

Guidelines to Support the Provision of a Common Conditions Service

Version 1

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1. Introduction

Registered pharmacists working in a retail pharmacy business (i.e. a community pharmacy) can now provide enhanced clinical care through a Common Conditions Service.

Common Conditions are mild or moderate illnesses or ailments that can be treated by pharmacists in community pharmacies. A 'Common Conditions Service' is defined in the legislation¹ as a service that may be provided by a registered pharmacist practising in a retail pharmacy business, which may include the provision of a prescription for a medicinal product following appropriate consultation, advice and counselling. Delivery of the Common Conditions Service by a registered pharmacist will be subject to that pharmacist adhering to Common Conditions Service Protocols.

This enables a pharmacist to manage and treat patients for a range of defined common conditions by offering patients self-care advice, safety netting, and, when appropriate, supplying certain over the counter medicines and prescribing prescription-only-medicines through approved clinical protocols.

To provide this service, a pharmacist must:

- Complete mandatory online training accessed via the website of the <u>Irish Institute of Pharmacy (IIOP)</u>².
- Adhere to the information and recommendations included in the approved clinical protocols³ specifically developed for this service by the Health Service Executive (HSE). Current versions of the <u>clinical protocols</u> can be accessed on the HSE website.
- Comply with legislation in place that relates to the delivery of the service and any associated PSI guidance.

This service in pharmacies increases access to healthcare for patients by leveraging pharmacists' knowledge and skills. It also aims to reduce pressure on other areas of the healthcare system.

¹ As set out in the Medicinal Products (Prescription and Control of Supply) (Amendment)(No.3) Regulations

² Regulation 5C.(1)(b) of the Medicinal Products (Prescription and Control of Supply)(Amendment)(No.3) Regulations 2025 requires that "the registered pharmacist has satisfactorily completed training as specified by the Society in accordance with education and training rules made by the Society".

³ Protocols have been developed by the Health Service Executive and approved by the Minister for Health for this service. These are referred to as Common Conditions Service Protocols. Throughout this document, these protocols will be referred to as clinical protocols.

2. Purpose of the Guidelines

The main purpose of these guidelines⁴ is to set out the key responsibilities of pharmacists and those in pharmacy governance roles to facilitate compliance with the Regulation of Retail Pharmacy Businesses (Amendment) Regulations 2025 and the Medicinal Products (Prescription and Control of Supply) (Amendment)(No.3) Regulations 2025 as they relate to a Common Conditions Service which is provided by a registered pharmacist practising in a community pharmacy.

The guidelines provide a principle-based framework for pharmacists delivering care under this service and are designed to promote consistency and safety, while also enabling pharmacists to apply their professional judgement in the best interests of individual patients.

The scope of these guidelines does not extend to clinical guidance or operational matters relating to the service.

3. Legislative Basis

To enable the Common Conditions Service, amendments were made to the following three pieces of legislation:

1. 540/2007 - Medicinal Products (Control of Placing on the Market) Regulations 2007

The <u>Medicinal Products (Control of Placing on the Market) (Amendment) Regulations 2025 (S.I. No. 504/2025)</u> support the implementation of the Common Conditions Service by adding "pharmacist" to the definition of "practitioner".

2. 540/2003 - Medicinal Products (Prescription and Control of Supply) Regulations 2003

The <u>Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 3)</u>
Regulations 2025 (S.I. No. 502/2025) provide for pharmacist prescribing of certain medicinal products, in accordance with specific protocols, as part of the Common Condition Service.
Schedule 13 lists the medicinal products which may be prescribed by registered pharmacists, in accordance with Regulation 5C of the Medicinal Products (Prescription and Control of Supply) (Amendment)(No.3) Regulations 2025.

⁴ These guidelines have been prepared with a view to publication in compliance with Regulation 14 of the Regulation of Retail Pharmacy Businesses Regulations 2008 (S.I. No. 488 of 2008), which provides that the PSI Council may publish guidelines for the purpose of facilitating compliance with these Regulations.

3. 488/2008 - Regulation of Retail Pharmacy Businesses Regulations 2008

The <u>Regulation of Retail Pharmacy Businesses</u> (<u>Amendment</u>) <u>Regulations 2025 (S.I. No. 503/2025)</u> set out certain requirements to be complied with by persons carrying on retail pharmacy businesses in their provision of the Common Conditions Service.

The operation of a registered pharmacy is governed by the Pharmacy Act 2007 and the Regulation of Retail Pharmacy Businesses Regulations 2008 (as amended) (S.I. No. 488 of 2008).

These guidelines focus on the requirements set out in Regulation of Retail Pharmacy Businesses Regulations (Amendment) Regulations 2025 and the Medicinal Products (Prescription and Control of Supply)(Amendment)(No.3) Regulations 2025 as they relate to a Common Conditions Service.

It should be noted that in addition to pharmacy and medicines legislation, pharmacy records must be retained in compliance with the provisions of the relevant Data Protection legislation. Further information on Data Protection is available on the Data Protection Commission's website.

All relevant pharmacy and medicines legislation can be accessed in full through the PSI website or www.irishstatutebook.ie

4. Guiding Principles

The guidelines set out seven guiding principles (see Figure 1), which aim to support the consistent delivery of safe, high-quality person-centred care.

Pharmacists and those in statutory governance roles⁵ also need to consider all relevant legislation and the <u>PSI Code of Conduct</u> when applying these principles. The guidelines are intended to be supportive and enabling, offering flexibility for implementation. This approach is intended to empower pharmacists to use their professional judgement to make informed decisions in the interests of person-centred care.

⁵ The statutory governance roles are pharmacy owner, superintendent pharmacist and the supervising pharmacist. Further information about governance responsibilities is available in <u>PSI Guidance on Pharmacy</u> Governance Roles.

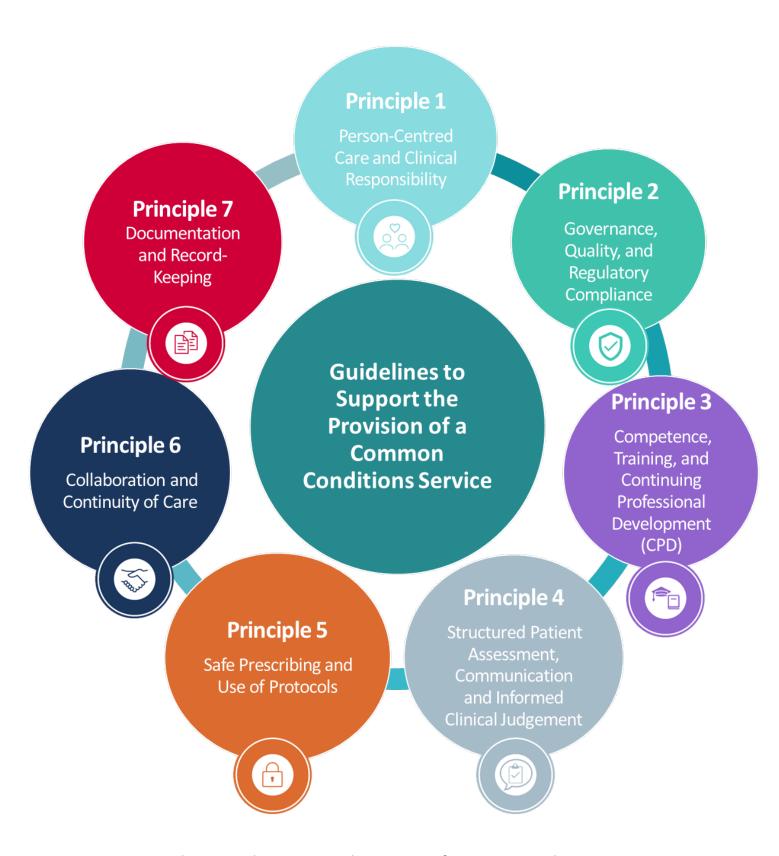


Figure 1. Guiding Principles to Support the Provision of a Common Conditions Service.

5. Principle Statement and Indicators

Each principle is:

- supported by a principle statement that defines and describes the principle,
- underpinned by concise, outcome-focused indicators that are intended to offer guidance on how adherence to each principle can be demonstrated.

Where 'you must' is used within the indicators, it denotes a mandatory duty on pharmacists or those in pharmacy governance roles to comply with the requirements set out in legislation and the accompanying guidance.



Principle 1: Person-Centred Care and Clinical Responsibility

Patients receive safe, appropriate and patient-centred care that recognises their individual needs and preferences when accessing the service. Person-centred care involves engaging the patient in meaningful dialogue, respecting their autonomy, and ensuring that treatment decisions are made in partnership.

Pharmacists providing this service are responsible for conducting assessments, making clinical decisions, and recommending treatments in accordance with the clinical protocols and relevant legislation. They are also required to ensure that patients have the option to choose the pharmacy where their prescription is dispensed.

Indicators supporting Principle 1:

These indicators apply to all pharmacists.

- 1.1 You must provide robust evidence-based advice having regard to proper patient care and, if required to prescribe, you must ensure that the selected medicine is both pharmaceutically and therapeutically appropriate to support the patient's ongoing care.
- 1.2 You engage in structured, person-centred consultations⁶ by actively listening to the patient, encouraging their questions, clearly explaining available options, and ensuring shared decision-making, confirming that the patient understands and is making informed choices based on their health status and preferences.
- 1.3 You take full responsibility for any decisions you make, including ensuring the decision is informed by the information and recommendations in the clinical protocols, and supported by appropriate documentation and record keeping.
- 1.4 Where prescribing and dispensing take place within the same pharmacy, you must ensure that this is in the best interest of the patient, and reflects the patient's choice.

⁶ Resources on communication skills are available in the mandatory training provided by the <u>IIOP</u>. Additional materials can also be accessed through the HSE <u>National Healthcare Communication Programme</u>.

1.5	You make your decisions based on the needs of the patient, ensuring that they are not influenced by commercial interests or external pressure.

Principle 2: Governance, Quality, and Regulatory Compliance

Those in governance roles, demonstrate commitment to their leadership responsibilities by ensuring the delivery of safe, reliable, and person-centred care across all aspects of service provision. Responsibilities also include ensuring that the service offered is inclusive and accessible, and that human rights and equality obligations are considered.

Robust structures and processes are consistently in place to support the pharmacy team in delivering safe, high-quality care. An environment is established where roles and responsibilities are clearly defined and transparent, with a strong emphasis on continuous service improvement.

Indicators supporting Principle 2:

These indicators apply to those in pharmacy governance roles.

- 2.1 You must establish and maintain robust governance structures that ensure the service adheres to relevant legislation, the most up-to-date clinical protocols, and PSI guidance to provide a safe, person-centred service. This includes:
 - Establishing pharmacy systems and procedures and leading the pharmacy team in maintaining these standards to ensure the provision of safe and effective care.
 - Ensuring all pharmacists complete mandatory training. Evidence of this training should be maintained and available for inspection upon request.
 - Maintaining adequate staffing levels to fulfil all clinical, operational and supervisory requirements.⁷
 - Tailoring care to individual patient needs through direct pharmacist consultation.
 - Providing a designated private area for confidential consultations.
 - Ensuring the pharmacy has appropriate operational equipment that may be necessary for the service provided.

⁷ Regulation 5(1)(d) of the Regulation of Retail Pharmacy Businesses Regulations 2008 (as amended) and Sections 26, 27, 28 and 29 of the Pharmacy Act 2007; requires that the sale or supply of all medicinal products in a pharmacy must be carried out "by or under the personal supervision of a registered pharmacist".

- Ensuring that, in circumstances where a prescription is issued as part of providing the service, prescribing and dispensing can occur in the same pharmacy, if it is in the best interest of the patient and if it is the patient's choice that this should happen.
- In circumstances where the medicinal product is dispensed in the same pharmacy, the pharmacist must complete a review of the patient's medicine therapy and provide counselling on the prescribed product.
- Maintaining required documentation and records.
- Supporting ongoing staff training and professional development.
- 2.2 You ensure that a structured quality assurance system is in place to support compliance with relevant legislation, clinical protocols, and PSI guidance. This includes systems for clinical audit, review of patient feedback, regular service evaluation, and ongoing service improvement. These mechanisms help confirm that pharmacists are delivering care in accordance with all legal and professional requirements and identifying areas for development or improvement.
- 2.3 You ensure that governance structures support a pharmacist's independent professional judgement, and clinical decision-making with clear documentation and appropriate oversight. Targets or incentives that could adversely influence decisions on patient care should not be in place.
- 2.4 You ensure that all patients have equitable access to the service, are treated with dignity and respect, and that reasonable accommodations are made for vulnerable groups, in accordance with equality and human rights legislation.
- 2.5 You ensure that, prior to providing a service, all fees or associated costs are communicated clearly to promote transparency and enhance patient trust.
- 2.6 You promote an open and honest safety culture within the pharmacy, where staff feel supported to raise concerns, report incidents, and actively participate in ongoing service improvements to enhance patient experience, patient safety and staff engagement.

Principle 3: Competence, Training, and Continuing Professional Development

All decisions must be guided by the professional judgement of pharmacists and remain within the scope of their clinical expertise, skills, and competence, and supported by the completion of all mandatory training. Competence in practice includes recognising when a patient's care needs fall beyond the scope of personal expertise and ensuring timely referral to the appropriate healthcare professional/provider.

Engaging in continuing professional development (CPD) enables pharmacists to maintain upto-date clinical knowledge, and apply professional judgement based on evidence and best practice.

Pharmacists are fully accountable for their actions and the decisions they make. This accountability includes the responsibility to deliver person-centred care, while adhering to relevant legislation, clinical protocols and PSI guidance. Pharmacists should also reflect on their ethical and professional responsibilities when assessing or treating patients.

Indicators supporting Principle 3:

- 3.1 Before providing the service, you must complete the mandatory training as specified by the PSI relating to the operation of the service. Evidence of completed training should be maintained and available for inspection upon request.
- 3.2 You provide the service in accordance with the PSI Code of Conduct, relevant legislation, approved and current clinical protocols and PSI guidance, ensuring that you maintain the competence and skills required for your role.
- 3.3 You follow established pharmacy systems and procedures and lead the pharmacy team in maintaining these standards to ensure the provision of safe and effective care.
- 3.4 You engage in ongoing continuing professional development (CPD) to maintain the up-to-date clinical knowledge and skills necessary to fulfil your role in delivering safe, person-centred care. This is particularly important in responding to updated clinical protocols and national guidelines, including those relating to antimicrobial stewardship.

Principle 4: Structured Patient Assessment, Communication and Informed Clinical Judgement

Structured patient assessment is essential to the safe delivery of person-centred care. A consistent and systematic approach to gathering information will enable pharmacists to identify patient needs accurately by ensuring decisions are based on a clear understanding of the patient's care needs.

Effective communication should underpin every stage of the assessment and care. It is important that the exchange of information with patients or their carer is clear, respectful, and person-centred, while always upholding confidentiality and protecting patient privacy. It is important to explain the nature of the condition, how treatment works, and what to expect.

Informed clinical judgement brings together structured assessment, effective communication, and professional judgement. By applying knowledge and skills within the scope of competence, and in line with relevant legislation, clinical protocols, and PSI guidance pharmacists can make informed decisions that ensure safe and effective care for patients.

Indicators supporting Principle 4:

- 4.1 Before recommending any treatment, you must engage in consultation with the patient or their carer to determine any prior history with the medicine therapy or course of treatment.
- 4.2 You adopt a consistent and systematic approach to patient assessment for the purpose of gathering all relevant information. Prior to making any clinical decisions, you determine that you have sufficient information and knowledge of the patient's health status and medical history to conduct an informed assessment.
- 4.3 You take all steps to maintain patient dignity, privacy and confidentiality, especially when carrying out consultations. Patients are facilitated and encouraged to speak privately with the pharmacist about their health and treatment in the patient consultation area.

- 4.4 You ensure that care, advice and patient counselling are provided in accordance with legal and professional requirements⁸, and in accordance with the clinical protocols, while also supporting and empowering patients to take an active role in managing their own health. Information should be delivered clearly, respectfully, and in a way that accounts for the patient's individual preferences.
- 4.5 Where treatment for a condition is not indicated, in line with the relevant clinical protocol, the patient should be supported through the appropriate referral pathway or provided with appropriate self-care and safety netting advice as set out in the clinical protocol.
- 4.6 You obtain informed consent⁹ from the patient prior to any assessment, treatment, or information sharing, ensuring the patient understands and agrees voluntarily in accordance with legal and professional requirements. It is important that patients understand the information provided, have the opportunity to ask questions and know when to seek additional follow-up care.
- 4.7 You ensure that clinical decisions are informed by assessment and communication with patients, in accordance with the clinical protocols, and are within the scope of your professional competence. Where there is any uncertainty, it may be necessary to seek advice or refer to an appropriate healthcare professional for further assessment.

⁸ Regulation 9 (1), (2) and (3) and 10 of the Regulation of Retail Pharmacy Businesses Regulations 2008 (as amended).

⁹ Resources on consent are available in the mandatory training provided by IIOP. Further information on consent is also provided in the <u>HSE National Consent Policy</u>.

Principle 5: Safe Prescribing and Use of Protocols

Safe prescribing requires structured patient assessment, informed clinical judgement, and pharmacists working within the scope of their professional competence. The clinical protocols support this process by providing clear, evidence-based criteria for decision making. Following them consistently will help ensure safe, effective and person-centred care.

Special attention should be given to the appropriate use of antimicrobials which includes antibiotics, antifungals, antivirals etc. Antimicrobial resistance is a significant and growing public health threat, and pharmacists have a critical role in supporting good antimicrobial stewardship¹⁰. As outlined in the HSE's Safe Prescribing Guidance¹¹, antimicrobials must only be prescribed when clearly indicated. Pharmacists must be alert to inappropriate use and promote responsible prescribing that protects both individual patients and broader community health.

Indicators supporting Principle 5:

- 5.1 You must only provide the service, including issuing a prescription where appropriate following the successful completion of the mandatory training, in accordance with the legislation and current clinical protocols.
- 5.2 You ensure that antimicrobials are prescribed only when clinically justified, in accordance with the clinical protocols and the principles of antimicrobial stewardship. Ensuring an accurate diagnosis is central to this.
- 5.3 Except in emergency situations, you should not prescribe treatment for yourself, family members, members of the pharmacy team, or those with whom you have a close personal relationship.

¹⁰ HSE AMRIC Antimicrobial Stewardship Guidance for all Healthcare Settings

¹¹ <u>HSE Antibiotic Prescribing,</u> this HSE webpage brings together all information and guidance on safe prescribing.

Principle 6: Collaboration and Continuity of Care

While pharmacists may deliver care independently, effective collaboration is important to ensuring continuity and consistency in patient care. Through purposeful and proportionate communication that complies with data protection legislation, along with coordinated practice across different settings, healthcare professionals can support safe and high-quality services.

Information should only be shared with the patient's consent and limited to what is relevant to their ongoing care. Patients should also be empowered to take responsibility for informing their healthcare providers of any other relevant services they receive. Continuity of care ensures that patients feel supported throughout their healthcare journey, with smooth transitions between services.

Indicators supporting Principle 6:

- 6.1 You obtain informed consent from the patient before sharing any information with other healthcare professionals. This process should respect confidentiality, comply with legal requirements, and ensure that the patient understands how their information will be used to support their ongoing care.
- 6.2 You use the most suitable method for sharing information with other healthcare professionals, taking into account existing systems and pharmacy processes. Communication should be clear, timely, especially in urgent situations, and documented appropriately. When collaboration with other healthcare professionals is not possible (e.g., out-of-hours), you ensure that patients receive advice on seeking further care and have access to relevant information.
- 6.3 You ensure that any information shared is always relevant to the patient's ongoing care and complies with legal and ethical requirements. In cases where consent is not provided but there is a risk of serious harm, you should use your professional judgement to determine whether disclosure of the information is necessary, ensuring such disclosures are lawful, proportionate, and clearly documented.

Principle 7: Documentation and Record-Keeping

Pharmacists are responsible for maintaining accurate, clear, and up-to-date records. This supports continuity of care, facilitates audit, protects patient safety, and provides evidence of professional decisions.

Effective record-keeping facilitates communication within the pharmacy team and provides a reliable reference for future care. It is especially important when the pharmacist performs both prescribing and dispensing roles, to ensure transparency and accountability in line with professional and ethical expectations.

Indicators supporting Principle 7:

- 7.1 You must ensure compliance with all record-keeping requirements, maintaining accurate and complete documentation at all times.
- 7.2 If you make a decision to issue a prescription for a medicinal product, you must keep a record in the register¹². The record must include all information required by the relevant legislation, ¹³ including:
 - a) the date of the decision;
 - b) the name and registration number of the registered pharmacist who made the decision to issue the prescription; and
 - c) details of the prescription.
- 7.3 You must ensure that any prescription issued as part of the service complies fully with the requirements set out in the relevant legislation¹⁴, in order to ensure its validity prior to dispensing. A prescription issued for dispensing must comply with the following:

¹² Regulation 10(1)(a) of the Medicinal Products (Prescription and Control of Supply) Regulations 2003 (as amended). This register is often referred to as the 'prescription register', 'daily dispensing report', 'daily audit' or 'daily print-out.

¹³ Regulation 10F of the Medicinal Products (Prescription and Control of Supply) (Amendment)(No.3) Regulations 2025.

¹⁴ Regulation 7(1) of the Medicinal Products (Prescription and Control of Supply) (Amendment)(No.3) Regulations 2025.

- a) be in
 - i. ink and signed by the pharmacist issuing it with his or her usual signature and be dated by him or her, or
 - ii. electronic form, transmitted by the national electronic prescription transfer system (Healthmail) and clearly indicate the date issued and, the registration number of the pharmacist issuing it, and must be traceable electronically back to him or her;
- b) include the address and name of the pharmacist issuing it, their profession, and registration number;
- c) specify the patients name, address, and age (if under 12).
- 7.4 You clearly record patient consent for treatment and sharing of information with other healthcare professionals in accordance with the HSE National Consent Policy.
- 7.5 You document patient referrals appropriately to ensure continuity of care and accountability. The level of detail recorded should be guided by your professional judgement.

6. More Information

1. Training and Continuing Professional Development

Training has been developed by the Irish Institute of Pharmacy (IIOP) and is available through the <u>IIOP Portal</u>.

The specified training approach consists of the following self-directed online CPD modules, which are mandatory for all pharmacists who intend to deliver the service:

- Core Regulatory Module
- Common Condition Specific Module (for each condition)

Further information about training and continuing professional development is available on the PSI website.

2. Clinical Protocols

Current versions of the clinical protocols can be accessed on the HSE website.

The clinical protocols, which are based on the most up to date evidence and in line with national guidelines, have been developed by the HSE and approved by the Minister for Health.

The clinical protocols will guide pharmacists in delivering clinical care and set out appropriate clinical inclusion and exclusion criteria, formulary and referral pathways. They contain the medicinal products which should be recommended for each condition, including appropriate prescription-only medicinal products.

The Common Conditions Service must be carried out in accordance with the clinical protocols.

3. PSI Guidelines and other Regulatory Tools to Support the Service

Additional regulatory supports to support the service are available on the PSI Website.

Pharmacists might also find the following guidance helpful:

- <u>PSI Guidelines to support Medicines Therapy Review, Counselling and Prescription</u>
 <u>Extension</u>, which offer further guidance on clinical decision-making and patient counselling.
- <u>PSI Guidance on Pharmacy Governance Roles</u>, which outlines the respective responsibilities of pharmacy owners, superintendent pharmacists, supervising pharmacists, and all pharmacists involved in the provision of care.



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