

Consultation on draft rules and standards for Responsible Pharmacists, and draft standards for Superintendent Pharmacists

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Contents

About the GPhC.....	1
Overview.....	2
Background.....	2
The legislation.....	2
About this consultation	2
Section 1 – The standards for Superintendent Pharmacists.....	3
Section 2 – The standards for Responsible Pharmacists	4
Section 3 – The rules for Responsible Pharmacists	4
Section 4 – The standards for registered pharmacies	4
Section 5 – The standards for pharmacy professionals.....	5
The consultation process.....	6
Responding to the consultation on draft rules and standards for Responsible Pharmacists, and draft standards for Superintendent Pharmacists.....	8
Part A: Draft standards for Superintendent Pharmacists	16
Part B: Draft standards for Responsible Pharmacists	31
Part C: Draft rules for Responsible Pharmacists	48
Part D: Draft annex for the standards for pharmacy professionals on authorisation and supervision	52

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. Our main work includes:

- setting standards for pharmacy professionals and pharmacies to enter and remain on our register
- asking pharmacy professionals and pharmacies for evidence that they are continuing to meet our standards, and this includes inspecting pharmacies
- acting 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

Background

Following the introduction of new legislation, the General Pharmaceutical Council (GPhC) and the Pharmaceutical Society of Northern Ireland (PSNI) are working to strengthen pharmacy governance.

The GPhC now has powers that allow us to:

- develop rules setting out the essential roles and responsibilities of Responsible Pharmacists, and
- set professional standards for Chief Pharmacists, Superintendent Pharmacists and Responsible Pharmacists

The first part of our work to strengthen pharmacy governance was to develop the Chief Pharmacist standards. This work has now finished and you can see the [Chief Pharmacist standards](#) on our website.

The second stage is to produce rules and standards for Responsible Pharmacists and standards for Superintendent Pharmacists. These draft rules and standards are attached and are the subject of this consultation.

When we have agreed and published the standards for Superintendent Pharmacists, and the rules and standards for Responsible Pharmacists, our next step will be to carry out a full review of, and consultation on, the standards for registered pharmacies and standards for pharmacy professionals.

The legislation

[The Pharmacy \(Responsible Pharmacists, Superintendent Pharmacists etc.\) Order 2022](#) came into force on 1 December 2022.

This Order introduces changes to the Medicines Act 1968, the Pharmacy Order 2010, the Pharmacy (Northern Ireland) Order 1976, and The Medicines (Pharmacies) (Responsible Pharmacist) Regulations 2008. The changes include giving the GPhC legal powers to set rules and describe the role and responsibilities of Superintendent Pharmacists and Responsible Pharmacists in terms of standards of conduct, ethics and performance.

The Order aims to clarify the relationship between pharmacy owners, Superintendent Pharmacists and Responsible Pharmacists to make sure that pharmacies deliver safe and effective care to patients and the public, making clear the accountability of each role within a pharmacy. In turn, this will strengthen pharmacy governance to support better use of the skill mix within pharmacy teams. This will allow teams to deliver more clinical services in the community, as well as more widely supporting the care provided by the NHS and Health and Social Care.

About this consultation

This consultation is asking for your views on the proposed standards for Superintendent Pharmacists, and the proposed rules and standards for Responsible Pharmacists. The aim of this consultation is to get the views of our stakeholders on the proposed standards and rules, and find out if there is anything else we should have included.

We are also asking for views on proposed changes to the standards for registered pharmacies and the standards for pharmacy professionals. We became aware of the need for these changes when

developing the standards for Superintendent Pharmacists and Responsible Pharmacists. You can see more information about the proposals under each section.

This consultation has five sections. Each section is designed to gather your views on a separate area.

- Section 1 – The standards for Superintendent Pharmacists
- Section 2 – The standards for Responsible Pharmacists
- Section 3 – The rules for Responsible Pharmacists
- Section 4 – The standards for registered pharmacies
- Section 5 – The standards for pharmacy professionals

The consultation questions are made up of:

1. some general background questions about you and, if you respond on behalf of an organisation, your organisation. We use this to help us analyse the possible impact of our plans on different groups
2. specific questions about each section of the consultation

You do not have to respond to each section. You will be able to skip sections of the consultation questions if they are not relevant to you.

Please note: new legislation on pharmacy supervision was made on 10 December 2025. Not all the changes introduced by the order take effect at the same time, but once all the changes are in force, pharmacists will be able to authorise registered pharmacy technicians to carry out, or to supervise others carrying out, the preparation, assembly, dispensing, sale and supply of medicines. Questions about this legislation are outside the scope of this consultation.

Section 1 – The standards for Superintendent Pharmacists

The draft standards for Superintendent Pharmacists set out the criteria a pharmacist must meet if they are to perform the role of a Superintendent Pharmacist, and their professional responsibilities. They also describe the knowledge a Superintendent Pharmacist must have – and the conduct and performance expected of them – if they are to support the organisation and its staff in delivering safe and effective operation of the pharmacy business.

In developing these standards, we worked with a broad range of stakeholders from across the pharmacy sector in England, Scotland and Wales. We analysed and used their feedback to develop these standards for Superintendent Pharmacists. Each standard includes examples of how it can be met in practice. The five standards are:

1. Provide strategic and professional leadership
2. Develop a workforce with the right skills, knowledge and experience
3. Delegate responsibly and make sure there are clear lines of accountability
4. Maintain and strengthen governance to ensure safe and effective delivery of pharmacy services
5. Make sure the pharmacy environment and premises safeguard the health, safety and wellbeing of patients and the public

To read the draft standards for Superintendent Pharmacists, please see Part A. If a Superintendent Pharmacist does not meet these standards it could result in the GPhC taking enforcement action.

Section 2 – The standards for Responsible Pharmacists

The draft standards for Responsible Pharmacists describe the role and responsibilities of Responsible Pharmacists. They also set the standards of conduct, ethics and performance they must meet to support the pharmacy and its staff to deliver safe and effective pharmacy services.

In developing these standards, we worked with a broad range of stakeholders from across the pharmacy sector in England, Scotland and Wales. We analysed and used their feedback to develop these standards for Responsible Pharmacists. Each standard includes examples of how it can be met in practice. The four standards are:

1. Prioritise patient safety
2. Provide the leadership and management needed to ensure the safe and effective operation of the pharmacy
3. Make sure, if using authorisation, to authorise responsibly and make clear the lines of accountability
4. Maintain and strengthen governance to ensure safe and effective delivery of pharmacy services

For more information about the draft standards for Responsible Pharmacists, please see Part B. If a Responsible Pharmacist does not meet these standards it could result in the GPhC taking enforcement action.

Section 3 – The rules for Responsible Pharmacists

Under the recent legislation, we now have powers to describe the role and professional responsibilities of Responsible Pharmacists. We have developed draft Responsible Pharmacist rules alongside the standards for Responsible Pharmacists.

In developing these draft rules, we have used the principle that any burdens they impose on businesses should be the minimum needed to secure the benefits expected to result, in general terms, from the draft rules.

In developing these draft rules, we worked with a broad range of stakeholders from across the pharmacy sector in England, Scotland and Wales. We analysed and used their feedback to develop the draft rules.

The draft rules contain specific requirements relating to the duty of Responsible Pharmacists to secure the safe and effective running of a pharmacy business at the premises from which it is carried on. For example, they specify:

- the maximum period the Responsible Pharmacist may be absent from the premises during the pharmacy's business hours, and
- the arrangements that must be made if the Responsible Pharmacist is absent.
- For more information about the draft rules for Responsible Pharmacists, please see Part C.

Section 4 – The standards for registered pharmacies

The aim of the standards for registered pharmacies is to create and maintain the right environment – both organisational and physical – for the safe and effective practice of pharmacy. These standards apply to all pharmacies registered with the General Pharmaceutical Council.

When we have agreed and published the standards for Superintendent Pharmacists, and the rules and standards for Responsible Pharmacists, we will be carrying out a full review of, and consultation on, the standards for registered pharmacies.

When developing the standards for Superintendent Pharmacists we found there are two areas that now need updating in the standards for registered pharmacies. We are asking for your views on these updates and using this early opportunity to ask whether there is anything else that should be considered when we carry out a full review of the standards for registered pharmacies in 2026/27.

You can see the standards for registered pharmacies on our website.

Section 5 – The standards for pharmacy professionals

These professional standards apply to all pharmacists and pharmacy technicians and are the core standards that pharmacy professionals in Great Britain must meet.

When we have agreed and published the standards for Superintendent Pharmacists, and the rules and standards for Responsible Pharmacists, we will be carrying out a full review of, and consultation on, the standards for pharmacy professionals.

However, upcoming legislation about supervision introduces new provisions which will have an impact on pharmacists and pharmacy technicians. This supervision legislation will allow:

- trained team members to hand out checked and bagged prescriptions, bringing legislation in line with present practices such as home delivery and 'lock box' services
- pharmacists to authorise registered pharmacy technicians to carry out, or supervise others carrying out, the preparation, assembly, dispensing, sale and supply of medicines
- pharmacy technicians to supervise the preparation, assembly and dispensing of medicines in hospital aseptic facilities

To make sure that pharmacists and pharmacy technicians know what this will mean for them, we are planning to produce an annex to the existing standards for pharmacy professionals before the supervision legislation comes into effect. The annex will set out:

- the standards pharmacists must meet, if they decide to authorise pharmacy technicians to carry out certain tasks, and
- the accountabilities and responsibilities of both pharmacists and pharmacy technicians if authorisation or supervision take place

We are asking for your views on whether you agree with this approach. We are not seeking views on the pharmacy supervision legislation itself as this falls outside the scope of this consultation. We are also taking this opportunity to ask whether there is anything else we should consider when we carry out a full review of the standards for pharmacy professionals in 2026/27.

You can see the standards for pharmacy professionals on our website. Please see Part D for the proposed annex to the standards for pharmacy professionals.

The consultation process

The consultation will run for 14 weeks and will close on Wednesday 25 March 2026. During this time, we welcome feedback from individuals and organisations. We will send this document to a range of stakeholders, including Superintendent Pharmacists, Responsible Pharmacists, pharmacists, pharmacy technicians, pharmacy owners, patients' representative bodies, and other people and organisations with an interest in this area.

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

Our report on this consultation

Once the consultation period ends, we will analyse the responses we receive and consider any changes that are needed.

Our governing Council will receive the analysis and will consider the responses when approving the final rules for Responsible Pharmacists and the standards for Responsible Pharmacists and Superintendent Pharmacists.

We will publish our analysis of the responses and an explanation of the decisions we take. You will be able to see this on our website www.pharmacyregulation.org.

Why we consult

Under the Pharmacy Order 2010, we have to consult before we set any standards or requirements. We will also consult, when we need to, to make sure we are carrying out our statutory duties effectively and proportionately to meet our main objective of protecting the public.

Responding to the consultation

How we use your information

We will use your response to help us develop our work. We ask you to give us some background information about you and, if you respond on behalf of an organisation, your organisation. We use this to help us analyse the possible impact of our plans on different groups. We are committed to promoting equality, valuing diversity and being inclusive in all our work as a health professions regulator, and to making sure we meet our equality duties. There is an equality monitoring form at the end of the survey. You do not have to fill it in, but if you do, it will give us useful information to check that this happens.

How we share your information

If you respond as a private individual, we will not use your name or publish your individual response. If you respond on behalf of an organisation, we will list your organisation's name and may publish your response in full unless you tell us not to. If you want any part of your response to stay confidential, you should explain why you believe the information you have given is confidential.

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

If you email a response to the consultation and this is covered by an automatic confidentiality disclaimer generated by your IT system this will not, in itself, be binding on the GPhC.

Your rights

Under data protection law, you may ask for a copy of your response to this consultation or other information we hold about you. You may also ask us to delete your response. For more information about your rights and who to contact please read our privacy policy on our website.

How to respond

You can respond to this consultation by going to www.pharmacyregulation.org/SP-RP-standards and filling in the online questionnaire there.

We encourage everyone to use the online questionnaire. However, if you want to send a response by email, please write your response to the consultation questions and send it to us at consultations@pharmacyregulation.org.

Other formats

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

Level 14, One Cabot Square

London

E14 4QJ

Please do not send consultation responses to this address.

Responding to the consultation on draft rules and standards for Responsible Pharmacists, and draft standards for Superintendent Pharmacists

If you can, please use the online survey at surveys.pharmacyregulation.org/s/SPRPstandards/.

If you want to send a response by email, please make sure you:

- give your response to all questions
- when answering the 'impact' questions, say what you think the impact will be for each group or characteristics we have listed. You can say 'no impact' or 'don't know' if you need to. This will help us to take account of your views in the same way as the ones we collect from our online survey.

You do not have to respond to each section. You will be able to skip sections of the consultation questions if they are not relevant to you.

Standards for Superintendent Pharmacists

The role of the Superintendent Pharmacist

The criteria for the role of the Superintendent Pharmacist are set out in legislation. The criteria must be met in full.

A Superintendent Pharmacist must:

1. be a pharmacist who maintains their registration with the GPhC, and
2. be a senior manager of the retail pharmacy business who has the authority to make decisions affecting the running of the retail pharmacy business in connection with the retail sale and supply of medicinal products. This includes having a significant role in:
 - making decisions about how the whole or a substantial part of the activities of a retail pharmacy business are managed or organised, or
 - the actual managing or organising of the whole or a substantial part of the activities of a retail pharmacy business, and
 - notify the GPhC in writing confirming their name and that they are the Superintendent Pharmacist for the retail pharmacy business. This notice provided to the GPhC must be signed by the Superintendent Pharmacist and signed on behalf of the retail pharmacy business

1. Do you think we should set additional minimum requirements for a pharmacist to become a Superintendent Pharmacist?

Yes

No

Don't know

If you selected 'Yes', please explain what requirements we should set, for example in terms of experience, skills, length of service or something else.

It is important that the GPhC is able to identify, at all times, who is performing the role of the Superintendent Pharmacist for a retail pharmacy business. This includes if the Superintendent Pharmacist leaves the role at short notice or is away from work for an extended period of time, for example on sick leave. We have proposed succession and contingency planning needs to be in place to make sure a replacement Superintendent Pharmacist can be immediately appointed. This will make sure the pharmacy business can continue to assure patient safety and operate lawfully.

2. When a Superintendent Pharmacist leaves their role or is unable to perform their legal and professional responsibilities, for example, due to an extended period of absence, do you think it is reasonable for the GPhC to require pharmacy owners to appoint a new permanent or interim Superintendent immediately?

Yes

No

Don't know

Please explain your responses.

Standards for Superintendent Pharmacists

We have proposed five standards for Superintendent Pharmacists. These are:

- a. Provide strategic and professional leadership
- b. Develop a workforce with the right skills, knowledge and experience
- c. Delegate responsibly and make sure there are clear lines of accountability
- d. Maintain and strengthen governance to ensure safe and effective delivery of pharmacy services
- e. Make sure the pharmacy environment and premises safeguard the health, safety and wellbeing of patients and the public

3. In the interests of patient and staff safety, do you think the standards will:

a. strengthen the safe and effective running of a pharmacy business?

Yes

No

Don't know

b. clarify the role of the Superintendent Pharmacist, making their accountabilities and responsibilities clear?

Yes

No

Don't know

Please explain your responses

4. The Superintendent Pharmacist has a key leadership role in the pharmacy and is responsible for securing the safe and effective running of the pharmacy business. Are there any other standards you think should be in place for Superintendent Pharmacists if they are to meet the requirements of this role?

- Yes
- No
- Don't know

If you have selected 'Yes', what standards do you think should be included?

Any other comments

5. **Is there anything else related to the standards for Superintendent Pharmacists that you would like to raise?**

Yes, I have some more comments that I have not already raised

No, I have provided all my feedback in my earlier responses

If you have selected 'Yes', please give your additional comments.

Standards for Responsible Pharmacists

The role of the Responsible Pharmacist

The **Medicines (Pharmacies) (Responsible Pharmacist) Regulations 2008** introduced the role of the Responsible Pharmacist. The owner of a retail pharmacy business must appoint a Responsible Pharmacist, who is a registered pharmacist, to be in charge of the registered pharmacy. The Responsible Pharmacist is responsible for the day-to-day running of the pharmacy. They are also responsible for securing the safe and effective operation of the pharmacy, so far as concerns the retail sale of medicinal products and the supply of medicinal products in circumstances corresponding to retail sale.

Please note, there is **new legislation on pharmacy supervision** which will allow pharmacists to authorise registered pharmacy technicians to carry out, or supervise others carrying out, the preparation, assembly, dispensing, sale and supply of medicines. Questions about this legislation are outside the scope of this consultation.

A Responsible Pharmacist can only be responsible for one pharmacy premises at a time.

6. **Do you think we should set minimum requirements for a pharmacist to become a Responsible Pharmacist?**

- Yes
- No
- Don't know

Please explain your response. If you have selected 'yes', what requirements should we set in terms of experience, skills, length of service or something else?

The Superintendent Pharmacist is responsible for organisational oversight of the management and operation of the pharmacy business. This includes keeping and maintaining records in relation to this (if there is not a requirement for a Superintendent Pharmacist to be appointed, this responsibility is the pharmacy owner's). The Responsible Pharmacist is responsible for keeping and maintaining records for the safe and effective day-to-day running of the pharmacy.

7. **What records do you think are the responsibility of the Responsible Pharmacist?**

Standards for Responsible Pharmacists

We have proposed four standards for Responsible Pharmacists. These are:

- a. Prioritise patient safety
- b. Provide the leadership and management needed to ensure the safe and effective operation of the pharmacy
- c. Make sure, if using authorisation, to authorise responsibly and make clear the lines of accountability
- d. Maintain and strengthen governance to ensure safe and effective delivery of pharmacy services

8. In the interests of patient and staff safety, do you think the standards will:

- a. strengthen the day-to-day running of the pharmacy?

Yes

No

Don't know

- b. clarify the role of the Responsible Pharmacist, making their accountabilities and responsibilities clear?

Yes

No

Don't know

Please explain your responses.

9. **The Responsible Pharmacist has a key leadership role in the pharmacy. The Responsible Pharmacist is responsible for the day-to-day running of the pharmacy and for securing the safe and effective operation of the pharmacy, including during periods of absence. Are there any other standards you think should be in place for the Responsible Pharmacist to meet the requirements of this role?**

Yes

No

Don't know

If you have selected 'Yes', what standards do you think should be included?

Any other comments

10. **Is there anything else related to the standards for Responsible Pharmacists that you would like to raise?**

Yes, I have additional comments that I have not already raised

No, I have provided all my feedback in my earlier responses

If you have selected 'Yes', please provide your additional comments.

Rules for Responsible Pharmacists

Under the law, there must be a Responsible Pharmacist in every registered pharmacy. We are proposing to continue with the present rule where a Responsible Pharmacist:

- can only be responsible for one pharmacy premises at any given time, and
- is not able to perform their role anywhere other than the pharmacy where they are signed in

11. Do you agree with our proposal to continue with the present ‘one pharmacy’ rule?

Yes

No

Don’t know

Please explain your response.

We propose to continue with the present rule that allows the Responsible Pharmacist to be absent from the pharmacy for up to two hours. If there is more than one Responsible Pharmacist scheduled during the pharmacy’s business hours, the two-hour limit applies to the total time when any of them is absent.

12. Do you agree with our proposal to continue with the current two-hour absence rule?

Yes

No

Don’t know

Please explain your response.

Any other comments

13. Is there anything else related to the rules for Responsible Pharmacists that you would like to raise?

Yes, I have additional comments that I have not already raised

No, I have provided all my feedback in my earlier responses

If you have selected ‘Yes’, please give your additional comments.

Standards for registered pharmacies

When we have agreed and published the standards for Superintendent Pharmacists and the rules and standards for Responsible Pharmacists, we will be carrying out a full review of and consultation on the standards for registered pharmacies.

When developing the standards for Superintendent Pharmacists we found there are two areas in the standards for registered pharmacies that need updating now, to provide clarity and maintain patient safety. These are:

- a. The present standards specifically relate to medicines and medical devices. This limits our ability to take enforcement action against poor practice arising from other services, or from unregulated products provided from pharmacies. We therefore propose to include ‘any other product intended for supply or administration’ under Principle 4 of the standards.

- b. Although our standards for pharmacy professionals cover consent, the present standards for registered pharmacies do not. As pharmacies are offering clinical services more and more – such as examinations, diagnosis, and hands-on treatment – it is important to include a specific standard around consent.
- 14. Do you agree with the inclusion of ‘any other product intended for supply or administration’ under Principle 4 of the standards? (Point (a) above.)**
- Yes
No
Don’t know
- 15. Do you agree with the inclusion of a specific standard around consent? (Point (b) above.)**
- Yes
No
Don’t know
- Please explain your responses.**
- 16. Is there anything else you think could put patient safety at risk and should be changed or added to the standards for registered pharmacies before the full review?**
- 17. Is there anything you would like to raise now for us to consider when we carry out the full review of the standards for registered pharmacies?**

Standards for pharmacy professionals

When we have agreed and published the standards for Superintendent Pharmacists and the rules and standards for Responsible Pharmacists, we will be carrying out a full review of, and consultation on, the standards for pharmacy professionals.

Ahead of the review, and in light of upcoming legislation on supervision and authorisation, we will be producing an annex to the standards for pharmacy professionals. This will be published alongside the standards for Responsible Pharmacists. The annex will set out what is expected of pharmacists and pharmacy technicians if a pharmacy decides to use authorisation. Please note: The Royal Pharmaceutical Society (RPS) will also be providing guidance covering authorisation.

- 18. Do you agree with our proposal to publish an annex to the standards for pharmacy professionals to cover authorisation?**
- Yes
No
Don’t know
- Please explain your answer.**
- 19. Is there anything else you think could put patient safety at risk and should be changed or added to the standards for pharmacy professionals before the full review?**
- 20. Is there anything you would like to raise now for us to consider when we carry out the full review of the standards for pharmacy professionals?**

Impact of the proposals

Impact on people sharing protected characteristics

We want to understand whether our proposals may have a positive or negative impact on any individuals or groups sharing any of the protected characteristics in the Equality Act 2010.

21. Do you think our proposals will have a positive or negative impact on individuals or groups who share any of the protected characteristics?

Table 1: Impact on protected characteristics

Protected characteristic	Positive impact	Negative impact	Positive and negative impact	No impact	Don't know
Age					
Disability					
Gender reassignment					
Marriage and civil partnership					
Pregnancy and maternity					
Race					
Religion					
Sex					
Sexual orientation					

Please describe the impact you think our proposals will have and the protected characteristic(s) concerned.

Impact on other groups

We also want to know if our proposals will have an impact on other individuals or groups (not related to protected characteristics) – specifically, patients and the public, Responsible Pharmacists, Superintendent Pharmacists, pharmacy owners or employers, pharmacy staff, other healthcare professionals, pharmacy students and pre-registration trainees.

22. Do you think our proposals will have a positive or negative impact on any of these groups?

Table 2: Impact on groups

Group	Positive impact	Negative impact	Positive and negative impact	No impact	Don't know
Patients and the public					
Superintendent Pharmacists					
Responsible Pharmacists					
Pharmacy owners/employers					
Pharmacy staffs					
Other healthcare professionals					
Pharmacist and pharmacy technician students and trainees					

Please describe the impact you think our proposals will have and the individuals or groups concerned.

Part A: Draft standards for Superintendent Pharmacists

Introduction

The Pharmacy (Responsible Pharmacists, Superintendent Pharmacists etc.) Order 2022

When we use the terms ‘pharmacists’ and ‘pharmacy technicians’ in these standards we mean pharmacists and pharmacy technicians registered with the GPhC.

The Pharmacy (Responsible Pharmacists, Superintendent Pharmacists etc.) Order 2022 has given the GPhC the legal powers to set standards that describe the role and professional responsibilities of Superintendent Pharmacists, as well as the conduct, ethics and performance expected of them.

These standards for Superintendent Pharmacists apply in England, Scotland and Wales. The Pharmaceutical Society of Northern Ireland are responsible for producing the standards for pharmacists in Northern Ireland.

One of the aims of these standards is to clarify the relationship between pharmacy owners, Superintendent Pharmacists and Responsible Pharmacists, making clear the accountability of each role. In turn, this will strengthen pharmacy governance to support better use of the skill mix in pharmacy teams. This will allow teams to deliver more clinical services in the community, as well as supporting wider Health and Social Care services and delivering safe and effective care to patients and the public.

Developing these Superintendent Pharmacist standards is part of a programme of work designed to strengthen pharmacy governance. The programme also includes producing professional **standards for Chief Pharmacists**, and rules and professional standards for Responsible Pharmacists.

The role of a Superintendent Pharmacist

The Medicines Act 1968 sets out the legal duty of the Superintendent Pharmacist to be responsible for securing the safe and effective running of a retail pharmacy business in connection with the retail sale and supply of medicinal products. A Superintendent Pharmacist must be in place if a retail pharmacy business is owned by a ‘body corporate’¹.

Criteria

The Medicines Act 1968 sets out the criteria a pharmacist must meet if they are to perform the role of the Superintendent Pharmacist. These must be met in full by all Superintendent Pharmacists.

The Superintendent Pharmacist must:

1. be a pharmacist who maintains their registration with the GPhC, and

¹ A body corporate is a legal entity that is incorporated under the laws of the UK, or those of another country or territory. It is separate from its members or directors and is capable of legal actions in its own name – such as entering into contracts, buying and selling property and suing and being sued.

2. be a senior manager of the retail pharmacy business who has the authority to make decisions affecting the running of the retail pharmacy business in connection with the retail sale and supply of medicinal products. This includes having a significant role in:
 - making decisions about how the whole or a substantial part of the activities of a retail pharmacy business are managed or organised, or
 - the actual managing or organising of the whole or a substantial part of the activities of a retail pharmacy business, and
3. notify the GPhC in writing confirming their name and that they are the Superintendent Pharmacist for the retail pharmacy business. This notice provided to the GPhC must be signed by the Superintendent Pharmacist and signed on behalf of the retail pharmacy business

The Superintendent Pharmacist therefore must have organisational oversight of, and be professionally responsible for, the management of each individual pharmacy owned by the retail pharmacy business. This includes providing clinical oversight and being accountable for the business's professional management at all times, including outside of business hours. The Superintendent Pharmacist's role involves setting, maintaining and communicating robust standard operating procedures, policies and procedures. This includes how the **legislation allowing pharmacists to authorise registered pharmacy technicians** to carry out, or supervise others carrying out, the preparation, assembly, dispensing and sale and supply of medicines is applied and recorded in each pharmacy. You can find more information on authorisation and supervision in the standards for Responsible Pharmacists, and in the annex for the standards for pharmacy professionals. The Royal Pharmaceutical Society has also produced **guidance on how to undertake authorisation**.

The Superintendent Pharmacist must make sure each individual pharmacy within the retail pharmacy business has appropriate indemnity arrangements in place for all pharmacy services provided.

Appointing a Superintendent Pharmacist

A Superintendent Pharmacist must be appointed by a body corporate if it is to lawfully conduct and operate the retail pharmacy business. A Superintendent pharmacist must be appointed if:

- a registered pharmacy is owned by a body corporate
- there is a change in ownership of a registered pharmacy, and the new owner is a body corporate, or
- a new Superintendent Pharmacist is replacing a previous Superintendent Pharmacist of an existing body corporate

If a Superintendent Pharmacist is away from work for an extended period, for example due to sickness, the Superintendent Pharmacist and the pharmacy owner should discuss – and come to an agreement about – whether the role and responsibilities of the Superintendent Pharmacist and the standards for Superintendent Pharmacists can still be met during this time.

If a Superintendent Pharmacist leaves their role, or it is decided that the Superintendent Pharmacist is not able to perform their legal and professional responsibilities during a period of extended absence, immediate arrangements must be put in place to replace the Superintendent. This may involve appointing an interim Superintendent Pharmacist until a permanent replacement can be appointed.

Under the law, the Superintendent Pharmacist must provide written notice to the GPhC that they are performing the role of the Superintendent Pharmacist for the retail pharmacy business.

The GPhC requires to be notified in writing within 28 days of the change taking effect, of the following:

- when the existing Superintendent Pharmacist stops being the Superintendent Pharmacist of the retail pharmacy business
- the name of the new Superintendent Pharmacist who has been appointed (whether permanent or interim)

This is to ensure that the GPhC can identify, at all times, the Superintendent Pharmacist in charge of a retail pharmacy business owned by a body corporate.

What to consider before taking on the role of Superintendent Pharmacist

Before taking on the role of Superintendent Pharmacist, pharmacists must:

- recognise and understand the extra responsibilities they will have, and
- make sure they can carry out the responsibilities properly while acting within the limits of their professional competence

Therefore, pharmacists should consider whether they can meet these standards and have the appropriate competencies and experience to make sure they can fulfil the duties of the Superintendent Pharmacist. But they must also consider how they will perform the extra professional and legal responsibilities of the Superintendent Pharmacist role.

Superintendent Pharmacists should consider the context of each individual pharmacy for which they are responsible. This includes:

- the range of pharmacy services provided, including those provided by a third party, agent or contractor
- how the pharmacy services are delivered – that is, in a traditional in-person way, at a distance, on the internet and so on
- the skill mix and number of staff in the pharmacy team
- the needs of patients and people who use pharmacy services

Performing the Superintendent Pharmacist role for more than one retail pharmacy business

Following changes to the law, a Superintendent Pharmacist can be responsible for retail pharmacy businesses owned and operated by more than one legal entity. This is likely to involve being responsible for multiple registered pharmacy premises with different owners.

If a Superintendent Pharmacist chooses to perform the role in these circumstances, they must make sure they meet these standards. They must also make sure they have the skills, experience, commitment, time and resources in place to ensure they carry out their legal, professional and regulatory responsibilities effectively. They must make sure each pharmacy premises they are responsible for operates safely and effectively in providing pharmacy services to patients and the public. This includes being responsible and accountable, along with the owner(s) of each retail pharmacy business, for making sure each registered pharmacy meets our **standards for registered pharmacy premises**.

Superintendent Pharmacists responsible for registered pharmacy premises across different legal entities are likely to encounter the following issues when performing the Superintendent Pharmacist role:

- Different and possibly complex business ownership structures
- Different governance frameworks, including different standard operating procedures, policies and procedures
- Safe delivery of a variety of pharmacy services (including clinical services which involve direct patient care) which may vary by each retail pharmacy business
- Different commercial interests
- Operating across different nations and being able to satisfy all legal and regulatory requirements that apply

This is not a complete list of the issues a Superintendent Pharmacist could encounter. They should satisfy themselves that they can effectively navigate and manage issues along the lines of the above.

The standards for Superintendent Pharmacists

The standards for Superintendent Pharmacists set out their professional responsibilities, as well as the knowledge, conduct, ethics and performance required of a Superintendent Pharmacist if they are to support each retail pharmacy business, and its staff, in delivering safe and effective pharmacy services.

Superintendent Pharmacists must meet the following standards:

- 1. Provide strategic and professional leadership**
- 2. Develop a workforce with the right skills, knowledge and experience**
- 3. Delegate responsibly and make sure there are clear lines of accountability**
- 4. Maintain and strengthen governance to ensure safe and effective delivery of pharmacy services**
- 5. Make sure the pharmacy environment and premises safeguard the health, safety and wellbeing of patients and the public**

The standards are designed to be 'outcome focused'. This is to acknowledge the different circumstances of individual registered pharmacies. We have provided examples of how the standards can be met in practice, but we accept that there may be multiple ways of achieving each outcome. We want to give Superintendent Pharmacists the flexibility to use their professional judgement in the interests of patients and the public. Superintendent Pharmacists must decide how to meet these standards and their other legal and professional responsibilities, while taking account of the requirements of the pharmacies they are responsible for.

The standards are also a statement of what patients and other people working with Superintendent Pharmacists can expect of them. They are essential in making sure that patients and the public receive safe and effective care.

Applying the standards

The standards for Superintendent Pharmacists are all equally important and must be met at all times.

Superintendent Pharmacists are directly accountable for meeting the standards set out in this document and must be able to justify their conduct and the decisions they make. However, they also share responsibility with the pharmacy owner and Responsible Pharmacist for ensuring:

- the safe and effective running of the pharmacy, and
- safe provision of pharmacy services

It is therefore vital that pharmacy owners and Responsible Pharmacists are familiar with these standards and that they work together to support the Superintendent Pharmacist in performing their role(s) and responsibilities. This is to ensure patients and the public are kept safe when using pharmacy services.

Alongside these standards, Superintendent Pharmacists must also meet the GPhC's **standards for pharmacy professionals** and any other relevant standards. They must also take into account **supporting guidance we publish on our website**. As explained earlier, the Superintendent Pharmacist shares responsibility with the pharmacy owner for meeting the GPhC's **standards for registered pharmacies**. Superintendent Pharmacists should follow any guidance that applies to them which is produced by other regulatory bodies and inspectorates, for example:

- the Care Quality Commission
- Healthcare Improvement Scotland
- Healthcare Inspectorate Wales, and
- the Medicines and Healthcare products Regulatory Agency

Superintendent Pharmacists should also keep up to date with and apply national guidance and best practice guidance. Following guidance is an important part of making sure that our standards are met.

There may be times when Superintendent Pharmacists are faced with conflicting legal and professional responsibilities. Or they may face complex situations that involve having to balance competing priorities. Both the standards for pharmacy professionals and these standards provide a framework to support and help Superintendent Pharmacists use their professional judgement and make difficult decisions. We expect Superintendent Pharmacists to act in the best interests of patients and the public, and to consider these standards, their legal duties and relevant guidance when making decisions.

How to demonstrate that the standards are being met

There are several ways that Superintendent Pharmacists can show they are meeting the standards, including:

- during a regulatory inspection discussion, and by demonstrating that the GPhC standards for registered pharmacies are being met
- during a regulatory inspection discussion with another regulatory body: for example, the Care Quality Commission (CQC), Healthcare Improvement Scotland (HIS), or Healthcare Inspectorate Wales (HIW)²
- by referring to the requirements of their role as a Superintendent Pharmacist when carrying out their revalidation work

² This may be the case if the pharmacy has an agreement with a third party to provide a service such as prescribing, then this part of the service may be regulated by the CQC/HIS/HIW.

- through investigation, if a concern is raised with the regulator:
- by a member of staff, a patient, a member of the public, or
- through inspections or other regulatory actions carried out by the Care Quality Commission, Healthcare Improvement Scotland, or Healthcare Inspectorate Wales
- during the regular performance reviews with their line manager
- If a Superintendent Pharmacist does not meet these standards we may investigate concerns about their fitness to practise. This could result in our taking enforcement action against the pharmacy, the pharmacy owner, the Superintendent Pharmacist, or all three. It's important to note that each case is considered individually, and that enforcement action isn't necessarily taken if a standard(s) is not met.

Standard 1: Provide strategic and professional leadership

Superintendent Pharmacists have significant responsibilities and influence over the culture and environment of the pharmacy. This includes setting the strategic direction that is needed to maintain the safe and effective delivery of pharmacy services. Superintendent Pharmacists also provide clinical oversight and professional leadership and management to the pharmacy workforce and support the management and best use of medicines.

Superintendent Pharmacists must:

- **Have a clear vision and strategy to deliver safe and effective pharmacy services**
- **Lead by example, taking responsibility for their own professional growth and development**
- **Be able to influence and work collaboratively with others, to meet the needs of patients and the public, and contribute to shared organisational and system objectives**
- **Make use of research, technology and innovation to enhance safety and improve services, taking into account the needs and available resources of the pharmacy**

Examples of how to meet this standard

Here are some examples of how Superintendent Pharmacists can meet this standard. It is not meant to be a complete list, and should be used as a prompt and not as a checklist:

- Set a positive example for the whole pharmacy workforce including people working towards registration as a pharmacist or pharmacy technician.
- Show leadership in delivering inclusive care and reducing health inequalities – promoting equality of opportunity and challenging discriminatory behaviours – across all interactions with people, colleagues and the wider public.
- Build effective relationships and work in partnership with stakeholders including the pharmacy owner, Responsible Pharmacist and pharmacy workforce.
- Keep up to date with developments in the pharmacy sector and adapt and innovate to meet the changing needs of patients and how pharmacy services are delivered in the context of each individual pharmacy.
- Provide professional support and expert pharmacy advice to colleagues or make sure that the team has access to someone suitable who can provide this.
- Empower staff to exercise their professional judgement in the interests and for the safety of patients and the public.
- Empower all staff to handle challenging situations confidently and professionally, whether that means having the right conversations with managers or knowing when and how to raise a concern.
- Appropriately manage personal and organisational goals, incentives or targets so that their professional judgement, or that of anyone in the pharmacy workforce, is not compromised in the delivery of safe and effective care.
- Demonstrate good decision-making and problem-solving skills and be able to analyse and interpret complex data and information, to positively affect how pharmacy services are delivered.

- Develop, implement and communicate the business continuity plans for individual pharmacies, taking into account the requirements, risks and recovery strategies of the pharmacy.

Standard 2: Develop a team with the right skills, knowledge and experience

The Superintendent Pharmacist is responsible for making sure the whole pharmacy workforce, including unregistered staff, provide safe and effective care and pharmacy services. The skill mix needed at each pharmacy will depend on the needs of patients and the public, which may change over time.

Superintendent Pharmacists need to be aware of these changing needs, as well as changes to the way services are delivered, and develop a workforce with the right skills, knowledge and experience.

Superintendent Pharmacists need to work with the Responsible Pharmacist to continually assess staffing levels and the appropriateness of the skill mix within the context of each individual pharmacy and in line with changing services, workload, and feedback, to ensure patient safety.

Superintendent Pharmacists must:

- **Assess the skills, knowledge and experience needed for the delivery of safe and effective pharmacy services in each of the pharmacies for which they are responsible**
- **Make the best use of resources, and get the right skill mix to deliver safe and effective pharmacy services**
- **Make sure succession and contingency planning is in place for key leadership roles like the Superintendent Pharmacist and Responsible Pharmacist so that they can be filled immediately without impacting patient safety**
- **Value staff and support their health and wellbeing**
- **Create and maintain a culture of equality, diversity and inclusion where:**
 - **people (including staff, patients and the public) are treated as equals, with dignity and respect, and**
 - **staff meet their own legal responsibilities under equality and human rights legislation, while respecting diversity and cultural differences**
- **Encourage and support a culture of continuous learning and development by creating and promoting a culture where staff feel safe to report errors and near misses, and can learn from them**
- **Make sure staff in their organisation know who the Superintendent Pharmacist is and can contact them, if required**

Examples of how to meet this standard

Here are some examples of how Superintendent Pharmacists can meet this standard. It is not meant to be a complete list, and should be used as a prompt and not as a checklist:

- Encourage staff to work collaboratively, including with other healthcare professionals.
- Empower pharmacists and pharmacy technicians to use their professional judgement when supervising and authorising the preparation, assembly, dispensing and the sale or supply of medicines.
- Develop and review organisational workforce policies and procedures – for example, around equality, diversity and inclusion training, such as that on building ‘cultural competence’.
- Develop a safe culture where staff feel confident and supported to:

- challenge behaviours such as discrimination, bullying and harassment, and
- raise concerns, in line with the duty of candour. This is the professional responsibility to be open and honest with patients when something goes wrong with their treatment or care which causes, or has the potential to cause, harm or distress.
- Understand the role and responsibilities involved in undertaking the tutoring, mentoring and supervision of trainee pharmacists and trainee pharmacy technicians.
- Develop recruitment and retention strategies, as well as succession and contingency planning, to manage staffing levels in the context of each individual pharmacy.
- Make sure that staff maintain and develop their competence – for example, through training, carrying out CPD, and coaching and mentoring. Make sure that unregistered pharmacy staff are enrolled on any education and training courses needed to meet the competency level needed for their role.
- Keep training records and up-to-date education and training plans for all staff, including when innovation and new technologies are introduced.
- Allow staff access to appropriate rest breaks, and adequate protected time to carry out training and induction, or to meet development needs.
- Make sure regular development reviews are carried out to identify gaps in skills, knowledge and experience so that necessary actions can be taken, such as developing a training strategy.
- Make sure systems are in place so that the workforce can provide feedback and suggestions – for example, about the need for additional training.
- Identify good practice and share it with all relevant staff.

Standard 3: Delegate responsibly and make sure there are clear lines of accountability

Superintendent pharmacists have wide-ranging responsibilities and often need to delegate to make sure services are delivered safely and effectively. To make sure this happens, Superintendent Pharmacists must delegate responsibly. As senior leaders when delegating, Superintendent Pharmacists are responsible and accountable for making sure lines of accountability are clear. Details of delegation must be recorded, including who is accountable and responsible. Records must be kept up to date and reflect any changes in delegated responsibilities or the staff involved. This will reduce errors and foster a culture of transparency and accountability.

Superintendent Pharmacists must:

- **Provide clarity about the roles, responsibilities and accountabilities of the pharmacy team**
- **Carry out appropriate risk assessments and only delegate to people who have the relevant skills, knowledge and experience, and who are confident about assuming the extra responsibility**
- **Put procedures in place to make sure that when tasks are delegated, the person is:**
 - **competent and has the appropriate education, training, skills and experience – that is, the task is within their scope of practice**
 - **willing to take on the task**
 - **clear about the responsibility and accountability they will be assuming**
 - **clear about the limits and extent of what is being delegated**
- **Communicate effectively and record delegation decisions accurately**

Examples of how to meet this standard

Here are some examples of how Superintendent Pharmacists can meet this standard. It is not meant to be a complete list and should be used as a prompt and not as a checklist:

- Make sure appropriate resources are in place so that staff can carry out tasks effectively.
- Offer training and ongoing support to staff to perform their new responsibilities.
- Allow staff to refuse a delegated task if they have a good reason – for example, if they:
 - feel the task is outside their scope of practice, experience or training, or
 - lack confidence in their ability to assume that level of responsibility.
- Make sure staff are aware of their responsibilities and those of others in the team, and the governance and reporting structure.

Standard 4: Maintain and strengthen governance to ensure safe and effective delivery of pharmacy services

Superintendent Pharmacists must have organisational oversight of the management and operation of the pharmacy, including:

- the management of medicines, medical devices or any other product intended for supply or administration, and
- how all pharmacy services are delivered

These services can include:

- prescribing and clinical services where direct care is provided to patients
- services provided by a third party, and
- unregulated services linked to the pharmacy

A key part of the Superintendent Pharmacist's role is to establish, strengthen and maintain clear governance. This includes setting, maintaining and communicating robust standard operating procedures, policies and procedures – including how authorisations are used and recorded in each pharmacy. The standard operating procedure for authorisations needs to specifically set out the requirement that authorisations must be accurately recorded in writing on the day they are given. You can find more information on authorisation and supervision in the standards for Responsible Pharmacists and in the annex for the standards for pharmacy professionals. **The Royal Pharmaceutical Society has also produced guidance on how to use authorisation.**

Superintendent Pharmacists are also responsible for the effective management of clinical, safety, financial and reputational risk across all the pharmacy services provided. They must anticipate, identify, monitor and respond to risks at both a local and organisation level. Risk assessments must consider the circumstances of each pharmacy, including:

- the staff working in it
- the pharmacy services provided, and
- the activities of third parties, agents or contractors

Superintendent Pharmacists must review and update risk assessments whenever services change, or when new risks are identified.

Superintendent Pharmacists must:

- **Identify and manage the risks associated with providing all pharmacy services, including those provided at a distance**
- **Have oversight of – and make sure that there are standard operating procedures in place for – the effective management of all pharmacy services**
- **Keep and maintain all the necessary records for the safe provision of pharmacy services**
- **Make sure regular reviews/audits are carried out on all the services provided, including any clinical services, and that any recommendations are actioned**
- **Establish and communicate clear lines of reporting**

- **Make sure there is a process to get feedback from staff, patients and the public – which includes feedback about interventions, errors and incidents – and that the process is reviewed regularly and appropriately managed**
- **Manage information to protect the privacy, dignity and confidentiality of patients and the public who receive pharmacy services**
- **Make sure medicines, medical devices and any other products intended for supply or administration are:**
 - **obtained from a reputable source**
 - **safe and fit for purpose**
 - **stored securely**
 - **safeguarded from unauthorised access**
 - **supplied to the patient safely**
 - **disposed of safely and securely**

Examples of how to meet this standard

Here are some examples of how Superintendent Pharmacists can meet this standard. It is not meant to be a complete list and should be used as a prompt and not as a checklist:

- Assess the safety and quality of the pharmacy services provided – including those provided by a third-party business, agent or contractor – by carrying out comprehensive checks, and that this is reviewed regularly.
- Have oversight of – and contribute to – the development and review of policies, making sure the necessary records are kept and are up to date, accurate and stored in line with the information security policy.
- Act on concerns raised under a whistleblowing policy.
- Plan and use resources effectively, considering any financial, audit and budgetary requirements.
- Make sure staff understand the outcome of risk assessments and can contribute to identifying and managing risks.
- Make sure everyone in the pharmacy workforce knows and understands the procedures in place, as well as their own duties and responsibilities and those of others.
- Make sure staff know how to handle private information and have a working knowledge of data protection requirements and General Data Protection Regulations (GDPR).
- Regularly review and act on internal and external complaints and concerns.
- Make sure the details of the Superintendent Pharmacist are visible on any digital platforms used, to help patients and the public know who has oversight for their safety and care when using the pharmacy.
- If providing services at a distance, including online, make sure there are systems in place to confirm the identity of patients requesting medicines and to identify inappropriate requests for medicines.

Standard 5: Make sure the pharmacy environment and premises safeguard the health, safety and wellbeing of patients and the public

The environment – including all the premises, equipment, facilities and digital platforms where pharmacy services are provided – must be safe and fit for purpose, in terms of the services provided and the scale of work carried out. Any associated premises, for example non-registered premises used to store or supply medicines, must also meet these standards.

Superintendent Pharmacists must:

- **Make sure the pharmacy premises, any associated facilities and digital platforms:**
 - are safe and appropriate for delivering services
 - are secure and safeguarded from unauthorised access
 - are accessible to patients and the public
 - protect the privacy, dignity and confidentiality of patients and the public who receive pharmacy services
- **Make sure action is taken to keep the pharmacy premises clean and properly maintained**
- **Make sure digital platforms are clear, accurate and updated regularly**
- **Make sure equipment and facilities are:**
 - obtained from a reputable source
 - safe to use and fit for purpose
 - stored securely
 - safeguarded from unauthorised access
 - appropriately maintained

Examples of how to meet this standard

Here are some examples of how Superintendent Pharmacists can meet this standard. It is not meant to be a complete list and should be used as a prompt and not as a checklist:

- Regularly review the layout, facilities and design of pharmacy premises to make sure they are suitable for the nature of the activities and consider improvements to meet the future needs of patients and the public.
- Make sure there are suitable hygiene and infection-control arrangements in place for specialist services, for example vaccination services and diagnostic testing.
- Provide appropriate training in using equipment and facilities safely, including using specialised equipment and new technology.
- Make sure equipment is calibrated, maintained and serviced regularly in line with the manufacturer's specifications.
- Keep maintenance logs for as long as appropriate.
- Understand how the software and operating systems work, what control systems are built in and whether there are any vulnerabilities.

- Make sure any advertising and promotion of medicines follows guidance set out by the Medicines Healthcare Regulator Agency (MHRA) and Advertising Standards Authority (ASA).
- Make sure staff know what to do if there is an incident affecting the environment or premises, and that there are systems in place to identify and report issues affecting the environment or premises.

Part B: Draft standards for Responsible Pharmacists

Introduction

The Pharmacy (Responsible Pharmacists, Superintendent Pharmacists etc.) Order 2022

When we use the terms ‘pharmacists’ and ‘pharmacy technicians’ in these standards we mean pharmacists and pharmacy technicians registered with the GPhC.

The Pharmacy (Responsible Pharmacists, Superintendent Pharmacists etc.) Order 2022 has given the GPhC the power to set rules and standards that describe the role and professional responsibilities of Responsible Pharmacists, as well as the conduct, ethics and performance expected of them.

These standards – and the accompanying rules for Responsible Pharmacists – apply in England, Scotland and Wales. The Pharmaceutical Society of Northern Ireland are responsible for producing the standards for pharmacists in Northern Ireland.

The rules for Responsible Pharmacists were developed alongside these standards.

One of the aims of these standards is to clarify the relationship between pharmacy owners, Superintendent Pharmacists and Responsible Pharmacists, making clear the accountability of each role. In turn, this will strengthen pharmacy governance to support better use of the skill mix in pharmacy teams. This will allow teams to deliver more clinical services and direct patient care in the community, as well as supporting wider Health and Social Care services and delivering safe and effective care to patients and the public.

Developing these Responsible Pharmacist standards is part of a programme of work to strengthen pharmacy governance. The programme also covers the production of rules for Responsible Pharmacists, professional standards for Chief Pharmacists, and professional standards for Superintendent Pharmacists.

Please note: the standards include reference to the Superintendent Pharmacist. In pharmacy premises without a Superintendent Pharmacist please substitute ‘pharmacy owner’ for ‘Superintendent Pharmacist’.

The role of Responsible Pharmacists

The Medicines Act 1968 was amended in 2009 and the **Medicines (Pharmacies) (Responsible Pharmacist) Regulations 2008** came into force on 1 October 2009. This introduced the role of the Responsible Pharmacist in connection with the lawful running of a retail pharmacy business.

Every registered pharmacy must have a responsible pharmacist present in the pharmacy. This requirement is enshrined in primary legislation – a pharmacy cannot operate without a Responsible Pharmacist being signed in and in charge. The introduction of the Pharmacy (Responsible Pharmacists, Superintendent Pharmacists etc.) Order 2022 does not change that requirement.

Criteria

The owner of a retail pharmacy business must appoint a Responsible Pharmacist, who is a registered pharmacist, to be in charge of the registered pharmacy. The Responsible Pharmacist is responsible for the day-to-day running of the pharmacy business, when it is operating. They are also responsible for securing the safe and effective operation of the pharmacy, so far as concerns the retail sale of medicinal products and the supply of medicinal products in circumstances corresponding to retail sale.

There are legal requirements associated with the Responsible Pharmacist role, including:

- the duty of the Responsible Pharmacist to secure the safe and effective running of the pharmacy
- **displaying a notice** that gives the details of the Responsible Pharmacist on duty
- making and keeping records on the day-to-day running of the pharmacy
- only being responsible for one pharmacy at a time
- the length of time that a Responsible Pharmacist can be absent from the pharmacy.

The Responsible Pharmacist must have organisational oversight of, and be responsible for the day-to-day management of, an individual pharmacy. This includes making sure that all pharmacy related services are delivered so that the health, safety, and wellbeing of patients and the public are safeguarded. Services include:

- the management and supply of medicines and medical devices
- other products intended for supply or administration; and
- the provision of any clinical advice or services

A Responsible Pharmacist can be absent from the pharmacy for a maximum of two hours during the pharmacy's business hours. If there is more than one Responsible Pharmacist during a business day, the total time when any of them is absent must not be more than two hours in a 24-hour period beginning and ending at midnight.

Also, if reasonably practicable, the Responsible Pharmacist must be contactable by other pharmacy staff while they are absent. The Responsible Pharmacist must also be able to return to the pharmacy premises with reasonable promptness, if they consider this is necessary to secure the safe and effective running of the pharmacy business. If this is not possible, arrangements must be made to make sure that another pharmacist is available and contactable to give advice.

A Responsible Pharmacist can only be responsible for one pharmacy premises at a time. They cannot perform this role in any location other than the pharmacy where they are signed in.

Keeping records

The Pharmacy (Responsible Pharmacists, Superintendent Pharmacists etc.) Order 2022 removes responsibility from Responsible Pharmacists to establish, maintain and keep under review operating procedures. This is now the responsibility of Superintendent Pharmacists.

The duty for Responsible Pharmacists to make certain records is also removed. However, Responsible Pharmacists are still expected to keep records on the day-to-day running of the pharmacy. These include, for example, records of interventions and consultations, and controlled drugs records (this is not a complete list). These must then be shared with the Superintendent Pharmacist. It is the

responsibility of the Superintendent Pharmacist to check these records and store them securely and for a prescribed period, and to make sure that any necessary follow-up action is taken.

It is the responsibility of the Superintendent Pharmacist to make sure that all records are properly maintained and are kept for a prescribed period. If there is not a requirement for a Superintendent Pharmacist to be in post, the pharmacy owner is responsible for making sure that all records are correctly maintained and stored.

What to consider before taking on the role of a Responsible Pharmacist

Responsible pharmacists must consider the context and needs of the pharmacy they are responsible for, including:

- how the pharmacy services are delivered – that is, in a traditional in-person way, at a distance, on the internet and so on
- the range of services provided, including those provided by a third party, agent or contractor
- the skill mix and number of staff in the pharmacy team
- the needs of patients and people who use their pharmacy services

Before taking on the role of Responsible Pharmacist, the pharmacist must:

- recognise and understand the extra responsibilities they will have, and
- make sure they can carry out the responsibilities properly while acting within the limits of their professional competence

Pharmacists should consider whether they can meet these standards and have the appropriate competencies and experience to make sure they can fulfil the duties of the Responsible Pharmacist. But they must also consider how they will perform the extra professional and legal responsibilities required of a Responsible Pharmacist.

Authorisation and supervision

The Human Medicines (Authorisation by Pharmacists and Supervision by Pharmacy Technicians) Order 2025 makes changes to the law that:

- allow pharmacists to authorise registered pharmacy technicians to carry out, or supervise others in carrying out, the preparation, assembly, dispensing, sale and supply of medicines
- allow pharmacists to authorise any member of the pharmacy team to hand out checked and bagged prescriptions without a pharmacist being present
- allow pharmacy technicians working in hospital aseptic facilities to take the main responsibility for preparing, assembling and dispensing medicinal products that do not have a special manufacturer's licence

This new legislation around supervision is 'enabling' in its effects, rather than imposing new rules. The changes allow pharmacists, and pharmacy technicians, to be more accessible to patients and the public. They do not change individuals' professional responsibility to work within their competence, whatever the permissions given in legislation.

The changes to the supervision legislation are not about:

- allowing ‘remote’ supervision
- removing the need for pharmacists to carry out appropriate clinical checks linked to the dispensing process. Pharmacists must still carry out the clinical check on a prescription to make sure that it is appropriate for the patient

Under section 10 of the Medicines Act 1968, pharmacists are entitled to carry out, or supervise the carrying out of, tasks of preparation, assembly and dispensing of medicinal products that do not have a manufacturing licence. This applies even if the product is altered in a way that means it is no longer supplied in line with the terms of its product licence, if it has one – as long as what is done is carried out in:

- a registered pharmacy
- a hospital
- a health centre, or
- a care home service

The Human Medicines (Authorisation by Pharmacists and Supervision by Pharmacy Technicians) Order 2025 amends the Medicines Act 1968 to allow a pharmacist to authorise a pharmacy technician to either:

- carry out these tasks, or
- with the permission of the pharmacist, to supervise others to carry out these tasks

Who can authorise

Authorisation can only be made by a registered pharmacist, and must take place in:

- a registered pharmacy
- a hospital
- a care home service, or
- a health centre

Authorisation must also be done with proper regard to patient safety.

The pharmacist remains professionally accountable for any selling or supplying under any authorisation they make, and for ensuring there is proper regard for patient safety.

The authorising pharmacist role is legally distinct from the Responsible Pharmacist and Superintendent Pharmacist roles. (But, in practice, all three roles could be fulfilled by one person in a retail setting). If a pharmacy has a separate Responsible Pharmacist and a Superintendent Pharmacist, only the Responsible Pharmacist or an authorising pharmacist can authorise. This will provide clear lines of accountability and responsibility.

Using authorisation

The pharmacy’s standard operating procedures should include instructions covering the ways any authorisation may be given and recorded.

Authorisation can be:

- general or specific, and contain conditions or restrictions
- given orally or in writing. Our expectation is that authorisation will be provided in writing, with oral authorisation being used only in an emergency. If oral authorisation is used, the authorising pharmacist must make a full written record of the authorisation by the end of the day on which the authorisation is made
- changed or withdrawn by the pharmacist who gives the authorisation

To show that an authorisation has been accepted, it must be signed by both the authorising pharmacist and the person being authorised.

The authorising pharmacist must:

- write a full record of the authorisation on the day that the authorisation is made, in line with the instructions set out in their standard operating procedures
- make sure that the Responsible Pharmacist is informed of all authorisations as they are made, or at the latest by the end of the day on which they are made
- submit written records of all authorisations they have made that day, to the Responsible Pharmacist, and make sure these records are submitted on the same day the authorisations are made
- make sure authorisation is used appropriately. This includes making sure the pharmacy technician being authorised, or in the case of handing out checked and bagged prescription items, any member of pharmacy staff being authorised, is:
 - competent and has the appropriate education, training, skills and experience, that is, the task is within their scope of practice
 - willing to take on the task
 - clear about the responsibility and accountability they will be assuming
 - clear about the limits and extent of what is being authorised

When providing any authorisation, a pharmacist must have proper regard to patient safety. If they do not, it will not make the authorisation invalid, but:

- it may constitute misconduct, and
- we may investigate concerns about their fitness to practise

Every authorisation by a pharmacist, including authorisations to supervise other staff members, must state that the authorised task can only be done at or from the registered pharmacy named in the authorisation.

A pharmacist can authorise a pharmacy technician to carry out a variety of tasks, including:

- preparing or dispensing medicinal products in line with prescriptions supplied after the authorisation is given
- procuring the preparation or dispensing of medicinal products in line with prescriptions supplied after the authorisation is given

A pharmacist can also authorise a registered pharmacy technician to supervise someone else in:

- preparing or dispensing medicinal products in line with prescriptions supplied after the authorisation is given, or
- procuring the preparation or dispensing of medicinal products in line with prescriptions supplied after the authorisation is given

A pharmacy technician must be authorised to supervise another member of staff to do something.

A pharmacist can authorise any member of the pharmacy team, not just pharmacy technicians, to hand out checked and bagged prescription items in the absence of a pharmacist or a pharmacist treated as absent.

Pharmacists must make sure that any member of the pharmacy team who is authorised to carry out or supervise a task has the appropriate knowledge and skills to do this. This responsibility also applies to locum pharmacists. When pharmacy staff are authorised to hand out checked and bagged prescription items, there must be procedures in place for if:

- a patient specifically asks for advice from a pharmacist, or
- a patient mentions or produces information that means they need to talk to a pharmacist

The pharmacy's standard operating procedures and 'sale of medicines protocols' must include clear instructions on the conditions under which:

- a sale or supply should not go ahead, and
- there needs to be a discussion between the patient and the pharmacist

Pharmacy technicians

The pharmacy technician must:

- make sure they have the appropriate education, training, skills and experience for the task(s) being authorised and are working within their scope of practice
- be willing to take on the task(s) being authorised
- be clear about the responsibility and accountability they will be assuming
- be clear about the limits and extent of what is being authorised, and work within this

Pharmacy technicians can say 'no' to an authorisation for several reasons, including if:

- they think the task is outside their scope of practice, or
- they do not feel confident in carrying out the task

The role of the Responsible Pharmacist

The **Responsible Pharmacist** must:

- check that all authorisations made in the pharmacy, during the time they are signed in, are in line with the relevant standard operating procedures
- submit all checked authorisation records to the Superintendent Pharmacist for them to store appropriately

Also, the Responsible Pharmacist can change or withdraw an authorisation given by another pharmacist if they believe:

- it does not meet patient safety obligations, or
- it poses a risk to the safe and effective running of the pharmacy and undermines their ability to meet their responsibility for this

There is more **guidance from the Royal Pharmaceutical Society (RPS) on how to undertake authorisation** and you can see this on their website.

Other points to consider when authorising

Controlled drugs

There are no changes with reference to the handling and dispensing of controlled drugs under the new provisions.

Aseptic facilities

The GPhC does not regulate aseptic facilities. Please see the updated **RPS standards for the Quality Assurance of Aseptic Preparation**. This gives information on the supervision legislation which allows pharmacy technicians in hospital aseptic facilities to take the main responsibility for preparing, assembling and dispensing medicinal products that do not have a manufacturer's 'specials' licence.

Clinical trials

During clinical trials, hospital and health centre pharmacies and dispensaries can assemble medicinal products for investigation without needing a manufacturing licence. The new arrangements for authorisation by pharmacists – and supervision by pharmacy technicians – will apply, in a simplified way, to the assembly of these 'investigational' medicinal products.

Pharmacist who is absent or treated as absent

If a pharmacist is going to be absent, or treated as absent, and they have dispensed or supervised a checked prescription which is then ready for sale or supply at or from a registered pharmacy, the pharmacist can authorise any member of the pharmacy staff to make the final supply of that medicine to or for a patient. The **RPS has produced guidance on how to undertake authorisation** and you can see this on their website.

A pharmacist is treated as being absent from premises that are a registered pharmacy if they are at the pharmacy, but:

- not available to intervene in the transaction in question, or
- not in a position to intervene in the transaction in question

For example, they may be in a consultation room with a patient.

The standards for Responsible Pharmacists

The standards for Responsible Pharmacists set out their professional responsibilities, as well as the knowledge, conduct, ethics and performance required of a Responsible Pharmacist if they are to support the pharmacy, and its staff, in delivering safe and effective pharmacy services.

The Responsible Pharmacist is responsible for the day-to-day running of the pharmacy business, when it is operating. They are also responsible for securing the safe and effective operation of the pharmacy, so far as concerns the retail sale of medicinal products and the supply of medicinal products in circumstances corresponding to retail sale.

Responsible pharmacists must meet the following standards:

- 1. Prioritise patient safety**
- 2. Provide the leadership and management needed to ensure the safe and effective operation of the pharmacy**
- 3. Make sure, if using authorisation, to authorise responsibly and make clear the lines of accountability**
- 4. Maintain and strengthen governance to ensure safe and effective delivery of pharmacy services**

The standards are designed to be ‘outcome focused’. This is to acknowledge the different circumstances of individual registered pharmacies. We have provided examples of how the standards can be met in practice, but we accept that there may be multiple ways of achieving each outcome. We want to give Responsible Pharmacists the flexibility to exercise their professional judgement in the interests of patients and the public. Responsible Pharmacists must decide how to meet these standards and their other legal and professional responsibilities, while taking account of the requirements of the pharmacy they are responsible for.

The standards are also a statement of what patients and those working with Responsible Pharmacists can expect of them. They are essential in making sure that patients and the public receive safe and effective care.

Applying the standards

The standards for Responsible Pharmacists are all equally important and must be met during the times when the registered pharmacist is signed in as the Responsible Pharmacist.

Responsible Pharmacists are directly accountable for meeting the standards set out in this document and must be able to justify their conduct and the decisions they make. However, they also share responsibility with the pharmacy owner and Superintendent Pharmacist for ensuring:

- the safe and effective running of the pharmacy, and
- safe provision of pharmacy services

It is therefore vital that pharmacy owners, Superintendent Pharmacists and pharmacy staff are familiar with these standards and that they work together to support the Responsible Pharmacist in performing their role(s) and responsibilities. This is to ensure patients and the public are kept safe when using pharmacy services.

Alongside these standards, Responsible Pharmacists must also meet any relevant legislation, and the GPhC’s **standards for pharmacy professionals**. They should also be familiar with:

- the GPhC's **standards for registered pharmacies**
- any supporting guidance published on our website, and
- guidance produced by other relevant regulatory bodies or pharmacy organisations, such as the Care Quality Commission, Healthcare Improvement Scotland, Healthcare Inspectorate Wales, and the Medicines and Healthcare products Regulatory Agency

Responsible Pharmacists should also keep up to date with and apply national guidance and best practice guidance. Following guidance is an important part of making sure that our standards are met.

There may be times when Responsible Pharmacists are faced with conflicting legal and professional responsibilities. Or they may face complex situations that involve having to balance competing priorities. Both the standards for pharmacy professionals and these standards provide a framework to help and support Responsible Pharmacists to use their professional judgement and make difficult decisions. We expect Responsible Pharmacists to act in the best interests of patients and the public, and to consider these standards, their legal duties and any relevant guidance when making decisions, including those covering medicines legislation.

How to demonstrate that the standards are being met

There are several ways that Responsible Pharmacists can show that they are meeting the standards, including:

- during a regulatory inspection discussion, and by demonstrating that the GPhC standards for pharmacy premises are being met
- during a regulatory inspection discussion with another regulatory body: for example, the Care Quality Commission (CQC), Healthcare Improvement Scotland (HIS), or Healthcare Inspectorate Wales (HIW)³
- by referring to the requirements of their role as a Responsible Pharmacist when carrying out their revalidation work
- through investigation, if a concern is raised with the pharmacy or the regulator:
 - by a member of staff, a patient or a member of the public, or
 - through inspections or other regulatory actions carried out by the Care Quality Commission, Healthcare Improvement Scotland, or Healthcare Inspectorate Wales
- during the regular performance reviews with their line manager.

If a Responsible Pharmacist does not meet these standards it could result in the GPhC taking enforcement action. This could be against the pharmacy, the pharmacy owner, the Superintendent Pharmacist, the Responsible Pharmacist, or all four. It is important to note that each case is considered individually, and that enforcement action is not necessarily taken if a standard is not met.

³ This may be the case if the pharmacy has an agreement with a third party to provide a service such as prescribing, then this part of the service may be regulated by the CQC/HIS/HIW.

Standard 1: Prioritise patient safety

As the person in charge of the day-to-day running of a pharmacy, Responsible Pharmacists have significant responsibilities for and influence over the culture, governance and environment of the pharmacy. This includes making sure that:

- the standard operating procedures are followed
- registered staff meet the standards for pharmacy professionals, and
- all staff maintain the safe and effective delivery of pharmacy services

The Responsible Pharmacist must:

- **Make patient safety a priority and take action to protect the wellbeing of patients and the public, including supporting staff to report incidents, near misses and errors**
- **Make sure that all pharmacy staff are aware of, and meet, all relevant legislation and standards, as well as following the standards and guidance set by other regulators and membership bodies**
- **Be clear and share with the team, the vision and strategy needed to safeguard the health, safety and wellbeing of patients and the public by managing and delivering safe and effective pharmacy services, including clinical advice and services, the management and supply of medicines and medical devices and any other product intended for supply or administration**
- **Make sure that all pharmacy staff are aware of, and follow, the standard operating procedures**
- **Work with all pharmacy staff to meet the needs of patients, including managing information to protect the privacy, dignity and confidentiality of patients and the public who receive pharmacy services**

Examples of how to meet this standard

Here are some examples of how Responsible Pharmacists can meet this standard. It is not meant to be a complete list, and should be used as a prompt and not as a checklist:

- Make sure staff understand their impact and the wider impact of pharmacy on patients.
- Make sure that patients know how to raise a concern or complaint, and then deal with any complaints or concerns in an appropriate and timely way.
- Provide opportunities for patients to give feedback.
- Embrace research, technology and innovation to enhance safety and improve services.
- Work with the Superintendent Pharmacist/pharmacy owner to adapt and innovate to meet the changing needs of patients, and changes to how services are delivered at, or from, the pharmacy.
- Provide professional support and expert pharmacy advice to colleagues.
- Empower staff to use their professional judgement in the interests of patients and the public.
- Appropriately manage personal or organisational goals, incentives or targets so that their own professional judgement – or that of the pharmacy team – is not compromised, and that safe and effective care can continue to be delivered.

- Set an example for the whole team, including people who are working towards registration as a pharmacist or pharmacy technician.
- Use interventions such as medication safety bulletins, quality improvement schemes and barcode scanning technology to ensure medication safety.

Standard 2: Provide the leadership and management needed to ensure the safe and effective operation of the pharmacy

During the time the Responsible Pharmacist is signed in, they are responsible for making sure the pharmacy team provide safe and effective care and pharmacy services. This includes registered pharmacy professionals and unregistered staff. The skill mix needed at each pharmacy will depend on the needs of patients and the public, which may change over time. Responsible Pharmacists need to be aware of these changing needs – as well as changes to the way services are delivered – and must develop a team with the right skills, knowledge and experience. Responsible Pharmacists need to work with the Superintendent Pharmacist or pharmacy owner to continually assess staffing levels and the appropriateness of the skill mix. This needs to be done within the context of each individual pharmacy and in line with changing services, workload and feedback, to ensure patient safety.

The Responsible Pharmacist must:

- **Make sure that the notice with their details is displayed in the pharmacy. In online pharmacies this can be done in various ways, including on the digital platform associated with the pharmacy, or it can be communicated to people when medicines are supplied**
- **Work collaboratively with the Superintendent Pharmacist (if there is one), the pharmacy owner and the pharmacy team, to contribute to:**
 - **shared organisational and system objectives**
 - **governance meetings, and**
 - **third-party meetings**
- **Be aware of the skill mix needed by the pharmacy team to deliver safe and effective pharmacy services in their setting, and work with the Superintendent Pharmacist to put this in place**
- **Support and value staff, and consider their safety, health and wellbeing**
- **Create and maintain a culture of equality, diversity and inclusion where:**
 - **people (including staff, patients and the public) are treated as equals, with dignity and respect, and**
 - **staff meet their own legal responsibilities under equality and human rights legislation, while respecting diversity and cultural differences**
- **Encourage and support a culture of continuous learning and development where staff feel safe to report errors and near misses, and can learn from them**
- **Lead by example, taking responsibility for their own professional growth and development**

Examples of how to meet this standard

Here are some examples of how Responsible Pharmacists can meet this standard. It is not meant to be a complete list, and should be used as a prompt and not as a checklist:

- Make sure that gaps in the skills, knowledge and experience of the pharmacy team are identified and that the necessary actions are taken to close those gaps.
- Make sure staff have regular development reviews and that any development needs are met.
- Encourage staff to work collaboratively, including with other healthcare professionals.

- Understand their role and responsibilities in tutoring and supervising trainee pharmacists and trainee pharmacy technicians.
- Make sure that within three months of starting in their role, any unregistered pharmacy staff are enrolled on the education and training courses needed to meet the competency level required for their role.
- Help to improve the experience and healthcare outcomes of patients and members of the public who use their pharmacy services.
- Work with the Superintendent Pharmacist to make sure systems are in place so that the team can provide feedback – for example if asked to perform training, or asked to carry out activities outside the scope of their normal ones.
- Develop a culture where staff feel confident about raising concerns, in line with the duty of candour. This is the professional responsibility to be open and honest with patients when something goes wrong with their treatment or care which causes, or has the potential to cause, harm or distress.
- Identify good practice and guidance and share with all relevant staff.
- Demonstrate good decision-making skills that positively affect how pharmacy services are delivered, and solve problems in a timely way.
- Keep up to date with developments in the pharmacy sector and apply any relevant learning to their organisation.
- Empower staff to handle challenging situations confidently and professionally, whether that means having the right conversations with managers or knowing when and how to raise a concern.

Standard 3: Authorise responsibly and make sure there are clear lines of accountability

Pharmacists, including Responsible Pharmacists, now have the option to authorise some tasks to be done by registered pharmacy technicians. When authorisation is used appropriately it can:

- help manage workload
- free up pharmacists' time for clinical work
- support pharmacy technicians in expanding their scope of practice, and
- provide development opportunities for the team

When authorisation is used, the Responsible Pharmacist must:

- **Make sure that authorising pharmacists and the staff being authorised are aware of – and follow – the relevant standard operating procedures**
- **Make sure authorisation is used appropriately. This includes making sure the pharmacy technician being authorised is:**
 - **competent and has the appropriate education, training, skills and experience – that is, the task is within their scope of practice**
 - **willing to take on the task**
 - **clear about the responsibility and accountability they will be assuming**
 - **clear about the limits and extent of what is being authorised**
- **Make sure authorisation records are accurate and complete**

All authorising pharmacists are responsible and accountable for the authorisations they make. If tasks are authorised to an appropriate person, such as a pharmacy technician, the responsibility and accountability for carrying out the task then rests with the pharmacy technician. However, the Responsible Pharmacist must be aware of all authorisations given by other registered pharmacists which are in force during the time that they are signed in as the Responsible Pharmacist.

Details of all authorisations, including those given orally, must be recorded accurately in writing and kept for five years. It is the responsibility of the Superintendent Pharmacist to put systems in place to record authorisation decisions and to maintain that system. However, it is the responsibility of the authorising pharmacist and the Responsible Pharmacist (if they are not the authorising pharmacist) to make sure that the records made are complete and accurate. This will reduce errors and foster a culture of transparency and accountability. It is the responsibility of the Responsible Pharmacist to make sure that all authorising pharmacists:

- are aware of the relevant standard operating procedures
- know how to authorise correctly
- know what can or can't be authorised
- know that the appropriate records must be made and submitted to the Responsible Pharmacist for checking by the end of the day on which the authorisation is made

Examples of how to meet this standard

Here are some examples of how Responsible Pharmacists can meet this standard. It is not meant to be a complete list and should be used as a prompt and not as a checklist:

- Successfully manage and lessen clinical, safety and reputational risk.
- Allow pharmacy technicians to use their professional judgement when they have been authorised to undertake certain tasks such as the preparation, assembly, dispensing and sale or supply of medicine.
- Make sure staff are aware of their responsibilities and those of others in the team, and the reporting structure.
- Make sure that staff maintain and develop their competence: for example, through training, CPD events, coaching and mentoring.
- Provide appropriate resources so that staff can carry out authorised responsibilities effectively.
- With the Superintendent Pharmacist, monitor and review the safety of authorisations, including incidents, errors and near misses.

Standard 4: Maintain and strengthen governance to ensure safe and effective delivery of pharmacy services

When a Responsible Pharmacist is signed in, they must have organisational oversight of the management of the pharmacy. This includes how pharmacy services are delivered at or from the pharmacy, and how any associated risks are managed. Having strong, clear governance in place is essential to provide safe, effective and good-quality services to patients and the public, and to safeguard their health, safety and wellbeing.

Responsible Pharmacists must:

- **Maintain accurate records on the pharmacy's day-to-day operations to ensure transparency and accountability**
- **Oversee and ensure compliance with legal and regulatory requirements**
- **Have oversight of, and make sure that there is effective management of, all pharmacy services and staff working at or from the pharmacy for which they are responsible**
- **Establish and communicate clear lines of reporting, including how to escalate major incidents, concerns and patient safety risks to the Superintendent Pharmacist or pharmacy owner**
- **Make sure staff know, understand and follow the pharmacy's clinical governance framework**

Examples of how to meet this standard

Here are some examples of how Responsible Pharmacists can meet this standard. It is not meant to be a complete list and should be used as a prompt and not as a checklist:

- Take part in audits and quality improvement projects, and work with the Superintendent Pharmacist to make sure the team are aware of and participate in them
- Depending on the services provided by the pharmacy, maintain accurate records of the day-to-day business carried on in the pharmacy. This could include dispensing and clinical records
- Develop a process to get feedback from staff and patients, which includes feedback about interventions, errors and incidents. They should make sure that the process is:
 - reviewed regularly
 - appropriately managed, and
 - shared with the Superintendent Pharmacist, or the pharmacy owner if there is no Superintendent Pharmacist
- Make sure the Superintendent Pharmacist is aware of any concerns raised under the pharmacy's whistleblowing policy
- Make sure everyone in the pharmacy team knows and understands the procedures in place in the pharmacy, and their own duties and responsibilities and those of other members of the team
- Maintain the systems which are in place to anticipate, identify and respond to risks
- Work with the Superintendent Pharmacist to make sure risk assessments are carried out that are specific to the pharmacy and team, and that all relevant staff are consulted and involved

- Contribute to risk assessments and make sure they are reviewed when needed – for example, if any changes take place
- Build effective relationships and work in partnership with others, including the pharmacy owner, Superintendent Pharmacist and pharmacy team
- Work with the Superintendent Pharmacist to contribute to the development and review of policies
- If providing services at a distance, including online, make sure that staff use the systems in place to confirm the identity of patients requesting medicines
- Regularly review and share with the Superintendent Pharmacist all internal and external complaints and concerns.

Part C: Draft rules for Responsible Pharmacists

The Medicines (Pharmacies) (Responsible Pharmacist) Rules 2026

Preamble

Made: [Date]

Laid before Parliament: [Date]

Laid before the Scottish Parliament: [Date]

Coming into force: [Date]

At the Council Chamber, Whitehall on the [Date]

By the Lords of His Majesty's Most Honourable Privy Council

The General Pharmaceutical Council has made the Medicines (Pharmacies) (Responsible Pharmacists) Rules 2026, which are set out in the Schedule to this Order, in exercise of the powers conferred by sections 72A(6) – (7A) and 84A(1) of the Medicines Act 1968.

In accordance with section 84A(4) of that Act, the General Pharmaceutical Council published draft rules and invited representations to be made to it about the draft by the Secretary of State, the Scottish Ministers, the Welsh Minister and such other persons appearing to it appropriate to consult about the draft

By virtue of section 84A(5) of that Act, such rules cannot come into force until approved by order of the Privy Council.

The Privy Council, having taken these Rules into consideration, are pleased and do approve them.

1. Citation and commencement

1. These Rules may be cited as the Medicines (Pharmacies) (Responsible Pharmacist) Rules 2026 and come into force on [*insert date 2026*].

2. Interpretation

2. In these Rules —

"the Act" means the Medicines Act 1968;

"the Order" means the Pharmacy Order 2010/231;

"pharmacist" means a *"registered pharmacist"* as defined in article 3(1) of the Order;

"pharmacy staff" means any pharmacist, pharmacy technician, or any other person who is working at or from the premises in question in a role connected to the retail pharmacy business;

"pharmacy technician" means a *"registered pharmacy technician"* as defined in article 3(1) of the Order;

"premises" means the premises at or from which the pharmacy business is carried on;

“retail pharmacy business” means the business in respect of which the responsible pharmacist has a duty under section 72A(1) of the Act;

3. Absence of the responsible pharmacist

- (1) The maximum period for which the responsible pharmacist may be absent from the premises is two hours during the pharmacy’s business hours.
- (2) If there is more than one responsible pharmacist during the pharmacy’s business hours, the maximum period in paragraph (1) relates to the combined total period of absence for all of them.
- (3) The responsible pharmacist must not be absent from the premises unless the arrangements in paragraph (4) or (5) have been put in place.
- (4) Where it is reasonably practicable for the responsible pharmacist to be contactable throughout the period of absence, arrangements must ensure that the responsible pharmacist can —
 - (a) be contacted by other pharmacy staff throughout the period of absence; and
 - (b) return to the premises with reasonable promptness if, in the opinion of the responsible pharmacist, this is necessary to secure the safe and effective running of the pharmacy business.
- (5) For any period of absence where it is not reasonably practicable to put in place the arrangements specified in paragraph (4), arrangements must ensure that another pharmacist is both available and contactable to provide advice to pharmacy staff.
- (6) The retail sale of medicinal products on a general sale list at or from the premises may continue during the period of absence of the responsible pharmacist.
- (7) In this rule —

“business hours” means the period during which the pharmacy business is operational on any day;

“day” means the 24-hour period beginning and ending at midnight.

4. The Pharmacy Record

- (1) The particulars which must be included in the pharmacy record are—
 - (a) the responsible pharmacist’s name;
 - (b) any number associated with the responsible pharmacist’s registration in the register maintained under article 19 of the Pharmacy Order 2010;
 - (c) the date and time at which the responsible pharmacist became the responsible pharmacist;
 - i) the date and time at which the responsible pharmacist ceased to be the responsible pharmacist; and
 - ii) in relation to any absence of the responsible pharmacist from the premises on a day on which they were the responsible pharmacist —
 - iii) the date of the absence;
 - iv) the time at which the absence commenced; and

- v) the time at which the responsible pharmacist returned to the premises.
- (2) The pharmacy record must be kept—
 - (a) in writing;
 - (b) in electronic form; or
 - (c) in both forms.
 - (3) The pharmacy record must be available at the premises for inspection by—
 - (a) the person carrying on the pharmacy business;
 - (b) the superintendent pharmacist, if any;
 - (c) the responsible pharmacist;
 - (d) pharmacy staff; or
 - (e) an inspector.
 - (4) The person carrying on the pharmacy business must secure that the pharmacy record is preserved for a period of not less than five years commencing on—
 - (a) in the case of a record in electronic form, the day on which it is created;
 - (b) in the case of a written record, the last day to which the record relates.
 - (5) In this rule –
 - "inspector"* means an inspector as defined at article 3(1) of the 2010;
 - "pharmacy record"* means the record referred to in section 72A(4) of the Act.

5. Authorisations

- (1) A responsible pharmacist must take such steps as are necessary to ensure they are aware of any authorisations:
 - (a) given to a pharmacy technician which are in force for the duration of the period they hold the role of responsible pharmacist at the premises;
 - (b) given to any other member of pharmacy staff in relation to the sale or supply of medicinal products dispensed by or under the supervision of a pharmacist who is absent or treated as absent
- (2) Where the responsible pharmacist forms the view, with due regard to patient safety, that any authorisation given to a pharmacy technician may adversely impact the safe and effective running of the retail pharmacy business, they may vary or withdraw such authorisation.
- (3) Where the responsible pharmacist forms the view, with due regard to patient safety, that any authorisation given to a member of pharmacy staff in relation to the sale or supply of medicinal products dispensed by or under the supervision of a pharmacist who is absent or treated as absent may adversely impact the safe and effective running of the retail pharmacy business, they may vary or withdraw such authorisation.
- (4) Where the responsible pharmacist varies or withdraws an authorisation they must:

- (a) in relation to an authorisation given to a pharmacy technician, inform the pharmacy technician of that as soon as reasonably practicable;
 - (b) in relation to the sale or supply of medicinal products dispensed by or under the supervision of a pharmacist who is absent or treated as absent, inform the member of pharmacy staff of that as soon as reasonably practicable.
- (5) In this rule –
- "authorisation"* means an authorisation given under sections 10(1A)(b) and 10A of the Act to a pharmacy technician, or an authorisation given under regulation 220B(1)(b) of the Human Medicines Regulations 2012.

Explanatory Note

These Rules make provision about the duties of responsible pharmacists who are required, by virtue of section 72A of the Medicines Act 1968 (the Act), to secure the safe and effective running of a pharmacy business at the premises from which it is carried on.

Rule 3(1) and (2) specifies the maximum permitted period that a responsible pharmacist may be absent from the premises during the pharmacy's business hours. Rule 3(3) provides that certain arrangements must be made in the event of the responsible pharmacist's absence. Rule 3(4) provides that where it is reasonably practicable for the responsible pharmacist to be contactable throughout the period of absence, arrangements must cover both being contactable during the period of absence and return to the premises with reasonable promptness if necessary. Rule 3(5) then provides that arrangements must cover another pharmacist being available and contactable if it is not practicable to make arrangements under rule 3(4). Rule 3(6) provides expressly that the retail sale of medicinal products on a general sale list may continue from the premises during the period of absence.

Rule 4 specifies the record which the responsible pharmacist must make and keep, which persons must be allowed to inspect the record and the period for which the person carrying on the pharmacy business must keep the record.

Rule 5 sets out the duty of a responsible pharmacist to make themselves aware of any authorisations given to pharmacy technicians under section 10(1A)(b) and 10A of the Act or pharmacy staff regulation 220B(1)(b) of the Human Medicines Regulations 2012. Where the responsible pharmacist considers an authorisation may adversely impact the safe and effective running of the pharmacy business they may vary or withdraw such authorisation and where they do so they must communicate that to the pharmacy technician.

An impact assessment has not been produced for this instrument as only a negligible impact on the private or voluntary sectors is foreseen.

Part D: Draft annex for the standards for pharmacy professionals on authorisation and supervision

Introduction

The Human Medicines (Authorisation by Pharmacists and Supervision by Pharmacy Technicians) Order 2025 sets out legislative changes that:

- allow pharmacists to authorise registered pharmacy technicians to carry out, or supervise others carrying out, the preparation, assembly, dispensing, sale and supply of medicines
- allow pharmacists to authorise any member of the pharmacy team to hand out checked and bagged prescriptions without a pharmacist being present
- allow pharmacy technicians working in hospital aseptic facilities to take the main responsibility for preparing, assembling and dispensing medicinal products that do not have a special manufacturer's licence.

The legislation changes are 'enabling' in their effects, rather than imposing new rules. The changes allow pharmacists, and pharmacy technicians, to be more accessible to patients and the public. They do not change individuals' professional responsibility to work within their competence whatever the permissions given in legislation.

The changes to the supervision legislation are not about:

- allowing remote supervision by a Responsible Pharmacist
- removing the need for pharmacists to carry out appropriate clinical checks linked to the dispensing process. Pharmacists must still carry out the clinical check on a prescription to make sure that it is appropriate for the patient

Under section 10 of the Medicines Act 1968, pharmacists are entitled to carry out, or supervise the carrying out of, tasks of preparation, assembly and dispensing of medicinal products that do not have a manufacturing licence. This applies even if the product is altered in a way that means it is no longer supplied in line with the terms of its product licence – if it has one – as long as what is done is carried out in:

- a registered pharmacy
- a hospital
- a health centre, or
- a care home service

The Human Medicines (Authorisation by Pharmacists and Supervision by Pharmacy Technicians) Order 2025 amends the Medicines Act 1968 to allow a pharmacist to authorise a pharmacy technician to either:

- carry out these tasks, or
- with the permission of the pharmacist, to supervise others to carry out these tasks

Who can authorise

Authorisation can only be made by a registered pharmacist, and must take place in:

- a registered pharmacy
- a hospital
- a care home service, or
- a health centre

Authorisation must also be done with proper regard to patient safety.

The pharmacist remains professionally accountable for any selling or supplying under any authorisation they make, and for ensuring there is proper regard for patient safety.

The authorising pharmacist role is legally distinct from the Responsible Pharmacist and Superintendent Pharmacist roles. (But, in practice, all three roles could be fulfilled by one person in a retail setting). If a pharmacy has both a Responsible Pharmacist and a Superintendent Pharmacist, only the Responsible Pharmacist or an authorising pharmacist can authorise. This will provide clear lines of accountability and responsibility.

Using authorisation

The pharmacy's standard operating procedures should include instructions covering the ways any authorisation may be given and recorded.

Authorisation can be:

- general or specific, and contain conditions or restrictions
- given orally or in writing. Our expectation is that authorisation will be provided in writing, with oral authorisation being used only in an emergency. If oral authorisation is used, the authorising pharmacist must make a full written record of the authorisation by the end of the day on which the authorisation is made
- changed or withdrawn by the pharmacist who gives the authorisation

To show that an authorisation has been accepted, it must be signed by both the authorising pharmacist and the person being authorised.

The authorising pharmacist must:

- write a full record of the authorisation on the day that the authorisation is made, in line with the instructions set out in their standard operating procedures
- make sure that the Responsible Pharmacist is informed of all authorisations as they are made, or at the latest by the end of the day on which they are made
- submit written records of all authorisations they have made that day, to the Responsible Pharmacist, and make sure these records are submitted on the day on which the authorisation is made

- make sure authorisation is used appropriately. This includes making sure the pharmacy technician being authorised, or in the case of handing out checked and bagged prescriptions, any member of pharmacy staff being authorised, is:
 - competent and has the appropriate education, training, skills and experience – that is, the task is within their scope of practice
 - willing to take on the task
 - clear about the responsibility and accountability they will be assuming
 - clear about the limits and extent of what is being authorised

When providing any authorisation, a pharmacist must have proper regard to patient safety. If they do not, it will not make the authorisation invalid, but:

- it may constitute misconduct, and
- we may investigate concerns about their fitness to practise

Every authorisation by a pharmacist, including authorisations to supervise other staff members, must state that the authorised task can only be done at or from the registered pharmacy named in the authorisation.

A pharmacist can authorise a pharmacy technician to carry out a variety of tasks, including:

- preparing or dispensing medicinal products in line with prescriptions supplied after the authorisation is given
- procuring the preparation or dispensing of medicinal products in line with prescriptions supplied after the authorisation is given

A pharmacist can also authorise a registered pharmacy technician to supervise someone else in:

- preparing or dispensing medicinal products in line with prescriptions supplied after the authorisation is given, or
- procuring the preparation or dispensing of medicinal products in line with prescriptions supplied after the authorisation is given

A pharmacy technician must be authorised to supervise another member of staff to do something.

A pharmacist can authorise any member of the pharmacy team, not just pharmacy technicians, to hand out checked and bagged prescription items in the absence of a pharmacist or a pharmacist treated as absent.

Pharmacists must make sure that any member of the pharmacy team who is authorised to carry out or supervise a task has the appropriate knowledge and skills to do this. This responsibility also applies to locum pharmacists. When pharmacy technicians are authorised to hand out checked and bagged prescriptions, there must be procedures in place for if:

- a patient specifically asks for advice from a pharmacist, or
- a patient mentions or produces information that means they need to talk to a pharmacist

The pharmacy's standard operating procedures and 'sale of medicines protocols' must include clear instructions on the conditions under which:

- a sale or supply should not go ahead, and

- there needs to be a discussion between the patient and the pharmacist

Pharmacy technicians

The pharmacy technician must:

- make sure they have the appropriate education, training, skills and experience for the task(s) being authorised and are working within their scope of practice
- be willing to take on the task(s) being authorised
- be clear about the responsibility and accountability they will be assuming
- be clear about the limits and extent of what is being authorised, and work within this

Pharmacy technicians can say “no” to an authorisation for several reasons, including if:

- they think the task is outside their scope of practice, or
- they do not feel confident in carrying out the task

The role of the Responsible Pharmacist

The Responsible Pharmacist must:

- check that all authorisations made in the pharmacy, during the time they are signed in, are in line with the relevant standard operating procedures
- submit all checked authorisation records to the Superintendent Pharmacist for them to store appropriately

Also, the Responsible Pharmacist can change or withdraw an authorisation given by another pharmacist if they believe:

- it does not meet patient safety obligations, or
- it poses a risk to the safe and effective running of the pharmacy and undermines their ability to meet their responsibility for this

There is more **guidance from the Royal Pharmaceutical Society (RPS) on how to undertake authorisation** and you can see this on their website.

Other points to consider when authorising

Controlled drugs

There are no changes with reference to the handling and dispensing of controlled drugs under the new provisions.

Aseptic facilities

The GPhC does not regulate aseptic facilities. Please see the updated **RPS standards for the Quality Assurance of Aseptic Preparation Services**. This gives information on the supervision legislation which allows pharmacy technicians in hospital aseptic facilities to take the main responsibility for preparing, assembling and dispensing medicinal products that do not have a manufacturer’s ‘specials’ licence.

Clinical trials

During clinical trials, hospital and health centre pharmacies and dispensaries can assemble medicinal products for investigation without needing a manufacturing licence. The new arrangements for authorisation by pharmacists – and supervision by pharmacy technicians – will apply, in a simplified way, to the assembly of ‘investigational’ medicinal products.

Pharmacist who is absent or treated as absent

If a pharmacist is going to be absent, or treated as absent, and they have dispensed or supervised a checked prescription which is then ready for sale or supply at or from a registered pharmacy, the pharmacist can authorise any member of the pharmacy staff to make the final supply of that medicine to or for a patient. **The RPS has produced guidance and you can see this on their website.**

A pharmacist is treated as being absent from premises that are a registered pharmacy if they are at the pharmacy, but:

- not available to intervene in the transaction in question, or
- not in a position to intervene in the transaction in question

For example, they may be in a consultation room with a patient.



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