General Pharmaceutical Council

Independent prescribing programme

University of Bolton

Report of an accreditation event

October 2017

Event summary and conclusions

Provider	University of Bolton
Course	Independent prescribing programme
Event type	Reaccreditation
Event date	27 October 2017
Accreditation period	February 2018 – January 2021
Outcome	Approval The accreditation team agreed to recommend to the Registrar of the General Pharmaceutical Council (GPhC) that the University of Bolton should be reaccredited as a provider of a pharmacist independent prescribing programme for a further period of three years.
Conditions	There were no conditions
Standing conditions	Please refer to Appendix 1
Recommendations	No recommendations were made
Registrar decision	Following the event, the Registrar of the GPhC accepted the accreditation team's recommendation and approved the reaccreditation of the programme for a further period of three years.
Key contact (provider)	Ms Emma Street, Academic Group Co-ordinator, Standards, Enhancement and Learner Experience and Non-Medical Prescribing Programme Lead
Accreditation team	Mr Mike Pettit, Event Chair, Senior Lecturer in Pharmacy Practice, University of Sussex Professor Angela Alexander, Professor Emerita, University of Reading
GPhC representative	Mrs Philippa McSimpson, Quality Assurance Officer, GPhC
Rapporteur	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 University of Bolton was accredited initially by the GPhC in 2011 to provide a programme to train pharmacist independent prescribers, for a period of 3 years. The programme was reaccredited in 2014 for a further period of 3 years subject to one condition and one recommendation. The condition was that the University must implement a valid and reliable quality assurance process for the OSCE assessment and this must be universally applied across all the DMPs. The team was of the view that the OSCE assessment then undertaken by the DMPs was a key competence assessment but was not fully under the control of the University QA procedures for assessment. Therefore the University must provide the GPhC with evidence of how it would achieve robust and consistent assessment of competence of pharmacists across all DMPs. This was to meet criteria 4.1 and 5.1. The University was required to submit evidence of how this condition had been met to the GPhC for approval by the accreditation team; thus, all OSCEs are now recorded digitally and assessed in practice by academic staff. The recommendation was that the University should develop a process for dealing with applications from self-funding or self-employed pharmacists; the current application process now involves ensuring that appropriate processes are in place to support self-funding applications with a telephone interview including ensuring that effective governance procedures are in place within the applicant's organisation. Since the 2014 reaccreditation there have been a further thirteen cohorts with a total of eighty four pharmacists. In line with the GPhC's process for reaccreditation of independent prescribing programmes, an event was scheduled on 27 October 2017 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 27 October 2017 at the GPhC headquarters, London, and comprised a number of meetings between the GPhC accreditation team and representatives of the University of Bolton prescribing programme.

Declarations of interest

There were no declarations of interest.

Key findings

Section 1: The programme provider

The team was satisfied that all of the four criteria relating to the programme provider are met (See Appendix 2 for criteria)

The Non-Medical Prescribing Programme delivered by the School of Health and Human Sciences was validated as per internal quality processes by the University two years ago at the time of the last NMC reaccreditation event and is subject to annual quality monitoring. The external examiner is an integral member of the module team and attends awards boards.

A maximum of forty students per cohort is supported, however usually numbers are at around twenty-five. There are currently nine planned cohorts; four starting in September 2017, four in January 2018 and one in May 2018. Of the four cohorts that commenced in September, one is being delivered on site at the University to a group of forty students, approximately fifty percent of whom are pharmacists; the other three cohorts are being delivered off-site to groups of twenty two, twenty four and nineteen students respectively, each with one to two pharmacists. There has been an increase in the number of cohorts delivered to support NHS partners. Most recent applicants have been funded directly by Health Education England, however there are some students who fund the course independently; funding is unlikely to continue beyond the current academic year with anticipated numbers of pharmacists at eight to ten per cohort.

The off-site teaching is carried out by the University teaching team on different days of the week and comprises the theory element of the programme, with all the clinical examination skills teaching taking place in the University simulation suite and supervised by a specialist respiratory nurse.

There are two whole time equivalent posts for the programme with a third whole time equivalent lecturer having been appointed recently, including a full-time pharmacist, with additional staff provision for two clinical examination skills days on each cohort. The designated pharmacist has re-designed the pharmacology component of the programme which most pharmacists still attend despite it being optional for pharmacists. The team agreed that the University be reaccredited to deliver the programme for the proposed nine cohorts, each with a maximum number of students of forty five.

Section 2: Pre-requisites for entry

The team was satisfied that all of the six criteria relating to the pre-requisites for entry are met, subject to wording amendments

All applications are checked by the programme team to ensure current registration with the GPhC, appropriate patient-oriented experience, identification of an area of practice, relevant up-to-date knowledge, continuing professional development, and a DMP familiar with the GPhC requirements. The team was told that most self-employed pharmacists applying for the programme were associated with GP practices and that references and sign-off could be obtained from their DMPs or CCG, supplemented by a telephone interview. In the case of a pharmacist wishing to prescribe in a new area of practice, the team was told that a decision on suitability would be taken on a case-by-case basis, but that the University would ideally require the pharmacist to have had at least twelve months' experience in the new area.

Prospective DMPs are sent the DMP Handbook at the time of the pharmacist's application and are invited to an induction meeting at the University, although the teaching team members now visit the DMPs in practice after the student has been accepted onto the programme. New DMPs are able to contact the University for information on their role and there is a DMP portal on the programme website which can be used to access the GPhC learning outcomes; the GPhC learning outcomes are not included

in the DMP Handbook as the team was told that when they were included previously, they caused confusion and are now contained in a separate document.

Section 3: The programme

The team was satisfied that all of the eight criteria relating to the programme are met

The programme carries 40 credits and is delivered at both Levels 6 and 7. There is an early formative assessment of the students to gauge the appropriate level of study, and students may decide at that juncture to change their level of study. Pharmacists often apply to study at Level 6 but then opt to change up to Level 7 based on career progression opportunities, with HEE NW encouraging pharmacists to study at Level 7. The major difference between the levels of study is related to the assessment, with the pharmacology and numeracy assessments being identical for both levels and the difference lying in the completion of the portfolio.

A blended learning approach is utilised, consisting of a mixture of classroom sessions; group work, reflective practice, problem-based learning, role-play and critical analysis and discussion of issues observed in practice relating to prescribing. Additionally, directed study using Moodle, e-learning materials and NMP web-based e-learning resources is required. The team was told that the Module Handbook had previously contained the GPhC LOs, but that this had proved confusing to students, with the result that the GPhC LOs are now provided to the students in a separate document and are discussed during the teaching sessions.

The clinical examination skills teaching takes place in the University simulation suite with pharmacists that require extra tuition in clinical examination skills being able to spend extra time with the clinical skills teacher. This teaching involves history-taking, diagnosis and generic physical examination skills, the last-named being tailored to cater for different levels of knowledge and student background. The clinical skills teaching is supported by formative OSCEs which provide feedback on any potential need for further teaching sessions, and there is a clinical skills workbook which is signed-off by the DMP after the period of learning in practice.

The programme is delivered over a period of 26 weeks at 1 day per week, and consists of 11 taught days, 6 option days (3 of which are pharmacology and a further three which are allocated as supported study for portfolio development and tutorials), and 9 directed study days. Students are encouraged to attend individual tutorials throughout the programme, and there is opportunity for three individual tutorials with additional tutorials available as needed. Pharmacists must attend all clinical sessions, and are required to undertake all assessments. Although the attendance requirements are contained on the virtual learning environment and is emphasised in the introductory sessions, the team considered that such information should be included in the Module Handbook.

Section 4: Learning in Practice

The team was satisfied that all of the five criteria relating to learning in practice are met

DMPs are issued with a handbook which summarises the programme and the expectations in terms of their role in teaching and assessment. They are also provided with a copy of the Clinical Assessment document and OSCE guidance and assessment. Practice visits are undertaken by the programme team and where issues are raised, action plans developed to support both the student and DMP. The team was told that the types of issues that arise during visits from the teaching team to DMPs in the practice setting depend on the DMP's previous experience of the role, and that the teaching team provides reactive support in the case of issues arising either by telephone or by visit. The team was told that there is occasional lack of understanding by DMPs of the role of the pharmacist after completion of the programme.

The team was of the view that it might be useful to provide DMPs with more guidance on their role in assessment of the pharmacists. Clinical skills are taught within the university-based sessions and then further practised and developed within practice. DMPs are required to complete a formal assessment of clinical skills which is submitted to the University as part of portfolio and summative assessment. OSCE practice sessions within the University provide opportunity for formative assessment and support within a simulated environment.

Section 5: Assessment

The team was satisfied that all of the four criteria relating to assessment are met, subject to wording amendments

There are four items of summative assessment within the programme: a pharmacology examination, a numeracy test with 100% pass mark, a portfolio, an OSCE/consultation in practice marked on a pass/fail basis in practice by the DMP, recorded and moderated by academic staff who also assess the prescription written during the OSCE; the external examiner receives a sample of the moderated material. The OSCE-type assessment has been moved to the practice environment in order to cater for the required specialist skills. Students are required to pass all the bullet point statements in the assessment tool although DMPs may annotate their decision. The portfolio, including three case studies in which safe prescribing decisions and reflections on consultation are required, represents the difference between the assessment for Levels 6 and 7, with Level 7 students being expected to demonstrate a greater degree of critical analysis than those studying at Level 6; to this end, the Level 7 portfolio is 1000 words longer than its Level 6 equivalent. At Level 7 a pharmacist who fails is allowed only one second attempt at the failed examination, and any potential opportunity to re-take the programme will be discussed with the pharmacist's manager. In the case of Level 6 study, failure at the second attempt of an examination will be discussed at the examination board with a view to allowing a further attempt. The team ascertained that the statement that any failure to identify a serious problem or an answer which would cause the patient harm will result in overall failure of the programme applies to all assessments, and that students are made aware of this stipulation.

Section 6: Details of Award

The team was satisfied that both of the two criteria relating to details of the award are met

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.