General Pharmaceutical Council

Independent prescribing programme

University of Sunderland

Report of a reaccreditation event

November 2016

Event summary and conclusions

Provider	University of Sunderland
Course	Independent Prescribing Programme
Event type	Reaccreditation
Event date	2 November 2016
Accreditation period	January 2017 – January 2020
Outcome	Approval with condition The accreditation team agreed to recommend to the Registrar of the General Pharmaceutical Council (GPhC) that the University of Sunderland should be reaccredited as a provider of a pharmacist independent prescribing programme for a further period of three years, subject to one condition.
Conditions	The assessment regulations must ensure that in any assessment a failure to identify a serious problem or an answer that would cause the patient harm must result in the overall failure of the programme. This must be communicated to all students and DMPs in all materials. This is to meet criterion 5.4.
Standing conditions	Please refer to Appendix 1
Recommendations	No recommendations were made
Registrar decision	Following the event a satisfactory response was received to meet the condition of reaccreditation. The Registrar of the General Pharmaceutical Council agreed with the accreditation team's recommendations and approved the course for reaccreditation for a further period of three years, until the end of January 2020.
Key contact (provider)	Dr Keith Holden, Principal Lecturer, University of Sunderland
Accreditation team	Professor Jane Portlock (event Chair), Professor of Pharmacy Practice, University of Portsmouth Professor Chris Langley, Professor of Pharmacy Law & Practice and Head of the School of Pharmacy, Aston University; Associate Dean, Taught Programmes, School of Life and Health Sciences
GPhC representative	Miss Jenny Clapham, Quality Assurance Officer, GPhC
Rapporteur	Mrs Jane Smith, Chief Operating 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 Sunderland was first accredited by the GPhC in 2007 to provide a programme to train pharmacist independent prescribers. The course was reaccredited in 2010 and again in 2013 for a period of four years. No conditions were set or recommendations made at the last reaccreditation event. In line with the GPhC's process for reaccreditation of independent prescribing programmes, an event was scheduled on 2 November 2016 to review the programme's suitability for further 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 2 November 2016 at the GPhC headquarters, London, and comprised a number of meetings between the GPhC accreditation team and representatives of the University of Sunderland 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 University of Sunderland is an established provider of undergraduate and postgraduate programmes in pharmacy, health, nursing and related biomedical subjects. The Independent Prescribing programme is delivered by the University of Sunderland's School of Pharmacy. The team recognised the huge support provided to the programme by the Programme Lead.

The programme is validated by the University at least once every six years, and was last revalidated in

June 2016. The external examiner for the programme is Dr Sarah Corlett, Medway School of Pharmacy, University of Kent.

Students on the programme have access to a new, purpose-built and well-equipped clinical skills teaching facility as well as more standard University facilities, including comprehensive library facilities, access to information technology resources and the availability of a virtual learning environment (VLE).

The team noted the recent expansion in the number of students admitted to the course and noted that this was being managed by maintaining cohort sizes at a maximum of 20 students, but by increasing the number of cohorts. The decision to keep cohort sizes at 20 students was commended by the team as this enables the provider to maintain its focus on teaching physical examinations skills and teaching by case study. The provider was reminded that the standing conditions of accreditation require that significant changes to the programme must be notified to GPhC. In this case, approval to grow the number of students on the programme had not been sought. However, the team was content that the growth had been appropriately resourced and the provider undertook to inform the GPhC in advance of any further planned changes.

Section 2: Pre-requisites for entry

All of the six criteria relating to the pre-requisites for entry are met.

All applicants are required to complete a University Postgraduate Studies application form and each applicant's registration details are checked against the GPhC or PSNI register. Applicants are also asked for information relating to any previous unsuccessful applications for IP courses or failure of a previous IP course of study.

Each applicant is interviewed to assess their eligibility and suitability for entrance to the course. Group interview days have recently been introduced and the interviews are used to establish that the applicant has an appreciation of the commitment needed as well as the support of their employers. The team asked how the provider ensured that self-employed pharmacists were able to apply to the programme, in terms of having a declaration from an employer or NMP lead. The provider stated that very few self-employed pharmacists apply to the programme, but those that do are asked to work with the local commissioning groups to identify a clinical lead, with the NMP lead signing the declaration.

The team noted that most DMPs have experience of the clinical education process and that support is available for all DMPs in the form of the DMP guide and more personally with phone calls or visits if required. Additionally, the DMP and candidate must complete and co-sign a Learning Contract; a negotiated agreement detailing the expectations, roles and responsibilities of the learner and the supervisor.

Section 3: The programme

All of the eight criteria relating to the programme are met.

The programme is taught at Level 7, consistent with the FHEQ descriptors of a Master's level course. The programme learning outcomes are identical to the GPhC learning outcomes and the team agreed that the assessments had been mapped accordingly.

Teaching on the programme is centred on clinical case-based learning supplemented by physical skills development. There are nine teaching days at the University which are delivered in the first 10 weeks of the 12 month programme. The taught days consist of clinical case studies in the morning and physical examination skills in the afternoon. Outside of these sessions, students are expected to undertake directed supplementary learning which is signposted at the start of the session and via material on the VLE. Attendance is monitored by registration on each of the taught days. Any missed sessions

automatically prevent progression and must be completed within 12 months of initial registration. The provider has regular email contact with students after the initial 10 weeks of teaching.

The team asked if the provider has considered expanding the programme to a 60 credit Postgraduate Certificate and was told that there is a 15 credit clinical audit module which students can select if they wish. This can also be used towards an MSc Clinical Pharmacy.

Section 4: Learning in Practice

All of the five criteria relating to learning in practice are met

Written guidance is made available for all prospective DMPs, with telephone, email and face-to-face guidance also available if required.

The team asked what quality assurance processes were in place for DMPs in relation to their role in signing off the competency of their students. The provider explained that DMPs are experienced in assessment and have access to the competency framework. In addition, every portfolio is scrutinised by the Programme Lead who will ask for clarification if he has any queries or concerns. The external examiner also reviews a sample of the portfolios. The team agreed that these processes were appropriate.

Section 5: Assessment

Three of the four criteria relating to assessment are met

The programme employs a variety of assessment techniques that are designed to examine a student's ability to demonstrate their factual, interpretive, applied and physical knowledge and skills in the context of independent non-medical prescribing. The assessments include an Objective Structured Clinical Examination (OSCE), a Multiple Choice Examination, oral presentations and defence and a written portfolio of evidence and in-practice assessment of competency. The team agreed that the assessments were robust and provided evidence that students had achieved the intended learning outcomes of the programme.

Within the clinical assessments there are a series of 'red flag' markers; specific pre-identified issues in the marking grids for the OSCEs that relate to patient safety (rather than a "serious problem" as defined in the criterion). Failure to identify a red flag would lead to the student failing the OSCE and being required to resit before they could progress. The team asked how the provider deals with serious errors in all assessments, such as the portfolio, and was told that wherever these errors are identified, they result in failure of that assessment and therefore non-progression. The team emphasised that where an error or omission could lead to serious patient harm, it is a requirement that the student must fail the whole programme with no resit opportunity, and this was not the case for this programme. It will therefore be a **condition** of reaccreditation that the assessment regulations must ensure that in any assessment a failure to identify a serious problem or an answer that would cause the patient harm must result in the overall failure of the programme. This must be communicated to all students and DMPs in all materials. This is to meet criterion 5.4.

Section 6: Details of Award

Both of the criteria relating to details of the award will be met

Students are awarded the practice certificate in independent prescribing on successful completion of the programme. However, the provider currently issues transcripts rather than certificates and the team asked the provider to issue students with a certificate containing the correct wording in order to meet the accreditation criteria.

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.