The accreditation of pharmacy courses leading to registration and annotation in Great Britain

Operational description: September 2013
1. Introduction

The General Pharmaceutical Council (GPhC) is the regulator for pharmacists, pharmacy technicians and registered pharmacy premises in Great Britain. Part of its education function is to check the standards of courses leading to registration and annotation as a pharmacist. It assumed responsibility for this work on September 27th 2010. Prior to that, it was the responsibility of the Royal Pharmaceutical Society of Great Britain (RPSGB).

This is version 2 of this document, which was issued originally in 2011.
2. About us

The General Pharmaceutical Council (GPhC) is the regulator for pharmacists, pharmacy technicians and pharmacy premises.

It is our job to protect, promote and maintain the health, safety and wellbeing of members of the public, and in particular those members of the public who use or need the services of pharmacy professionals or the services provided at a registered pharmacy.

Our principal functions include:

- setting standards for conduct, ethics, proficiency, education and training, and continuing professional development (CPD);
- establishing and promoting standards for the safe and effective practice of pharmacy at registered pharmacies;
- establishing fitness to practise requirements, monitoring pharmacy professionals’ fitness to practise and dealing firmly and fairly with complaints;
- approving qualifications for pharmacists and pharmacy technicians; and
- maintaining a register of pharmacists, pharmacy technicians and pharmacy premises.

We will aim to ensure that regulation is fair and proportionate – that is, in line with the level of risk posed to public health, safety and wellbeing – and not over-burdensome. We want it to be flexible enough to respond to the changing demands made of the profession and to allow for innovation at the same time as maintaining high quality practice.
3. Background

Pharmacy is a regulated profession. This includes the regulation of education and training leading to registration and annotation as a pharmacist and registration as a pharmacy technician. The GPhC has two related education quality processes: accreditation and recognition. Accreditation involves the approval of a course designed and delivered by a provider (for example, an MPharm degree designed and delivered by a university) whereas recognition involves the approval of a national qualification (for example, an NVQ) which is quality assured by a national qualifications body (for example, Ofqual).

The GPhC accredits the following courses:

- MPharm degrees (including those delivered in part overseas);
- Overseas Pharmacists’ Assessment Programmes (OSPAPs; courses for non-EEA pharmacists wanting to register in Great Britain). OSPAPs are postgraduate diplomas;
- Foundation degrees in pharmacy leading to entry to an MPharm;
- Non-medical prescribing courses for pharmacists;
- Pharmacy technicians courses offered by independent providers; and
- Pharmacy support staff courses offered by independent providers.

The GPhC recognizes the following courses:

- Knowledge qualifications for pharmacy technicians; and
- Competence qualifications for pharmacy technicians.

The GPhC has the right to accredit outside Great Britain, which includes Northern Ireland. The GPhC accredits courses in Northern Ireland jointly with the Pharmaceutical Society of Northern Ireland.

3.1 NEW INITIAL EDUCATION AND TRAINING STANDARDS FOR PHARMACISTS

We have issued two sets of education and training standards to complement this new methodology. The standards are:

- *Future pharmacists: standards for the initial education and training of pharmacists in Great Britain* (MPharm degree and pre-registration standards); and
- *Education and training standards for non-EEA pharmacists wanting to register in Great Britain* (OSPAP standards).

The new accreditation methodology has been designed to test these standards. Each document has 10 standards and each standard includes criteria, required evidence and advice on meeting the standard.
In the standards, we have moved away from a reliance on inputs to an emphasis on outcomes - what students can actually do. The standards are:

Standard 1: Patient and public safety;
Standard 2: Monitoring, review and evaluation of initial education and training;
Standard 3: Equality, diversity and opportunity;
Standard 4: Selection of students and trainees;
Standard 5: Curriculum delivery and the student experience;
Standard 6: Support and development for students and trainees;
Standard 7: Support and development for tutors and academic staff;
Standard 8: Management of initial education & training;
Standard 9: Resources and capacity; and
Standard 10: Outcomes.

The initial education and training for pharmacists in Great Britain comprises a four-year MPharm degree, 52 weeks of pre-registration training and a national Registration Assessment. There is one five-year MPharm degree with intercalated periods of pre-registration training. The new standards refer to pre-registration training but are written, primarily, for the MPharm degree. A five year MPharm with integrated – rather than intercalated - pre-registration training is an aspiration and were such degrees to be introduced, we would revisit this methodology.

3.2 THE PRINCIPLES OF ACCREDITATION

This document does not describe every single permutation of the accreditation methodology. Instead it states the principles of accreditation and applies them to one course: the MPharm degree. The methodology as described in this document will be applied to other courses but with variations as appropriate.

The principles are that accreditation is:

1. proportionate;
2. transparent;
3. public;
4. evidence based;
5. cyclical; and
6. based on peer review.
Although professional accreditation is separate from other quality assurances processes in universities, it will take account of them where possible. This includes taking account of the views of external examiners, while not using the examiners themselves as part of the accreditation process.

3.3 THE LEGAL BASIS OF ACCREDITATION

3.3.1 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 (approval being the generic term for accreditation and recognition) by appointing ‘visitors’ (accreditors and recognisers) 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.

3.3.2 It is a requirement that the GPhC maintains a list of qualifications which are accredited and a list of those qualifications which were previously accredited.

3.3.3 It is a requirement that reports of accreditation and recognition events are public. Public reports will contain judgements about whether an MPharm degree provider has met the requirements of accreditation.

3.3.4 It is requirement of the Order that education providers must supply information to the GPhC to assist it in discharging its accreditation and recognition function. If providers do not assist the GPhC, accreditation may be refused or withdrawn or providers may be placed on probation.

3.4 MAKING DECISIONS

3.4.1 Accreditation decisions will be the responsibility of the GPhC’s Registrar on advice from accreditors. The exception is the refusal or withdrawal of accreditation, which is reserved to the GPhC’s Council.

3.4.2 Reports will be written after accreditation events which will be made public. Providers will be required to provide written responses to reports, which will also be made public.

3.5 APPEALS

The Order describes the appeal mechanism for accreditation and recognition decisions, at the heart of which is the right of a provider to challenge a decision by, first, providing additional evidence and, second, by making an appeal to the GPhC’s independent Appeals Committee.

The form and manner of an appeal is described in the Order.
3.6 SUMMARY OF THE METHODOLOGY

Diagrammatically, the methodology can be summarised as:

Submit document → Pre-visit → Main visit → Registrar/Council decision → Report → Three year practice visit → Revisit after six years → Submit document
4. Additional features of accreditation

4.1 Using data more effectively
As well as receiving periodic visits, schools of pharmacy must submit an annual return about student numbers, staffing, funding and student fitness to practise. We intend to integrate the annual return into the accreditation methodology to provide accreditors with a more dynamic profile of a school. This should enable us to identify schools which are at higher risk and those at lower risk. Our principal concern is the standard of courses but we accept that resources have a bearing on standards. In time we may consider varying the periodic cycle of visits for particular schools on the basis of heightened or lower risk derived from our data set.

Through the annual return we intend to monitor student fitness to practise so we build up a national picture of key themes and issues.

4.2 A practice visit
As has been explained, the reporting requirements for education standards in the Order are more explicit than in previous legislation. Because ‘nature, content and quality’ must be covered, teaching/learning and placement activities need to be observed. The practice visit will take three years after a main visit and the results of the visit will form an appendix to the main report. Because we will be observing activities that are already timetabled, there will be minimal intrusion and the visits will not be a significant burden on institutions. Practice visits will take place at the university and placement sites.

The practice visit is not a secondary accreditation and the GPhC’s accreditation judgement from the main visit will stand unless evidence comes to light requiring it to be reconsidered. This evidence could come from a practice visit or from any other source or activity.

Separately, we will issue an operational document for practice visits. This will clarify the mechanics of a visit and what is required of schools.

4.3 The cycle of accreditation
The main accreditation cycle has been extended from five years to six. This means there is an engagement with a provider every three years.
4.4 Stakeholder involvement

The methodology places greater emphasis on stakeholder views, especially the views of patients, the public and previous students.

First it will be a requirement for schools to submit an analysis of views about their MPharm degree from current pre-registration trainees and recent registrants who studied on the MPharm degree being reaccredited. Recent registrant means someone who has been registered as a pharmacist with the GPhC for up to three years (or in Northern Ireland, registration with the Pharmaceutical Society of Northern Ireland). This will be explored during accreditation visits.

Second, the new initial education & training standards requires accreditors to gather and analyse data about equality & diversity.

Third, schools will be required to demonstrate how patients and the public have been, and are, involved in course design and delivery and their views on the course.

4.5 Enhancement and assurance

An assurance accreditation process would just report on whether a minimum standard had been met whereas an enhancement process goes further, commenting on areas of good practice, areas needing improvement and generally giving qualitative feedback to course providers. Given that our reporting requirements relate to nature, content and quality, an assurance only process is not adequate and enhancement elements are included. This is the approach taken by other healthcare regulators and, most recently, by the Quality Assurance Agency in its Institutional review of higher education institutions in England and Northern Ireland (www.qaa.ac.uk).

Assurance judgements will be made public, as described above. Enhancement comments will be fed back to schools confidentially for quality enhancement purposes.

5. Other quality measures in higher education

The GPhC’s proposed new methodology will complement and not duplicate the Quality Assurance Agency’s new quality check on higher education: institutional review, which does not include subject/disciplinary review. We note that the QAA has reached a similar conclusion about enhancement: that it is appropriate and that pure assurance is insufficient.

Universities have their own well established quality assurance processes and our data set will draw on the outputs of those processes. Our new education & training standards make it clear that we will drawn on existing university documentation as a large part of our evidence base.
6. Data set

Under each standard in *Future Pharmacists* there are data requirements, which form the core data set. In summary they are:

- **Patient and public views**: Increasingly, schools are using the views of patients and the public to inform course design and delivery. We will expect to see evidence of this;
- **Staffing**: Evidence of how the staffing mix will deliver an MPharm degree of the right standard;
- **Resources**: Evidence of how they are sufficient to support the design and delivery of a master’s degree;
- **Strategies for teaching, learning and assessment**: We have emphasised the importance of feedback in assessment. We would observe that modular courses tend to over assess, sometimes at the expense of more useful timely feedback;
- **Pre-registration trainee/recent registrant evaluation report** involving the last 3 years of trainees and recent registrants;
- **External examiners’ reports** for the last three years;
- **Internal quality reports and evaluations**, including minutes of staff-student committees;
- **Academic regulations**: Principally, our scrutiny of academic regulations will be to ensure that threshold standards are being maintained and that pass criteria are true pass criteria;
- **Practice/placement report** from interim visit;
- **Annual data return from schools**;
- **Registration Assessment/Examination data** for the last three years.
7. The steps of the methodology

1. Before the start of an academic year: accreditation timetable for the following academic year is agreed.
2. Pre-visit minus 6 weeks: one-volume self evaluation document is submitted electronically and in hard copy (x10). All other documents in the core data set must be submitted electronically at this time.
3. Pre-visit (one month before the main visit): the meetings schedule, attendance list and additional data requirements are agreed. After the meeting, the self evaluation document is sent to accreditors.
4. Main visit.
5. Main visit + 6 weeks: report is sent to course provider and accreditors to comment on factual accuracy.
6. Main visit + 10 weeks: agreed report is sent to Registrar for consideration.
7. Main visit + 13 weeks: final version of report sent to course provider. Course provider asked to produce written response.
8. Main visit + 24 weeks: final version of report and course provider’s response posted on GPhC’s website.
9. 4th year of accreditation: pre-visit to agree teaching and placement observation schedule.
10. 4th year of accreditation: 3-year practice visit. Observations take place
11. Practice visit + 4 weeks: teaching and placement observation reports sent to course provider. Reports become an appendix to the main report.

Note: This timeline is indicative.
New schools of pharmacy

We have a 7-year step-based approach to accrediting new schools of pharmacy. The reason for this is that new schools are more likely to be at risk than existing ones while they are still recruiting staff, developing facilities and recruiting initial cohorts of students. The steps are:

1. initial presentation by course provider [students minus 3 years]. This step will explore the strategic case for a new course, the regional case for a new course, the impact on the local pre-registration economy of a new course and supporting infrastructure, how the views of patients, public and local/regional pre-registration providers (not just preferred partners) have been fed into the new course proposal, investment by the university in the course and its supporting infrastructure (including recent key appointments);
2. the business case [students minus 2 years]. This step will examine the business case in depth (including key appointments made between step 1 and step 2) as well as the philosophy of the integrated course, the learning, teaching and assessment strategy, plans for patient and public involvement in course design and delivery, the inter-professional learning strategy and the plan for practice activities;
3. the curriculum [students minus 1 year]. This step will examine the course in depth and will consider the development of the learning, teaching and assessment strategy, plans for patient and public involvement in course design and delivery, the inter-professional learning strategy and the plan for practice activities. It will also consider key appointments made between step 2 and step 3;
4. first year of delivery. The focus will be course delivery and preparing for a second cohort of students, including staffing and resource implications;
5. second year of delivery. The focus will be course delivery and preparing for a third cohort of students, including staffing and resource implications;
6. third year of delivery. The focus will be course delivery and preparing for a fourth cohort of students, including staffing and resource implications;
7. fourth year of delivery. The focus will be course delivery and the presentation of a revised course for full accreditation (if successful).

NB If a new five-year MPharm degree with integrated pre-registration training blocks is proposed, then the process will be extended to 8 steps, where the final two are:

7. fourth year of delivery, including the first block of pre-registration training. NB This step replaces 7. above;
8. fifth year of delivery, including the second block of pre-registration training.

There can be no more than one step event in a given academic year.
9. Outcomes of accreditation

9.2 NEW MPhARM DEGREES

The initial process for accrediting a new MPharm degree is probationary throughout. This must be made clear to all students and applicants until the first cohort of students has graduated successfully.

9.2.1 The step 1 event is advisory.

9.2.2 Outcomes of step 2 events:

1. granting probationary accreditation. Probationary accreditation will be granted if it can be demonstrated that standards are likely to be met; or
2. refusal to accredit. Accreditation of a new MPharm degree may be refused, if it can be demonstrated that the standards are not likely to be met.

9.2.3 Outcomes of step events 3-6 for a 4-year degree and events 3-7 for a 5-year degree are:

1. continuance of probationary accreditation. Continuing probationary accreditation will be given if it can be demonstrated that standards are likely to be met; or
2. withdrawal of accreditation. Accreditation of a new MPharm degree may be withdrawn, if it can be demonstrated that the standards are not being met or are not likely to be met.

9.2.4 Outcomes of step 7 events for a 4-year degree and step 8 events for a 5-year degree are:

1. full accreditation. Full accreditation of a new MPharm degree may be given if it can be demonstrated that standards are being met and are likely to be met for an accreditation period. The normal period of full accreditation is six years;
2. withdrawal of accreditation. Accreditation of a new MPharm degree may be withdrawn, if it can be demonstrated that the standards are not being met or are not likely to be met.

9.2.5 A step event can be repeated once. A repeat event must be in another academic year.
9.3 EXISTING MPhARM DEGREES

Outcomes of reaccreditation events are:

1. continuance of full accreditation. Continuing full accreditation will be granted if it can be demonstrated that standards are likely to be met. Normally continuing reaccreditation will be granted for a period of six years. This period can be varied; or

2. imposition of probationary accreditation. If a serious concern arises through accreditation or by other means, an existing MPharm may be placed on probation. Like all accreditation decisions, this will made public. Probationary accreditation will be imposed for a specified period, after which only outcomes 1. and 3. can be considered. Any provider placed on probation must produce an action plan documenting how concerns will be addressed in the specified time period; or

3. withdrawal of accreditation. Accreditation of a new MPharm degree may be withdrawn, if it can be demonstrated that the standards are not being met or are not likely to be met.

9.4 NEW & EXISTING MPhARM DEGREES

In accordance with the Order, accreditation of an MPharm degree may be refused if a course provider fails to provide information and assistance to the GPhC. Course providers must provide information proactively as well as on request.

The accreditation process is developmental. As part of the process, conditions may be imposed and/or recommendations may be made. Conditions must be met within a specified timescale; recommendations must be considered.

The GPhC reserves the right to investigate any matter brought to its attention which may have a bearing on the accreditation of a course.

9.5 VOLUNTARY WITHDRAWAL

A course provider may withdraw from the accreditation process. In these circumstances, the provider must inform the GPhC how the best interests of students currently on an accredited course will be served. Voluntary withdrawal does not preclude either re-entering the accreditation process or entering it afresh from the beginning. The GPhC will decide at what point a provider may join/rejoin the process.
10. Related documents

*Code of conduct for pharmacy students* [GPhC, 2010]

*Future pharmacists, standards for the initial education and training of pharmacists* [GPhC, 2011]

*Guidance on student fitness to practise in schools of pharmacy* [GPhC, 2010]

*Institutional review of higher education institutions in England and Northern Ireland* [QAA, 2011]