General Pharmaceutical Council

Reaccreditation of an Education and Training Programme to prepare Pharmacist Independent Prescribers, University of York

Report of a reaccreditation event, 24 February 2016

Introduction

The General Pharmaceutical Council (GPhC) is the statutory regulator for pharmacists and pharmacy technicians and is the accrediting body for pharmacy education in Great Britain. The GPhC's right to check the standards of pharmacy qualifications leading to annotation and registration as a pharmacist is the Pharmacy Order 2010. It requires the GPhC to 'approve' courses by appointing 'visitors' (accreditors) to report to the GPhC's Council on the 'nature, content and quality' of education as well as 'any other matters' the Council may require.

Background

The independent prescribing programme at the University of York is offered by the Department of Health Sciences and the programme was reaccredited by the GPhC in March 2013 for a period of three years; on that occasion, there were no conditions or recommendations. In line with the GPhC's process for reaccreditation of independent prescribing programmes, an event was scheduled on 24 February 2016 to review the programme's suitability for reaccreditation and the following is a report of that event. The accreditation process was based on the GPhC's 2010 accreditation criteria for Independent Prescribing.

Documentation

The University provided copies of its application documentation in advance of the visit, in line with the agreed timescales. The application documentation was reviewed by the panel and it was deemed to be satisfactory to provide a basis for discussion.

The Accreditation Team

The GPhC accreditation team ('the team') comprised:

Name	Designation at the time of accreditation event
Professor Anne Watson	Accreditation team member (Chair of event), Assistant Director of Pharmacy, NHS Education for Scotland
Professor Chris Langley	Accreditation team member, Associate Dean – Taught Programme (LHS) and Professor of Pharmacy Law and Practice, Aston University

along with:

Name	Designation at the time of visit
Mrs Philippa McSimpson	Quality Assurance Officer, General Pharmaceutical Council
Professor Brian Furman	Rapporteur, Emeritus Professor of Pharmacology, University of Strathclyde

Declaration of potential conflicts of interest

No potential conflicts of interest were declared.

The accreditation criteria

	Accreditation team's commentary
Section 1: The programme provider	The programme is offered by the Department of Health Sciences which is part of the Faculty of Sciences at the University of York and was validated by the University in 2010. The Department is affiliated with the Ridings Medical Group, Brough, East Yorkshire, Humber NHS Foundation Trust, Health and Social Care Information Centre (HSCIC) and the York Hospitals NHS Foundation Trust in the delivery of the non-medical prescribing programme. The quality assurance processes applying to the programme include an annual scrutiny and a six yearly review; the team was informed that the latter was to take place in the spring of 2016, and reminded the departmental representatives that the outcome of this review should be communicated to the GPhC. The physical, staffing and financial resources available to the programme were described in the documentation. The programme is delivered by a core team of five teaching staff and is supported by other internal and external speakers. The programme senior team includes a practising pharmacist, who is an independent prescriber. 57 places, divided between two cohorts each admitted successively in October and January, are funded annually by Health Education England across Yorkshire and Humber; these numbers include places for nurses, pharmacists and allied health professionals.

	All four criteria relating to the programme provider are met.
Section 2: Pre-requisites for entry	The team was satisfied that processes are in place to ensure that pharmacists are only admitted onto the programme if they meet all the GPhC requisites for entry. Although the programme is primarily taken by pharmacists in the NHS whose places are funded, the team was satisfied that the provider has a process in place for reviewing the eligibility of self-funded and self-employed pharmacists. Where applicants have experience in an area different from that in which they wish to practise, they may be recommended to undertake other courses to gain experience/knowledge before coming on the independent prescribing course, or may be accepted onto the course and then mentored in the specific area. The team noted that the requirement for pharmacists to have 'at least two years appropriate patient-orientated experience in a UK hospital, community or primary care setting following their preregistration year' (criteria 2.2) was included inconsistently in programme documentation and on application guidance and website information. The team advised that the full requirement must be documented clearly and consistently. All applicants must have an identified Designated Medical Practitioner (DMP) who is willing to support them throughout their period of learning. These DMPs must meet the criteria set down by the Department of Health Guidance and their General Medical Council (GMC) registration is checked by the programme team as part of the admission process. **All six criteria relating to the 'pre-requisites for entry' are met.**
Section 3: The programme	The programme is offered at FHEQ levels 6 and 7 and the learning outcomes at both levels reflect the descriptors set down by the FHEQ (2008). The team had identified inaccuracies and numerous inconsistencies in the mapping of GPhC learning outcomes (Appendix B) to the programme learning outcomes and was unable to see how the GPhC learning outcomes were shown either to the students or to the DMPs. Therefore criterion 3.2 was not met and the team imposed a condition that the programme learning outcomes must be re-mapped to reflect accurately the GPhC learning outcomes at level 6 and at level 7. Additionally, the GPhC learning outcomes and their mapping to the programme outcomes must be communicated clearly to both students and DMPs. The teaching, learning and support strategies used to assist pharmacists in building on their background knowledge and experience and acquiring competence in prescribing were described in the documentation. Teaching methods include lectures, workshops, seminars, directed studies, clinical skills sessions, and tutorials. All teaching materials are hosted on the University's virtual learning environment (VLE). Further support for students is available via the Student Support Hub, the Maths Skills Centre (for support with numeracy) and the Writing Skills Centre (for support with academic writing). Individual students are allocated an academic supervisor, who is a member of the teaching team. In collaboration with

	their academic supervisors, students establish their background knowledge and experience and consider how that can be developed to acquire competence in prescribing. The students' development is supported by a specific timetable for pharmacists, together with tutorials with their academic supervisors. As the programme progresses, students, in collaboration with their DMP, are required to develop a learning contract in each competency area that makes explicit their learning objectives, the strategies they will use to achieve learning, and the evidence that they will provide to demonstrate learning and competence. Development of prescribing competencies is supported by the provision of bespoke clinical skills teaching sessions which address the particular requirements of each pharmacist and their chosen clinical field. Consultation skills are taught and practised and assessed throughout the programme and opportunities for the application of learning to clinical practice and to develop their clinical competence are available under the supervision of their DMPs. Students must achieve 80% attendance overall and must attend all scheduled teaching and learning sessions that provide instruction on clinical examination and diagnosis. **Seven of the eight criteria relating to 'the programme' are met; criterion 3.2 is not met (see condition 1).**
Section 4: Learning in Practice	DMPs are provided with clear and practical guidance on helping their students to complete the period of learning in practice, including their role in student assessment. If required, practice visits are undertaken by the programme team to have a one-to-one discussion with a DMP. It is mandatory for individual pharmacists in collaboration with their DMP to identify the specific clinical skills required for safe practice in their own area. The skills are identified within their application and subsequently in their learning contracts. These become the focus for their development throughout the period of learning in practice and the DMPs are responsible for verifying competence in clinical skills. DMPs are required to confirm in writing that the pharmacist has satisfactorily completed at least 12 x 7.5 hour days supervised practice and that in their opinion the skills demonstrated in practice confirm the pharmacist to be suitable for annotation as an 'Independent Prescriber'. **All five criteria relating to 'Learning in Practice' are met.**
Section 5: Assessment	The range of formative and summative assessments used to test students' learning against the required learning outcomes and standards of the programme include an OSCE, a portfolio of evidence, an unseen examination paper, and a reflective commentary for level 7 students. Assessment of achievement of the prescribing competencies from a practice perspective, including the use of relevant diagnostic techniques, is the responsibility of the designated medical practitioners. Compensation between elements of assessment is not allowed. In any summative assessment, failure to identify a serious problem, or the production of an answer that would cause direct harm to a patient will result in overall failure of the programme; this is made explicit in the assessment guidelines. Students are given one opportunity to re-sit the assessments.

	All four criteria relating to 'Assessment' are met.
Section 6: Details of Award	Successful candidates are awarded a 'Practice Certificate in Independent Prescribing' which confirms that the candidate has successfully completed the programme and the period of learning in practice. Following ratification of the examination results by the Board of Examiners and the Board of Studies, the pass list is certified by the Student Assessment Office and is sent to the General Pharmaceutical Council by the Student Information Service Manager. The team expressed disappointment that the Department had not acted on the comment made at the previous reaccreditation event, emphasising that the letter to the GPhC must state that the students have been awarded a Practice Certificate in Independent Prescribing and include the pharmacists' GPhC registration numbers. The team advised that this must be addressed before the programme is reaccredited. **Both criteria relating to 'Details of Award' are met.**

Summary and Conclusions

The team has agreed to recommend to the Registrar of the General Pharmaceutical Council (GPhC) that the University of York should be reaccredited as a pharmacist independent prescribing programme provider for a further period of three years, subject to one condition.

Condition

1. The Department must remap the programme learning outcomes to reflect accurately the GPhC learning outcomes at level 6 and at level 7. There are currently inconsistencies and inaccuracies between application template 2 and the module descriptors, at both levels. The GPhC learning outcomes and their mapping to the programme outcomes also must be communicated clearly to both students and DMPs. This is to meet criterion 3.2.

As an additional requirement of reaccreditation, the Department must make the necessary changes to the processes and documentation to ensure that all the required information is provided to the GPhC in relation to those pharmacists who have passed the programme (criteria 6.2). This was a requirement at the last reaccreditation event and has not yet been addressed. Documentation must be sent to the GPhC for review before the programme can be reaccredited.

Standing conditions of accreditation:

1. The full record and report include other comments from the team and the Registrar regards the record and report in its entirety as its formal view on provision. Providers are required to take all comments into account as part of the reaccreditation process.

2. Any required amendments to be made to documents for accuracy or completeness have been identified and are detailed in the record. The provider must confirm the changes have been made but the GPhC does not require documents to be submitted for its approval.
3. The provider must respond to the definitive version of the record and report within three months of receipt. The summary report, along with the provider's response, will be published on the GPhC's website and remain for the duration of the accreditation period. The record remains confidential to the provider and the GPhC.
4. On an annual basis, all institutions and other providers approved by the GPhC must give such information and assistance as the GPhC may reasonably require including changes to the curriculum and/or resources.

The provider was asked to note the following:

1. The programme is not reaccredited until approval has been given by the Registrar and all conditions have been met satisfactorily.
2. The team's recommendations are not binding on the Registrar, who may accept, modify or reject them.
3. The accreditation team's feedback is confidential until it has been ratified by the Registrar of the GPhC but may be shared with staff and students internally.

The *Pharmacy Order 2010* states:

Part 5 Education, training and acquisition of experience and continuing professional development

Information to be given by institutions or other providers

46. (3) Whenever required to do so by the Council, any institution or other provider to which this article applies must give to the Council such information and assistance as the Council may reasonably require in connection with the exercise of its functions under this Order.

(4) Where an institution or other provider refuses any reasonable request for information made by the Council under this article, the Council may, in accordance with article 47, refuse to approve or withdraw approval from, any course of education or training, qualification, test or institution or other provider to which the information relates.

For full details of the legislative obligations and powers of the General Pharmaceutical Council, please refer to the *Pharmacy Order 2010.*

Reference: http://www.legislation.gov.uk/uksi/2010/231/contents/made

Following the above event, the provider submitted documents to address the condition of reaccreditation and the accreditation team was satisfied that this condition had been met. The Registrar of the GPhC subsequently accepted the team's recommendation and approved the programme for reaccreditation for a further period of three years, until the end of May 2019.

Appendix A

GPhC Accreditation criteria for pharmacist independent prescribing programmes

Section 1: The programme provider

1.1 Must be part of, or be closely associated with, a higher education institution which implements effective quality assurance and quality management and enhancement systems and demonstrates their application to prescribing programmes. The programme must be validated by its higher education institution.
1.2 Must have adequate physical, staff (academic and administrative) and financial resources to deliver the programme including facilities to teach clinical examination skills.
1.3 Must have identified staff with appropriate background and experience to teach the programme, ideally including practising pharmacists with teaching experience and staff with clinical and diagnostic skills.
1.4 Must have an identified practising pharmacist with appropriate background and expertise who will contribute to the design and delivery of the programme. The identified pharmacist must be registered with the General Pharmaceutical Council (GPhC), and where possible should be a pharmacist independent prescriber.

Section 2: Pre-requisites for entry

2.1 Entrants must be a registered pharmacist with the GPhC or the Pharmaceutical Society of Northern Ireland (PSNI).
2.2 Entrants must have at least two years appropriate patient-orientated experience in a UK hospital, community or primary care setting following their preregistration year.
2.3 Entrants must have identified an area of clinical practice in which to develop their prescribing skills and have up-to-date clinical, pharmacological and pharmaceutical knowledge relevant to their intended area of prescribing practice.
2.4 Entrants should demonstrate how they reflect on their own performance and take responsibility for own CPD.
2.5 The provider must ensure that the DMP, identified by the pharmacist, has training and experience appropriate to their role. This may be demonstrated by adherence to the Department of Health Guidance (2001). The DMP must have agreed to provide supervision, support and shadowing opportunities for the student, and be familiar with the GPHC's requirements of the programme and the need to achieve the learning outcomes.
2.6 Entrants who are not registrants of the GPhC or PSNI may undertake the taught components of the programme but may not undertake the period of supervised practice.

Section 3: The programme

3.1 Must be taught at least at bachelor's degree level (FHEQ (2008), level 6) and reflect the fact that since June 2002, pharmacists have graduated and practise at master's degree level (FHEQ (2008), level 7).

3.2 Must achieve the 16 learning outcomes listed in the curriculum for independent prescribing, which must be mapped against the programme's learning outcomes and assessments. The programme learning outcomes must be aligned with the relevant level of study.
3.3 Must include teaching, learning and support strategies which allow pharmacists to build on their background knowledge and experience and acquire competence in prescribing.
3.4 Must provide opportunities for pharmacists to demonstrate how they will apply their learning to the conditions for which they will be prescribing.
3.5 Must contain learning activities equivalent to 26 days, normally over a period of three to six months.
3.6 Must have robust systems to monitor attendance and progression.
3.7 Must have a clear policy on attendance and participation and the obligations of pharmacists who miss part of the programme. Pharmacists must attend all scheduled teaching and learning sessions that provide instruction on clinical examination and diagnosis.
3.8 May recognise and allow reduced learning time for previous learning or experience, which is directly equivalent to programme content and for which evidence is provided. Recognition should be according to established institutional procedures on previous learning or experience. Regardless of previous learning or experience, all pharmacists must undertake all assessments.

Section 4: Learning in Practice

4.1 The provider must support the DMP with clear and practical guidance on helping the pharmacist successfully to complete the period of learning in practice including arrangements for quality assurance of summative assessments. The roles of the programme provider and the DMP for teaching the skills for clinical assessment of patients must be clearly set out.
4.2 The provider must support the DMP with clear and practical guidance on their role in the assessment of the student.
4.3 The provider must obtain formal evidence and confirmation from the DMP using the specified wording; "the pharmacist has satisfactorily completed at least 12x7.5h days supervised practice".
4.4 The provider must obtain a professional declaration from the DMP using the specified wording; "In my opinion as the DMP, the skills demonstrated in practice confirm the pharmacist as being suitable for annotation as an Independent Prescriber"'
4.5 Failure in the period of learning in practice cannot be compensated by performance in other assessments.

Section 5: Assessment

The programme provider should ensure that assessment strategies meet the requirements of the curriculum particularly:

5.1 Evidence from a range of assessments that the student has achieved the intended learning outcomes of the programme.
5.2 The programme will be assessed separately from any other programmes or programme components and lead to a freestanding award which confirms the competence of the pharmacists as an independent prescriber.
5.3 The assessment scheme should demonstrate that the criteria for pass/fail and any arrangements for compensation between elements of assessment, together with the regulations for resit assessments and submissions, are consistent with safe and effective prescribing and the achievement of all learning outcomes.
5.4 In any assessment, a failure to identify a serious problem or an answer which would cause the patient harm should result in overall failure of the programme.

Section 6: Details of Award

6.1 The provider should award successful candidates a *'Practice Certificate in Independent Prescribing'* confirming that the candidate has successfully completed the programme and the period of learning in practice.

6.2 The provider should send a certified copy of the pass list to the Registrar of the GPhC, via the Registration Manager, containing the names and registration numbers of the pharmacists who have successfully completed the programme and confirming that they are eligible for annotation on the GPhC Register as independent prescribers.

Appendix B

Independent Prescribing Programme Learning Outcomes

All GPhC accredited independent prescribing courses need to ensure that following qualification pharmacist independent prescribers are be able to:

- Understand the responsibility that the role of independent prescriber entails, be aware of their own limitations and work within the limits of their professional competence – knowing when and how to refer / consult / seek guidance from another member of the health care team.

- Develop an effective relationship and communication with patients, carers, other prescribers and members of the health care team.

- Describe the pathophysiology of the condition being treated and recognise the signs and symptoms of illness, take an accurate history and carry out a relevant clinical assessment where necessary.

- Use common diagnostic aids e.g. stethoscope, sphygmomanometer

- Able to use diagnostic aids relevant to the condition(s) for which the pharmacist intends to prescribe, including monitoring response to therapy.

- Apply clinical assessment skills to:
    - inform a working diagnosis
    - formulate a treatment plan for the prescribing of one or more medicines, if appropriate
    - carry out a checking process to ensure patient safety.
    - monitor response to therapy,
    - review the working differential diagnosis and modify treatment or refer
    - consult/seek guidance as appropriate

- Demonstrate a shared approach to decision making by assessing patients' needs for medicines, taking account of their wishes and values and those of their carers when making prescribing decisions.
- Identify and assess sources of information, advice and decision support and demonstrate how they will use them in patient care taking into account evidence based practice and national/local guidelines where they exist.
- Recognise, evaluate and respond to influences on prescribing practice at individual, local and national levels.
- Prescribe, safely, appropriately and cost effectively.
- Work within a prescribing partnership.
- Maintain accurate, effective and timely records and ensure that other prescribers and health care staff are appropriately informed.
- Demonstrate an understanding of the public health issues related to medicines use.
- Demonstrate an understanding of the legal, ethical and professional framework for accountability and responsibility in relation to prescribing.
- Work within clinical governance frameworks that include audit of prescribing practice and personal development.
- Participate regularly in CPD and maintain a record of their CPD activity.

Appendix C

Indicative content

It is expected that education providers will use the indicative content to develop a detailed programme of study which will enable pharmacists to meet the learning outcomes.

Consultation, decision-making, assessment and review

- Autonomous working and decision making within professional competence.
- Understanding own limitations

- Accurate assessment, history taking, and effective communication and consultation with patients and their parents/carers
- Patient compliance and shared decision making
- Building and maintaining an effective relationship with patients, parents and carers taking into account their values and beliefs
- Effective communication and team working with other prescribers and members of the health care team
- A knowledge of the range of models of consultation and appropriate selection for the patient
- Formulating a working diagnosis
- Development of a treatment plan or clinical management plan, including lifestyle and public health advice
- Confirmation of diagnosis/differential diagnosis – further examination, investigation, referral for diagnosis
- Principles and methods of patient monitoring
- Chemical and biochemical methods for monitoring the treatment of the condition(s) for which the pharmacist intends to prescribe on qualification and responses to results.
- Clinical examination skills relevant to the condition(s) for which the pharmacist intends to prescribe.
- Recognition and responding to common signs and symptoms that are indicative of clinical problems. Use of common diagnostic aids for assessment of the patient's general health status; e.g. stethoscope, sphygmomanometer, tendon hammer, examination of the cranial nerves.
- Assessing responses to treatment against the objectives of the treatment plan/clinical management plan
- Working knowledge of any monitoring equipment used within the context of the treatment/clinical management plan
- Identifying and reporting adverse drug reactions
- Management options including non-drug treatment and referral

Influences on and psychology of prescribing

- Patient demand versus patient need including partnership in medicine taking, awareness of cultural and ethnic needs.
- External influences, at individual, local and national levels.
- Awareness of own personal attitude and its influence on prescribing practice.

Prescribing in a team context

- The role and functions of other team members
- Communicating prescribing decisions to other members of the team.
- The responsibility of a supplementary prescriber in developing and delivering a clinical management plan.
- The professional relationship between pharmacist prescribers and those responsible for dispensing.
- Interface between medical and non-medical prescribers and the management of potential conflict
- Documentation, and the purpose of records
- Structure, content and interpretation of health care records/clinical notes including electronic health records

- The framework for prescribing budgets and cost effective prescribing

Applied therapeutics

- Pharmacodynamics and pharmacokinetics
- Changes in physiology and drug response, for example the elderly, young, pregnant or breast feeding women and ethnicity
- Adverse drug reactions and interactions, to include common causes of drug-related morbidity
- Pathophysiology of defined condition(s) for which the pharmacist intends to prescribe.
- Selection and optimisation of a drug regimen for the patient's condition
- Natural history and progression of condition(s) for which the pharmacist intends to prescribe.
- Impact of co-morbidities on prescribing and patient management

Evidence-based practice and clinical governance

- Local and professional clinical governance policies and procedures
- Development and maintenance of professional knowledge and competence in relation to the condition(s) for which the pharmacist intends to prescribe.
- The rationale for national and local guidelines, protocols, policies, decision support systems and formularies – understanding the implications of adherence to and deviation from such guidance
- Prescribing in the context of the local health economy
- Principles of evidence-based practice and critical appraisal skills
- Reflective practice and continuing professional development, support networks, role of self, other prescribers and organisation
- Auditing, monitoring and evaluating prescribing practice
- Risk assessment and risk management
- Audit and systems monitoring
- Analysis, reporting and learning from adverse events and near misses

Legal, policy, professional and ethical aspects

- Policy context for prescribing
- Professional competence, autonomy and accountability of independent and supplementary prescribing practice
- GPhC's *Standards of Conduct, Ethics and Performance*
- Legal frameworks for prescribing, supply and administration of medicines e.g. patient group directions, supply in hospitals.
- Medicines regulatory framework including Marketing Authorisation, the use of medicines outside their product licence.
- The law applied to the prescribing, dispensing and administration of controlled drugs and appropriate counselling of patients

- Compliance with guidance arising from the Shipman enquiry
- Ethical considerations of the supply and administration of medicines
- Application of the law in practice, professional judgment, liability and indemnity
- Accountability and responsibility to the employer or commissioning organisation, awareness of local complaints procedures
- Consent
- Prescription pad administration, procedures when pads are lost or stolen
- Writing prescriptions
- Record keeping, documentation and professional responsibility
- Confidentiality, Caldicott and Data Protection, Freedom of Information
- Suspicion, awareness and reporting of fraud or criminal behaviour, knowledge of reporting and 'whistle blowing' procedures

Prescribing in the public health context

- Patient access to health care and medicines
- Duty to patients and society
- Use of medicines in populations and in the context of health priorities
- Public health policies, for example the use of antibiotics, antivirals and vaccines
- Inappropriate use of medicines including misuse, under and over-use
- Inappropriate prescribing, over and under-prescribing

Note: The standards of proficiency for supplementary prescribers are included in the standards for independent prescribers.