General Pharmaceutical Council

In practice: Guidance for pharmacist prescribers

November 2019



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

About this guidance

In applying this guidance in practice, pharmacist prescribers must be able to justify their decisions and use their professional judgement in the person's best interests.

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

It should also be applied 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. When pharmacy owners provide pharmacy services at a distance, including on the internet, they should also apply our guidance for registered pharmacies providing services at a distance, including on the internet.

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 or the Advertising Standards Authority.

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

It gives guidance to pharmacist prescribers in applying the standards when prescribing. The guidance applies whatever setting pharmacist prescribers work in. It sets out the key areas pharmacist prescribers should consider when applying the standards to their prescribing practice.

Not following this guidance, or not taking the appropriate steps to ensure safe prescribing, could result in the registration of the pharmacist prescriber being at risk.

We want this guidance to support the appropriate and effective provision of pharmaceutical care and medicines, which keeps to the law 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.

All pharmacy professionals should make sure they are familiar with the areas 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 organisations, including professional leadership bodies and other regulators.

We have a **range of guidance on our website** to help pharmacy professionals apply our standards. For more information on writing prescriptions, using electronic prescriptions,

and the RPS competency framework for all prescribers please see 'Other sources of information' at the end of this document.

Pharmacist prescribing

Pharmacist prescribers play a vital role in the delivery of high-quality healthcare services and in the improvement of person-centred care across many healthcare sectors in England, Scotland and Wales. They are well placed to use their knowledge of medicines, and their skills as prescribers, in the existing and various new roles which are being developed and integrated into care models. Pharmacist prescribers are responsible for creating a culture of personcentred professionalism wherever they work, and for ensuring prescribing itself and 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 and medical devices.

In this guidance we use the term 'pharmacist prescriber' to include both supplementary prescribers and independent prescribers, as they can both work in the same settings. But where supplementary prescribers cannot prescribe certain medicines we have highlighted this.

What do we mean by a 'supplementary prescriber'?

A supplementary prescriber works with a medical or dental practitioner within a specific clinical management plan (CMP) but does not prescribe independently. The law sets out what the CMP must include, and the limitations on what the PSP can prescribe and under what circumstances. A supplementary prescriber cannot prescribe veterinary medicines or non-surgical cosmetic products. A PSP may become a PIP through further training and by converting their qualification. They can then work as both a PSP and a PIP.

What do we mean by a '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. The GPhC sets standards for the education and training of pharmacists to become a PIP.

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 for the treatment of addiction (cocaine, dipipanone and diamorphine), and unlicensed cannabisbased medicinal products (CBMPs).

A change in the law in November 2018 made cannabis and certain cannabis-based medicinal products (CBMPs) Schedule 2 controlled drugs under the Misuse of Drugs Regulations 2001. However, unlicensed CBMPs can be prescribed only by a specialist doctor registered on the General Medical Council (GMC) Specialist Register. Once a substance receives a marketing authorisation, this restriction no longer applies and it can be prescribed by any prescriber. Pharmacist independent prescribers can also prescribe certain prescription-only veterinary medicines, in line with the present Veterinary Medicines Regulations.

A PIP can act as both a supplementary and independent prescriber. For example, if a PIP is working in a new area of competence they may decide to act under a clinical management plan as a supplementary prescriber, while still being confident to prescribe in another area of competence as an independent prescriber.

Prescribing in context

Prescribing can take place in different ways. It may involve the pharmacist prescriber making an independent decision, after a diagnosis, to supply or refuse to supply a prescription-only medicine or medical device on prescription. It may also include giving advice and information on the person's medicines. This could happen across all settings, but usually the prescribing process is complex and is about more than just writing a prescription.

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

Pharmacist prescribers in community pharmacy may prescribe for people who walk in, or have been referred, for a range of minor conditions and short-term illnesses as well as for some long-term conditions. Some pharmacist prescribers work remotely and carry out consultations on the phone from GP practices, or prescribe online. More and more often, pharmacy owners are employing or contracting with a pharmacist prescriber or service provider to provide online prescribing services. Pharmacist prescribers may also prescribe in community health teams, prisons, the armed forces, care homes, for travel and other vaccinations, and in private cosmetic clinics.

In hospitals, care homes and GP surgeries pharmacist prescribers make the best use of medicines in treating long-term conditions, diagnosing and treating acute illness and monitoring the results of treatment. When pharmacist prescribers carry out medication reviews for people taking a large number of medicines, this often leads to a shared decision, in partnership with the person and the multidisciplinary team, to stop unnecessary medicines being prescribed (called 'deprescribing'). This may include reviews for people in care and residential homes and in other care settings.

Pharmacist prescribers may prescribe for people when they are admitted to hospital for existing conditions diagnosed, for example, by their GP. They may also write prescriptions when the person is discharged. There may be situations when the pharmacist prescriber may not be competent to diagnose patients with a particular condition. So, to ensure continuity of care they may continue to prescribe a prescription made by another clinician.

Working as part of a multidisciplinary team (MDT) is key to improved care and patient safety. Pharmacist prescribers are an important part of MDTs, working alongside other healthcare professionals to jointly agree on a person's care. For example, on a ward round, the pharmacist prescriber may prescribe under the direct guidance or advice of another prescriber such as a consultant or specialist.

In this case the prescribing is not their sole responsibility.

Pharmacist prescribers, as part of their role, may also: clarify and amend prescriptions, either electronically or manually; make dosage adjustments; deal with referrals and test requests; and carry out follow-up care.

1. Taking responsibility for prescribing safely

People receive safe, effective and personcentred 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 or deprescribe, and for their prescribing decisions. To improve patient safety and to keep risks to patients as low as possible, pharmacist prescribers must make sure their prescribing is evidence-based, safe and appropriate. Any prescribing decisions must be made in partnership with the person being assessed, to make sure the care meets their needs and that the pharmacist prescriber has consent to prescribe, when this is appropriate. In hospitals there are situations where this may not always be possible, as there is 'implied' consent when a person is admitted to hospital. This would include access to the person's medical notes.

Pharmacist prescribers must 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

- assess whether the person has the capacity to make a decision about their care or consent. There may be cases when the person may lack capacity either physically (for example, because they are unconscious), or because they are unable to make decisions about their care.
- come to a shared decision about the care they provide. They must do this by getting all the relevant information from the person, and giving the person – and carer whenever appropriate – all the relevant information in a way they can understand, so they can make an informed decision and choice.
- make sure the person is aware of any risks involved in their treatment and the risks of any reasonable alternative or different treatment option

For more information on consent and capacity, please see our <u>In practice – guidance on consent</u>, June 2018. This includes information about individuals with powers of attorney that cover health and welfare decisions (England, Wales and Scotland), for example:

- the Lasting Power of Attorney (LPA) in England and Wales
- guardians with welfare powers in Scotland

Pharmacy professionals must take responsibility for making sure person-centred care is not compromised by their own personal values and beliefs. People receive safe and effective care

when professionals recognise and value diversity and respect cultural differences. All pharmacy professionals, including pharmacist prescribers, have the right to practise in line with their religion, personal values and beliefs as long as they act in line with equalities and human rights law and make sure that personcentred care is not compromised.

For more information please see <u>In practice:</u> <u>Guidance on religion, personal values and beliefs.</u>

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 at a distance.

Pharmacist prescribers must make sure incentives and targets do not compromise their professional judgement. 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.

For more information on incentives and targets please see our 'Other sources of information' at the end of this document.

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

1. Having all the necessary information to prescribe safely

To prescribe safely, it is important to be able to have access to a person's medical records. However, access may not be possible or may be limited, and there are potential risks in prescribing without these records. Pharmacist prescribers should assess whether they have sufficient information and knowledge of the person's health and medical history to make an assessment of the condition. This includes using medical records such as the summary care record (SCR) (in England), the **emergency care** summary (in Scotland) or the Welsh GP **record**, when these are available. Pharmacist prescribers should use other sources of information, such as recent hospital discharge letters, test results and clinic letters to get a clear understanding of the person's condition, so they are able to reduce any risks in deciding whether they can prescribe safely. They should be able to demonstrate that they have assessed the risks when making a professional judgement, for example by keeping a record of their reasons to prescribe in these circumstances. (For more information please see Section 3.1.)

What do we mean by medical history?

This may include finding out about:

- their family and social history
- recent surgery
- 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), overthe-counter medicines, herbal medicines, alternative medicines and medicines bought online
- other medicines and medical conditions which may or may not be on their record (for example, chemotherapy, medicines prescribed for mental health and homecare medicines)

They should encourage the person to be open about the way they take their medicines, and about whether they have taken prescribed medicines in the way they were prescribed.

They should assess the risks of prescribing:

- for different groups of patients (for example babies, children, young people, women and girls of child-bearing age, pregnant women and women who are breastfeeding, older people) and people with reduced kidney or liver function and the conditions caused by this
- for people who share protected characteristics
- certain categories of medicines (for example, controlled drugs) and prescribing in certain circumstances
- prescribing in different pharmacy settings

and also, for:

people seeking medicines or treatment inappropriately

 requests for large quantities of, or frequent requests for, medicines – particularly ones that may be abused, overused or misused

and do everything they can to make those risks as low as possible

2. Prescribe safely

Pharmacist prescribers must prescribe only within the limits of their knowledge, skills and area of competence. They should:

- fully assess the person and carry out an examination, when it is necessary, in an appropriate environment which ensures the person's privacy and confidentiality
- prescribe in line with clinical¹, national and local guidelines – which are evidence-based – whenever possible
- when prescribing and reviewing the person's medicines, communicate and document any changes to the person's medical record as soon as possible, to improve patient safety, care and continuity of care. This should include:
 - a record of discussions, especially when prescribing is outside the national guidelines or is for an unlicensed or 'offlabel' medicine
 - the reasons for their prescribing decisions, and

Public Safety (Northern Ireland), All Wales Medicines Strategy Group (Wales) and medical colleges and other authoritative sources

¹ NICE (England), Scottish Medicines Consortium and Health Improvement Scotland, Department for Health, Social Services and

- arrangements for follow-up and monitoring
- explain their reasons for not prescribing, and any other options available to the person when they consider prescribing to be inappropriate
- refer the person to an appropriate healthcare professional when they need further examination or assessment
- be able to show that all prescribing arrangements are transparent, and that there is no conflict of interest such as:
 - prescription direction
 - restricting a person's choice, or
 - unduly influencing or misleading, deliberately or by mistake, people wanting prescribing services
- make prescribing decisions based on the needs of the person and not because of commercial interests or pressure from people, colleagues, employers or pharmaceutical companies
- consider the impact of their prescribing on the person they are prescribing for
- consider when it may be appropriate to withhold medicines, deprescribe or alter a prescribed dose
- review prescriptions with repeats, and repeat prescriptions, as part of the NHS repeat dispensing service (England and Wales), the Medicines: Care and Review (MCR) (Scotland), or when reviewing a person's medicines. They should check whether there have been any changes in the person's circumstances, such as a

- hospital stay, or changes to their medicines following a hospital or home visit
- in the case of an unlicensed or 'off-label' medicine, make sure there is sufficient evidence and experience of its safety and effectiveness, and of the appropriateness of its use to meet the needs of the person.
 Some medicines are routinely used outside the terms of their licence, for example in paediatrics and palliative care

What do we mean by 'unlicensed' or 'off - label' medicines?

The term 'unlicensed medicine' is used to describe medicines which have no licence for use in the UK.

'Off-label' medicines are ones that are licensed but are being used outside the terms of their UK licence.

Prescribing an unlicensed or 'off-label' medicine may be necessary to meet the patient's needs. For example, when:

 only an 'adult' formulation is licensed, but the patient is a child, or

• the suitably licensed medicine is not

available because of medicines shortages It may not always be appropriate to explain that the medicine is unlicensed: for example, in emergencies, or if it is likely to cause distress to the patient or the carer. For more information on unlicensed medicines please see our **guidance for registered pharmacies preparing unlicensed medicines** August 2018 and 'Other sources of information' at the end of this document.

3. Follow-up

The pharmacist prescriber should:

- provide relevant information including patient information leaflets – in a way the person can understand, and check they have understood this
- decide what monitoring is needed following the prescribing activity and allow the person access to this monitoring to ensure continuity of care. This could be, for example, by giving them any relevant forms if the medicine prescribed needs following up by therapeutic drug monitoring
- use reporting mechanisms for suspected adverse drug reactions (ADRs), such as the Yellow Card Reporting Scheme, and make sure the person knows how to report ADRs
- use reporting mechanisms for suspected patient safety incidents: the NHS National Reporting and Learning System (NRLS) (England and Wales), and local reporting systems such as NHS Scotland regional health boards
- take action when there is a need for urgent referral to another healthcare professional
- make sure the person seeking care knows who to contact if they have any questions or concerns
- plan appropriate follow-up reviews that meet the needs of the person seeking care
- assess and monitor the outcome of the prescribing activity to make sure safe and effective care is provided
- tell the person that if their condition gets worse, or there are any new symptoms or changes in their condition, to come back to

the pharmacist prescriber to make sure no serious conditions are missed (this is called 'safety netting')

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 a generalist. As these roles continue to develop and expand, pharmacist prescribers must maintain, develop and use the professional knowledge and skills relevant to their role and prescribing area, to make sure the person receives safe, appropriate and up-to-date care. They should use the Royal Pharmaceutical Society **A Competency framework for all prescribers**, the GPhC **Standards of initial education and training for pharmacist prescribers** and the learning outcomes, as well as other reference sources², to help identify any gaps in their knowledge.

Whatever the person'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

Pharmacist prescribers can get support from, and give support to, their peers. This could be,

for example, when working in a multidisciplinary team which helps them to communicate, learn and develop alongside other healthcare professionals. This may also include having a close working relationship with their medical supervisor or mentor after qualifying.

When a person's condition or the medicines prescribed are outside a prescribing pharmacist's scope of practice, they must consider the person's best interests and decide whether or not they have the competence to prescribe. If they are not competent to prescribe they must refer the person to another appropriate prescriber.

When returning to prescribing practice after a break, or when prescribing in a different or extra clinical area, pharmacist prescribers should undertake any additional training they need. This may include, for example, completing the **CPPE return to prescribing course**, work shadowing or having work experience in the new prescribing area. Pharmacist prescribers should also be familiar with the relevant resources, and make sure that they are competent, for example using the RPS competency framework to demonstrate their competence when prescribing in a new area.

² MHRA drug safety updates, NHS Central Alerting System, the National Institute for Health and Clinical Excellence (NICE) <u>Medicines</u> <u>and prescribing</u>, <u>the electronic Medicines</u> <u>Compendium</u>, patient information leaflets

(PILs), British National Formulary (BNF) and British National Formulary for Children (BNFC), local formularies and clinical guidelines. Pharmacist prescribers should record the activities they have undertaken, for example by keeping a portfolio with evidence of supervised practice areas and any training and assessments.

Pharmacist prescribers must make sure they are competent in the new area of prescribing. They must also check that they are covered by their professional indemnity insurer for any new or different prescribing roles they undertake, and must review their cover regularly to make sure of this.

For more information on a portfolio of evidence when returning to practice, please see the **returning to the register** section of our website.

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 stay up to date with current guidelines when prescribing.

To continually improve their prescribing skills and the care they give, pharmacist prescribers should get another person to regularly audit and monitor their prescribing. This may include a peer review focusing on prescribing. This would review the clinical outcomes of their

prescribing and reflect on any feedback, errors or complaints received.

Pharmacist prescribers may work outside NHS settings and where clinical governance systems may be different, or not applied in the same way. If so, they are responsible for understanding the governance arrangements they work in to make sure they are competent to practise.

For more information on training please see 'Other sources of information' at the end of this document and <u>accredited courses for independent prescriber training</u> on our <u>website</u>.

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 the people they prescribe for. They should make sure people know they are prescribing as a pharmacist prescriber, as part of either an NHS or private arrangement, and about any charges that apply.

Pharmacist prescribers must make sure they maintain a person's confidentiality and privacy, especially when carrying out consultations by phone or at a distance. This is a vital part of the relationship between the pharmacist prescriber and the person seeking care.

For more information on confidentiality please see our *In practice: Guidance on confidentiality*, June 2018.

3.1 Working with people seeking care and sharing information with their regular prescriber

Having all the available and relevant medical information about a person and their medicines is vital to ensure safe prescribing. This information may come from:

- the person
- the person's regular prescriber, or
- the person's medical record

If someone's gender identity is different to what their records say, pharmacist prescribers should communicate in a way that is person-centred and with respect.

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 clear information, so that the person receiving care 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.

For every prescribing consultation, pharmacist prescribers must use their professional judgement and take into account the person's best interests to decide whether they have the information they need to prescribe safely. There may be occasions when:

- they do not have access to the person's medical records or to information from secondary or specialist care
- the person refuses to give consent to contact their regular prescriber for more information
- the person does not have a regular prescriber

- medication has been prescribed by another healthcare professional
- a person is from outside the UK

The pharmacist prescriber must then decide whether or not to prescribe. They will need to think about the person's best interests, make a risk-based assessment about whether they can prescribe safely and made a clear record, setting out their justification for prescribing, or not prescribing.

Prescribing information should be shared with the person's prescriber, or others involved in their care, so the person receives safe and effective care. Pharmacist prescribers should use their professional judgement when deciding what information to share³. This is especially important when prescribing medicines that are liable to abuse, overuse or misuse, when there is a risk of addiction or when ongoing monitoring is important.

Pharmacist prescribers should make sure the person has given consent and is clear about what information is going to be shared with the other prescriber or healthcare professional. The pharmacist prescriber should give the other prescriber any relevant clinical information accurately and as soon as possible, so their medical record can be updated. This could be,

for example: information on medicines prescribed, changes in doses, the reasons for any changes, and any further monitoring requirements. This information should be clearly recorded.

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, the pharmacist prescriber 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. An example of this could be supporting colleagues to further develop effective judgement and leadership skills, to improve their prescribing.

Pharmacist prescribers who prescribe for people in places such as their home, or a care home, nursing home or hospice should take care to make sure they prescribe only for the specific needs of the person, and not for the convenience of others involved in their care.

please see 'Other sources of information' at the end of this document.

³ For guidance on safe and appropriate online and remote provision of sexual health services

They should communicate with the person or their carer and give the information and advice they need. They must make sure any information is understood by the person and carer.

When a person transfers between care settings, pharmacist prescribers should check the information provided. They must make sure all the necessary information about the person's medicines is accurately recorded.

When a pharmacist prescriber continues the treatment prescribed by another prescriber, they are still professionally accountable and responsible for the prescribing decisions they make. They must make sure the medicine and the prescription is appropriate, meets the person's needs and allows continuity of care⁴ for them.

When there is shared responsibility with a colleague for a person's care, for example when working as part of a multidisciplinary team in a hospital, pharmacist prescribers 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 recorded and 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 oversight to make sure safe and effective care is provided.

For more information on the role of the DPP please see 'Other sources of information' at the end of this document.

effective healthcare throughout the treatment process.

⁴ 'Continuity of care' is the quality of care over time. It is the process by which the patient's GPled care team work together to provide safe and

4. Prescribing considerations and clinical judgement

4.1 Prescribing for self, family and friends

Pharmacist prescribers must not prescribe for themselves or for anyone with whom they have a close personal relationship (such as family members, friends or colleagues), other than in exceptional circumstances. This is especially important in the case of controlled drugs and drugs that are liable to abuse.

Exceptional circumstances when a pharmacist prescriber might justifiably prescribe for someone with whom they have a close personal relationship include:

- 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 needed immediately to:
 - save a life
 - avoid serious deterioration in the person's health and wellbeing, or
 - relieve otherwise uncontrollable pain or distress

In these circumstances, if a pharmacist prescriber prescribes for themselves or anyone they have a close relationship with, they must:

- be able to justify their decision to prescribe
- consider whether their professional judgement is influenced or impaired

because of the person they are prescribing for

- refer to another prescriber if they are not confident to prescribe
- 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

4.2 Prescribing and supplying

Pharmacist prescribers should keep the initial prescribing separate from the supply of medicines prescribed. This is to protect the person's safety and minimise risk. When possible, a second suitably competent person should be involved in carrying out the final accuracy check and the check for clinical appropriateness. Pharmacist prescribers should use their professional judgement when considering whether or not to prescribe and supply. The pharmacist prescriber should have robust procedures and arrangements in place, and weigh up the risks of supplying against not supplying. The person should be given the choice to take their prescription to another pharmacy for supply.

In all cases, any decision to prescribe and supply must be made in the person's best interests, and the pharmacist prescriber must make sure that the person's health and safety are not compromised.

There may be circumstances when the medicine may be supplied at the same time. These could

be, for example: in an emergency, in certain hospital situations, in remote or rural areas where there is no other pharmacist available, or when the person needs the medicine urgently. If a pharmacist prescriber does prescribe, carry out the clinical check and supply the medicines at the same time, this must be within their competence and scope of practice.

They must also make a record of their prescribing and the reasons for their prescribing decision.

A pharmacist prescriber may also administer a medicine – for example, in a hospital or other setting. If this is the case, they must make sure person-centred care is delivered, and that the care of the person is their first priority. Pharmacist prescribers must protect patient safety, and should have processes in place to keep any risks as low as possible. If a pharmacist prescriber administers medicines, or delegates the administering of medicines to another person, they must make sure that they or that person have the necessary and appropriate training and skills to administer safely.

4.3 Prescribing non-surgical cosmetic products

A growing number of aesthetic pharmacists are now prescribing non-surgical cosmetic medicinal products, such as botulinum toxin, and medical devices. Pharmacist prescribers have an important role in making sure prescribing is safe and effective in this area, minimising any risks to the person. Section 1 of this guidance, on prescribing safely, applies. They must also use their professional and clinical judgement, so they act in the person's best interests and only prescribe medicines and

non-surgical cosmetic products which are appropriate, taking extra safeguards when needed.

Pharmacist prescribers who prescribe, supply and administer non-surgical cosmetic products must have the appropriate training relevant to these products and the experience to prescribe safely. They must prescribe and administer non-surgical cosmetic products in line with good practice guidelines, 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 products.

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 way, and in an environment which is safe and appropriate for the procedures being carried out. Pharmacist prescribers must make sure that anyone they delegate the administration of the products to is a healthcare professional with the appropriate training and skills to administer and carry out the procedure. When the pharmacist prescriber delegates the administration they are still responsible for the ongoing oversight of the person, and the safe outcome of the treatment. This includes assessing the outcomes, any interventions and reporting adverse incidents.

For more information on training and qualification requirements, and good practice guidelines for prescribing non-surgical cosmetic products, please see 'Other sources of information' at the end of this document.

Before prescribing or administering nonsurgical cosmetic products, pharmacist prescribers must:

- have professional indemnity insurance to cover all activities
- have the person's consent to carry out the procedure
- consider whether the person has capacity to consent to have the procedure carried out, especially if they are a young person, and
- be competent to manage medical emergencies that may occur as a result of cosmetic treatment – for example, adverse drug reactions – and manage any complications arising from the treatment

Pharmacist prescribers should also:

- be familiar with the procedure, including:
 - what it involves
 - how long it will take
 - whether the products are appropriate and meet approved guidelines, and
 - any other options available
- consider the psychological needs of the person, and
- 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 discuss alternative options and record the decisions

Pharmacist prescribers must work with the person to make sure the person has all the relevant information to make an informed

decision and choice about whether to have the procedure. Pharmacist prescribers should make sure the person:

- has realistic expectations and is clear about the potential outcomes
- is clear about the potential risks and complications of the procedure and about any alternative products or procedures that could meet their needs with less risk
- has enough information to support continuity of care
- knows what follow-up and aftercare will be provided, including an assessment of the outcome and
- knows when and how to get more help if there is a negative reaction or if something goes wrong

If the person gives consent, the pharmacist prescriber should tell the person's regular prescriber about any relevant information, when this is appropriate.

4.4 Online prescribing and safeguards for the online prescribing of certain medicines

More and more often, people are using pharmacist prescribers at a distance, rather than in the traditional face-to-face way. This will be either by phone or video link, or more usually online through prescribing services. In these cases, as well as keeping to section 1 of this guidance on prescribing safely, pharmacist prescribers must make sure patient safety is not compromised. This is especially important when the person is vulnerable or at risk of addiction to certain medicines. Pharmacist prescribers must make an adequate and safe clinical

assessment, communicate effectively and get the person's consent to access their medical record. It is especially important when prescribing at a distance that pharmacist prescribers assess the capacity of the person seeking care.

Prescribing medicines at a distance, either as part of an online prescribing service or independently over the internet, brings different risks from those when there is a face-to-face consultation. Certain medicines are not suitable to be prescribed online (for example non-surgical cosmetic products), and for some medicines there should be extra safeguards in place.

In light of the very real patient safety risks, pharmacist prescribers must not make prescribing decisions for high-risk medicines based mainly on online questionnaires with no access to the person's medical history or consent to contact the person's regular prescriber. (High-risk medicines are, for example, those liable to abuse, overuse or misuse, or when there is a risk of addiction and ongoing monitoring is important.) Appropriate risk management and safeguards must be in place, or the registration of the pharmacist prescriber could be at risk.

Pharmacist prescribers are accountable for their prescribing decisions, including when prescribing at a distance. They should prescribe only when they have adequate knowledge of the person's health and their full medical and prescribing history: for example, by using the person's medical records and other sources of

information to establish any allergies or interactions. They must be satisfied that the medicines serve the person's needs. Any decisions about treatment are for both the pharmacist prescriber and the person to consider together during the consultation.

If the pharmacist prescriber has not carried out a 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.

Although pharmacist prescribers can prescribe unlicensed or 'off-label' medicines, when prescribing for a person abroad they must make sure the medicine they prescribe has the marketing authorisation needed for it in the country of destination. This is required by law⁵. They should make sure they have considered the product's licensed name, its 'indications', (what it is used for) and the recommended dosage in that country, and made sure the person can get the medicine there. Pharmacist prescribers should consider how they or the person's local healthcare professional will monitor the person.

Pharmacist prescribers must assess and manage any risks related to their prescribing and the care they provide, and make sure that they have sufficient indemnity insurance in place. This applies whoever they are prescribing for and wherever that person is located. Before

⁵ Regulation 28 of the Human Medicines (Amendment) Regulations 2013

prescribing at a distance, pharmacist prescribers should consider:

- how they can check that the person is who they claim to be, by carrying out an appropriate identity check⁶ (for example, by keeping to the <u>Identity Verification and Authentication Standard for Digital Health and Care Services</u>, which provides a consistent approach to identity checking across online digital health and care services)
- the limitations on effective communication with the person through the consultation at a distance (for example, not being able to see physical symptoms or read their body language, not being able to ask follow-up questions)
- which medicines are appropriate for prescribing and supplying at a distance, including online
- whether they can assess if the person has capacity to decide about their medicines
- whether a physical examination or other assessment is needed
- who the person should contact if they have any questions or want to discuss something
- how they identify requests for medicines that are inappropriate – by being able to

identify multiple orders to the same address or orders using the same payment details. This includes inappropriate combinations of medicines and requests that are too large or too frequent

Safeguards for the online prescribing of certain medicines

Some categories of medicines are not suitable to be prescribed or supplied at a distance unless further safeguards have been put in place to make sure that they are clinically appropriate. The categories include:

- **antimicrobials (antibiotics).** It is important to effectively manage their use, to help slow the emergence of antimicrobial resistance and make sure that antimicrobials remain an effective treatment for infection. These should be supplied only in line with good practice guidance, taking into account the antimicrobial stewardship guidelines⁷ relevant for the person and their location
- medicines liable to abuse, overuse or misuse, or when there is a risk of addiction and ongoing monitoring is important. For example: opioids, sedatives, laxatives, and gabapentinoids
- medicines that require ongoing monitoring or management. For example: medicines with a narrow therapeutic index⁸,

managing common infections 2019. Health Improvement Scotland Antimicrobial Stewardship, Health Improvement Scotland Safeguarding antibiotics for Scotland, now and for the future.

⁸ Drugs with a narrow therapeutic index are drugs with small differences between therapeutic and toxic doses.

⁶ For guidance on appropriate identity checks for online and remote provision of sexual health services please see 'Other sources of information' at the end of this document. ⁷ Public Health England <u>antimicrobial</u> <u>prescribing and stewardship competencies</u> 2013, Public Health England <u>Summary of</u> <u>antimicrobial prescribing guidance –</u>

such as lithium and warfarin; and medicines used to treat diabetes, asthma, epilepsy and mental health conditions. A particular example of a medicine that needs ongoing monitoring and management is sodium valproate, which is used to treat epilepsy and bipolar disorder but which puts babies in the womb at a high risk of malformations and developmental problems

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

If a pharmacist prescriber decides to prescribe at a distance or work with an online prescribing service, the above categories of medicines should not be prescribed unless the prescriber:

- has robust processes in place to check the identity of the person, to make sure the medicines prescribed go to the right person

 for example, by keeping to the Identity
 Verification and Authentication Standard for Digital Health and Care Services, which provides a consistent approach to identity checking across online digital health and care services
- 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 contacted the GP in advance of issuing a prescription for medicines which are liable to abuse, overuse or misuse (or where there is a risk of addiction and ongoing monitoring is important) and the GP has confirmed to the prescriber that the prescription is appropriate for the person and that appropriate monitoring is in place
- has systems in place for circumstances
 when the person does not have a regular
 prescriber such as a GP, or there is no
 consent to share information, and the
 pharmacist prescriber has decided, in
 exceptional circumstances, still to issue a
 prescription. They should make a clear
 record setting out their justification for
 prescribing (for example: how they have
 kept any risks as low as possible; the
 immediate need; how they have arrived at
 their decision to prescribe; and the
 exceptional circumstances)
- is working within national and local prescribing guidelines for the UK and good practice guidance. This would include following relevant guidance on prescribing a licensed medicine for an unlicensed purpose (called 'off-label' prescribing)

For more information please see our <u>Guidance</u> for registered pharmacies providing pharmacy services at a distance, including on the internet and 'Other sources of information' at the end of this document.

5. Raising concerns

All pharmacy professionals, including pharmacist prescribers, must speak up when they have concerns or when things go wrong. This is in line with their professional and statutory 'duty of candour'. Pharmacist prescribers must be candid with the person concerned and with colleagues and employers, which means being honest when things go wrong.

If any pharmacy professional, including a pharmacist prescriber, 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 with the relevant person or regulator.

For more information, please see our standards for pharmacy professionals and our guidance <u>In</u> <u>practice: Raising concerns</u> May 2017.

The quality of care people receive is improved when pharmacist prescribers learn from feedback (which may include complaints) 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.

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

6. Information for employers of pharmacist prescribers

Employers of pharmacist prescribers, in whatever setting and context, must have governance arrangements in place to protect patient safety. Other regulators (in England and Wales) or Health Boards (in Scotland) regulate NHS trusts and GP practices. But all organisations and employers of pharmacist prescribers must have procedures in place to identify and manage the risks involved in providing and managing prescribing pharmacy services. This includes when a pharmacy owner works with an online prescribing service. When pharmacist prescribers work within organisations (including the NHS and private ones) or are employed by pharmacy owners, employers should make sure:

- appropriate governance arrangements are in place to make sure pharmacist prescribers meet local and nationally agreed prescribing policies and standards
- there is a risk-based process to manage prescribing and supplying
- pharmacist prescribers can meet their own professional and legal obligations, and are able to use their professional judgement in the interests of patients and the public
- pharmacist prescribers are competent and maintain their competencies in the area in which they prescribe
- all members of the pharmacy or multidisciplinary team are familiar with the areas raised in 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 are safe to use and appropriately maintained
- they have systems in place for circumstances when the person does not have a regular prescriber such as a GP, or there is no consent to share information, and the pharmacist prescriber has decided, in exceptional circumstances, still to issue a prescription. The prescriber should make a clear record setting out their justification for prescribing (for example: how they have kept any risks as low as possible, the immediate need, how they have arrived at their decision to prescribe, and the exceptional circumstances)
- incentives or targets do not compromise the health, safety and wellbeing of patients and the public, or the professional judgement of staff

6.1 Pharmacy owners working with online prescribing services

Pharmacy owners must not work with online providers who are trying 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, creates significant extra risks for patients and the public. During recent pharmacy inspections, significant patient safety concerns have been identified around the supply of high-risk medicines online.

For more information about online pharmacy services please see our <u>statement on unsafe</u> <u>supply of high-risk medicines by some online pharmacies</u>, <u>Principles for good practice</u> <u>issued to protect patients online</u>, our Guidance for registered pharmacies providing pharmacy services at a distance, including on the internet, and 'Other sources of information' at the end of this document.

Questions to ask yourself

Below are some key questions that pharmacist prescribers should ask themselves when thinking about how they can make sure, 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:

Candour

 Joint statement of <u>professional duty of</u> <u>candour</u>

Conflicts of interest

- Joint statement from the Chief
 Executives of statutory regulators of health and care: conflicts of interest
- Focus on conflicts of interest, GPhC, Regulate, August 2017 (the article includes case studies on prescription direction)

Healthcare settings

- <u>Professional guidance on the</u>

 <u>administration of medicines in</u>
 <u>healthcare settings</u>, Royal Pharmaceutical

 Society, January 2019
- <u>Keeping patients safe when they</u>
 <u>transfer between care providers -</u>
 <u>getting the medicines right</u>, Royal
 Pharmaceutical Society, 2012

Online prescribing

- Online advice, Advertising Standards Authority, February 2015
- Online primary care: information for providers, Care Quality Commission, 2019
- Statement from regulators on online primary care services, 26 September 2019

- Pharmacy regulator takes action on unsafe supply of high-risk medicines by some online pharmacies, General Pharmaceutical Council, 18 September 2019
- <u>Principles for good practice issued to</u> <u>protect patients online</u>, Inter regulatory, 8 September 2019

Prescribing

- <u>Guidance on care standards</u>, Care Quality Commission (CQC)
- Standards for Online and Remote
 Providers of Sexual and Reproductive
 Health Services for guidance on safe and appropriate online and remote provision of sexual health services, Faculty of Reproductive Sexual Health (FRSH) and British Association for Sexual Health and HIV (BASHH)
- Good practice in prescribing and managing medicines and devices, General Medical Council, March 2013
- <u>Guidance about sharing information</u>
 <u>with colleagues</u>, General Medical Council,
 December 2014
- A guide to good prescribing practice for prescribing pharmacists in NHS Scotland, NHS Education for Scotland, July 2012
- <u>Prescribing and Clinical Skills</u>, NHS Education for Scotland
- A competency framework for all prescribers, Royal Pharmaceutical Society, July 2016

- A practical guide to support pharmacist independent prescribers, Royal Pharmaceutical Society, November 2018
- <u>Non-medical prescribing in Wales</u>, The All Wales Medicines Strategy Group (AWMSG), May 2017

Prescribing cosmetic products

- <u>Cosmetic interventions</u>, Advertising Standards Authority, January 2016
- <u>Code of practice</u>, British Association of Aesthetic Plastic surgeons, 2013
- <u>Code of practice</u>, British Association of Plastic Reconstructive and Aesthetic Surgeons, 2016
- <u>Cosmetic procedures what do I need to</u> <u>consider</u>, General Medical Council, June 2016
- Guidance for doctors who offer cosmetic interventions, General Medical Council, lune 2016
- <u>Guidance for practitioners who provide</u>
 <u>cosmetic interventions</u>, Joint Council for
 Cosmetic Practitioners/Cosmetic Practice
 Standards Authority
- <u>Professional Standards for Cosmetic</u>
 <u>Surgery</u>, Royal College of Surgeons, 2016
- Standards for Accreditation, Save Face.
 Save Face also hold a national register of accredited practitioners who provide non-surgical cosmetic treatments

Prescribing unlicensed medicines

- <u>Prescribing specials</u>, Royal Pharmaceutical Society, April 2016
- Off-label or unlicensed use of medicines: prescribers' responsibilities, The Medicines and Healthcare products Regulatory Agency (MHRA), 2014
- Supply unlicensed medicinal products
 (specials), the Medicines and Healthcare
 products Regulatory Agency (MHRA), 2014

Training

- Optimise programme Deprescribing, Centre for Pharmacy Postgraduate Education
- <u>Prescribing</u>, Centre for Pharmacy Postgraduate Education, 2019
- <u>Prescribing in general practice</u>, Centre for Pharmacy Postgraduate Education
- Qualification requirements for delivery of cosmetic procedures: non-surgical cosmetic interventions and hair restoration surgery, Health Education England, November 2015
- Report on implementation for qualifications requirements for cosmetic procedures, Health Education England, 2015
- Standards for the education and training of pharmacist independent prescribers, GPhC January 2019
- Antimicrobial Resistance and Stewardship: Educational resources to support antimicrobial resistance, prescribing and stewardship within NHS Scotland, NHS Education for Scotland

- <u>Professional & Clinical Modules</u>, The Royal College of General Practitioners Curriculum, <u>2016</u>
- Royal Pharmaceutical Society is developing a <u>Competency framework</u> for Designated Prescribing Practitioners (DPPs)

Writing prescriptions and using electronic prescriptions

• British National Formulary

