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

Report of a reaccreditation event, 8 October 2010

Introduction

The General Pharmaceutical Council (GPhC) is the statutory regulator for pharmacists and pharmacy technicians and is the accrediting body for pharmacy education in the United Kingdom.

The University of Leeds was accredited by the Royal Pharmaceutical Society (RPSGB) in 2007 to provide a programme to train pharmacist independent prescribers, for a period of 3 years. In line with the General Pharmaceutical Council’s (GPhC) process for reaccreditation of independent prescribing programmes, an event was scheduled on 8 October 2010 to review the programme’s suitability for reaccreditation.

Documentation

The University provided copies of its application documentation in advance of the visit, in line with the agreed timescales. The University additionally provided an evaluation of the clinical skills teaching elements of the programme.

The application documentation was reviewed by the panel and it was deemed to be satisfactory to provide a basis for discussion

The following documents were submitted by the training provider in advance of the accreditation event:

- Completed application template part 1 ‘Addressing the accreditation criteria’
- University validation documentation
- Application form for pharmacist independent prescribing full course
- Applicants’ declaration
- Employer/manager declaration
- Non-medical prescribing lead declaration
- Designated medical practitioner declaration
- Completed application template part 2 ‘Mapping of independent prescribing learning outcomes (Level M)
- Completed application template part 2 ‘Mapping of independent prescribing learning outcomes (Level 3)
- Student module handbook
- The case-based discussion
- Timetable
- Designated medical practitioner supervisor’s handbook
- Marking grid for written assignments
- The practice certificate

The application documentation was reviewed by the panel and it was deemed to be satisfactory to provide a basis for discussion.

The accreditation process was based on the GPhC’s 2010 accreditation criteria for Independent Prescribing.

The event:

The event was held on 8 October 2010 at the GPhC headquarters in Lambeth.

The Accreditation Team:

The GPhC accreditation team (‘the team’) comprised:

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<tr>
<th>Name</th>
<th>Designation at the time of accreditation event</th>
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<tbody>
<tr>
<td>Dr Carol Candlish</td>
<td>Former principal lecturer, University of Sunderland (Chair of event)</td>
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<tr>
<td>Dr Jane Portlock</td>
<td>Principal lecturer, University of Portsmouth School of Pharmacy</td>
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<tr>
<td>Ms Joanne Martin</td>
<td>Accreditation and Recognition Manager, General Pharmaceutical Council</td>
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<td>Ian Marshall</td>
<td>Rapporteur</td>
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along with:
## Accreditation Criteria

<table>
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<th>Accreditation team’s commentary</th>
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<tr>
<td><strong>Section 1: The programme provider</strong></td>
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<td><strong>Section 2: Pre-requisites for entry</strong></td>
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<td><strong>Section 3: The programme</strong></td>
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case-based discussions consist of a presentation by the student for 10-15 min, followed by the DMP and module leader asking questions. The student chooses the subject to discuss and the sessions are filmed if the academic cannot attend.

The team noted that the learning outcomes in the student handbook were expressed differently from the GPhC learning outcomes. Accordingly, it will be a **recommendation** of this report that the University add the mapping document of the General Pharmaceutical Council learning outcomes to the student handbook. The team also noted that the learning outcomes in the application were worded differently from those of the GPhC, including a split into skills and knowledge outcomes. Subject to the satisfaction of the above recommendation, it is likely that criterion 3.2 will be met.

<table>
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<tr>
<th>Section 4: Learning in Practice</th>
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<td>Four of the five criteria in this section were <strong>met</strong>. There is a comprehensive DMP handbook, plus a briefing is offered. The DMP, plus an academic, attend the case-based discussions and work is marked by both the DMP and the academic. The evidence for the period spent on learning in practice is logged on the Framework of Supervised Practice form by the student and signed off by the DMP. It is clearly stated that failure in the period of learning in practice cannot be compensated by performance in other assessments. However the team noted that the form of wording used in the professional declaration signed by the DMP should use the term “annotated” rather than “registered”. Accordingly, it will be a <strong>condition</strong> of this report that in order to meet the requirements of the General Pharmaceutical Council criterion 4.4 must be reworded, changing “registration” to “annotation”. Subject to the satisfaction of this condition, it is likely that criterion 4.4 will be met.</td>
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<th>Section 5: Assessment</th>
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<td>All four criteria in this section were <strong>met</strong>. A range of assessments is used, including MCQs, short written answers, OSCE, portfolio. Assessments are also linked to the learning outcomes, and there are stand-alone entry requirements, regulations and award. The team noted the appropriateness of the marking criteria in the marking grid and judged the pass/fail decision to be at an appropriate level to ensure safe practice. There is a statement to the effect that a failure to identify a serious problem or an answer which would cause the patient harm will result in overall failure of the programme in the student handbook and in the marking grid.</td>
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<th>Section 6: Details of Award</th>
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<td>The team noted that the sample certificate in the submission stated “Practice Certificate in Independent and Supplementary Prescribing”. The University representatives explained the rationale for this wording which appeared to the team to be persuasive. The GPhC Accreditation and Recognition Manager agreed to seek a ruling on this issue. Subject to the outcome of the above ruling, criterion 6.1 will be met. The team agreed that it be a <strong>condition</strong> of this record that a signed certified copy of the pass list be sent to the GPhC Registration Manager. This must be done with immediate effect. Subject to the satisfaction of the above condition, criterion 6.2 will be met.</td>
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Summary and Conclusions

The accreditation team agreed to recommend that the University of Leeds should be reaccredited as a pharmacist independent prescribing programme provider for a further period of 3 years, subject to conditions and recommendations:

There are 2 conditions:

1. All references to the RPSGB as the regulator must be removed from all teaching materials, handbooks and documentation. These must be replaced with the General Pharmaceutical Council as the body who regulates pharmacy. This must be done with immediate effect. Also, in order to meet the requirements of the General Pharmaceutical Council criterion 4.4 must be reworded, changing “registration” to “annotation” and a signed certified copy of the pass list must be sent to the GPhC Registration Manager to meet criterion 6.2. This must be done with immediate effect.

2. The University must amend the application form to state that applicants must identify 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. This is to meet criterion 2.3 and must be done with immediate effect.

There is 1 recommendation:

1. That the University add the mapping document of the General Pharmaceutical Council learning outcomes to the student handbook

The accreditation commended the provider on the use of the case-based discussion. The team viewed this as an innovative approach to developing the skills and knowledge of pharmacists. This is an example of good practice.

The full record and report includes other comments from the team and the Registrar regards the record and report in its entirety as its formal view on provision. Providers are required to take all comments into account as part of the reaccreditation process.

The provider should note the following:

1. The General Pharmaceutical Council has assumed responsibility for the regulation of pharmacy education. The Pharmacy Order, the legislation establishing the General Pharmaceutical Council as regulator, states that the General Pharmaceutical Council accept previous decisions of the Society. In this context, that means previous accreditation decisions of the Society will stand.
2. The accreditation team’s recommendations are not binding on the Registrar and the Registrar may add, remove or modify points on reflection and in light the accreditation panel views.

3. The General Pharmaceutical Council’s record and report will be sent to you shortly to comment on factual accuracy. The providers must respond to the definitive version of the record and report within three months of receipt.

4. Thereafter the summary report, along with your response, will be published on the General Pharmaceutical Council’s website and remain for the duration of the accreditation period. The record remains confidential to the institution and the General Pharmaceutical Council.

5. All accredited providers are required to inform the General Pharmaceutical Council annually of changes to the curriculum and/or resources.

Please note that the accreditation team’s feedback is confidential until it has been ratified by the Registrar of the General Pharmaceutical Council.

Following the above accreditation event, satisfactory evidence was provided to meet the above conditions of reaccreditation.

The Registrar of the General Pharmaceutical Council agreed the accreditation team’s recommendation and approved the course for reaccreditation for a further three years, until the end of January 2014.
Appendix 1

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 (appendix C), which must be mapped against the programme’s learning outcomes and assessments (appendix B). 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.

Pharmaceutical Council, independent prescribing programme reaccreditation report
University of Leeds, 8 October 2010
5.3 The assessment scheme should demonstrate that the criteria for pass/fail and any arrangements for compensation between elements of assessment, together with the regulations for resit assessments and submissions, are consistent with safe and effective prescribing and the achievement of all learning outcomes.

5.4 In any assessment, a failure to identify a serious problem or an answer which would cause the patient harm should result in overall failure of the programme.

Section 6: Details of Award

6.1 The provider should award successful candidates a ‘Practice Certificate in Independent Prescribing’ confirming that the candidate has successfully completed the programme and the period of learning in practice.

6.2 The provider should send a certified copy of the pass list to the Registrar of the GPhC, via the Registration Manager, containing the names and registration numbers of the pharmacists who have successfully completed the programme and confirming that they are eligible for annotation on the GPhC Register as independent prescribers.

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.

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.