General Pharmaceutical Council

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

Report of a reaccreditation event, 26 April 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

Keele University was first accredited by the Royal Pharmaceutical Society of Great Britain in 2007 to provide a programme to train pharmacist independent prescribers. In line with the GPhC's process for reaccreditation of independent prescribing programmes, the programme was reaccredited in 2010 and again in July 2013 event for a period of three years. On that occasion the team imposed the condition that a derogation from University regulations should be obtained in order to ensure that a pharmacist who, in any assessment, fails to identify a serious problem or who causes harm to a patient will fail the programme; this was to meet criterion 5.4. This was undertaken in July 2013 and the regulation was modified to read "In accordance with the requirements of the General Pharmaceutical Council (GPhC) for the accreditation of the IP course, for any course assessment including the OSCE examination, no reassessment is permitted where a student has failed to identify a serious problem or given an answer which would cause the patient harm. In these circumstances the student will fail the IP course". A reaccreditation event was arranged for April 2016 and the following is a record of that event. The reaccreditation 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 team), Associate Director of Pharmacy, NHS Education for Scotland
Mr Mike Petit	Accreditation team member, Senior Lecturer in Pharmacy Practice, University of Sussex

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
Miss Nasreen Begum	Quality Assurance Administrator, General Pharmaceutical Council (observer)

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, which has been fully validated by the University, is delivered by the School of Pharmacy at Keele University through the Centre for Professional Development and Lifelong Learning (CPD4ALL), with quality assurance being undertaken by the University through an annual process known as Curriculum Annual Review and Development (CARD), and an internal quality audit (IQA) involving external assessors every five years. The team was content with the resources available to the programme, including accommodation, equipment and facilities for teaching clinical examination skills, as well as the staffing. The programme has access to a multidisciplinary staff, comprising particularly pharmacists and GPs, who contribute to the design and delivery of the programme. The Director of Prescribing Education

	is a pharmacist and also a qualified non-medical prescriber (NMP) and has been fully involved in the design and delivery of the full IP programme since its inception. Funding for the programme has been partly through commissions from Health Education West Midlands and the School is currently in the process of being commissioned by the North Midlands Medical Director to train a cohort of local pharmacist prescribers. At present, the course is delivered to two cohorts, each of up to 60 students, with each cohort being split into groups as necessary to facilitate the face-to-face teaching that takes place at the University. The School wished to have the flexibility to increase the number of cohorts per year to three to respond to demand for the course, but with the same maximum number of students per year (120). The team was content that the changes that had been made to accommodate the extra cohort, including an increase to the staffing resource, were sufficient to accommodate this proposed change. **All four criteria relation to the 'programme provider' are met.**
Section 2: Pre-requisites for entry	Although the team was satisfied that the entry criteria are applied to all pharmacists admitted to the programme, it advised that the application pack did not fully reflect all aspects of the entry requirements and advised that the application pack should be reviewed to ensure that it did. In particular the need for patient experience to be UK based, and for GPhC/PSNI registration numbers to be provided by the applicant. The team was told that applicants who have failed on a previous independent prescribing programme are expected to demonstrate appropriate CPD and additional experience before being considered to be allowed to retake the programme at Keele University. **All six criteria relating to the 'pre-requisites for entry' are met.**
Section 3: The programme	The full course is provided as a stand-alone short course with 60 'M' level credits (FHEQ level 7). The aims and learning outcomes are as stipulated by the GPhC, and the GPhC indicative content has been mapped onto the learning outcomes. The course comprises seven days of face-to face contact, 455 hours of open/distance learning incorporating completion of a reflective portfolio, and 90 hours (equivalent to 12 X 7.5 hour days) of learning in practice with the DMP. Opportunities are provided for pharmacists to demonstrate how they will apply their learning to the conditions for which they will be prescribing. This will be achieved through formal University assessments including a written report from a practice-based audit and an oral presentation of a case, as well as confirmation by the DMP of the achievement of relevant learning outcomes and related prescribing competencies. The documentation confirmed that the course comprises learning activities equivalent to 26 days and must be completed in its entirety, including submission of assessments, within 6 months of initial registration. Students are required to

	have three formal review meetings with their DMPs throughout the 6-month learning period to assess their progress and their level of competence in relation to the 'Course Learning Outcomes' and 'Prescribing Competencies'. **All of the eight criteria relating to 'the programme' are met.**
Section 4: Learning in Practice	The arrangements for supporting DMPs and pharmacists include a webinar to support DMPs; this covers everything including details of assessment and frequently asked questions. DMPs also have the full contact details of the course management and delivery team, and are provided with a comprehensive DMP handbook giving full details of the course and clear guidance in relation to their roles and responsibilities. The clinical examination skills and the monitoring of treatment relevant to the condition(s) for which the pharmacist intends to prescribe, including the relevant diagnostic aids, will be taught principally under the supervision of the DMP, based on the baseline assessment of the pharmacist's learning needs completed as part of the application process; this will also be supported with guided study for distance learning, as well as reflective activities within the reflective portfolio. At the end of the six-month period, where the DMP has found a student to be not yet competent, the student will be permitted to repeat up to 12 days of supervised learning in practice, and be assessed again by the DMP; this is allowed to happen once only and further inability to demonstrate competence will result in failure of the programme unless there are extenuating circumstances, when the period of learning in practice can be extended. The team was concerned by the use of the term 'up to 12 days', rather than simply '12 days' in the context of a repeating student, although was told that the number of days would be discussed on a case-by-case basis with the DMP. However, the team remained of the belief that this required firming up and therefore recommended that pharmacists who fail the period of learning in practice should repeat the full 12 days; this is because the team agreed that repeating only a proportion of the number of the days on a case-by-case basis is not a robust way to ensure that the period of learning in practice has been passed satisfactorily (See 'Summary and Conclusions'). Because of the role of DMPs in the assessment, especially in relation to the case-based discussion (See section 5) and in the absence of clear quality assurance in relation to the DMPs' role in the assessment, the team agreed that criterion 4.1 was not met; the team therefore set a condition (see 'Summary and Conclusions') that the School must implement a valid and reliable quality assurance process for the case-based discussion that takes place during the period of learning in practice. **Four of the five criteria relating to 'Learning in Practice' are met; criterion 4.1 is not met.**
Section 5: Assessment	Assessments used to demonstrate that the student has achieved the intended learning outcomes include various formative assessments with feedback from the University tutors, as well as summative assessments. The summative assessments comprise one oral case presentation with a written summary assessed by university tutors, one case discussion assessed by the DMP along with a written summary assessed by University staff, a practice-based audit, objective, structured clinical examinations (OSCEs), and the reflective portfolio. The reflective portfolio includes reflection

	on significant events that will enable the pharmacist to demonstrate achievement of the learning outcomes and related prescribing competencies for final verification by a University-based tutor. A pharmacist's clinical and diagnostic skills are assessed using the OSCE, their learning in practice time including the case based discussion, and through the reflective portfolio. For the case-based discussion assessment the candidate must find a patient diagnosed with a relevant condition; the student must then undertake differential diagnosis and discuss the case with the DMP from diagnosis through to management. The assessment of the case-based discussion is undertaken by the DMP. The student is also required to write a 1000 word account of the case, which must be very precise in relation to actions taken; this goes into the portfolio and is assessed by academic tutors at the University. The programme representatives acknowledged that there was no other check on the DMP's assessment and that DMPs were not observed but told the team that DMPs were all required to have the appropriate skills and must be working in training practices. Moreover, there was a suite of assessments to determine prescribing competency, with students' skills being signed off towards the end of the course. However, the team remained concerned about the reliance on the DMP's assessment without academic control or moderation, other than what was written; the team therefore set a condition that the School must implement a valid and reliable quality assurance process for the case-based discussion that takes place during the period of learning in practice; this relates to criterion 5.1 (See 'Summary and Conclusions'). **Three of the four criteria relating to 'Assessment' are met; criterion 5.1 is not met.**
Section 6: Details of Award	The course has been approved by the University to be offered as a stand-alone module with 60 'M' level credits leading to the award of 'Practice Certificate in Independent Prescribing'. Once the pass list has been agreed by the relevant Board of Examiners and the External Examiner, it is signed by the Head of School of Pharmacy and the Director of Postgraduate Studies and sent to the GPhC Applications Team. The accreditation team emphasised that the Student Handbook should make clear that annotation as an independent prescriber is not automatic but that successful completion of the programme will allow application for annotation; moreover, it must be made clear that pharmacists may not prescribe until such annotation on the GPhC register has taken place. **Both criteria relating to 'Details of Award' are met**

Summary and Conclusions

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

1. The provider must implement a valid and reliable quality assurance process for the case based discussion that will take place during the period of learning in practice. This is because the team agreed that this assessment undertaken by the DMPs in the workplace is not fully under the control of the University quality assurance procedures. This is to meet criteria 4.1 and 5.1. This is to be met before the start of the September 2016 cohort.

There is one recommendation:-

1. It is recommended that pharmacists who fail the period of learning in practice should repeat the full 12 days. This is because the team agreed that repeating only a proportion of the number of the days on a case-by-case basis is not a robust way to ensure that all 12 days have been passed satisfactorily.

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.

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 August 2019.

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

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.