General Pharmaceutical Council

Independent prescribing programme

University of Birmingham

Report of a reaccreditation event

October 2018

Event summary and conclusions

Provider	University of Birmingham
Course	Independent prescribing programme
Event type	Reaccreditation
Event date	31 October 2018
Accreditation period	December 2018 – December 2021
Outcome	Approval The accreditation team agreed to recommend to the Registrar of the General Pharmaceutical Council (GPhC) that pharmacist independent prescribing programme provided by the University of Birmingham should be reaccredited for a further period of three years.
Conditions	There were no conditions
Standing conditions	Please refer to Appendix 1
Recommendations	No recommendations were made
Registrar decision	The Registrar of the GPhC accepted the team's recommendation and approved the reaccreditation of the programme for a further period of 3 years.
Key contact (provider)	Mrs Parbir Jagpal, Director of Postgraduate Studies, Programme Director – Practice Certificate in Independent Prescribing
Accreditation team	Professor Angela Alexander, Professor Emerita of Pharmacy Education, University of Reading (Team Leader) Mr Mike Pettit, Senior Lecturer in Pharmacy Practice, University of Sussex
GPhC representative	Mr Chris McKendrick, 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/uksi/2010/231/contents/made

Background

The University of Birmingham was first accredited by the GPhC in December 2015 to provide a programme to train pharmacist independent prescribers, for a period of three years. Accreditation was subject to validation by the University, which was subsequently achieved, and to one condition. This was that the University must ensure that, in any assessment, a failure to identify a serious problem or the production of an answer which would cause the patient harm, will result in an overall failure of the programme and that this is communicated clearly to pharmacists and DMPs in all course documentation. This was to meet criterion 5.4. The University provided satisfactory evidence to the GPhC that this condition had been met.

The first year of accreditation of an independent prescribing programme is provisional and subject to a satisfactory monitoring event after completion of the first cohort of students. A monitoring event therefore took place in December 2016 at which accreditation was confirmed. There were no conditions and no formal recommendations arising from the monitoring visit.

In line with the GPhC's process for reaccreditation of independent prescribing programmes, an event was scheduled on 31 October 2018 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 31 October 2018 at the GPhC headquarters, London, and comprised a number of meetings between the GPhC accreditation team and representatives of the University of Birmingham 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 programme is delivered by the School of Pharmacy which sits within the College of Medical and Dental Sciences at the University of Birmingham. The School also offers four and five-year MPharm programmes. Several quality enhancements have been made to the independent prescribing programme since it was introduced in December 2015. These are focused on extending the support available to students, particularly around clinical skills teaching.

The programme has formal University validation and undergoes an annual review in line with the wider University quality assurance processes. Validation rolls on from this annual review; there is no formal revalidation date.

The resources available to support the programme are appropriate. Clinical skills teaching facilities are available in two buildings and, although shared with a range of other healthcare courses, there are no capacity issues. There are sufficient pharmacist and non-pharmacist staff associated with the programme.

In some areas, including the description of the physical resources, the submission appears not to have been updated since the first accreditation event, suggesting intention rather than current practice. Future submissions must be reviewed for accuracy.

Section 2: Pre-requisites for entry

All six criteria relating to the pre-requisites for entry are met. Three criteria require minor amendments.

The application process ensures that applicants are required to be registrants of the GPhC or PSNI, to have relevant experience, to have identified an area of clinical practice in which to develop their prescribing skills and to have up-to-date clinical, pharmacological and pharmaceutical knowledge relevant to their intended area of prescribing practice. However, several amendments were required to the application form to make these requirements more apparent to applicants.

Pharmacists wishing to move to a new area of clinical practice will not be admitted to the programme. Instead, they will be advised to gain some experience in this new area before re-applying at a later date, to ensure that they have the required baseline knowledge and experience.

Appropriate checks are in place to ensure that the DMP meets the eligibility criteria and they are made aware of the GPhC's requirements of the role. A DMP mentor scheme is in place and has been particularly effective in providing support for those who are considering taking on the role for the first time.

Section 3: The programme

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

The programme is taught at Masters FHEQ level 7 over a period of 6 months and consists of two 20-credit modules, Prescribing: Scientific Principles and Practice and Prescribing: Safe Effective Practice.

The programme achieves the 16 GPhC learning outcomes for independent prescribing which are appropriately mapped to the programme learning outcomes and assessments described in the programme specification. However, there are discrepancies between the learning outcomes presented in the programme handbook and those in the programme specification. The provider must check all documentation for consistency to ensure that all documents use the version in the programme specification, as these are validated by the University and appropriately mapped to the GPhC learning

outcomes.

Teaching and learning activities comprise distance learning, campus-based teaching days, individual tutorials and workplace-based experience. The minimum overall learning time is as follows:

Activity	**Time**
Taught face-to-face campus-based teaching	76 hours (9.5 x 8 hour days)
Directed learning and activities	132 hours (16.5 x 8 hour days)
Period of supervised learning in practice	90 hours (12 x 7.5 hour days)
Completion of electronic 'structured learning and reflective portfolio'	48 hours (6 x 8 hour days)
Self-directed and private study	54 hours (8.5 x 8 hour days)
Total	400 hours

Appropriate systems and processes are in place to monitor attendance and progression. All study days, including clinical sessions, are compulsory and must be attended in order for students to pass the course. Students who miss parts of the programme are required to attend the next scheduled equivalent study day which may not be available until the next cohort of students have commenced the programme. This is clearly stated in the student handbook.

Section 4: Learning in Practice

All five criteria relating to learning in practice will be met, subject to one criterion requiring minor amendments.

DMPs are provided with a DMP Handbook to support them in their role. This includes resources on learning styles and teaching, support for assessing competencies on the basis of Miller's triangle and support for formatively assessing case-based discussions. DMPs are also invited to an induction event and have access to the DMP mentor throughout the programme.

As currently worded, the DMP's declaration states that the pharmacist has completed at least 12 x 7.5 days' supervised practice; the word 'hours' is missing and must be added to the declaration in order to ensure that it is factually accurate and meets the criterion.

It is clear that failure in the period of learning in practice cannot be compensated by performance in other assessments

Section 5: Assessment

All four criteria relating to assessment are met. One criterion requires minor amendments.

The assessment strategy is designed to be multi-modal, including written assessments, case presentations, extended matching questions and an OSCE. Assessments for each module are as follows:

	Module 1	**Module 2**
Structured learning and reflective portfolio, reviewed by course tutors and DMP	Must Pass	Must Pass
Individual case presentation	30% of module mark	

Virtual scenario-based assessment	70% of module mark	
Calculations Examination (100% pass mark)	Must pass	
Completion of 90 hours supervised learning in practice (validated and signed off by DMP)		Must Pass
Three station OSCE		70% of module mark
One hour Extended Matching MCQ examination + short answer examination (80% pass mark)		30% of module mark

The OSCE is designed to measure communication and clinical skills which are marked using an analytic checklist, as well as 'softer' skills which are marked using a global checklist. Each of the three stations must be passed.

Some of the written assessments are tailored for individual students according to their intended area of prescribing practice. If the necessary expertise to set and mark these questions is not available from within the programme team, then external input is sought.

All portfolios are moderated and for written papers a sample are second marked, according to the University policy.

Students who fail the programme are eligible to apply to re-enrol. However, they are encouraged to take a period of time for reflection and further development before reapplying. To date, no student has failed the programme due to a failure to identify a serious problem or an answer which would cause the patient harm. Consideration has been given to how these cases would be managed and the provider was advised to formalise this policy so that it is clear to students how errors such as this will be handled and to ensure consistency between cases. A version of the National Patient Safety Agency's risk assessment grid has been used successfully by some providers to assist with decision-making in this area.

The assessment strategy is consistent with ensuring safe and effective prescribing and the achievement of the 16 learning outcomes.

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 and a certified copy of the pass list is sent to the Registrar of the GPhC, via the Applications Team.

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.