General Pharmaceutical Council

Accreditation of an Education and Training Programme to prepare Pharmacist Independent Prescribers, University of the West of England

Report of an accreditation event, 13 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.

The University of the West of England approached the GPhC with an application for accreditation of a programme to train pharmacist independent prescribers. In line with the GPhC's process for accreditation of independent prescribing programmes, an event was scheduled for 13 April 2016 to review the programme's suitability for accreditation. In line with the GPhC's process for new providers of pharmacist prescribing programmes, the event was held on site at the University to allow for the GPhC's accreditation team to view the teaching facilities available. The event ran alongside the University validation event and a Nursing and Midwifery Council (NMC) accreditation visit. 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 event

The event was held on 13 April 2016 and comprised a number of meetings between the GPhC accreditation team and representatives of the University of the West of England prescribing programme.

The Accreditation Team

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

Name	Designation at the time of accreditation event
Professor Angela Alexander	Accreditation team member (Chair of GPhC team at event), Professor of Pharmacy Education and Director of the Centre for Inter-Professional Postgraduate Education and Training
Professor Anne Watson	Accreditation team member, Associate Director of Pharmacy, NHS Education for Scotland

along with:

Name	Designation at the time of visit
Ms Jenny Clapham	Quality Assurance Officer, General Pharmaceutical Council
Mrs Jane Smith	Rapporteur, Chief Operating Officer, European Association for Cancer Research

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 of the four criteria relating to the programme provider are met, subject to receiving written confirmation from the University that the programme has been validated (See Appendix A for criteria)** The University of the West of England, Bristol (UWE) is the largest University in the south west of England. In addition to campuses in Bristol, it has a campus in Gloucester and delivers a range of programmes off campus in venues across the south west region. UWE has been awarded a contract from Health Education England South West (HEESW) to deliver one multi-professional independent and supplementary prescribing programme across the south west region. The programme will be based in UWE's Department of Nursing and Midwifery within the Faculty of Health and Applied Sciences. The Department already runs an independent prescribing programme approved by the Nursing and Midwifery Council (NMC) and the Health and Care Professions Council (HCPC). The proposed new programme will be delivered by UWE in partnership with the University of Bath (UoB) which currently delivers its own GPhC-approved Pharmacist Prescribing Programme. Although working in partnership, the new programme will be wholly owned and quality assured by UWE. The new prescribing programme was considered for University validation and NMC approval alongside the GPhC's accreditation visit. There will be up to nine cohorts of students per year with up to 40 students in each cohort. Although there is a core team of only 4.8 full-time equivalent staff associated with the programme, many more staff from both UWE and UoB will teach on the programme. UWE has robust quality assurance mechanisms in place to ensure the programme adheres to both University and external standards. External examiners are appointed as part of the quality assurance processes. The provider has advertised for a pharmacist with experience of prescribing courses to act as an external examiner for the new course, to work alongside the existing external examiner for nurses. The programme will use on-campus simulated practice and independent learning facilities at UWE and UoB. When delivering at other locations, UWE has experience of using local hotels and training facilities. This off-campus clinical skills teaching has been successful on other programmes, and has received positive feedback from students. In addition, e-learning platforms will be used on the programme to enhance accessibility and minimise travel for students.

	All programme team members have the relevant training and qualifications to deliver the programme.
Section 2: Pre-requisites for entry	**All of the six criteria relating to pre-requisites for entry are met, subject to ensuring that DMPs are made aware of the GPhC learning outcomes.** UWE staff will verify the entrant's GPhC number against the online GPhC register. Applicants who have previously attempted independent prescribing courses elsewhere are not automatically prevented from enrolling, but staff will carry out a telephone interview with them to ascertain their suitability and any additional support needs. Applicants will be required to provide written evidence to demonstrate that they have at least two years patient-orientated experience in a UK hospital, community or primary care setting following their preregistration year. They will also be asked to describe the area in which they intend to train, and to submit two continuing professional development cycles in this this area. A further question will require the Non-Medical Prescribing Lead or employer to confirm that there is a clear area of prescribing need in the workplace setting where appropriate. If there is any lack of clarity on the form, the Programme Lead will contact the Non-Medical Prescribing Lead or employer. Criteria for undertaking the DMP role are explicit within Department of Health Guidance (2001). The application form requires the DMP to confirm their adherence to the guidance and their availability to support the learner. A DMP information pack will be sent to applicants to share with potential DMP's. It gives clear guidance on the aims and objectives of the programme, the roles and responsibilities of the student and of the University. It also highlights the need for exposure to a range of learning opportunities within the supervised practice learning and gives clear and practical advice on how to complete the Single Competency Framework documentation. It was noted that DMPs need to be made aware of the GPhC learning outcomes as part of the application process and the provider undertook to include this information in the DMP pack.
Section 3: The programme	**All of the eight criteria relating to the programme are met, subject to ensuring that pharmacists on the programme are made aware of the GPhC learning outcomes.** The programme for pharmacists will be offered at Framework for Higher Education Qualifications (FHEQ) level 7 only. Credits gained from the programme can be used towards the multi-professional MSc Advanced Practice and the MSc Specialist Practice, or transferred into the postgraduate diploma in Clinical Pharmacy Practice at the University of Bath. The programme would continue to be offered to nurses and AHPs at both level 6 and level 7. A condition of validation by

	the University would be for the Level 6 and Level 7 modules to be excluded combinations. The team congratulated the provider on a very clear and thorough mapping of the 16 GPhC learning outcomes against the programme learning outcomes and assessments. However, there is a need for students to be made aware of the GPhC Learning Outcomes and the provider undertook to provide this information. The programme's underpinning pedagogy is one of integrated, active learning encouraging independent inquiry, problem-solving skills, a critical approach and an evaluation of knowledge. The programme is designed to provide students with the framework to develop the knowledge, skills and attitudes of an independent prescriber, in the context of their own clinical area of expertise. The integration of theory and practice is key to ensuring that students are safe and competent to prescribe within their own sphere of practice. The proposed programme provides: • 7.5 hours x 12 days – face-to-face teaching (90 hours) • 7.5 hours x 14 days - directed learning activities (105 hours) • Supervised practice (90 hours) • Private Study Time (115 hours) Students from all professions will come together for a joint induction, but it is recognised that each professional group will need different support on the proposed programme. For pharmacists, this means a greater emphasis on clinical examination, assessment, communication and consultation skills. Students will be made aware on application to the programme that there is a requirement for 100% attendance and that registers will be kept. Where students miss clinical sessions, then they will be required to make up missed time within a six month period. This might require students to join another cohort or delay completion of the programme; the multiple start points of the programme are helpful in this regard. The provider has well established procedures for both prior certified and prior experiential learning. However, in the context of this professional programme, it is not possible for certified learning to be accredited.
Section 4: Learning in Practice	**All of the five criteria relating to learning in practice are met.** Each DMP will be provided with a welcome email from the Programme Lead including key contact details, the process for how to get in touch with a member of the programme team and how information/guidance will be provided to support

	them in their role. They will also be sent an electronic DMP information pack containing information about the programme design and delivery, and their role in supporting the learner in their supervised learning time, carrying out summative assessment of the learner and providing information on how clinical examination skills would be taught and assessed in the programme, and their role in relation to this. A pre-agreement between the student and DMP of how the supervised practice time will be spent, along with a joint review of the log of supervised practice at a midpoint review and again at the end of the programme, provide quality assurance of the DMP's oversight of the 90 hours and aim to give the DMP confidence in confirming completion. At the end of each programme, feedback will be invited from DMPs and fed into the programme evaluation and end of year report.
Section 5: Assessment	**All of the four of the criteria relating to assessment are met, subject to amending the module specification and guidance to remove reference to 'referral' and to replace with 'failure'.** The assessment strategy for the programme has been developed following consultation with stakeholders from each profession and is designed to ensure equality of student experience and proficiency as a non-medical prescriber, regardless of profession or previous experience. The individual elements of the assessments must be completed and passed by all students. They will be regularly reviewed to reflect current changes in legislation. The assessments are split into two components: • Component A – pass/fail, consisting of the DMP confirmation of successful completion of the period of learning in practice, an OSCE, a 2.5 hour unseen applied pharmacology exam (80% needed for a pass) and a numeracy test (100% needed for a pass) • Component B – consisting of a portfolio of evidence relating to the student's area of practice (50% needed to pass and 50% weighting) and a clinical practice algorithm relating to the student's area of practice. This is a complex piece of work requiring students to describe the whole diagnostic and decision-making process (50% needed to pass and 50% weighting). Component B will be assessed against the indicative qualities required at Level 7. The team noted that the OSCE in Component A consists of only 3 stations. A true OSCE usually consists of 8-10 stations for validity and reliability. The provider might wish to consider renaming the OSCE, for example to Extended Patient Interactions. The team also noted that the OSCE mark sheet contains no reference to the need for basic introductions and consent. The provider confirmed that if a student misses these, they will fail and undertook to update the mark sheet accordingly.

	The module specification clearly states that assessments are non-compensatory and that all must be passed. The provider confirmed that to give an answer, or make an omission, within a summative assessment which would cause the patient harm will result in overall failure of the whole programme and require all elements to be retaken. The team noted that the module specification and guidance actually state that students will be 'referred' not that they will fail. The provider stated that this was an error which will be corrected. Students will be offered two summative opportunities for each assessment element. Extenuating circumstances will be determined through the normal University procedures.
Section 6: Details of Award	**Both of the criteria relating to details of the award are met.** The provider undertook to remove a statement on the draft certificate which referred to the need for the award to be validated by the professional body.

Summary and Conclusions

The accreditation team agreed to recommend to the Registrar of the General Pharmaceutical Council (GPhC) that the University of the West of England should be accredited as an Independent Prescribing programme provider for a period of three years, with the first year being provisional and subject to a monitoring event after completion of the first cohort of students. No conditions were set.

The accreditation team highlighted the following area of strength:

The partnership working between the University of the West of England and the University of Bath in developing a multi-professional course for delivery across the whole of the south west region.

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 accreditation 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.
5. For quality assurance purposes, all Universities offering newly accredited Independent Prescribing Programmes will be expected to undertake an evaluation of the teaching provided to enable students to develop clinical examination skills, once the first cohort has completed the programme. The evaluation must include assessment results for this essential core element and feedback from students on the teaching provided. The evaluation report must then be forwarded to the Quality Assurance (Education) team of the GPhC.

The provider was asked to note the following:

1. The programme is not accredited until approval has been given by the Registrar.
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 Registrar of the General Pharmaceutical Council subsequently accepted the accreditation team's recommendation and approved the course for accreditation for a period of three years, until the end of June 2019, subject to a monitoring event after completion of the first cohort of students.

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.