrying out the final accuracy check and the check for clinical appropriateness.

The pharmacist prescriber must make a record of their prescribing and the reasons for their prescribing decision.

4.3 Prescribing, supplying and administering

When a pharmacist prescriber prescribes, supplies and administers – for example, in the case of non-surgical cosmetic medicines or travel vaccines – they should make sure person-centred care is delivered, making the care of the



person their priority. If a pharmacist prescriber delegates the administering of these medicines to another person, they must make sure the other person has the necessary training and skills to administer them safely.

5. Prescribing non-surgical cosmetic medicinal products

An increasing number of aesthetic pharmacists are now prescribing non-surgical cosmetic medicinal products. Pharmacist prescribers have an important role in making sure prescribing is safe and effective in this area, minimising any risks to the person. They must use their professional judgement so they act in the person's best interests and only prescribe medicines which are appropriate – taking extra safeguards when necessary.

Pharmacist prescribers who prescribe and administer non-surgical cosmetic medicinal products must be appropriately trained¹⁷. They must prescribe and administer non-surgical cosmetic medicinal products only in line with good practice guidelines,^{18,19} and only after there has been a physical examination of the person. For this reason, it is not appropriate to carry out a remote consultation for non-surgical cosmetic medicinal products.

¹⁷ The JCCP and CPSA have produced **guidance for practitioners who provide cosmetic interventions**. Health Education England was commissioned by the Department of Health in 2015 to **develop qualification requirements for the delivery of non-surgical cosmetic interventions**. The aim of this work was to improve and standardise the training available to practitioners. Necessary training depends on prior experience and adequate insurance provision.

¹⁸ **Guidance for doctors who offer cosmetic interventions**, GMC, June 2016

¹⁹ **Professional Standards for Cosmetic Surgery**, RCS, 2016, **Qualifications requirements for delivery of cosmetic procedures**, NHS HEE, 2015, **Report on implementation for qualifications requirements for cosmetic procedures**, NHS HEE, 2015, **Code of practice**, British Association of Aesthetic Plastic surgeons, 2013, **Code of practice**, British Association of Plastic Reconstructive and Aesthetic Surgeons, 2016

Pharmacist prescribers must be satisfied that the services they are prescribing for meet the relevant registration and regulatory requirements. They must make sure any procedures are carried out in an appropriate and professional manner, and in an environment safe and appropriate for the procedures being carried out. Pharmacist prescribers must make sure that any person they delegate the administration of the products to has the necessary training and skills to administer and carry out the procedure.

Before prescribing or administering non-surgical cosmetic medicines, we expect pharmacist prescribers to:

- have the necessary training and experience to practise safely and know whether the medicines being prescribed meet approved guidelines
- have professional indemnity insurance to cover both NHS and private activities
- have the person's consent to carry out the procedure
- be familiar with the procedure, including: what it involves, how long it will take and whether the products are appropriately licensed
- consider whether the person has capacity to consent to having the procedure carried out
- consider the psychological needs of the person

- be prepared not to carry out the prescribing or the procedure if they think it is not appropriate, or if the person wants more time to consider the procedure. In this case the pharmacist prescriber should explain why, discuss alternative options and record the decisions
- make sure that, if they delegate the administration, they delegate only to people who are competent and appropriately trained

Pharmacist prescribers should work with the person to make sure they have all the relevant information to make an informed decision and choice, to make sure they:

- have realistic expectations
- are clear about the potential risks and complications of the procedure and the outcomes
- have enough information to decide whether to have the procedure
- have enough information to support continuity of care²⁰
- know what follow up and after care will be provided, and
- know when and how to get more help if there is a negative reaction or if something goes wrong

Pharmacist prescribers should make sure the person's GP is kept informed.

effective healthcare throughout the treatment process.

²⁰ Continuity of care is the quality of care over time. It is the process by which the patient's GP-led care team work together to provide safe and

6. Remote prescribing

Important: In this section, the draft guidance refers to other guidance which will be published in the next few months, and which may change before publication.

More and more often, people are accessing pharmacist prescribers not in the traditional face-to-face way, but remotely²¹. This will be either by phone or video link, or more usually online through prescribing services. In these cases, pharmacist prescribers should make sure they can make an adequate and safe clinical assessment, communicate effectively and obtain the person's consent.

Prescribing medicines remotely, either as part of an online prescribing service or independently via the internet, brings different risks than those when there is a face-to-face consultation.

Pharmacist prescribers are accountable for their decisions to prescribe. They should prescribe only when they have the relevant knowledge of the person's health and medical history, and are satisfied that the care meets the needs of the person. This includes when prescribing remotely.

If pharmacist prescribers do not have access to a person's medical records, or have not carried out a previous face-to-face consultation with the person, they should explain to the person how the remote consultation will be carried out.

Pharmacist prescribers who prescribe for people in other countries must keep to any other laws that apply. Countries have different restrictions, and some do not allow the online supply of medicines at all. Pharmacist prescribers should make sure the medicine they prescribe has the marketing authorisation needed for it in the country of destination²². They should make sure the person can obtain the medicine and that they have considered the product's licensed name, indications and recommended dosage regimen in that country.

Whoever they are prescribing for and wherever that person is located, pharmacist prescribers must assess and manage any risks related to their prescribing and the care they provide. Before carrying out a remote consultation, pharmacist prescribers should consider:

- how they can verify the person's identity
- the limitations of effective communication with the person through the remote consultation (not being able to see physical symptoms or read their body language, not being able to ask follow-up questions)
- whether they can assess if the person has capacity to decide about their medicines

²¹ See ***Guidance for registered pharmacies providing pharmacy services at a distance, including on the internet***, GPhC, April 2015

²² Regulation 28 of the Human Medicines (Amendment) Regulations 2013

7. Safeguards for the remote prescribing of certain medicines

Important: In this section, the draft guidance refers to other guidance which will be published in the next few months, and which may change before publication.

Pharmacist prescribers should be aware that some categories of medicines are not suitable to be prescribed or supplied remotely unless further safeguards have been put in place to make sure that they are clinically appropriate. The categories include:

- **antimicrobials (antibiotics)**
 - when it is important to effectively manage their use, to help slow the emergence of antimicrobial resistance and ensure that antimicrobials remain an effective treatment for infection. These should be supplied only if in line with good practice guidance, taking into account the 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 index²³, and medicines used to treat diabetes, asthma, epilepsy and mental health conditions. A particular example of

this 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**
 - in line with good practice guidelines, these should be prescribed and supplied only after a physical examination of the person

If a pharmacist prescriber decides to prescribe remotely or work with an online prescribing service, the above categories of medicines should be prescribed only if the prescriber:

- has robust processes in place to check identities, to make sure the medicines prescribed go to the right person
- has asked the person for the contact details of their regular prescriber, such as their GP, and for their consent to contact them about the prescription
- will proactively share all relevant information about the prescription with other health professionals involved in the care of the person (for example their GP)
- has systems in place so that the pharmacy team can clearly document the prescriber's decision to issue a prescription, if the person does not have a regular prescriber such as a GP or when there is no consent to share information

²³ Drugs with a narrow therapeutic index are drugs with small differences between

therapeutic and toxic doses. For example, lithium, warfarin, digoxin.

- is working within national prescribing guidelines for the UK and good practice guidance²⁴

8. Raising concerns

All pharmacy professionals, including pharmacist prescribers, must speak up when they have concerns or when things go wrong²⁵. The quality of care people receive is improved when pharmacist prescribers learn from feedback and incidents, and challenge poor practice and behaviours. It is important that pharmacist prescribers record, report and learn from errors and near misses, to manage the risk of making and repeating mistakes.

If any pharmacy professional, including pharmacist prescribers, considers the prescribing of a colleague is unsafe for a person, they should question the decision or action, and raise concerns if the person's health and wellbeing may be at risk. When pharmacist prescribers pick up concerns about prescribing data, they must also raise these.

Pharmacist prescribers must reflect on feedback or concerns raised by colleagues, people or carers about their own practice and act when appropriate, to prevent the same thing happening again.

²⁴ **Good practice in prescribing and managing medicines and devices**, GMC, February 2013

A Competency Framework for all Prescribers, RPS, July 2016

The CQC publishes **guidance on care standards on their website**

NICE also publishes **a range of guidance on their website**

The GMC has **guidance about sharing information with colleagues** on their website **Valproate banned without the pregnancy prevention programme**, MHRA news article, April 2018

²⁵ **In practice: Raising concerns**, GPhC, May 2017

9. Information for pharmacy owners and employers of pharmacist prescribers

Pharmacy owners must have governance arrangements in place which safeguard the health, safety and wellbeing of patients and the public. Pharmacy owners must identify and manage the risks involved in providing and managing pharmacy services, including a prescribing service which may be online.

Pharmacy owners who employ pharmacist prescribers must make sure that:

- pharmacy professionals can meet their own professional and legal obligations, and are able to exercise their professional judgement in the interests of patients and the public
- they identify and manage the risks of providing prescribing services remotely (including online), to ensure the safe and effective practice of pharmacy
- all members of the pharmacy team are familiar with the areas raised within this guidance and understand their own responsibilities in relation to pharmacist prescribers
- where pharmacist prescribers carry out assessments and provide diagnostic testing to assess a person's condition, the equipment and facilities in the pharmacy are safe to use and appropriately maintained
- they have systems in place so that the pharmacist prescriber can clearly document their decision to issue a prescription if the person does not have a GP, or if there is no consent to share information

- incentives or targets do not compromise the health, safety and wellbeing of patients and the public, or the professional judgement of staff

9.1 Working with online prescribing services

Pharmacy owners should not work with online providers who 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 additional risks for patients and the public. If pharmacy owners decide to work with prescribers or prescribing services operating outside the UK, they should make sure that:

- they successfully manage the additional risks that this may create
- they have sufficient indemnity insurance in place to cover:
 - the 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 the country where the prescription is issued and can lawfully issue prescriptions online
- the prescriber is working within national prescribing guidelines for the UK



Questions to ask yourself

Below are some key questions that pharmacist prescribers should ask themselves when thinking about how they can ensure and demonstrate that they have provided person-centred care.



Other sources of information

Pharmacist prescribers can get more information and guidance from professional bodies, indemnity insurance providers, and from other independent bodies such as those listed below:

- ***A Competency framework for all prescribers***, Royal Pharmaceutical Society, July 2016
- ***A guide to good prescribing practice for prescribing pharmacists in NHS Scotland***, NHS Education for Scotland, July 2012
- ***A practical guide to support pharmacist independent prescribers***, Royal Pharmaceutical Society, November 2018
- ***Cosmetic procedures - what do I need to consider***, General Medical Council, June 2016
- ***Good practice in prescribing and managing medicines and devices***, General Medical Council, March 2013
- ***Guidance for doctors who offer cosmetic interventions***, General Medical Council, June 2016
- ***Non-medical prescribing in Wales***, The All Wales Medicines Strategy Group (AWMSG), May 2017
- ***Prescribing: maintaining competence and confidence*** Centre for Pharmacy Postgraduate Education, February 2017
- ***Prescribing specials***, April 2016
- ***Qualification requirements for delivery of cosmetic procedures: non-surgical cosmetic interventions and hair restorative surgery***, Health Education England, November 2015
- ***Standards for the education and training of pharmacist independent prescribers***, GPhC, January 2019

Consultation questions

Important: Some of the guidance is based on requirements from the GPhC's standards for pharmacy professionals and therefore will not change as a result of this consultation. Some parts of the guidance have already been consulted on in our discussion paper on the safe and effective delivery of online services, so we have not asked further questions about these. This means that not all the feedback we get will result in change if it directly relates to our standards or to a previous consultation.

We welcome your views on the following questions. Please go to www.pharmacyregulation.org/guidance-pharmacist-prescribers to fill in the online survey.

Views on the proposals

Key areas for safe and effective prescribing

In developing this guidance, we have identified nine key areas that relate to the provision of safe and effective prescribing.

1. Have we identified all the necessary areas for ensuring safe and effective care is provided?

Yes

No

Don't know

2. For each of the nine key areas, do you agree or disagree with the guidance we have proposed?

1. Taking responsibility for prescribing safely
2. Keeping up to date and prescribing within your level of competence
3. Working in partnership with other healthcare professionals and people seeking care
4. Prescribing in certain circumstances
5. Prescribing non-surgical cosmetic medicinal products
6. Remote prescribing
7. Safeguards for the remote prescribing of certain medicines
8. Raising concerns
9. Information for pharmacy owners and employers of pharmacist prescribers

3. Please explain your responses to the two questions above.

(You will be asked questions later in the consultation about what pharmacist prescribers must do in order to prescribe safely, and to carry out both prescribing and supplying; and about the safeguards for remote prescribing.)

Prescribing safely

In section 3.1 of our proposals we say that having all the relevant medical information about a person and their medicines is vital to ensure safe prescribing. This may be obtained by communicating with the person's regular prescriber or by having access to the person's medical records. We provide guidance on what pharmacist prescribers must do in order to prescribe safely, including:

- asking for consent from their regular prescriber to access a person's medical records
- giving the person receiving care clear information so they can make an informed decision, and
- discussing other available options when it is not appropriate to prescribe

We also describe circumstances where pharmacist prescribers must decide whether they can prescribe safely, such as when:

- they do not have access to the person's medical records
- the person refuses to give consent to contact their prescriber for more information
- the person has not been referred to the pharmacist prescriber by their own prescriber, or
- the person does not have a regular prescriber (such as a GP)

4. Do you agree or disagree that these are circumstances when a pharmacist prescriber must decide whether they can prescribe safely for a person?

- Agree
- Disagree
- Don't know

5. Are there any other circumstances when a pharmacist prescriber must decide whether they can prescribe safely for a person?

- Yes
- No
- Don't know

6. Please explain your responses to the two questions above and describe any additional circumstances that should be considered.

Prescribing and supplying

In section 4.2 of our proposals we say pharmacist prescribers should usually keep the initial prescribing separate from the supply of medicines prescribed, to protect the person's safety. We describe exceptional circumstances when it may be necessary to prescribe and supply, and have also identified certain circumstances when a pharmacist prescriber may prescribe and supply on a regular basis – for example, when administering travel vaccines.

7. Are there any other circumstances where you think a pharmacist prescriber should be able to prescribe and supply?

- Yes
- No
- Don't know

8. Please describe any additional circumstances that should be considered.

Safeguards for the remote prescribing of certain categories of medicines

In section 7 of our proposals we describe prescribing remotely, including online, for certain categories of medicines. We say that certain medicines are not suitable to be prescribed remotely unless further safeguards have been put in place to make sure they are clinically appropriate.

In our recent discussion paper on our guidance for registered pharmacies providing pharmacy services at a distance, including on the internet, respondents agreed that before prescribing remotely, additional safeguards should be put in place to make sure the medicines are clinically appropriate for the person.

We have proposed five safeguards for making sure certain categories of medicines are prescribed safely. These say that the prescriber must:

- have robust processes in place to check identities, to make sure the medicines prescribed go to the right person
- have asked the person for the contact details of their regular prescriber, such as their GP, and for their consent to contact them about the prescription
- proactively share all relevant information about the prescription with other health professionals involved in the care of the person (for example their GP)
- have systems in place so that the pharmacy team can clearly document the prescriber's

decision to issue a prescription if the person does not have a regular prescriber, such as a GP, or if there is no consent to share information

- work within national prescribing guidelines for the UK and good practice guidance

9. Are there any other safeguards that should be put in place to make sure certain medicines are prescribed safely remotely?

Yes

No

Don't know

10. Please describe any additional safeguards you think there should be.

Impact of the proposals

We are keen to hear views about the impact of the draft guidance.

11. What kind of impact do you think our proposals will have on patients and the public?

Positive impact

Negative impact

Both positive and negative impact

No impact

Don't know

12. What kind of impact do you think our proposals will have on pharmacist prescribers?

Positive impact

Negative impact

Both positive and negative impact

No impact

Don't know

13. What kind of impact do you think our proposals will have on other pharmacy professionals?

- Positive impact
- Negative impact
- Both positive and negative impact
- No impact
- Don't know

14. What kind of impact do you think our proposals will have on employers or pharmacy owners?

- Positive impact
- Negative impact
- Both positive and negative impact
- No impact
- Don't know

15. Please give comments explaining your responses to questions 11 to 14.

Equality impact

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. We also want to understand whether our proposals may benefit any of these individuals or groups.

16. Do you think our proposals will have a negative impact on certain individuals or groups who share any of the protected characteristics listed below? Please tick all that apply.

- Age
- Disability
- Gender reassignment
- Marriage and civil partnership
- Pregnancy and maternity
- Race
- Religion or belief
- Sex
- Sexual orientation
- None of the above

17. Do you think our proposals will have a positive impact on certain individuals or groups who share any of the protected characteristics listed below? Please tick all that apply.

- Age
- Disability
- Gender reassignment
- Marriage and civil partnership
- Pregnancy and maternity
- Race
- Religion or belief
- Sex
- Sexual orientation
- None of the above

18. Please describe the impact on each of the individuals or groups you have ticked in questions 16 and 17.



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