

Consultation on changes to requirements for training as a pharmacist independent prescriber and being annotated as an independent prescriber on the Register of Pharmaceutical Chemists

04 March 2022 – 30 May 2022

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About the Pharmaceutical Society of Northern Ireland

1. The Pharmaceutical Society of Northern Ireland is the regulatory body for pharmacists and pharmacies in Northern Ireland.
2. Our primary purpose is to ensure that practising pharmacists in Northern Ireland are fit to practise, keep their skills and knowledge up to date and deliver high quality, safe care to patients.
3. It is the organisation's responsibility to protect and maintain public safety in pharmacy by:
 - setting and promoting standards for pharmacists' admission to the Register and for remaining on the Register, and the standards for pharmacy premises;
 - maintaining a publicly accessible Register of pharmacists and pharmacy premises;
 - handling concerns about the Fitness to Practise of pharmacists, acting as a complaints portal and acting to protect the public; and
 - ensuring high standards of education and training for pharmacists in Northern Ireland.

Why are we consulting?

4. There have been significant changes in pharmacy education and training in the last 18 months. These include the introduction of new Initial Education and Training Standards for pharmacists and the introduction of a Foundation Training Year to replace pharmacist pre-registration training.

5. The Governments in the United Kingdom have set a clear direction which will see pharmacist independent prescribers becoming increasingly important in the delivery of pharmacy services. This has led to one of the major changes in new standards for the initial education and training of pharmacists. Once these standards have been implemented in full, it will mean that all trainees will become independent prescribers at the point of joining the Register of Pharmaceutical Chemists (the Register).

6. The proposed changes in this consultation arise from this development and seek to ensure that the present requirements for annotating the register the Register are appropriate and workable. It also makes proposals to revise the Standards for Education and Training of pharmacist independent prescribers, for stand-alone independent prescribing courses, to ensure they can meet the requirements of future service delivery and the development of the profession whilst maintaining public and patient safety.

7. In summary, the main proposals we are consulting upon are as follows:
 - a. to agree in principle to removing the requirement set out in the Pharmaceutical Society of Northern Ireland (General) Regulations (Northern Ireland) 1994, (the Regulations), that a pharmacist must be on the Register for two years or more before they can be annotated as an IP;
 - b. to remove the two-year requirement for entry onto stand-alone pharmacist independent prescribing courses, contained in the Standards for the Education and Training of Independent Prescribers, replacing it with an assessment, by course providers, of competence to enter the course; and
 - c. to remove the requirement to have relevant experience in a specific clinical or therapeutic area and to replace it with the requirement to have relevant experience in appropriate clinical setting(s).

How can I respond to this Consultation?

8. You can find the Consultation document and all documents relating to the Consultation on the Pharmaceutical Society NI website: <http://www.psni.org.uk/publications/consultations/>
9. You will be asked to complete a response form based on the questions outlined below and return it to the Pharmaceutical Society NI.
10. This **8-week** Consultation starts on the 4th April 2022 **and ends at 12 noon on Monday 30th May 2022.**
11. Responses can be returned electronically to consultations@psni.org.uk and hard copy responses may be sent to Mark Neale at:

Revising the education and training requirements for pharmacist independent prescribers
Pharmaceutical Society of Northern Ireland
73 University Street
Belfast
BT7 1HL
12. For further information on responding to this Consultation, please contact Mark Neale at consultations@psni.org.uk or telephone 02890 326927.

Consultation Questions

13. We would welcome any views you may wish to submit on the questions outlined below. **It is important that you provide reasons for your answers, where possible, so that the Council of the Pharmaceutical Society NI can**

understand the rationale for your views. We have provided a response template to complete which is available on the website: <http://www.psni.org.uk/publications/consultations/>

1. Should the requirement be removed from the Regulations that a pharmacist must be on the Register for a period of two years or more before they can be annotated as an IP?
2. Should the two-year time requirement for entry to stand-alone pharmacist independent prescribing training be removed?
3. 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)?
4. Should we retain the requirement that applicants must identify an area of clinical or therapeutic practice on which to base their learning?
5. Are there any other issues relating to the medium and long-term future of the register which we have not considered?

The Pharmaceutical Society NI has carried out an equality screening on the proposals within this consultation. Our assessment concluded that there are no differential impacts on any of the equality categories. We would however, welcome any further feedback on this important area.

6. Do any aspects of our proposals have equality implications for groups or individuals based on one or more of the following categories? If yes, please explain what could be done to change this.
 - Age
 - Gender
 - Disability
 - Pregnancy and maternity
 - Race /ethnicity

- Religion or belief
- Political Opinion
- People with dependants
- Sexual orientation
- Marital Status

Accessibility of information

14. If you are having difficulties accessing the documentation or if you need us to make adjustments to enable you to respond to this Consultation, please contact us and we will do our best to address the issue.
15. If you wish your response to remain confidential, you should indicate this in your response and the Pharmaceutical Society NI will generally respect this request. However, the information you provide may be subject to disclosure under the Freedom of Information Act 2000.

How will we respond to Consultation feedback?

16. Once the Consultation period ends, all Consultation responses will be considered and a report analysing the Consultation responses will be produced and published on our website.
17. The Council of the Pharmaceutical Society NI will consider all the Consultation responses and, based on the feedback received, decide upon its next steps.

Background

18. Independent prescribers are practitioners responsible and accountable for the assessment of patients with previously undiagnosed or diagnosed conditions and for decisions about the clinical management required, including prescribing 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.
19. Pharmacist independent prescribing was introduced in 2006 with pharmacists able to have their entry on the Register 'annotated' to show they are an independent prescriber (IP). Since then, the number of pharmacist IPs has increased. There are, in April 2022, 672 pharmacists who are annotated as IPs on our Register, which is over 23% of pharmacists registered with the Pharmaceutical Society NI.

Independent Prescribing – Current Requirements

20. At present, pharmacists can only be annotated as an IP on the Register if they meet the following requirements set out in the Pharmaceutical Society of Northern Ireland (General) Regulations (Northern Ireland) 1994, (the Regulations):
 - they have been registered as a pharmacist for a period of two years or more; and
 - they have completed an Independent Prescribing course, accredited by us.
21. We currently adopt the GPhC's separate standards for initial education of independent prescribers which were published in 2019. These standards set out the knowledge and skills pharmacists will acquire during their education and training to become independent prescribers. The standards also set the requirements for course providers.

22. The standards further set the entry requirements pharmacists must meet before being able to join an accredited IP course. Working with the GPhC, we accredit stand-alone courses for pharmacists who are already registered pharmacists against these criteria.

Entry requirements to current stand-alone IP courses

23. The entry requirements to the current stand-alone IP courses are as follows:
- a) Applicants are registered as a pharmacist with the General Pharmaceutical Council (GPhC) and/or with the Pharmaceutical Society NI.
 - b) Applicants are in good standing with the GPhC and/or the Pharmaceutical Society NI and any other healthcare regulator with which they are registered.
 - c) 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.

24. 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.

25. In Northern Ireland, the NI Centre for Pharmacy Learning and Development (NICPLD) and Queen's University Belfast (QUB) provide accredited courses for pharmacist IPs. There are also 39 providers accredited by the GPhC in England, four in Wales and two in Scotland.

New Developments

26. After working with GPhC, the Council of the Pharmaceutical Society NI approved and adopted the new Standards for the Initial Education and Training of Pharmacists in January 2021. These set out key reforms including the introduction of IP knowledge and skills throughout the five years of initial education and training. This will lead to IP annotation at the point of registration.

27. Alongside general reforms, 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.

28. This was, in part, to meet the clear desire and policy of the Chief Pharmaceutical Officers in all four countries of the UK to:
 - increase the number of pharmacist prescribers;
 - create pharmacist prescribers with the key generic skills and attributes in their 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).

29. The Pharmacy Workforce Review published in 2020 also recommended that all pharmacists should be supported to undertake foundation training progressing to independent prescribing and advanced pharmacy practice aligned to service and patient needs.

What does the introduction of new Initial Education and Training Standards mean for pharmacy?

30. The introduction of the 2021 IETP standards is a significant change. We expect the 2021 IETP standards to be implemented in full by 2025/26. This will mean that the first full group of pharmacists with an IP annotation at the point of first registration will join the Register in the Summer of 2026.
31. Arriving at this point requires a period of ongoing, managed transition in Northern Ireland. An Education Reform Implementation Group was established in 2021 to help manage this period of change. The group consists of those organisations directly involved in implementation of reform, namely, the Department of Health, the Pharmaceutical Society NI, the NI Centre for Pharmacy Learning and Development (NICPLD), Queen's University Belfast (QUB) and Ulster University (UU).
32. In addition, from the year 2020/21 the Foundation Training Year is being delivered in Northern Ireland by NICPLD with the Pharmaceutical Society taking on the role of quality assurance, focussing on patient safety and ensuring the maintenance of the standards set out in the IETP.
33. For those students and trainee pharmacists who will complete the Foundation Training Year before 2026, an interim set of learning outcomes has been introduced. These do not include the requirement for trainee pharmacists to both register and have the IP annotation at the same time.

34. To deliver on the target of trainees joining the Register in 2026 and beyond as IPs, a series of actions need to be undertaken. These include:

- legislative approval from the Northern Ireland Assembly to remove the requirement within the Pharmaceutical Society of Northern Ireland (General) Regulations (Northern Ireland) 1994, that a person is only entitled to have an IP annotation where they have been registered as a pharmacist for a period of two years or more;
- developments within Northern Ireland universities 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 NICPLD 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;
- the development of services, for when the 2026 cohort joins the Register, that will make use of their prescribing skills and
- the development of quality assurance mechanisms for the Foundation Training Year.

Protecting the Public and Patients

35. Our primary role is public protection. The introduction of pharmacist IPs directly joining our Register in 2026 requires suitable assurance mechanisms. Working with the GPhC, our focus will be on quality assuring the undergraduate programme and, independently, we will develop an appropriate quality assurance mechanism for the Foundation Training Year to ensure it also meets the required standards under the IETP.

36. For this to happen, several things need to be carefully examined and achieved, these include but are not limited to:

- trainee pharmacists must be able to 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. At present, the Regulations are very prescriptive and only allow for trainee pharmacists to be situated in community, academia, industry or hospital settings for specified periods. To expand the opportunities of a trainee to gain IP experience beyond their core training environment, for example, in a GP practice, will require legislative change;
- trainee pharmacists must have access to a DPP. The DPP will sign off a trainee pharmacist as being fit to practise as an IP;
- trainee pharmacists must also have access to patients to learn how to become an IP; and
- resources must be in place to deliver IP in foundation training.

37. We are working closely with our colleagues on the Education Reform Implementation Group to ensure that our standards can be met as we work towards 2026 and that these reforms can be delivered successfully in Northern Ireland.

Facilitating innovation whilst ensuring public protection

38. We are satisfied that, if the steps outlined above are carried out, pharmacists joining the Register in 2026 as IPs will be appropriately trained and skilled to ensure that standards are met and the public is protected.
39. Our role is to protect the public but we are clear that our regulatory objective should not be an unnecessary obstacle to the development of the profession and better services being provided to the public.
40. From 2026 onward, all pharmacists first joining the Register from the Foundation Training Year will automatically be annotated as an IP. 672 pharmacists in Northern Ireland are already IPs.
41. Those who have gone through their undergraduate and Foundation Training Year under the Interim IETP standards, and who join the Register prior to 2026, will, however, not be automatically annotated as IPs. There are also some 2,200 pharmacists on our Register that are currently not IPs.
42. Reflecting on the objectives of the four Chief Pharmaceutical Officers to increase the number of pharmacist prescribers, to create pharmacist prescribers with the key generic skills and attributes in their careers and to reduce the time it takes to become annotated as independent prescriber, we consider it appropriate to explore regulatory changes that can help facilitate these objectives, if it is safe to do so.
43. The legacy workforce, i.e those already on the Register at the time of this consultation, and those who graduate through the Foundation Training Year from 2022 – 2025, will not benefit from automatic annotation and will, if nothing changes, be subject to time limitations on their ability to become annotated as

IPs. Therefore, given the move to entirely competence-based course entry, this consultation proposes that the existing time constraints on entry to the course and annotation be replaced with competency requirements on course entry.

44. We are, therefore, seeking views on the following proposals for Northern Ireland:

- removing the requirement set out in the Regulations that a pharmacist must be on our Register for a period of two years before they can be annotated as an IP;
- changing the standards for the education and training of pharmacist independent prescribers, for free standing IP courses in Northern Ireland, to remove the two-year time requirement to gain entry onto the course. This would be replaced with a requirement for pharmacists already on the Register to demonstrate their suitability to train on a stand-alone course. Course providers (currently NICPLD and QUB) would be required to evaluate applications and assure themselves of a candidate's suitability before allowing them onto the IP course; and
- changing the standards for the education and training of pharmacist independent prescribers, for free standing IP courses, to remove the necessity to have a relevant clinical or therapeutic expertise in a specific area before becoming eligible to enrol on an IP course or programme.

Removing the 2-year requirement to gain entry onto a stand-alone IP course

45. With a view to safely facilitating the timely development of the profession and services, it is considered appropriate to remove the requirement to have at least two years' appropriate patient-orientated experience after registration in a relevant UK practice setting and to replace it with a course provider assessment of suitability to train as an IP on a stand-alone course.

46. In coming to this conclusion, we consider the following factors to be important:

- Public protection and patient safety will be maintained by course providers making an assessment of how applicants have demonstrated their suitability to train as an IP on a stand-alone course. Examples of how applicants might demonstrate this may include:
 - i. evidence of experience working with patients;
 - ii. experience of clinical prescribing by others (for example, in observing or assisting);
 - iii. taking part in clinical interventions and medicines optimisation activities to improve patient outcomes; and
 - iv. experience of the multi-disciplinary aspects of prescribing.
- Whilst a two-year time period potentially demonstrates a certain level of experience, focused experience gained over a shorter period of time may make a candidate as suited or more suited to joining an IP course. The focus will be on quality of experience not the quantity.
- As services change and independent prescribing becomes embedded in pharmacy practice across its sectors, there should be more opportunities for pharmacists to gain suitable, concentrated and relevant experience thereby making the two-year rule a potential future barrier to pharmacists gaining an IP qualification and annotation.

Facilitating an efficient transition for trainees in foundation training in 2021/22 to 2025/26

47. Trainee pharmacists who complete their foundation training between 2021/22 and 2025/26 will have had a fifth year of training based on interim learning outcomes which will focus significantly more on the clinical skills needed for prescribing competence.

48. If the two-year rule is removed, following an assessment of their suitability, these trainees will no longer be prevented from being able to enrol on a stand-alone training course accredited by the GPhC and Pharmaceutical Society NI within their first two years of registration. Should the two-year requirement not be removed, there is a potential that this cohort's suitability to join an IP course may be diminished over the two-year period from joining the Register.

Removing the requirement to have experience in the area of clinical or therapeutic practice

49. Currently, pharmacists wishing to gain entry onto a freestanding IP course, must 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. This, combined with the two-year rule, focused access to independent prescribing on experienced pharmacists who have developed a degree of specialisation in their practice.
50. Once IPs have been annotated on the Register, they are free to develop and move on to deliver services in a different clinical or therapeutic practice area, as long as they have appropriate additional education, training and supervision and continue to practice within their own competency. The Code (2016) already places a requirement upon all pharmacists to practice only within their areas of competence.
51. As independent prescribing is being developed to be a component part of registration after 2026, and the independent prescribing skills being attained are with a view to having a flexible workforce that can safely apply and develop their IP skills across healthcare, it is considered that maintaining an entry requirement

that focuses on pre-specialisation may present an unnecessary barrier to the development of the profession and individual practitioners.

52. Such an approach would also cause a significant barrier for those joining the Register prior to 2026 who will have gained additional skills in independent prescribing but will not be automatically registered as IPs.
53. The purpose of the 2021 IETP standards 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.
54. One of the present entry requirements for IP training is 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.*
55. It will still be important for applicants to be able to identify areas of clinical practice to focus on during their learning. However, we do not consider that 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.
56. Changing this entry requirement will not reduce the standards that must be met before a pharmacist can complete their course and be signed off by a DPP as fit to be annotated on our Register as an IP. We, therefore, consider that public protection and patient safety would not be an issue if the changes outlined below were to be introduced.

The proposal

57. The detailed proposal is to change the wording in relation to experience in the entry requirements for a stand-alone IP course and separate into two distinct points:

- *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.*
- *To develop their independent prescribing practice, applicants must identify an area of clinical or therapeutic practice on which to base their learning.*

58. By changing this, we will allow applicants with limited experience of an area of clinical specialty to enrol onto the stand-alone IP courses. It will also allow more generalist prescribing as a starting point.

59. 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. However, this does not mean they are restricted to that area of practice once they qualify.

60. 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 students 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.
 - Employers will need to ensure 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.
61. This will ensure that prescribers can deliver services that meet the needs of patients and will allow flexibility provided the IP is operating within their scope of practice and level of competency.
62. We consider that this will result in all pharmacists being able to enrol on a stand-alone 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.
63. 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, without compromising public and patient safety. We consider that these proposals allow for public safety to be maintained whilst facilitating the development of the profession within the clear policy direction set by the four Chief Pharmaceutical Officers.

The future of the Register

64. With all pharmacists who register with us from 2026 onwards, via our Foundation Training Year, being IPs upon registration, and a potential increase in those on the Register gaining a stand-alone IP qualification and annotation, the future makeup of the Register is likely to change significantly in the medium to long term.

65. We consider that these overall changes will have the following impact our Register:
- there may be a consistent, but receding, cohort of pharmacists who do not wish to gain an IP annotation and practise as an IP; and
 - those seeking to join our Register from another jurisdiction, upon qualification or thereafter, may not be trained as an IP and, therefore, not annotated.
66. At present, we consider that annotations on the Register should be made for the following reasons:
- They are necessary for the purpose of patient and public safety
 - They are needed to provide clarity of scope of practise
 - They are necessary to reflect specific legislated activities.
67. In the future, all pharmacists, who have studied and trained in the UK will join our Register as IPs. Over time, this will mean that most pharmacists on our Register will be IPs. Based on the purpose of annotation outlined above, there may come a time when it is more appropriate to provide an annotation for those who are not an IP or to sub-divide the Register in some way.
68. This may also provide greater clarity for the public in relation to those joining the Register from other jurisdictions who may not be allowed to carry out independent prescribing upon registration.
69. We are raising this issue in our consultation to begin a conversation about the future implications for the status of registration and annotation. We are making no proposals in relation to these issues but are seeking feedback on whether there are any other issues we have not considered.

Consultation Questions

- i. Should the requirement be removed from the Regulations that a pharmacist must be on the Register for a period of two years or more before they can be annotated as an IP?
- ii. Should the two-year time requirement for entry to stand-alone pharmacist independent prescribing training be removed?
- iii. 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)?
- iv. Should we retain the requirement that applicants must identify an area of clinical or therapeutic practice on which to base their learning?
- v. Are there any other issues relating to the medium and long-term future of the register which we have not considered?

The Pharmaceutical Society NI has carried out an equality screening on the proposals within this consultation. Our assessment concluded that there are no differential impacts on any of the equality categories. We would however, welcome any further feedback on this important area.

- vi. Do any aspects of our proposals have equality implications for groups or individuals based on one or more of the following categories? If yes, please explain what could be done to change this.
 - Age
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