General Pharmaceutical Council

University of Hertfordshire
Report of a reaccreditation event
November 2017
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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/uksi/2010/231/contents/made

Background

The University of Hertfordshire was accredited by the General Pharmaceutical Council (GPhC) in 2011 to provide a programme to train pharmacist independent prescribers, for a period of 3 years. A reaccreditation event was held on 13 November 2014. On that occasion the team agreed to recommend to the Registrar that the University should be reaccredited as a pharmacist independent prescribing course provider for a further period of three years, subject to 2 conditions. The conditions were: 1) that the University must ensure that the programme learning outcomes and assessments are consistent and clearly stated in all course materials and that these are accurately mapped to the GPhC learning outcomes. This must also be communicated to students to ensure that they are aware of how the programme and assessments enable them to meet the GPhC learning outcomes. This was to meet criteria 3.2. 2) that the University be required to review the assessment strategy to ensure that pharmacists must demonstrate competence in clinical and physical examination and diagnostic skills and that the summative assessment be subject to robust quality assurance measures. This was because the team was concerned that the arrangement in which DMPs could sign off a pharmacist as ‘competence not yet achieved’ may allow students to pass the programme without demonstrating competence. This was to meet criteria 4.1 and 5.1. The condition was met by removal from the Portfolio of Evidence of the column referring to ‘competence not achieved’. In line with the GPhC’s process for reaccreditation of independent prescribing programmes, an event was scheduled on 3 November 2017 to review the programme’s suitability for reaccreditation. The accreditation process was based on the General Pharmaceutical Council’s 2010 accreditation criteria for Independent Prescribing.

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 was deemed to be satisfactory to provide a basis for discussion.

The event

The event was held on 3 November at the GPhC headquarters, London, and comprised a number of meetings between the GPhC accreditation team and representatives of the University of Hertfordshire prescribing programme.
Declarations of interest

There were no declarations of interest.

Key findings

Section 1: The programme provider

The team was satisfied that all four criteria relating to the programme provider will be met. One criterion requires the provider to undertake minor wording amendments. (See Appendix 2 for criteria)

The programme is managed by the Department of Adult Nursing and Primary Care, working in close collaboration with the Department of Pharmacy, Pharmacology and Postgraduate Medicine and was last validated by the University in 2012. Whilst validation normally occurs every 5 years, further review has been deferred until 2018-19 due to the forthcoming release of revised professional standards by the Nursing & Midwifery Council.

As a result of increased recruitment to the programme, the University now runs three groups of 45 students to cope with the demand for places. The programme leader has changed, with the former programme leader now being heavily involved in admissions and working with the programme’s commissioners. Due to the approximate doubling of student numbers on the programme since the previous reaccreditation the University has engaged more staff members in anticipation of further potential increases in demand for places. Thus the new programme leader, a medical doctor and a teacher-practitioner pharmacist had been employed and other existing staff members have had their share of the teaching to the programme increased. The clinical skills teaching resources have been strengthened and improved with the facilities at Meridien House having been refurbished, along with the development of a new skills suite in the Science Building, comprising community pharmacy and hospital suites.

The current whole time equivalent teaching time devoted to the programme is 4.5WTE plus the potential of an extra 1.0WTE in the intended virement of a post from adult nursing to non-medical prescribing, along with 0.8WTE extra staff commitment from the Department of Pharmacy, giving a total of 6.3WTE devoted to the programme. The team was told that Pharmacy is now much more part of the programme and that the University is committed to providing staff for the programme. The input of the pharmacists on the programme will increase from 0.1 to 0.2 of their time, with the pharmacists teaching the pharmacology component of the programme, providing student support through being personal tutors to pharmacist students, and being members of the Programme Committee and Examination Boards.

The team agreed to approve the provider to deliver a maximum of five cohorts per year comprising eight groups of a maximum of 45 students each.

Section 2: Pre-requisites for entry

The team was satisfied that all six criteria relating to the pre-requisites for entry are met. One criterion requires the provider to undertake minor wording amendments.

The admissions process, undertaken in collaboration with sponsoring Trusts & organisations, enables the University to ensure that all accepted applicants meet the required entry criteria. Applications are checked by the Programme Tutor prior to the offer of a place on the programme, a supporting reference from a senior professional or supervising pharmacist is sought for applicants with self-employed status,
and the applicant’s registration status with the regulatory body is checked, together with that of their DMP.

The information that entrants must have at least two years appropriate patient-orientated experience is obtained via a CPD application form. A Supporting Admissions Form provides details of the applicant’s intended field of prescribing practice and confirmation from their manager that the organisation will support the applicant, that there is a clinical need for the prescribing role and that the applicant has clinical, pharmacological and pharmaceutical knowledge which is up-to-date and relevant to their intended area of prescribing practice.

Applicants are required to provide a personal statement with the CPD application form and to submit a curriculum vitae to ensure that there is evidence of a reflective approach to personal and professional development. DMPs are provided with details of the arrangements for the period of learning in practice prior to admission of the pharmacists to the programme, and applicants are encouraged to share documentation and information with their DMPs.

Section 3: The programme

The team was satisfied that all eight criteria relating to the programme are met. One criterion requires the provider to undertake minor wording amendments

The programme is delivered at Level 7 and carries thirty credits. The team noted a number of apparent mapping errors in the submission with some lack of correspondence between the mapping in Part 2 of the submission and the assessment matrix presented in Appendix 3, and was told that the assessment matrix represents the correct version which is supplied to students. The team agreed that it will expect to see a more accurate mapping of the learning outcomes at any subsequent reaccreditations.

The team considered that several of the examples of assessments submitted were clearly not at Level 7 and was told that the Level 7 learning relates to the practice learning and is evidenced in the portfolio in which pharmacists are required to conduct a strengths, weaknesses, opportunities and challenges (SWOC) analysis of their own knowledge and skills, and that the student’s personal tutor has a role in determining that the pharmacist is learning at the correct level. A blended approach to teaching and learning is used, incorporating lectures, skills workshops, reflective analyses and consideration of case studies. The programme is organised around three taught themes including pharmacology and prescribing practice, systematic approaches to assessment and diagnosis, and legal, ethical and professional issues.

The programme is delivered over a five-month period and involves twenty six days’ study, including thirteen face-to-face teaching days, eleven guided study days and two days focused on student assessment. Student progress is monitored by the personal tutor with students being encouraged to submit work, have discussions with their DMP at intervals, and to attend regular tutorials. It is expected that students will attend every teaching session and that attendance at other sessions can be organised for missed sessions with students being advised that they will be unable to complete the programme if they do not attend the alternative session(s) offered. Students are notified of the requirement to attend all instruction on clinical examination and diagnosis on the timetable as soon as they are accepted for the programme, and on the University website.

Section 4: Learning in Practice

The team was satisfied that all five criteria relating to learning in practice are met. One criterion requires the provider to undertake minor wording amendments Information about the programme and its requirements are provided within a DMP Handbook, together with information about their role. Support for DMPs includes visits to their practice location and the SoundCloud recorded commentary, a facility which the team found useful. Prior to the period of learning in practice, pharmacists undertake two days’ university-based training focused on assessment and diagnostic skills which enables them to
practise in a safe environment to develop hands-on skills, followed by a minimum of twenty hours within their practice experience focused on their development of clinical assessment and diagnostic skills. Students are expected to develop and demonstrate competence in taking a systematic assessment of the patient’s history and to demonstrate their understanding of the principles of systematic examination.

Section 5: Assessment

The team was satisfied that all four criteria relating to assessment are met. One criterion requires the provider to undertake minor wording amendments

The assessment process includes an unseen paper on applied pharmacology, a numeracy assessment, a prescribing analysis essay, an OSCE, and a portfolio of evidence demonstrating aspects of the student’s experience and development in practice. The team was interested to know what elements of the assessment determined that pharmacists had reached Level 7, and was told that the OSCE requires a critical analysis of the evidence base for prescribing decisions, the academic essay is marked using University descriptors for the appropriate level, and that these plus the portfolio determine that pharmacists achieve Level 7; the numeracy and pharmacology assessments are essentially pass/fail for pharmacists. The team was told that the assessment of the use of diagnostic aids occurs in practice with a DMP sign-off, supplemented in the OSCE by the requirement to explain how to use such aids.

Quality assurance is ensured by the pharmacist being required to spend a minimum of twenty hours with the DMP directly, plus time with a range of practitioners. The programme is subject to the University’s Policy and Regulations concerning Assessments and Examinations which confirm that students failing assessments are normally allowed to submit the assessment once more only. A fail grade is awarded if the student is not successful on second submission and the student is required to re-take the programme. The team noted that the external examiner had made comments about the inconsistency of marking and was told that this had occurred when the teaching team had been extended to cater for the increased student numbers, and that now there is a pre-marking meeting with a smaller team of markers than previously. As pharmacist students are involved in setting their own OSCE by submitting three possible scenarios which the teaching team consider and selects the scenario for testing, the team was also interested to know how a consistent standard was maintained across different OSCE scenarios. The team was told that the same marking scheme is used irrespective of the subject matter of the OSCE, that safe practice has primacy, and that the same marker and service user is present at each station. Although there is no standard setting, there is standard grading to ensure safe practice. The team confirmed that an overall failure of the programme will result from a failure to identify a serious problem or to provide an answer which would cause the patient harm in any assessment; this is a programme-specific regulation approved by the University and is included within the Programme Specification.

Section 6: Details of Award

Both criteria relating to details of the award are met

The wording of the certificate issued by the University’s Examination and Awards Office reflects GPhC requirements.
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 be 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.


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.