General Pharmaceutical Council

Independent prescribing programme

University of Leeds

Report of a reaccreditation event

November 2016

Event summary and conclusions

Provider	University of Leeds
Course	Independent prescribing
Event type	Reaccreditation
Event date	4 November 2016
Accreditation period	February 2017 - January 2020
Outcome	Approval with conditions The accreditation team agreed to recommend to the Registrar of the General Pharmaceutical Council (GPhC) that the University of Leeds should be reaccredited as a provider of a pharmacist independent prescribing programme for a further period of three years, subject to one condition.
Conditions	1. The provider must implement a valid and reliable quality assurance process for the assessment of clinical and physical examination skills that is currently undertaken by the DMPs. The provider must provide the GPhC with evidence of how it will ensure consistent standards of assessment of clinical and physical examination skills in order to ensure safe and effective practice. This is to meet criteria 4.1 and 5.1.
Standing conditions	Please refer to Appendix 1
Recommendations	1. The OSCE element of assessment is reviewed to: a. make sure that the number of stations is appropriate to ensure a valid and reliable assessment. This is because OSCE are considered to be most valid and reliable when they comprise a greater number of stations than those currently in place. b. create a more consistent approach to quality assurance. Standard setting may be considered, for example, by using Angoff or another evidence-based method. This recommendation relates to criterion 5.1
Registrar decision	Following the event, the provider submitted a response to the condition of reaccreditation, and the accreditation team agreed it had been met satisfactorily. The Registrar accepted the team's recommendation and approved the accreditation of the programme for a further period of three years.
Key contact (provider)	Dr Mary-Claire Kennedy, Module Lead for Independent and Supplementary Prescribing for Pharmacists, University of Leeds
Accreditation team	Mr Mike Pettit, (event Chair)Senior Lecturer in Pharmacy Practice, University of Sussex Dr Ruth Edwards, Senior Lecturer & MPharm Course Leader, Robert Gordon University

GPhC representative	Mrs Philippa McSimpson, Quality Assurance Officer, GPhC
Rapporteur	Professor Ian Marshall, Emeritus Professor of Pharmacology, University of Strathclyde, Proprietor, Caldarvan Research (Educational and Writing Services)

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 School of Healthcare, University of Leeds, and in particular the pharmacy professional group of the Academic Unit of Pharmacy, Radiography and Healthcare Science has run accredited prescribing courses for pharmacists since 2003; first as a supplementary prescribing module and then as an independent and supplementary prescribing module from January 2008. Previously, the University offered a conversion course for supplementary prescribers to train as independent prescribers, but this has recently been discontinued.

The University of Leeds was last reaccredited by the GPhC in 2013 to provide a programme to train pharmacist independent prescribers, for a period of 3 years. There were no conditions or recommendations made by the accreditation team at this event. In line with the GPhC's process for reaccreditation of independent prescribing programmes, an event was scheduled on 4 November 2016 to review the programme's suitability for 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 4 November 2016 at the GPhC headquarters, London, and comprised a number of meetings between the GPhC accreditation team and representatives of University of Leeds prescribing programme.

Declarations of interest

There were no declarations of interest.

Key findings

Section 1: The programme provider

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

The programme is subject to annual review which includes feedback from student's and the external examiner. Changes emanating from the annual review of the provision have included greater support for portfolio writing, and obtaining evidence from the student's workplace.

Although university validation is not required on a routine basis, any proposed changes to the programme trigger the need for validation. Changes are normally put through the validation process in advance of GPhC reaccreditation and as such the programme is normally validated every three years in line with the GPhC reaccreditation cycle.

The course is supported by a formal contract with Health Education England. The programme is multidisciplinary and comprises two cohorts of students per year, each of approximately 30 pharmacists, along with an equal number of nurses/midwives. It was estimated that the staff Whole-time Equivalent devoted to the course was at least 1.2, with an expansion of the teaching team since the last reaccreditation event, including a new module leader. The school is investing in development of its clinical skills facilities and the programme will enjoy an increase in facilities from 2017 which will include additional simulation areas with recording capabilities. The team was satisfied that the programme had sufficient quality assurance mechanisms in place and those resources, in terms of both staffing and physical resources, were satisfactory and appropriate to support the programme.

Section 2: Pre-requisites for entry

All of the six criteria relating to the pre-requisites for entry are met with one subject to amendment

Pharmacists apply to the programme via both a university application form and programme-specific application form. Self-employed pharmacists who are unable to provide a line manager's declaration on their application are interviewed by the provider to ascertain suitability for the programme and meeting of the pre-requisites.

The team noted that the application form did not stipulate that the two years' appropriate experience must be in a UK hospital, community or primary care setting, and advised that it must be made clear in all documentation that such experience should have been gained in the UK. All applications are scrutinised by the School before acceptance and the applicant's evidence of CPD is reviewed as part of the application process.

The course team confirms the suitability of any self-employed applicant by discussing their application by telephone and checking that they have appropriate support. DMPs are informed of the criteria for pharmacist prescribers through the DMP Handbook which is issued once a student has been accepted onto the course. The team agreed that the provider may wish to consider making the DMP Handbook available to DMPs at the point of application rather than at the time of acceptance rather than providing this on a piece-meal basis when requested.

Section 3: The programme

The course will be delivered and assessed at M-level only from the 2017 intake. The team was told that students would likely need support for reflective writing and that this would be provided in portfolio-writing sessions with additional support as needed. The programme learning outcomes were clearly and consistently mapped to the GPhC outcomes. There are two modes of study, 8 days of blended learning taken by the vast majority of pharmacists, or 26 days of face-to-face teaching and learning only taken by small numbers. Support for students on the blended learning option pathway includes recorded teaching

sessions and pre- and post-session tasks. Any problems identified from student feedback are dealt with by providing extra resources on the virtual learning environment. Pharmacists that require additional support for their clinical skills' development are identified and requested to start working on such skills with their DMP earlier than usual. The School itself teaches basic clinical skills during a morning and an afternoon session, plus extra 1.5 hour sessions are available before students join their DMPs. The case-based discussion and portfolio represent a means for students to discuss or write about the appropriate therapeutics and decision-making relevant to the conditions for which they will be prescribing. There are two rounds of formative OSCEs, and students are encouraged to submit up to 20 percent of their portfolio for formative support.

Section 4: Learning in Practice

Three of the four criteria relating to learning in practice are met with one of the three subject to correction

All DMPs are issued with a handbook outlining their role in supervision and assessment. Additional support and guidance is provided by the programme team, as needed. In the case of difficulties, DMPs are encouraged both by the School and by the students to contact the School and several have done so. The DMPs are not visited in practice by the provider routinely, but the provider does undertake visits if requested or if issues come to light. The team was told that the DMP undertakes the case-based discussion element of the assessment which forms part of the portfolio. The overall portfolio is then assessed by the School which can obtain corroborative evidence from viewing videos of the case-based discussions. However, the team learned that the assessment of clinical and examination skills does not form part of the case-based discussion video, and that the DMP has the responsibility of assessing and signing off these skills. The team was told that the quality assurance of this process was dependent on the DMPs being trainers to a standard, but that the School and University had no role in the process. The team agreed that this quality assurance process was insufficiently robust, and hence it will be a **condition of reaccreditation** that that the University must implement a valid and reliable quality assurance process for the assessment of clinical and physical examination skills that is currently undertaken by the DMPs. The University must provide the GPhC with evidence of how it will ensure consistent standards of assessment of clinical and physical examination skills in order to ensure safe and effective practice. This is to meet both criteria 4.1 and 5.1 (condition 1). Additionally, the team noted that the wording of the DMP's professional declaration, while factually correct, did not contain the exact wording of t the approved statement, and as such was reference to the GPhC should be removed from the statement.

Section 5: Assessment

Three of the four criteria relating to assessment are met with one of the three subject to clarification

The programme is assessed via an Objective Structured Clinical Examination (OSCE), reflective assessment, portfolio, case based discussion and drug calculation and prescription writing. The team noted the proposal of the School to remove the formal examination from the assessment schedule from the January 2017 cohort onwards, in order to avoid over-assessment. The team was pleased to note the thorough consideration and that had been given to making this change and agreed that its removal was appropriate.

The team reviewed the OSCE element of assessment and noted that it consisted of only three 8-minute stations. The team advised that evidence suggests that a greater number of stations are considered to be optimal for a valid and reliable OSCE. OSCE are drawn from an ever-growing bank of 80-90 assessments which have been reviewed by the programme team and external examiner. The team considered that although this this review process was satisfactory, it was not the optimal method for ensuring standardisation across sittings. Accordingly, the team made a **recommendation** that that the OSCE element of assessment be reviewed to: a) make sure that the number of stations is appropriate to ensure a valid and reliable assessment. This is because OSCE are considered to be most valid and reliable

when they comprise a greater number of stations than those currently in place and b) create a more consistent approach to quality assurance. Standard setting may be considered, for example by using Angoff or another evidence-based method.

Although it was confirmed to the team that a major failure to identify a serious problem or an answer which would cause the patient harm will result in overall failure of the whole module, the team agreed that this was not clear in all the documentation being, for example, there were ambiguities in the Module Handbook. The team advised that the programme materials must be updated to ensure that this policy be made clear to students.

Also, as described in the commentary under Section 4, the team learned that the assessment of clinical and examination skills does not form part of the case-based discussion video, and that the DMP has the responsibility of assessing and signing off these skills, with the School and University having no role in this process. The team agreed that the quality assurance of this important element of the assessment was insufficiently robust, and hence condition 1 was set.

Section 6: Details of Award

The two criteria relating to details of award are met.

The team was satisfied that pharmacists who pass the course are given the correct award and that there is a set process in place for issuing of certificates and confirmation of pass lists to the GPhC for annotation purposes.

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.
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.