University of Central Lancashire
Report of an accreditation event
June 2017
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<td>The accreditation team agreed to recommend to the Registrar of the General Pharmaceutical Council (GPhC) that the University of Central Lancashire should be provisionally accredited as a pharmacist independent prescribing course provider for a period of three years, subject to one condition, with a monitoring event taking place after completion of the first cohort of students.</td>
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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 Central Lancashire approached the GPhC with an application for accreditation of a programme to train pharmacist independent prescribers. In line with the GPhC’s process for accreditation of independent prescribing programmes, an event was scheduled for 13 June 2017 to review the 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.

The University currently provides a non-medical prescribing (NMP) course run through the Faculty of Health and Wellbeing, which is accredited by the NMC, HCPC and GPhC. This course is long-established, and due for re-accreditation by the GPhC in Autumn 2017. The number of pharmacists accessing this course has been traditionally low, accounting for less than 10% of cohort numbers. Dialogue with local pharmacy employers during 2016 established that they preferentially chose to send their pharmacists to courses designed specifically for pharmacist independent prescribing rather than generic NMP. Local employers, primarily secondary care Chief Pharmacists and education and training leads, desired the School of Pharmacy and Biomedical Sciences to offer an Independent Prescribing course for pharmacists only. Further discussion through the School’s External Advisory Board, which had primary care representation, also endorsed this course development.

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 Central Lancashire on 13 June 2017 and comprised a number of meetings between the GPhC accreditation team and representatives of the University of Central Lancashire prescribing programme, and a tour of the University’s teaching facilities.

Declarations of interest
Ian Marshall declared that he had worked for the University of Central Lancashire on the development of its original MPharm degree and had subsequently worked in an advisory capacity up to 2014, but had had no involvement in the University’s independent prescribing provision.

Key findings

Section 1: The programme provider

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

The University of Central Lancashire is a Higher Education Institution with quality assurance systems and explicitly detailed QA mechanisms. The independent prescribing module will form part of a new MSc programme in Advanced Pharmacy Practice but will also be available as a stand-alone module. The Practice Certificate in Independent Prescribing will be delivered through the School of Pharmacy and Biomedical Sciences (the School). An institutional validation event for the MSc in Advanced Pharmacy Practice took place in February 2017.

Teaching delivery will utilise generic teaching space in the Maudland Building which houses the School, or in adjacent buildings. More specialised teaching, namely clinical examination skills, will draw on the School of Medicine Practice Skills Suite. In addition, the space dedicated for pharmacy practice teaching is currently being re-modelled. This space will also include equipment and appropriate facilities, for example, hand-washing and screened bed areas to teach clinical examination skills.

The University is part of the Northern HEE Consortium whose effort currently is capacity-building of prescribing pharmacists. It is anticipated that the maximum intake to the course will be forty pharmacists with one intake a year in September, but if the University’s current tender to the HEE is successful, it is considered possible that the HEE might require a rolling programme with an additional January/February intake, and with the additional possibility of flexible exit points. The MSc in Advanced Pharmacy Practice was launched in April 2017 with eleven students on course; if the independent prescribing module is accredited, they would be joined by up to twenty nine additional pharmacists in September 2018 to make up the cohort to forty.

The business plan has made provision for the appointment of a 0.4 FTE at Lecturer/Senior Lecturer level in addition to eight named teaching staff to help deliver the MSc and stand-alone programmes associated with independent prescribing. It was estimated that the IP course would require 1.0 WTE staff input, and a new 0.5 WTE position in pharmacy practice will contribute towards this as part of their workload, along with contributions from the eight named staff, and representation from a group of medical doctors who are available to the small-group demonstrating of clinical skills. The programme leader is the designated pharmacist.

Section 2: Pre-requisites for entry

The team was satisfied that all six criteria relating to the pre-requisites for entry will be met

There is a standalone application form for the IP course that must be completed in advance of the more generic University application form. Applications are sent from University Admissions to the School and are reviewed by the programme leader and deputy leader with applicants being interviewed if deemed appropriate. Potential candidates must describe their experience on the application form, and must demonstrate to the satisfaction of the course leader that they have at least two years’ appropriate, post-registration, patient-orientated experience in a UK hospital, community or primary care setting. The application form requires a written declaration of the applicant’s level of knowledge in their proposed specialist subject area of prescribing; decisions on interviews for admission are partly based on this information. Applicants must provide their CPD records over the previous twenty four months to provide confirmation of their continuing learning and to help identify and gaps in their experience; these are
reviewed by the programme leader and deputy programme leader. Non-registrants are ineligible to join this programme and thus will not be permitted to undertake any of its components.

It is the applicant’s responsibility to identify their own DMP, and the School has not yet engaged with any DMPs as it is not sure yet how many will be required. Prior to an applicant being accepted on the course a number of checks will be conducted by the course team to satisfy themselves that the person identified by the candidate will be in a position to act as the DMP. New DMPs will likely require support in the way of visits to their practice base. The School does not anticipate problems in terms of the University having two IP provisions, both requiring DMPs, although the Faculty of Health and Wellbeing course is moving to provide teaching to four cohorts per year due to the current demand to up-skill the healthcare workforce, and with demand for places on IP course increasing throughout the country.

Section 3: The programme

The team was satisfied that all eight criteria relating to the programme will be met

As part of a Masters degree, the IP module will be taught at M-level only and carries 40 credits. The programme learning outcomes were mapped appropriately against the current GPhC learning outcomes. The ethos of the course is to enhance practitioner skills, behaviours and attitudes, underpinned by portfolio building to demonstrate acquisition of the competencies in the GPhC learning outcomes. Clinical assessment skills are demonstrated through competency-based approaches. A ‘flipped learning classroom’ environment has been adopted for face-to-face study days, which requires students to undertake directed work before each study day. The programme will consist of nine face-to-face study days (67.5 hours), eight days of online learning materials from CPPE (60 hours), nine days of directed learning for preparation and consolidation of face-to-face study days (67.5 hours), seventeen days of self-directed study (115 hours), plus the experiential learning with DMP (90 hours).

The School does not specifically intend to teach knowledge of therapeutic areas, and as part of entry requirements students must satisfy the course leader that their knowledge in their intended scope of prescribing is up to date. Furthermore, students will be required to construct a personal development plan (PDP) to ensure that they maintain or improve their knowledge in that field. Experiential learning in practice is embedded within a requirement for reflective practice and is linked in to portfolio requirements. Personal development will take place through self-reflection informed by interaction with their DMP and other mentors whilst undertaking experiential activity. The programme has been designed to be as flexible as possible with the first group of face-to-face teaching sessions early in the course being delivered in a block so that students understand what is required/expected of them, and for them to learn physical examination skills, allowing them to work with their DMP from early in the programme.

The team agreed that the amount and positioning of the teaching of physical examination skills in the programme was appropriate. If students encounter problems with insufficient protected time for their studies, it is their responsibility to report back to the School who will approach the employer on their behalf. Students that miss sessions, especially the clinical skills sessions, will have the opportunity to make up such sessions in the final week of the programme which is a mock practice session. In addition, students can observe video recordings and make up the missed sessions in their own time.

Section 4: Learning in Practice
The team was satisfied that all five criteria relating to learning in practice will be met

A handbook will be provided to DMPs, and the School will attempt to visit each DMP before the student starts their experiential learning in practice, or each DMP will be contacted via telephone to discuss their role and the University’s requirements. The DMP will not be expected to teach clinical skills but rather to provide students with opportunities to practise the skills they have gained during teaching sessions held during the face-to-face study days which will be taught by qualified medical doctors or independent prescribers during timetabled sessions. However, the DMP will need to sign off the student’s experiential experience. There will be pro-active checks on student progression, not organised on a fixed-point basis but by encouraging students to report any problems as early as possible. The role of the DMP in assessment will be the provision of in-practice assessment of clinical skills to be taken in conjunction with student performance in the OSCE. The RPS Competency Framework will be used for both formative and summative assessments, encompassing both self-assessment by the student and the DMP’s assessment. The student has to complete the learning in practice to the satisfaction of the DMP and through submission of a learning log in the portfolio. Failure to complete learning in practice will result in failure and no other element of assessment will compensate this failure. Students will be told this at the first study day and this information will be available in written form in the course handbook and/or through Blackboard space.

Section 5: Assessment
The team was satisfied that two of the four criteria relating to assessment will be met with 2 criteria subject to a condition

The summative assessments are an OSCE and an online reflective portfolio, which includes a variety of compulsory activities, with the OSCE is a measure of competence and the portfolio providing a measure of student progress with an experiential log. The joint competence/reflective approach is designed to help students to be aware of the issues involved in moving from one role in practice to another. The reason for not including a summative assessment of knowledge is so that the provider can gauge that the student is able to perform a task rather than just describing it.

A 4-station OSCE is the main summative assessment of competence; the team was concerned about the robustness of the OSCE given that a minimum of ten stations is normally required and that the reliance on a small-station OSCE and a portfolio was likely to be insufficiently robust. The provider argued that no current IP programmes adopt the above multi-station approach, but the team pointed out that other providers of IP courses that utilise OSCEs with a small number of stations do also have other forms of assessment of knowledge. Currently, OSCE examples are taken from a variety of sources but the team will start to write extra stations and take advice from Medicine on more developed OSCEs. As a result of the team’s concerns, it will be a condition of accreditation that the University must review and revise the assessment of competency to ensure that best practice is followed and the assessment(s) is/are robust, reliable and valid within each assessment instrument. This applies to criterion 5.1 which is not met. The University must provide the GPhC with a revised written competency assessment strategy for review and approval by this accreditation team. The condition must be met before the intake of any pharmacists onto the programme. Students must pass all assessments, and Pass criteria appeared consistent with safe and effective prescribing. However, as a result of the team’s above concerns around the robustness of the assessment strategy the condition of accreditation will also apply to criterion 5.3 which is not met.

Although the IP module is a component part of the MSc in Advanced Pharmacy Practice, it will be assessed separately. The Postgraduate Diploma taught element of the MSc runs from September to Easter the following year and the examination boards are held in May. As a result, the candidates for the IP module will complete the course and be apprised of the outcome some six weeks later. The School has introduced a Patient Safety Panel that considers potential patient harm that results from student actions in assessments. Students’ attention will be drawn to this in the course handbook and reinforced verbally at the first face to face study day. The team welcomed the establishment of the Patient Safety Panel which had been trialled in the undergraduate degree. However, the team found the statements in the documentation about the outcome of causing serious patient harm somewhat ambiguous, but was assured that causing such harm would result of failure of the entire course, not just of the individual assessment. The team agreed that this should be made clear in all documentation.

Section 6: Details of Award

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

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**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.
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.