General Pharmaceutical Council

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

Report of a reaccreditation event, 23 October 2015

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 University of Bradford 'the provider' was first accredited by RPSGB in July 2007 to provide a pharmacist independent prescribing programme for an initial period of three years. In May 2010 the programme was approved for reaccreditation for a further period of three years. Following an accreditation event held in June 2013, the University of Bradford was reaccredited by the GPhC to provide a programme to train pharmacist independent prescribers, for a period of three years. Accreditation was subject to one condition: to devise a formal process for quality assuring programme documentation to ensure it remained current and accurate. There was also a recommendation to ensure that information provided to students and DMPs highlighted that failure to identify a serious problem which could cause patient harm in any assessment would result in overall failure of the programme. Both the condition and recommendation were subsequently met by the provider.

The provider had approached the GPhC to request an early reaccreditation event as they wished to make changes to the delivery of the programme for January 2016, moving from 16 days of face-to-face delivery to eight days face-to-face teaching and eight days of online delivery. In line with the GPhC's process for reaccreditation of independent prescribing programmes, an event was therefore scheduled on to review the programme's suitability for reaccreditation. 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. To comply with the process for reaccreditation the University also provided a response to the recommendation set by the panel at the original accreditation of the programme.

The event

The event was held on 23 October 2015 at the GPhC's offices in London and comprised a number of meetings between the GPhC accreditation team and representatives of the University of Bradford prescribing programme.

The Accreditation Team

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

Name	Designation at the time of accreditation event
Mr Mike Pettit	Accreditation team member (Chair of event), Senior Lecturer in Pharmacy Practice, University of Sussex
Professor Helen Howe	Accreditation team member, retired hospital Chief Pharmacist

along with:

Name	Designation at the time of visit
Ms Jenny Clapham	Quality Assurance Officer, General Pharmaceutical Council
Mrs Jane Smith	Rapporteur, Director of Qualifications and Standards, British Psychological Society

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	**All four of the criteria relating to the programme provider are met.** (See Appendix A for criteria). The programme was offered by the School of Nursing in the Faculty of Health Studies at the University of Bradford. It was jointly led by members of staff with backgrounds in nursing and pharmacy and was managed through a Programme Management Team with representation from members of staff from the School of Pharmacy in the Faculty of Life Sciences. The provider wished to alter the course so that eight of the total 16 days of material was delivered via distance learning, rather than face-to-face. This would be offered as an option to all pharmacists applying to start the programme in January 2016, and from then on would be the only version of the programme offered to pharmacists. The main changes to the programme were: 1. Increased input from lecturers from the School of Pharmacy to supervise and assess students. 2. Reduction of face-to-face taught days at the University from 16 to eight days. 3. Provision of distance learning materials to replace some of the material currently covered face-to-face. 4. Reduction of the programme credit weighting from 40 credits to 30 credits. 5. Revision of the learning outcomes to mirror those used by the GPhC. The provider confirmed that these changes had been approved by the University, subject to accreditation being achieved. They would provide the GPhC with minutes of relevant meetings to confirm this was the case. In terms of on-going quality assurance processes, the team prepared a Programme Enhancement Plan (PEP) twice a year, which fed into a Faculty Review. The PEP was sent to the external examiner and was also peer-reviewed. All courses at the University were also subject to a five-year periodic review. The programme had access to fully equipped clinical skills suites which were used for multi-professional teaching across the Faculty of Health Studies. The new delivery model would enable the student intake to be increased to a maximum of 50 students per cohort (including students from other professions) with two cohorts a year. The School of Pharmacy had identified extra staff members and clinicians in practice to provide extra student support. It was noted that each tutor would have a maximum of 10 students.

Section 2: Pre-requisites for entry	**All six of the criteria relating to pre-requisites for entry will be met subject to amendments to the application form.** The pre-requisites for entry to the course were in line with the GPhC's requirements, but several issues relating to the application form in use by the provider were highlighted. These included: • Reference to the RPSGB rather than the GPhC; • The implication that applications were not accepted from those with no manager or employer, which was not the case; • No evidence of on-going CPD, to support the statement asking applicants to demonstrate how they reflected on their own performance and took responsibility for their professional development. • The need to expand the wording in relation to the DMP role, which had been requested at the last accreditation event. The provider undertook to review and revise the application form to address these issues, and to send a copy of the new form to the GPhC as soon as it was available. Applications to the programme were considered jointly by the Programme Leader and the organisational non–medical prescribing lead, to ensure that the DMP identified by the applicant was suitable for the role. Pharmacists employed in organisations without a non-medical prescribing lead and self- employed pharmacists were also asked to complete a pre-placement audit which was also reviewed by the Programme Leaders. The team asked how DMPs were made aware, specifically, of the GPhC requirements and / or the programme learning outcomes. DMPs were offered a half-day orientation day, as well as a visit by academic staff. A DMP handbook was also provided, outlining the requirements of the role, and email and telephone contact was made available as needed. The provider also checked the GMC registration of all DMPs.
Section 3: The programme	**All eight of the criteria relating to the programme are met.** The programme was offered at both FHEQ Level 6 and Level 7. The modules had been subject to the relevant University of Bradford quality assurance processes. The external examiner's report confirmed that the student performance was comparable to similar programmes in other higher education Institutions. The programme was designed to develop the pharmacist's skills as a reflective practitioner and critical thinker and to promote continued engagement in lifelong learning. Pharmacists would be taught alongside other healthcare professionals on the eight face-to-face study days; this presented opportunities for valuable inter-professional learning.

	The programme consisted of 26 theory days; eight days of face-to-face teaching, eight days of distance learning and 10 days of individualised guided study. Students undertook a self-assessment early in the module and an individual learning contract was drawn up between the student, the programme leader and the personal tutor. In addition students undertook 12 days of supervised clinical prescribing practice with a DMP. It was noted that there were only five hours of teaching of clinical skills on the programme, which was substantially less than the norm for prescribing courses. The team agreed that it would be a **recommendation** that this be reviewed. In the document mapping the Level 7 learning outcomes, outcome 2.11 had not been mapped to the GPhC outcomes or any of the programme learning outcomes. The provider would review this. It was also noted that students were not provided with information about how the OSCE and MCQ assessments mapped to specific learning outcomes. The provider undertook to share this information with students. An electronic attendance monitoring system was in place in the University. Students on the programme were expected to have 100% attendance and were asked to suspend their studies if attendance fell below 80%. Formative assessment was undertaken throughout the module using OSCE type scenarios. A mock MCQ and OSCE helped to monitor progression. No accreditation of prior learning was allowed.
Section 4: Learning in Practice	**Four of the five criteria relating to learning in practice are met.** A handbook was provided for all DMPs which described the programme outcomes, entry requirements and roles and responsibilities of the DMP. The DMP was also offered a half day support session at the beginning of the programme and invited to contact the programme leaders for advice. DMPs were required to complete a detailed assessment of their student's behavioural competency in prescribing practice using nationally agreed competencies (NPC 2012). This included assessing the student's clinical assessment skills. This was considered by a member of the teaching team and made available to the external examiner. It was found that there was no quality assurance process for the summative assessment of clinical skills made by DMPs during the student's period of learning in practice and it would be a **condition of reaccreditation** that this was addressed. Guidance provided to the DMP made it clear that they were required to certify that the student had satisfactorily completed the period of practice experience of 12 days, had achieved all of the competency statements on a pass/refer/fail basis and had demonstrated competency in numeracy, relevant to their area of practice.

	The guidance also stated that, while some of clinical hours may be spent with other relevant healthcare professionals, the DMP had overall responsibility for the assessment of competence against the competency framework. The provider was clear that the level of competence demonstrated should be the same for all prescribers, whether pharmacist or non-pharmacist. Failure in the period of learning in practice could not be compensated by performance in other assessments.
Section 5: Assessment	**Two of the four criteria relating to assessment are met.** The programme was a free standing award and was run and assessed separately from any other programme. It was assessed by means of a multiple choice examination and short answer questions; an Objective Structured Clinical Examination (OSCE); satisfactory completion of 12 days in practice with the DMP and completion of the competency framework; and coursework presented in a 3,000 word portfolio to include a reflective case study and a critical evaluation of practice specific formulary. The OSCE consisted of two stations and took the form of a full consultation based around a clinical management plan. As such, it might involve clinical examination skills, but this was not necessarily part of this assessment. Rather, clinical skills were routinely assessed by the DMP in practice. The team had concerns that there was no quality assurance of these assessments; the provider had no way of knowing that all DMPs assessed to the same standard. It would therefore be a **condition of reaccreditation** that this be addressed. Students undertaking the module at Level 7 were normally permitted to resubmit failed elements on one occasion, but students undertaking the module at Level 6 were permitted two resit attempts. The team questioned if allowing students three attempts at one assessment was consistent with safe and effective prescribing. It will therefore be a **condition of reaccreditation** that the University must review its resit regulations for the pharmacist independent prescribing programme to ensure safe and effective practice. It was made clear in the programme handbook that in any assessment, a failure to identify a serious problem or an answer which would cause the patient harm would result in overall failure of the programme.
Section 6: Details of Award	**Both of the criteria relating to details of the award are met.**

	Successful candidates were awarded a Practice Certificate in Independent Prescribing confirming that the candidate had successfully completed the programme and the period of learning in practice. It was noted that the pass list should now be sent to the GPhC Applications Team, rather than the Registrar.

Summary and Conclusions

The accreditation team agreed to recommend to the Registrar of the General Pharmaceutical Council (GPhC) that the University of Bradford should be reaccredited as an Independent Prescribing programme provider for a further period of three years, subject to two conditions.

The conditions were:

1. The provider must implement a valid and reliable quality assurance process for the assessment of clinical and physical examination skills that is currently undertaken by the DMPs. The GPhC must be provided with evidence of how the provider will ensure consistent standards of assessment of clinical and physical examination skills in order to ensure safe and effective practice. This is to meet criteria 4.1 and 5.1.

2. The University must review its resit regulations for the pharmacist independent prescribing programme to ensure safe and effective practice. The team agreed that the current regulation that would allow an automatic third attempt at an assessment for all students at Level 6 is not consistent with achievement of this outcome. This is to meet criterion 5.3.

The provider must submit evidence of how these conditions have been met to the GPhC, for approval by the accreditation team. This must be done before the next intake of pharmacists onto the programme.

The team also made the following recommendation:

1. The University should review the amount of teaching of physical examination and diagnostic skills within the timetabled sessions to enable pharmacists to develop these keys skills. The team agreed that the current amount of timetabled teaching appears low for a pharmacist independent prescribing programme. This related to criterion 3.3.

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 *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 a satisfactory response was received to meet the conditions of reaccreditation. The Registrar of the General Pharmaceutical Council agreed with the accreditation team's recommendations and approved the course for reaccreditation for a further period of three years, until the end of August 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 Applications Team, 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.