General Pharmaceutical Council

Independent prescribing programme

University of Sussex

Report of an accreditation event

June 2018

Event summary and conclusions

Provider	University of Sussex
Course	Independent prescribing programme
Event type	Accreditation
Event date	1 June 2018
Accreditation period	July 2018 - July 2021 (provisional) NB. Accreditation is confirmed after a satisfactory monitoring event has taken place following completion of the first cohort of students.
Outcome	Approval The accreditation team agreed to recommend to the Registrar of the General Pharmaceutical Council (GPhC) that the pharmacist independent prescribing programme provided by the University of Sussex should be provisionally accredited for a period of three years, with a monitoring event taking place after completion of the first cohort of students.
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 provisional accreditation of the programme for a period of 3 years.
Key contact (provider)	Professor Jane Portlock, Director of Pharmacy Postgraduate Education
Accreditation team	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 Mrs Sandra Hall, Head of Pharmacy Practice, Leicester School of Pharmacy, De Montfort University
GPhC representative	Mr Chris McKendrick, Quality Assurance Officer
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 accreditation 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 Sussex approached the GPhC with an application for accreditation of a new programme to train pharmacist independent prescribers. The University was seeking approval to train up to 60 students in two cohorts per year, each cohort with a maximum of 30 students. The University is currently going through the accreditation process for an MPharm programme, having received Step 5 accreditation in March 2018. In line with the GPhC's process for accreditation of independent prescribing programmes, an event was scheduled for 1 June 2018 to review this programme's suitability for accreditation. In line with the GPhC's process for new providers of pharmacist prescribing programmes, the event was held on site at the University to allow for the GPhC's accreditation team to view the teaching facilities available.

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 onsite at the University of Sussex on 1 June 2018 and comprised a number of meetings between the GPhC accreditation team and representatives of the University of Sussex prescribing programme, and a tour of the university's teaching facilities.

Declarations of interest

None

Key findings

Section 1: The programme provider

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

The independent prescribing programme will be provided by Sussex Pharmacy, within the University of Sussex's School of Life Sciences.

The programme was validated by the University on 18 April 2018, with five conditions and two recommendations. Evidence has been provided that the conditions have now been achieved and the course is fully validated. One of the conditions is that it must be made clear which elements of the portfolio align to each module, as one assessment cannot count towards two modules. The programme is delivered as two separate modules: Professional and Clinical Aspects of Prescribing (45 credits) and Enhanced Clinical Skills (15 credits). The clinical skills module is planned to be available as a stand-alone CPD course as well as contributing to the independent prescribing programme, hence the decision not to combine the two modules. As originally proposed, elements of the assessment for both of these modules are contained within a single portfolio. In response to the University's validation condition, it has been decided to assess each module via a separate portfolio, so that it is clear to students which assessments are associated with each module. All course documentation must be updated to reflect the fact that there will be two portfolios, submitted at the same time.

The programme will be subject to the appropriate quality assurance processes including an Annual Course Review and a periodic review every six years. In addition, a more in-depth analysis will be carried out for this programme and will include feedback from students and DMPs, a review of student outcomes in terms of completion and progression, information on significant events that have affected delivery, peer review of teaching and curriculum and learning development initiatives. These will be reported to the GPhC after the first cohort has completed the programme.

The external examiner will attend the module and programme examination boards, review all of the assessments and student feedback and meet student representatives.

The teaching facilities, which were visited as part of the event, include a clinical skills teaching space equipped with diagnostic teaching aids and a community pharmacy simulation facility. Teaching on the programme will be delivered over five residential weekends, when the facilities will not be in use by undergraduate students. If numbers permit, a second cohort will be offered, in which case teaching will take place during the week, again at times when the facilities are not in use by undergraduate students.

The teaching facilities are suitable for a cohort size of up to 30 students, provided all rooms are available.

Appropriate staff resources are also in place and include a number of very part-time staff. Satisfactory arrangements are in place to ensure that communication, consistency and continuity across the course will be achieved. The programme is flexible with the order of sessions able to be adjusted to address any unavoidable staff absences.

Section 2: Pre-requisites for entry

The team was satisfied that all six criteria relating to the pre-requisites for entry will be met. One criterion requires minor amendments.

The application process ensures that students admitted to the programme have the relevant qualifications and experience. The application form asks applicants to provide their year of first registration. This is ambiguous; it could mean year of first registration with the GPhC, rather than the first year of registration as a pharmacist. The form will be updated to remove this ambiguity.

The application process also ensures that the DMP identified by the pharmacist has training and experience appropriate to their role. A DMP Guidance document will be provided to the potential DMP, via the applicant, when the applicant requests the application form. This contains the GPhC learning outcomes.

Section 3: The programme

The team was satisfied that all eight criteria relating to the programme will be met. One criterion requires minor amendments.

The programme will be taught and assessed at FHEQ Level 7 as a 60 credit Postgraduate Certificate and will be delivered over nine months, including the assessment period. It will consist of two modules: Professional and Clinical Aspects of Prescribing (45 credits) and Enhanced Clinical Skills (15 credits).

The taught elements of the programme will be delivered via 10 face-to-face study days at the University, comprising a balance of lectures, practical workshops and clinical skills sessions. The equivalent of 16 days of activities will be via delivered via Canvas, the University's new online learning structure. This will provide closely directed study, for example requiring students to carry out specific preparation for the study days and follow-up activities afterwards. Students' engagement with the online learning will be monitored and poor engagement by individual students will be followed up by the programme team. Attendance at all the study days is compulsory and registers will be taken. If a session is unavoidably missed, the student will be required to catch up on the taught component, either by attending the next available session or via an individual taught session. Students will not be permitted to complete the assessment unless they have attended the pre-requisite number of days dedicated to clinical examination and diagnosis. Reduction of learning time based on previous learning or experience is not permitted within the programme.

An initial learning needs assessment will allow the pharmacist to build on their background knowledge and experience and tailor their learning to meet the learning outcomes and to develop skills in their chosen clinical area.

In addition to the DMP support, students will be supported by an academic advisor. The role of the advisor will be to review the training needs identified through the learning needs analysis and to support the students' progression. Meetings between the student and the academic advisor will be by phone, or face-to-face at the study days, depending on student need.

The 16 GPhC learning outcomes have been appropriately mapped to the programme learning outcomes. Programme Learning Outcome 3 is mapped to GPhC Learning Outcome 4: 'Use diagnostic aids e.g. stethoscope, sphygmomanometer'. The wording of the programme learning outcome could be seen as ambiguous and suggests that the use of diagnostic aids might relate only to the student's specific area of practice, which might not cover common diagnostic equipment. It will be reworded to make it clear that, in relation to diagnostic aids, it is general and not limited to the specific area of practice.

Section 4: Learning in Practice

The team was satisfied that all five criteria relating to learning in practice will be met.

DMPs are provided with a DMP Guidance Handbook which details their role in helping the student to successfully complete the period of learning in practice. Students will initially be offered a provisional place on the programme, subject to a three-way conversation taking place between the provider, the student and the DMP. This meeting will provide an opportunity to go through the Handbook and to discuss the opportunities for learning provided by the DMP, the Learning Needs Analysis, the DMP's role in assessment and how to deal with any concerns. Only once this meeting has taken place and both the student and DMP have agreed that they are happy to progress will the offer of a place be confirmed.

DMPs are supported with clear and practical guidance on their role in the assessment of the student.

The DMP's assessment of the student's competencies are reviewed by the programme team in their overall portfolio assessment and form part of the overall view of the student's progression and performance. However, clinical skills are summatively assessed and quality assured by members of the programme staff at the university.

Failure of the period of learning in practice will result in failure of the portfolio assessment of the Professional and Clinical Aspects of Prescribing module. As there is no compensation within or between modules, this will result in failure of the programme.

Appropriate statements will be provided by DMPs at the completion of the period of learning in practice.

Section 5: Assessment

The team was satisfied that all four criteria relating to assessment will be met. One criterion requires minor amendments.

The assessment scheme for the programme is as follows:
Professional and Clinical Aspects of Prescribing (45 credits)

- Case study (50% pass mark)
- Therapeutic Framework (50% pass mark)
- Portfolio (Pass/Fail)
- Clinical Skills Assessment (Pass/Fail)

Enhanced Clinical Skills

- Essay (episode of care) (50% pass mark)
- Portfolio (Pass/Fail)
- Clinical Skills Assessment (Pass/Fail)

The therapeutic framework, case study and portfolio will be first and second marked by programme staff. They will also be moderated internally and a sample will be reviewed by the external examiner.

As two of the four clinical skills assessments will be tailored to individual students' area of practice, external expertise will be used to design and assess these skills if there is not sufficient expertise in the relevant area on the staff team.

There are no compensation arrangements for assessment between components within each module, or between each module. Students are normally entitled to one resit attempt in all failed modules, provided there is no failure to identify a serious problem or an answer which would cause the patient harm. (Exceptions can be made if the student has extenuating circumstances). Resits can be taken as in-course retrieval. If the resit is also failed, then the student will fail the module. As there is no compensation, this means that the programme will be failed. Students are able to apply to restart the programme with attendance in this case, although they may be advised to take some time to gain more experience in a particular area before they restart.

The GPhC had received evidence in advance of the visit that the University of Sussex's standard resit regulations had been over-ridden so that, in any assessment, a failure to identify a serious problem or an answer which would cause the patient harm will result in overall failure of the programme.

The submission mistakenly stated that a failure to identify a serious problem or an answer which would cause the patient harm in formative assessments will result in overall failure of the programme. In fact, failure only applies to summative assessments. Any documentation containing this error will be corrected.

In cases of failure due to serious error or potential patient harm, a serious error team will meet within the School to review the issue. That team might decide that the error not only leads to failure of the programme, but is also a Fitness to Practise issue. Only in these cases, will the student be referred to the University Fitness to Practise process, and also to the GPhC, recognising that students on the programme

will be registered pharmacists.

Section 6: Details of Award

The team was satisfied that both criteria relating to details of the award will be met.

The external examiner is a full member of the Examination Board. Students will be awarded a 'Practice Certificate in Independent Prescribing' confirming that they have successfully completed the programme and the period of learning in practice and a certified copy of the pass list will be provided to the GPhC.

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.