General Pharmaceutical Council

Accreditation of an Education and Training Programme to prepare Pharmacist Independent Prescribers, University of East Anglia

Report of an accreditation event, 26 January 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 East Anglia (UEA) 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 26 January 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 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 26 January 2016 and comprised a number of meetings between the GPhC accreditation team and representatives of the University of East Anglia 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 event), Professor of Pharmacy Education, Director of Centre for Inter-Professional Postgraduate Education and Training, University of Reading
Dr Ruth Edwards	Accreditation team member, Senior lecturer and MPharm Course Leader, Robert Gordon University

along with:

Name	Designation at the time of visit
Ms Jenny Clapham	Quality Assurance Officer, General Pharmaceutical Council
Professor Ian Marshall	Rapporteur, Caldarvan Research (Educational and Writing Services)

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 team was confident that all of the 4 criteria relating to the programme provider will be met, subject to confirmation of the clinical teaching team** UEA has a school of pharmacy offering an MPharm degree, with a Postgraduate Diploma in General Pharmacy Practice being added to the school portfolio in 2008. The Practice Certificate in Independent Prescribing has been accepted as a new programme by the School of Pharmacy and was signed off by the Faculty and at University level on 15 September 2015 as a new programme for 2016. The course team consists of four members of UEA School of Pharmacy practice staff, equating to 0.45 FTE. Delivery of face-to-face study days will also be supported by relevant clinical practitioners. Planned student numbers for intake per cohort is 10 trainees per intake (with two intakes per year). The School is working with the Head of Clinical Teaching in the School of Medicine to identify suitable teachers for the teaching of clinical examination and assessment skills, and to devise appropriate learning outcomes. The team was assured that the Head of Clinical Teaching was aware of the requirements for pharmacists, but nevertheless requested that the GPhC be informed of the clinical skills teaching team once it has been selected. The team inspected the Clinical Skills Resource Area at the nearby Norfolk and Norwich University Hospital Foundation Trust (NNUHFT) which it considered suitable for purpose.
Section 2: Pre-requisites for entry	**The team was confident that all of the 6 criteria relating to pre-requisites for entry will be met, with one criterion subject to an agreed amendment** Applicants must have been registered as practising pharmacists with the GPhC or the PSNI for at least two consecutive years prior to enrolment. However, the team considered that the supporting statement from the applicant's employer should be more explicit and should stress the requirement for 2 years' appropriate patient-orientated experience. The programme team agreed to amend the application form appropriately. An unusual feature of the programme is that the programme is designed primarily for those pharmacists who have completed at least a postgraduate certificate in general pharmacy practice within the Joint Programmes Board. Applicants who have not completed a postgraduate certificate will be required to undertake and pass an equivalent MCQ and Structured Clinical Simulation examination to be eligible for the programme.

Section 3: The programme	**The team was confident that 4 of the 8 criteria relating to the programme will be met** The programme will be taught at FHEQ (2008) level 7 with no provision for level 6 entry, and will carry 40 credits. The team noted that there were inconsistencies and inaccuracies in the listing and mapping of programme outcomes between application template 2, the programme handbook and the DMP handbook and these could be misinterpreted. Accordingly, it will be a **condition** of accreditation that the University must revise and remap its programme learning outcomes to reflect accurately the GPhC learning outcomes, particularly learning outcomes 4, 7 and 10, and ensure that the correct outcomes are used across the programme documentation. It is proposed that trainees will be able to apply for exemption from 4 days of learning activities relating to physiology, pharmacology and pharmacotherapeutics. The provider also proposes to recognise prior clinical training of pharmacists through the Joint Programmes Board Postgraduate Diploma in General Pharmacy Practice by automatically exempting entrants from 12 days of learning activities and not formally providing such activities in the programme. The provider contended that the PGCert meets a large number of the required therapeutic knowledge, clinical outcomes and requirements/outcomes of the GPhC standards. The provider therefore proposed to offer a condensed programme. As a result, assessment of the parts of the programme from which the students would be exempted would not be done within the programme itself, but rather on or before entry to the programme. The team stated that the proposed idea of exempting applicants from an element of the prescribed learning by not including such learning as a formal part of the programme, and hence shortening the programme below the level specified in the Department of Health guidelines for independent prescribing programmes, was not in accord with the criteria for accreditation. Therefore, it will be a **condition** of accreditation, applying to three of the criteria, that the University must ensure that the programme contains structured learning activities equivalent to 26 days and that all assessments of the GPhC learning outcomes take place within the approved programme. This is because the team agreed that the current provision of 14 days of structured learning activities does not meet the requirements of criterion 3.5 and noted that the proposed pre-requisite and APEL arrangements as outlined in the submission include assessment of GPhC learning outcomes outside of this programme.
Section 4: Learning in Practice	**The team was confident that 4 of the 5 criteria relating to learning in practice will be met, with one criterion subject to a correction** The DMP will be provided with a DMP Course Handbook detailing the roles and responsibilities of the DMP in relation to supporting the trainees learning in practice, with reference to the personal development plan and learning needs assessment and the reflective practice log, and the Student Course Handbook. The DMP induction will include details

	regarding accessing the virtual learning environment, Blackboard site. The approach adopted by the provider involved the DMP in many more activities than usually encountered in independent prescribing provisions, including all core examination skills, Mini Clinical Evaluation Exercise (Mini-CEX), Medicines Related Consultation Framework (MRCF) and Case-based Discussions. The provider also proposes that an additional assessor, who may be a nurse or a healthcare assistant, can assess some aspects of learning in practice but said the assessor for the MRCF must be the DMP. The team queried the quality assurance of such assessments where different assessors are involved and agreed that it be a **condition** of accreditation that the University must implement a valid and reliable quality assurance process for the full range of assessments that will take place during the period of learning in practice. This is because the team considered that the assessments undertaken by the DMPs and other assessors in the workplace are not fully under the control of the University quality assurance procedures.
Section 5: Assessment	**The team was confident that 2 of the 4 criteria relating to assessment will be met** Students will be assessed through submission of a portfolio and all of the components of the portfolio assessment must be passed individually. The Final Competence Progression Review (FCPR) will involve a structured review of the student's portfolio and their progression throughout the programme. The FCPR covers everything in the portfolio apart from the essay and the Structured Clinical Simulation (SCS) examination and the work examined is restricted to that delivered in the IP programme. If a student fails a component of the portfolio, they will be required to re-sit that component and they must pass the re-sit using the same criteria as the first assessment. Students can only re-sit once, and if they do not pass at their re-sit they will not be awarded the Practice Certificate in Independent Prescribing. If students fail an aspect of the portfolio they will be allowed one more attempt at the FCPR by resubmission. It was reiterated during the meeting that unsafe practice in any assessment will lead to an overall failure of the whole programme and that the student would be required to re-take the whole programme, depending upon the University's regulations. The team was concerned that the assessment regimen did not include any examination of the knowledge and skills from which the students are exempted, for example, ADRs and drug interactions, pharmacokinetics and pharmacodynamics, renal and hepatic impairment and antimicrobial stewardship. These subjects, although included in the GPhC learning outcomes, do not represent a formal part of the proposed programme. Accordingly, it will be a **condition** of accreditation that the University must ensure that the programme contains structured learning activities equivalent to 26 days and that all assessments of the GPhC learning outcomes take place within the approved programme. This is because the APEL arrangements as outlined in the submission include assessment of GPhC learning outcomes outside of this programme.

Section 6: Details of Award	**The team was confident that both of the 2 criteria relating to details of the award will be met** The team was told that successful candidates will be awarded a Practice Certificate in Independent Prescribing. The team asked that a sample certificate be submitted to the GPhC for checking.

Summary and Conclusions

The team agreed to recommend to the Registrar of the General Pharmaceutical Council (GPhC) that the University of East Anglia should be accredited as a pharmacist independent prescribing programme provider for a period of three years, subject to three conditions, with the first year being provisional and subject to a monitoring event after completion of the first cohort of students.

The conditions are:

1. The University must revise and remap its programme learning outcomes to reflect accurately the GPhC learning outcomes, particularly learning outcomes 4, 7 and 10, and ensure that the correct outcomes are used across the programme documentation. This is because there are inconsistencies and inaccuracies between application template 2, the programme handbook and the DMP handbook and these could be misinterpreted.

   This is to meet criterion 3.2.

2. The University must ensure that the programme contains structured learning activities equivalent to 26 days and that all assessments of the GPhC learning outcomes take place within the approved programme. This is because the team agreed that the current provision of 14 days of structured learning activities does not meet the requirements of criterion 3.5 and noted that the proposed pre-requisite and APEL arrangements as outlined in the submission include assessment of GPhC learning outcomes outside of this programme.

   This is to meet criteria 3.3, 3.5, 3.8, 5.1 and 5.2.

3. The University must implement a valid and reliable quality assurance process for the full range of assessments that will take place during the period of learning in practice. This is because the team considered that the assessments undertaken by the DMPs and other assessors in the workplace are not fully under the control of the University quality assurance procedures.

   This is to meet criteria 4.1 and 5.3.

The University 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 programme can be accredited and before any students are admitted.

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 their entirety as the 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. Once agreed by the Registrar, the definitive version of the record and report will be sent to the provider for their records. 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 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 University is asked to note the following:

1. The programme is not accredited until approval has been given by the Registrar and all conditions have been met satisfactorily.

2. The recommendations of the team are not binding on the Registrar, who may accept, modify or reject them.

3. This feedback is confidential until it has been ratified by the Registrar of the GPhC but it may be shared with staff and students internally.

The *Pharmacy Order 2010* states:

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

Information to be given by institutions or other providers

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

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

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

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

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