Revising the education and training requirements for pharmacist independent prescribers



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### About the GPhC

#### Who we are

We regulate pharmacists, pharmacy technicians and pharmacies in Great Britain.

We work to assure and improve standards of care for people using pharmacy services.

#### What we do

Our role is to protect the public and give them assurance that they will receive safe and effective care when using pharmacy services.

We set standards for pharmacy professionals and pharmacies to enter and remain on our register.

We ask pharmacy professionals and pharmacies for evidence that they are continuing to meet our standards, and this includes inspecting pharmacies.

We act to protect the public and to uphold public confidence in pharmacy if there are concerns about a pharmacy professional or pharmacy on our register.

Through our work we help to promote professionalism, support continuous improvement and assure the quality and safety of pharmacy.

### Foreword

As the regulator for pharmacists, pharmacy technicians and registered pharmacies, the GPhC sets standards for education and training. This supports two of our strategic aims:

- to deliver an adaptable standards framework that meets public and professional needs that are changing quickly, and
- to drive improvements in pharmacy care by modernising how we regulate education and training

There have been significant changes in pharmacy education and training in the last 18 months. These include:

- new initial education and training standards for pharmacists
- the introduction of a foundation training year to replace pharmacist pre-registration training, and
- new education and training standards for pharmacy support staff

Over this time it has been clear that pharmacist independent prescribing is becoming more and more important in supporting the delivery of pharmacy services. This has led to one of the major changes in the new standards for pharmacists. Once this has been implemented in full, it will mean that all trainees will become independent prescribers at the point they register. The proposed change put forward in this consultation arises from this development. It also supports a wider aim to increase the number of pharmacist independent prescribers,

and reduce the time it takes to become one, while still ensuring patient safety.

The present standards for education and training of pharmacist independent prescribers were agreed in 2019. This consultation focuses on two specific aspects of the entry requirements:

- the time requirement of two years of clinical practice before training as a pharmacist independent prescriber on a free-standing training course, and
- the requirement for applicants to have experience in a specific clinical or therapeutic area of practice

Through this consultation, we are asking for your views on the proposed changes.



**Nigel Clarke** Chair



**Duncan Rudkin**Chief Executive and Registrar

### The consultation process

The consultation will run for eight weeks and will close on 23 November 2021. During this time, we welcome feedback from individuals and organisations. We will send this document to a range of stakeholders, including: pharmacy professionals, pharmacist prescribers, independent prescribing course providers, pharmacy owners, patient representative bodies, the statutory education bodies and others with an interest in this area.

#### Our report on this consultation

Once the consultation period ends, we will analyse the responses we receive. Our governing council will receive the analysis at a meeting in the first half of 2022. It will take the responses into account when considering the final version of the education and training standards for pharmacist independent prescribers.

We will also publish a summary of the responses and an explanation of the decisions taken. You will be able to see this on our website **www.pharmacyregulation.org**.

#### Why we consult

We have to consult before we set any standards or requirements under the Pharmacy Order 2010. We will also consult, when we need to, to make sure we carry out our statutory functions 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, and 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 **filling in the online questionnaire.** 

If you want to submit a response by email, please send it to us at **consultations@pharmacyregulation.org.** 

#### Other formats

Please contact us at

communications@pharmacyregulation.or gif you would like a copy of the consultation survey in another format (for example, in larger type or in a different language).

### Comments on the consultation process itself

If you have concerns or comments about the consultation process itself, please send them to: **feedback@pharmacyregulation.org**, or post them to us at:

Governance team General Pharmaceutical Council 25 Canada Square London E14 5LQ

<u>Please do not send consultation responses</u> to this address.

### Background

Independent prescribers are healthcare professionals able to prescribe drugs, medicines and appliances without consulting another prescriber. In pharmacy, this means a pharmacist can prescribe a medicine to a patient without consulting, say, a doctor. Pharmacist independent prescribing was introduced in 2006, with pharmacists able to have their entry on our register 'annotated' to show they are an independent subscriber (IP). Since then the number of pharmacist independent prescribers has increased. There are now 11,698 on the register, which is just under 20% of pharmacists registered with the GPhC.

At present, pharmacists can only enrol on courses to become independent prescribers if they meet a number of conditions. These include:

- having worked for at least two years in a UK practice setting after registration, and
- having relevant experience in a specific area of clinical or therapeutic practice in which they will base their prescribing

#### A new development

Given the rapid developments in pharmacy practice, including during the pandemic, we published revised standards for the initial education and training of pharmacists (IETP) in January 2021. These set out key reforms, including the introduction of independent prescribing (IP) knowledge and skills throughout the five years of initial education and training.

This would lead to IP annotation at the point of registration.

The standards have been created to make sure that, **upon registration**, pharmacists are recognised as being:

- **experts** in medicines
- confident about and capable of working in multi-professional teams across a variety of healthcare settings to meet diverse and changing patient and public needs
- dedicated to person-centred care, both in person and during remote consultations
- able to ensure the high-quality use of medicines that incorporates both safety and effectiveness alongside compassion and empathy
- proficient prescribers whose skills can be used to work with and support the wider, complex healthcare systems across Great Britain and Northern Ireland

The key changes in IETP are to:

#### Independent prescribing

- incorporating the skills, knowledge and attributes for prescribing
- enabling independent prescribing from the point of registration

#### **Learning outcomes**

- designing, delivering and assessing the full five years of education and training
- linking to trainees' continued development after registration

#### Science in clinical practice

 focusing on key skills including professional judgement, clinical decision making, management of risk, and diagnostic and consultation skills

#### Foundation training year

- strengthening clinical supervision and support
- enabling collaborative working between universities, statutory education bodies and employers

#### **Equality, diversity and inclusion (EDI)**

- placing greater emphasis on EDI
- dealing with discrimination and health inequalities

# Independent prescribing – the current requirements and numbers

At the moment we have separate standards for the initial education and training of independent prescribers. These were published in 2019 and we will continue to accredit these free-standing courses for pharmacists who are already registered with us. The entry requirements are:

- a. Applicants are registered as a pharmacist with the General Pharmaceutical Council (GPhC) or, in Northern Ireland, with the Pharmaceutical Society of Northern Ireland (PSNI).
- b. Applicants are in good standing with the GPhC and/or PSNI and any other healthcare regulator with which they are registered.
- Applicants have at least two years' appropriate patient-orientated experience after registration, in a relevant UK practice setting.
- d. Applicants have an identified area of clinical or therapeutic practice in which to develop their independent prescribing practice.

  They must also have relevant clinical or therapeutic experience in that area, which is suitable to act as the foundation of their prescribing practice while training.
- e. Applicants have a designated prescribing practitioner (DPP) who has agreed to supervise their learning in practice. The DPP must be a registered healthcare professional in Great Britain or Northern Ireland with legal independent prescribing rights, who:

- is suitably experienced and qualified to carry out this supervisory role, and
- has demonstrated current CPD or revalidation relevant to this role.

Although an applicant may be supervised by more than one person, only one prescriber must be the designated prescribing practitioner. The DPP is the person who will certify that successful pharmacists are competent to practise as independent prescribers.

There are 47 providers accredited by the GPhC to deliver IP courses: 39 in England, four in Wales, two in Scotland and two in Northern Ireland. Of these, 23 are accredited to use DPPs to certify pharmacists' competency as independent prescribers. This number will continue to grow as more of the providers are accredited to use DPPs, therefore providing an extensive network to support more pharmacists being trained. Each course is delivered as a freestanding module, which tends to be a term or a semester in length. It includes academic study and learning in practice, in which a trainee is supervised by a DPP. Some courses are just for pharmacists, but most are delivered to a mixture of pharmacists, nurses and other healthcare professionals.

# Independent prescribing – the need for change

When pharmacist independent prescribing was introduced in 2006, pharmacists who applied tended to be in their mid to late careers and wanted to train as specialists in a specific clinical or therapeutic area. In recent years, pharmacists starting IP training courses were more likely to want to develop a more generalist set of skills in response to changing patient needs. We see this as a natural evolution. Having a balance of specialist and generalist training simply reflects the breadth and diversity of the profession and is a response to the needs of the health service. When we discussed with student and trainee pharmacists what they expected their future practice to be like, it is clear that clinical practice, including IP, is what most of them expect.

Some parts of the health and care sector are seeing the benefits of pharmacists being prescribers, although IP is not yet widely adopted in all sectors of pharmacy. Also, annotation as being an IP is not a condition of (ongoing) registration and pharmacists may decide not to practise as an IP. While accepting that point, we expect IP to become more and more central to the practice of pharmacists as part of the natural evolution of the profession.

#### The 2021 IETP standards

The new IETP standards are designed to help bring about a more flexible pharmacist workforce, able to work in a variety of settings and increasingly using clinical skills, including prescribing. The Chief Pharmaceutical Officers in all four countries of the UK have set out a clear desire and policy to:

- increase the number of pharmacist prescribers
- create pharmacist prescribers with the key generic skills and attributes in their early careers, and
- reduce the time it takes to become annotated as an independent prescriber (currently seven to eight years from the start of initial education and training)

### Independent prescribing – managing the transition

# Managing the transition before IP is fully part of initial education and training, including the foundation training year

The introduction of the 2021 IETP standards is a significant change. This means there needs to be a 'transition' period before the full set of learning outcomes, which include prescribing, can be implemented. Therefore we have introduced an **interim** set of learning outcomes, for student and trainee pharmacists. These **do not** include the requirement for trainee pharmacists to both register and have the IP annotation at the same time. These have been introduced from the Foundation Training Year 2021/22 (which began in July 2021).

We expect the 2021 IETP standards to be implemented **in full** by **2025/26**. The first full group of pharmacists with an IP annotation at

the point of registration will therefore enter the register in the summer of 2026. Statutory education bodies and universities, working with employers and other stakeholders, are implementing this.

The timetable above reflects the significant work that needs to be done to bring in the changes and requirements, including:

 developments within higher education institutions so that courses can focus on the attributes and skills of a prescriber and give trainees the practical experience of prescribing that they will need

- the introduction by the statutory education bodies of a foundation training year that includes the IP period of learning in practice
- having the number of DPPs needed with the ability to supervise trainees in the foundation training year
- having services 'up and running' when new pharmacists register – particularly in community pharmacy – that will make use of their prescribing skills
- developing quality assurance processes in each country for foundation training
- changes to infrastructure, including:
  - an understanding of how the system will be quality controlled and managed
  - support systems
  - reporting systems, and
  - relationship management: for example between the statutory education bodies and higher education institutions

As a result, we expect the following conditions to be met:

a. Patient and public safety comes first, and IP cannot be introduced into foundation training unless trainee pharmacists can be supported and developed to be safe IP practitioners. The national statutory education bodies must lead on this but may delegate functions to employers. There must be an auditable process in place for doing this.

- b. The statutory education bodies must be responsible for all the foundation training within their jurisdiction. This is to make sure that IP can be delivered to the required standard in their country. This does not mean that statutory education bodies must actually deliver IP training.
- c. Trainee pharmacists must train in an environment where they can take part in IP activity or, at the very least, have access to such an environment regularly enough to be able to meet the learning outcomes. This may include experience of IP in multiple sectors or locations.
- d. A trainee pharmacist must have access to a DPP. The designated prescribing practitioner will sign off a trainee pharmacist as being fit to practise as an IP.
- e. A trainee pharmacist must have access to patients, to learn how to become an IP.
- f. Resources must be in place to deliver IP in foundation training. Resourcing is the responsibility of statutory education bodies and employers.

### What does this mean for the pace of change?

# How do we enable pharmacists already on the register, or joining the register before summer 2026, to become independent prescribers earlier?

Given the rapid changes in pharmacy and the urgent need for more pharmacist independent prescribers, we do not think it is right simply to wait until 2025/26.

We have heard from key stakeholders about the need to make sure that people who are newly qualified, or are due to join the register in the next four years, are able to start working towards IP qualifications sooner. (At the moment they need to have been registered for two years.) This is to make sure that the number of pharmacists beginning their careers without an IP qualification does not continue to grow and lead to a bottleneck in the present post-registration courses.

We also want to take account of the fact that, during the transition period, we expect trainees to be building up prescribing skills year-on-year. As a result, we believe that removing the two-year requirement in the present prescribing standards would help achieve the overall aim. This would apply to pharmacists who are already registered and ones who have begun their initial education and training and will register before the summer of 2026.

It would also act on proposals from some statutory education bodies for IP training to be

included in their post-registration foundation training programmes. This would lead to education being continued in the first two years after registration and therefore reduces the time before newly qualified pharmacists can enrol on an IP course.

# The proposal – two-year time requirement

When the present standards for the education and training of pharmacist independent prescribers were agreed in 2019, a small majority of respondents were in favour of removing the two-year time requirement. At the time we decided it was safer to keep it, given that independent prescribing was relatively new to the profession, and to review it again later. Given the changing context described above, we believe the time is now right to do that.

If the two-year time requirement is removed:

- pharmacists already on the register will have to demonstrate their suitability to train as an IP on a free-standing course, and
- course providers will have to evaluate applications with that in mind

Suitability will be about the quality of an applicant and their experience, rather than their time on the register. It may take more, or less, than two years for an applicant to become suitable, depending on the nature of their experience. The course provider will be responsible, as they are now, for checking that an applicant is suitable to train (they have this same responsibility for any course of education and training).

If the two-year requirement is removed, our assurances about the competence of IPs in training will be:

 free-standing IP courses: applicants from the present workforce with less than two years' experience will have to provide evidence of their suitability to enter training. This will be based on their clinical work to date, which must be evaluated by the course providers. Applicants must demonstrate the quality of their experience rather than its quantity. Examples of this may include:

- evidence of experience of working with patients
- experience of clinical prescribing by others (for example, in observing or assisting)
- taking part in clinical interventions and medicines optimisation activities to improve patient outcomes, and
- experience of the multi-disciplinary aspects of prescribing
- trainees in foundation training 2021/22
  to 2025/26: trainee pharmacists who
  complete their foundation training between
  2021/22 and 2025/2026 will have had a fifth
  year of training. This will be based on
  interim learning outcomes which focus
  significantly more on the clinical skills
  needed for prescribing competence.
- Immediately following registration they will be able to enrol on a free-standing accredited IP course, or other postregistration training accredited by the GPhC which includes prescribing competencies.
- If one or more countries are able to implement the prescribing outcomes in the

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foundation training year before 2025/26, then individuals who have completed this can apply to be annotated as an independent prescriber immediately after registration. (The regulator must have quality assured the provision in the foundation training year, and the details of this will need more work.) Overall, this should provide the necessary flexibility for individual countries while making sure that, on registration, the required standards remain the same across all countries

 trainees in foundation training from 2025/26: trainee pharmacists from 2025/2026 onwards will have completed an MPharm degree based on 2021 IET standards and a quality-assured foundation training year. These will take in all the required prescribing competencies, and so trainees will be annotated as IPs at the point of registration.

We therefore propose to remove the requirement for registrants to complete two years in practice before becoming eligible to enrol on an accredited independent prescribing course. We believe this will result in all the routes to becoming an IP being built on a stronger clinical base, not relying on time served as a measure of quality.

### What about the requirement for having experience in the area of clinical or therapeutic practice?

As mentioned above, when independent prescribing was first introduced in 2006 the pharmacists completing free-standing IP courses were experienced ones and often held specialist roles focusing on a specific clinical area. Therefore being able to prescribe was a natural next step.

Over the years we have seen more people follow this route, but then move on to deliver services in a different clinical or therapeutic practice area. Stakeholders who have been involved in the IETP standards have raised and questioned the 'experience' entry requirements. For example, they have asked us to consider what this means for people joining the standalone courses in their early years on the register. Also, we are clear in the new 2021 IETP standards that the purpose of the prescribing element is to introduce the high-level principles, skills and attributes that pharmacist prescribers will apply once they register. Therefore it is vital that the IP 2019 standards are able to deliver this too.

One of the present entry requirements for IP training says that:

Applicants have an identified area of clinical or therapeutic practice in which to develop independent prescribing practice. They must also have relevant clinical or therapeutic experience in that area, which is suitable to act as the foundation of their prescribing practice while training.

We believe it will still be important for applicants to be able to identify areas of clinical

or therapeutic practice to focus on during their learning. But we do not believe it should be necessary to have relevant clinical or therapeutic expertise in this one area before becoming eligible to enrol on an IP course or programme.

# The proposal – area of clinical or therapeutic experience

When the 2006 IP standards were introduced it was essential to have relevant clinical or therapeutic experience in a defined area. That was because this was a new concept and the target audience was experienced pharmacists with expert knowledge and experience in their specialist area of practice.

Since then, people studying on an IP course have chosen to train in a specialist or a generalist area, building on the skills they have developed as clinicians. And – if they have appropriate additional education, training and supervision – pharmacists can also add additional prescribing areas to their portfolio.

We propose to change the wording in relation to experience in the entry requirements for a free-standing IP course and separate it into two distinct points:

- 1. Applicants must have relevant experience in a pharmacy setting and be able to recognise, understand and describe the skills and attributes needed by a prescriber as the foundation of their prescribing practice while training.
- 2. To develop their independent prescribing practice, applicants must identify an area of clinical or therapeutic practice on which to base their learning.

By changing this we will allow people with limited experience of an area of clinical specialty to enrol onto the standalone IP courses. It will also support the desire of many of the key

pharmacy stakeholders to promote generalist prescribing as a starting point.

The course providers will still require their students to identify an area of clinical or therapeutic practice, but this could include, for example, common clinical conditions. The skills and attributes of a prescriber will be covered in the course and the purpose of the defined clinical or therapeutic practice area is to allow the student to focus their learning. But this does not mean they are restricted to that area of practice once they qualify.

For this to be agreed we will need the following:

- The course providers will need to have a robust selection and admissions process to make sure that people starting their course:
  - have relevant experience
  - have an understanding of what the role of a prescriber is, and
  - can identify an area of practice to draw upon during their learning
- The learners will understand that the course provider will require them to choose one or more therapeutic areas as their basis for learning. This will not restrict their area of practice upon annotation.
- The employers will need to make sure that their IPs, once annotated on the register, are suitably trained and competent to prescribe and that a review of their competence is regularly carried out.

This will make sure that prescribers can deliver services that meet the needs of patients and it will allow flexibility provided the IP is operating within their scope of practice.

We believe this means all pharmacists will be able to enrol on a free-standing IP course, if they want to. Their chosen area of clinical or therapeutic practice will form the basis on which to learn and develop their independent prescribing practice.

Overall, this will still ensure that pharmacists develop the generic skills and attributes of a prescriber and can apply them in practice to a specific area, whatever their previous experience in that area.

#### **Timetable**

Depending on the outcome of the consultation and Council approval, the proposals would come into effect in early 2022 and apply to:

- a. people registering on or after the implementation date until 1 August 2026, when all registrants will be annotated as prescribers upon registration
- b. people already registered before the implementation date (that is, the present workforce and the student/trainee pharmacists who had started their training)

# Appendix A: Collated consultation questions

We are particularly interested in your views on the following points, although we welcome your comments on any issues that you want to raise about revising the education and training requirements for pharmacist independent prescribers.

- 1 Should the two-year time requirement for entry to free-standing pharmacist independent prescribing training be removed?
- 2 Should the requirement to have relevant experience in a specific clinical or therapeutic area be removed and replaced with the requirement to have relevant experience in appropriate clinical setting(s)?
- 3 Should we retain the requirement that applicants must identify an area of clinical or therapeutic practice on which to base their learning?

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:

- Age
- Disability
- Gender reassignment
- Marriage and Civil partnership
- Pregnancy and maternity
- Race
- Religion or belief
- Sex
- Sexual orientation
- 4 Do you think our proposals will have a positive or negative impact on individuals or groups who share any of the protected characteristics?

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, pharmacy owners and employers, pharmacy professionals, and pharmacy students and preregistration trainees.

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

