



Independent
prescribing
programme

Edge Hill University

Report of a reaccreditation event

September 2017

Event summary and conclusions

Provider	Edge Hill University
Course	Independent prescribing programme
Event type	Reaccreditation
Event date	29 September 2017
Accreditation period	December 2017 – December 2020
Outcome	Approval The accreditation team agreed to recommend to the Registrar of the General Pharmaceutical Council (GPhC) that Edge Hill University should be reaccredited as a provider of a pharmacist independent prescribing programme for a further period of three years.
Conditions	There were no conditions.
Standing conditions	Please refer to Appendix 1.
Recommendations	1. The provider should devise a written procedure for managing cases of students demonstrating patient harm in an assessment. The accreditation team was satisfied that a student would fail the programme in cases of serious harm, but as the provider has not yet had to deal with this scenario, the team agreed that it would be beneficial to have a documented procedure in place.
Registrar decision	Following the event, the Registrar of the GPhC accepted the accreditation team's recommendation and approved the reaccreditation of the programme for a further period of three years.
Key contact (provider)	Louise Cope, Joint Programme Co-ordinator / Senior Lecturer Non-Medical Prescribing
Accreditation team	Professor Jane Portlock, Professor of Pharmacy Postgraduate Education, University of Sussex Sandra Hall, Head of Pharmacy Practice, Leicester School of Pharmacy, De Montfort University
GPhC representative	Miss Jenny Clapham, Quality Assurance Officer, GPhC
Rapporteur	Mrs Jane Smith, Chief Executive Officer, European Association for Cancer Research

Introduction

Role of the GPhC

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 reaccreditation process is based on the GPhC's 2010 accreditation criteria for Independent Prescribing.

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 powers and obligations of the GPhC in relation to the accreditation of pharmacy education are legislated in the Pharmacy Order 2010. For more information, visit: <http://www.legislation.gov.uk/ukxi/2010/231/contents/made>

Background

Edge Hill University was first accredited by the Royal Pharmaceutical Society (RPS) in 2006 to provide a programme to train pharmacist independent prescribers. The programme was reaccredited by the RPS in 2008 and by the GPhC in December 2011 and December 2014. A Level 7 programme was also accredited in 2014, although this has not admitted any students to date.

There was one condition of reaccreditation in 2014. This was that, in order to meet criterion 5.4, the assessment regulations must ensure that, in any assessment, a failure to identify a serious problem or an answer which would cause the patient harm must result in the overall failure of the programme. This must be communicated to pharmacists in all materials. The University was required to submit evidence of how this condition had been met to the GPhC for approval by the accreditation team before the next intake of pharmacists onto the programme. The University responded appropriately and added this requirement to the student and mentor handbooks.

In line with the GPhC's process for reaccreditation of independent prescribing programmes, an event was scheduled on 29 September 2017 to review the programme's suitability for further reaccreditation.

Documentation

Prior to the event, the provider submitted documentation to the GPhC in line with the agreed timescales. The documentation was reviewed by the accreditation team and it was deemed to be satisfactory to provide a basis for discussion.

The event

The event was held on 29 September 2017 at the GPhC headquarters, London, and comprised a number of meetings between the GPhC accreditation team and representatives of Edge Hill University prescribing programme.

Declarations of interest

There were no declarations of interest.

Key findings

Section 1: The programme provider

All four criteria relating to the programme provider are met. (See Appendix 2 for criteria).

The multi-professional Independent Prescribing Programme at Edge Hill University is delivered as part of the Continuing Professional Development portfolio of the Faculty of Health and Social Care. The programme is offered at Level 6 and Level 7 and is next due for revalidation in July 2020 (Level 6) and May 2018 (Level 7). Quality assurance and quality management processes are well documented and the programme is subject to an internal annual review process. There have been few changes to the programme since the last reaccreditation event and feedback from pharmacists on the programme is generally very positive.

The programme is appropriately staffed and resourced with good use made of visiting lecturers from a wide variety of prescribing backgrounds. In terms of quality assurance, all staff, including visiting lecturers, are subject to the University's peer review processes and students are also encouraged to give feedback to the programme team. The Joint Programme Co-ordinator is a practising pharmacist and is qualified as an independent prescriber.

The number of pharmacists admitted to the programme has increased and approval was sought at this event to move from three to four cohorts per year from 2017-18, with a maximum of 40 students per cohort. Additional academic and administrative support staff will be made available by the University to support this growth in student numbers. This approval was given.

Section 2: Pre-requisites for entry

All six criteria relating to the pre-requisites for entry are met.

The application processes are appropriate and ensure that students have the requisite qualifications and experience to undertake the programme and have identified an area of clinical practice in which to develop their prescribing skills. In the unusual event that a self-employed pharmacist applies to the programme, then the provider reviews the application and the proposed DMP closely to ensure that support and opportunities to develop prescribing skills are available.

The team was also satisfied that DMPs have appropriate training and experience and are able to support students to achieve the GPhC learning outcomes. DMPs are provided with a comprehensive Handbook and are encouraged to contact the programme team at any point in the programme if they have queries or concerns.

Section 3: The programme

All eight criteria relating to the programme are met. One criteria requires minor amendments.

The programme is delivered as a stand-alone single module, awarding 45 credits at Level 6 and 30 credits at Level 7. The 16 GPhC Learning Outcomes are mapped to 12 Programme Learning Outcomes at both levels. Pharmacists on the programme are made aware of the GPhC learning outcomes in a face-to-face session on the first day. They are also available in the Student Handbook and on the virtual learning environment.

It was noted that Programme Learning Outcome 2 at Level 6 and Level 7 currently requires students to be able to "Synthesise comprehensively, the knowledge and skills required for the examination, investigation and diagnosis of patients with those conditions for which they may prescribe; demonstrating knowledge of the underlying pathophysiology." This is intended to deliver GPhC Learning

Outcome 4, “Following qualification, Pharmacist Independent Prescribers will be able to use common diagnostic aids e.g. stethoscope, sphygmomanometer”. There is a possibility that the conditions for which a student may prescribe might not cover common diagnostic aids, so Programme Learning Outcome 2 at Level 6 and Level 7 should be amended to ensure that it clearly covers common diagnostic aids. With this amendment, the GPhC learning outcomes are achieved by both the Level 6 and Level 7 programmes.

The Programme is delivered using a variety of methods including problem-based approaches to learning, teacher-led classroom-based working, group working, lectures with breakaway directed study, practice-based learning, directed and self-directed study and web based learning through the virtual learning environment. At Level 6, learning time is made up of 150 hours of teaching, 210 hours of guided independent study and 90 hours of practice-based learning. At Level 7 this is 150 hours of teaching, 60 hours of guided independent study and 90 hours of practice-based learning.

It was noted that the difference in the number of hours of learning associated with the Level 6 and Level 7 programmes (450 hours and 300 hours respectively) is to some extent determined by the number of credits associated with each Programme (45 and 30 respectively), and the requirement for a notional 10 hours of study per credit. To date, no students have enrolled on the Level 7 programme, although as a result of a successful consortium bid a number of pharmacists will enrol on this programme in 2018.

Arrangements for monitoring attendance and progression are appropriate. It was noted that there have not been issues with persistent non-attendance.

Section 4: Learning in Practice

All five criteria relating to learning in practice are met. Two criteria require minor amendments.

Appropriate arrangements are in place to support DMPs with information and guidance on the period of learning in practice and on their role in assessing students. The period of practice-based learning is quality assured through the Learning Needs Analysis prepared by the student and the DMP and via student feedback. It is clear that failure in the period of learning in practice cannot be compensated by performance in other assessments.

Two minor amendments were required to documentation. In order to meet criterion 4.1, the DMP Handbook, and other course documentation must be updated to reflect the fact that the 12 days of learning in practice totals 90 hours, rather than 78 hours as currently stated. In order to meet criterion 4.3, the phrase ‘or equivalent’ must be removed from the DMP declaration, so that it reads: “The above named pharmacist has satisfactorily completed at least 12 x 7.5 hour days supervised practice in order to complete the practice component of the Independent Non-Medical Prescribing Module”.

Section 5: Assessment

All four criteria relating to assessment are met. One recommendation was made.

The programme is assessed via an unseen multiple choice and short answer examination, a calculations examination, an Objective Structured Clinical Examination (OSCE), a prescribing case study (Level 6 only) and a practice-based portfolio. This range of assessments provides evidence that students have achieved each of the 16 GPhC learning outcomes.

It was clear that students will fail the programme if they fail to identify a serious problem or an answer which would cause the patient harm. Students in this position would be allowed to re-start the programme, but would have to start from the beginning and re-take all assessments. It was noted that there is no documented procedure for managing cases of students demonstrating patient harm in an assessment. As this scenario has not yet occurred, it was recommended that it would be beneficial to

have a documented procedure in place.

Section 6: Details of Award

Both criteria relating to details of the award are met.

Successful candidates are awarded a 'Practice Certificate in Independent Prescribing' confirming that the candidate has successfully completed the programme and the period of learning in practice and a certified copy of the pass list is sent to the Registrar of the GPhC.

Appendix 1 - Standing conditions

The following are standing conditions of accreditation and apply to all providers:

1. The record and report include other comments from the team, and providers are required to take all comments into account as part of the accreditation process. The provider must confirm to the GPhC that required amendments have been made.
2. 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.
3. The provider must seek approval from the GPhC for any substantial change (or proposed change) which is, or has the potential to be, material to the delivery of an accredited course. This includes, but is not limited to:
 - a. the content, structure or delivery of the accredited programme;
 - b. ownership or management structure of the institution;
 - c. resources and/or funding;
 - d. student numbers and/or admissions policy;
 - e. any existing partnership, licensing or franchise agreement;
 - f. staff associated with the programme.
4. The provider must make students and potential students aware that successful completion of an accredited course is not a guarantee of annotation or of future employment as a pharmacist independent prescriber.
5. The provider must make students and potential students aware of the existence and website address where they can view the GPhC's accreditation reports and the timescales for future accreditations.
6. Whenever required to do so by the GPhC, providers must give such information and assistance as the GPhC may reasonably require in connection with the exercise of its functions. Any information in relation to fulfilment of these standing conditions must be provided in a proactive and timely manner.

Appendix 2 – Accreditation criteria

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 their 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 3 – Learning outcomes

Independent prescribing programme learning outcomes

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

1. 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.
2. Develop an effective relationship and communication with patients, carers, other prescribers and members of the health care team.

3. 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.
4. Use common diagnostic aids e.g. stethoscope, sphygmomanometer
5. Able to use diagnostic aids relevant to the condition(s) for which the pharmacist intends to prescribe, including monitoring response to therapy.
6. 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
7. 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.
8. 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.
9. Recognise, evaluate and respond to influences on prescribing practice at individual, local and national levels.
10. Prescribe, safely, appropriately and cost effectively.
11. Work within a prescribing partnership.
12. Maintain accurate, effective and timely records and ensure that other prescribers and health care staff are appropriately informed.
13. Demonstrate an understanding of the public health issues related to medicines use.
14. Demonstrate an understanding of the legal, ethical and professional framework for accountability and responsibility in relation to prescribing.
15. Work within clinical governance frameworks that include audit of prescribing practice and personal development.
16. Participate regularly in CPD and maintain a record of their CPD activity.

Appendix 4 – 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.