

Methodology: the initial approval of pharmacist Foundation Training Year programmes delivered independently of an MPharm degree

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Introduction

Pharmacy is a regulated profession in which the General Pharmaceutical Council (GPhC) holds the role of regulator for pharmacists, pharmacy technicians and registered pharmacy premises in Great Britain. Part of its education function is to check the standards of programmes or courses leading to registration as a pharmacist or pharmacist technician and annotation as a pharmacist independent prescriber. It assumed responsibility for this work on 27 September 2010. Prior to this, it was the responsibility of the Royal Pharmaceutical Society of Great Britain (RPSGB).

Background

The GPhC has two related education quality processes: accreditation and recognition. Accreditation involves the approval of a programme or 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 designed by an awarding organisation (for example, an NVQ) which is regulated by a national qualifications authority (for example, Ofqual).

The GPhC has historically accredited a number of different programmes and courses. This document adds Foundation Training Year (FTY) programmes, delivered independently of an MPharm degree, covering the final year of initial pharmacist education and training. These programmes replace the existing Pre-Registration Training Year and, along with the MPharm degree, permit those who complete them successfully and pass the GPhC registration assessment, to register as a pharmacist in Great Britain (GB).

The accreditation of Foundation Training Year programmes

The introduction of the 2021 standards for the initial education and training of pharmacists (IETP standards) make a number of reforms to the education and training process for pharmacy education including the introduction of a Foundation Training Year which, along with a reformed MPharm degree, will allow graduates to become prescribers upon registration as pharmacists.

The Foundation Training Year is subject to the 2021 IETP standards, which cover:

- Standard 1: Selection and admission
- Standard 2: Equality, diversity and fairness
- Standard 3: Resources and capacity
- Standard 4: Managing, developing and evaluating Foundation Training Year programmes
- Standard 5: Foundation year design and delivery
- Standard 6: Assessment
- Standard 7: Support and development for trainee pharmacists and everyone involved in the delivery of the Foundation Training Year
- Standard 8: The Foundation Training Year
- Standard 9: The Foundation Training Year supervision

By 2025/26, the Foundation Training Year programmes must have been assessed as meeting these standards through an accreditation (approval) process. Successful completion of an approved foundation

training year programme and passing the registration assessment will enable eligibility to apply to register as a pharmacist and annotate as an independent prescriber.

The scope of this methodology

This methodology concerns the initial approval through accreditation of Foundation Training Year programmes forming the final year of the initial education and training of pharmacists where this is not integrated into an MPharm degree. We require that all Foundation Training Year programmes are in place and meet our standards by the academic year commencing 2025/26.

Transition arrangements

When new education standards are introduced, it is expected that there will be a period of transition whilst current students and trainees complete their training to the previous iteration of the standards. The introduction of the 2021 IETP standards is no different, and whilst our methodology for accreditation of Master of Pharmacy (MPharm degrees) takes account of this, contingency arrangements are necessary for those students who do not for whatever reason graduate with the rest of their cohort by Summer 2024, or graduate on time but are unable to begin their foundation training.

Statutory Education Bodies are therefore asked to offer transition arrangements for an initial period of three years from 2025/26 to 2027/28 to accommodate trainees undertaking foundation training to the 2011 standards and the interim learning outcomes. These trainees will complete their education and training to the 2011 standards and will not be eligible for annotation as an independent prescriber upon registration.

This will mean that from 2025/26 the current foundation training year provision will continue to be delivered for a small number of trainees and run in parallel to the new foundation training year to the 2021 standards.

These transition arrangements will be explored during the step 3 accreditation event.

What needs to be approved?

The GPhC will approve Foundation Training Year programmes

We will approve, by accreditation, the Foundation Training Year programmes proposed by Statutory Education Bodies (SEBs) - also referred to as Foundation Training Year providers - and their partners.

To receive GPhC approval, programmes must meet all the standards for the Foundation Training Year, including all the aspects of the delivery of the Foundation Training Year to which GPhC standards apply. We will not approve individual organisations but the proposed programmes of learning along with its assessments, arrangements for delivery, and quality management processes.

Accreditation is an evidence-based process and requires programmes providers to demonstrate evidence against the standards.

Approval of placements and supervisors will be delegated to SEBs in future

At present, we approve the foundation training placements and designated supervisors unless there is an agreement - such as a Memorandum of Understanding (MOU) - to delegate this function to the country specific SEB. As part of the 2021 IETP standards, we intend to delegate this function entirely to SEBs as part of the approval of the Foundation Training Year programme, where a current agreement is

not already in place. SEBs (referred to as Foundation Training Year providers) will quality manage placement sites and designated supervisors and provide the list of their approved placement sites and supervisors to the GPhC.

Outcomes

We have provided interim outcomes along with guidance on their management for the transition period to the 2021 IETP standards. These are a subset of the full outcomes and as such we will accredit Foundation Training Year programmes to the 2021 IETP standards; transitional approval against the interim outcomes is not permitted as their implementation is a precursor to the implementing 2021 IETP outcomes in full.

The role of the GPhC and the Statutory Education Bodies (SEBs)

The 2021 IETP standards state that:

- Foundation Training Year programmes will be delivered by the Statutory Education Bodies, employers and higher-education institutions, all working together. The precise nature of this collaboration will be decided between these organisations and will be approved by the GPhC.
- The Statutory Education Bodies will be responsible for foundation trainees in their respective jurisdictions¹.

The standards also set out a structure in which:

- The GPhC quality assures FTY providers and their partners against the standards for the delivery of the Foundation Training Year.
- The FTY providers and their partners carry out quality management and oversee the delivery of the Foundation Training Year locally by employers and supervisors.
- Employers and supervisors carry out and control the quality of the programme or course day-to-day.

We will seek assurance about the quality of the Foundation Training Year primarily from the SEB in each country. While we recognise that Foundation Training Year programmes will be delivered by a range of partners working under agreement, the SEB (referred to as FTY provider) will hold primary responsibility for the programme and all foundation trainees in its jurisdiction.

Who would need to bring forward a programme or a course for accreditation?

In this methodology, the term 'Foundation Training Year provider' is used to describe the body that designs and develops the Foundation Training Year programme and takes responsibility for its quality management to meet the 2021 IETP standards. While it is possible that the standards may be identical with the Statutory Education Body (SEB) in each jurisdiction, this arrangement allows the SEB to form a partnership to perform these functions, for example, with one or more pharmacy schools or employers in its jurisdiction to be accountable for the management of processes to design, implement, and manage the Foundation Training Year programme. We would expect a Dean (or equivalent) within an SEB to hold overall responsibility for the quality of the programme.

¹ With the exception of Foundation Training years delivered as part of an integrated MPharm.

The SEB (referred to as the Foundation Training Year provider) will be expected to have formal agreements in place with employers of trainee pharmacists to provide the day-to-day delivery of the programme and ensure supervision by appropriately qualified supervisors.

The legal basis of accreditation

The Pharmacy Order 2010 allows the GPhC to check the standards of pharmacy qualifications leading to registration as a pharmacist or pharmacy technician and annotation as a pharmacist independent prescriber. It requires the GPhC to 'approve' programmes or courses ('approval' being the generic term for accreditation and recognition) by appointing 'visitors' (an accreditation team drawn from our Accreditation and Recognition Panel) 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 Foundation Training Year programme will form part of the overall training leading to registration as a pharmacist and, in the future (2025/26 onwards), will include annotation as a prescriber². As such, our right to check and approve Foundation Training Year programmes is consistent with the principles and functions as set out in the Pharmacy Order 2010.

Decision making

Accreditation decisions will be the responsibility of the GPhC Registrar on the advice (recommendation) provided by an accreditation team. The exception is the consideration of an accreditation team's recommendation to refuse or withdraw accreditation, which is reserved to the GPhC's Council.

Reports will be written after accreditation events which will be made public. Providers may choose to provide a written response to reports, which will also be made public.

Appeals

The Pharmacy Order 2010 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 Independent Appeals Committee. The form and manner of an appeal is described in the Order.

Principles of approval

The GPhC will apply the following principles to the initial accreditation of Foundation Training Year programmes:

- **Proportionality:** the process will aim to seek assurance using proportionate processes.
- **Evidence-based:** we will seek evidence about the design and management of programmes.
- **Peer review:** we will make use of the judgements of appropriately qualified and experienced experts in decision making.
- **Public:** the outcome of accreditation will be accessible to all on our website.
- **Transparent:** we will set out our requirements at each step clearly.

² Where a student has completed and passed a full programme of study to the 2021 IETP standards.

- **Flexibility:** while some aspects of the process will be completed at specific times, the timing of other aspects will reflect the progress of providers in implementing standards.
- **Parity:** while the methodology may vary, foundation training programmes will need to meet the same standards whether they are delivered as part of an integrated MPharm degree or independently.

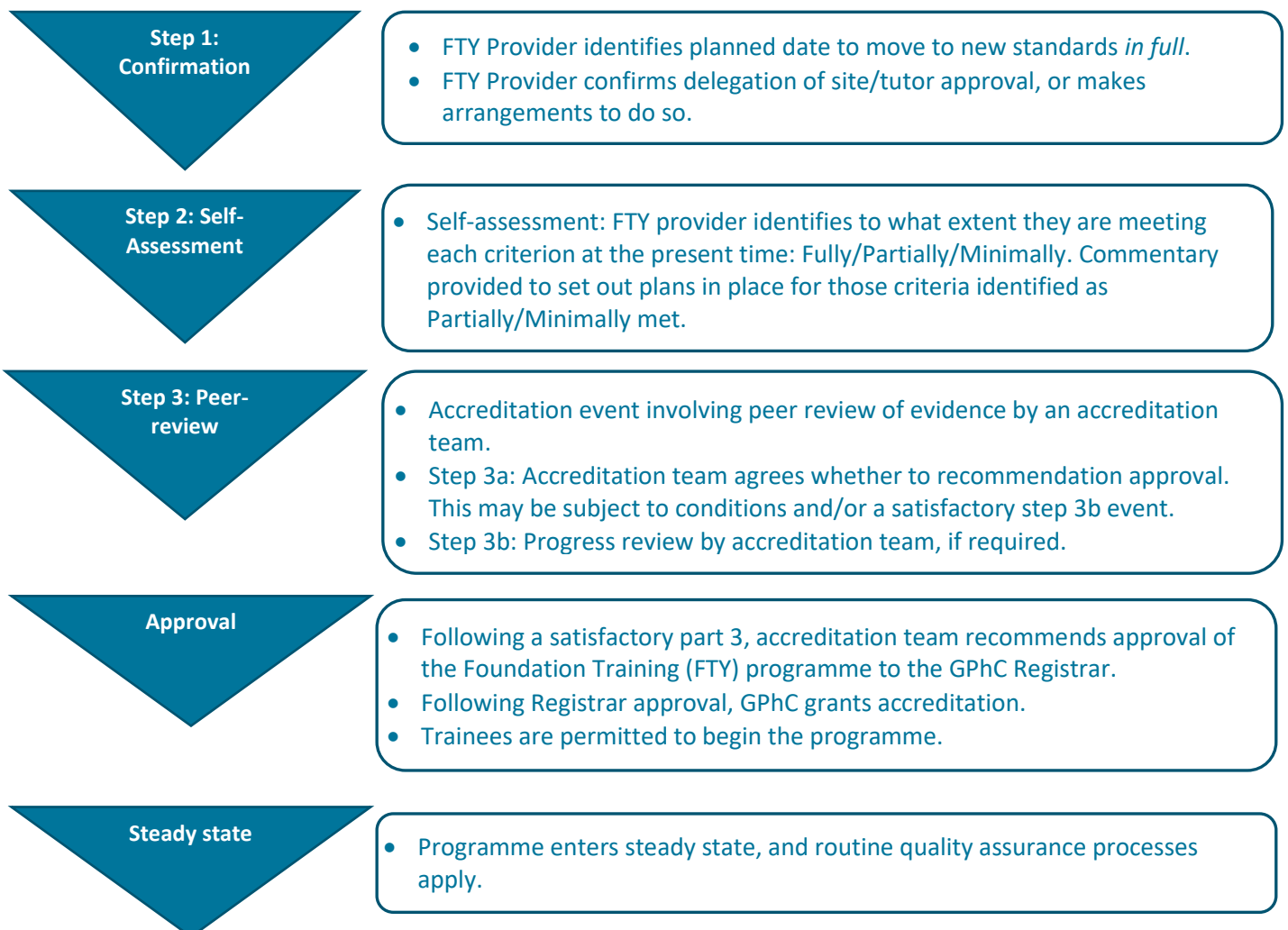
NB our methodologies to date have included the principle of cyclical review. This is not included within this document because this is a one-time methodology; the ongoing methodology is yet to be agreed.

Methodology for initial approval

Summary of methodology for initial approval:

Initial approval must be achieved no later than the Foundation Training Year intake starting in 2025/26. At Steps 1-2, the GPhC will provide optional feedback to the Statutory Education Bodies (referred to as the FTY providers) about their plans.

Step 3 will involve an accreditation event and review by an accreditation team which will culminate in a recommendation on the accreditation of the programme. At Step 3, the GPhC will write and publish a report about each programme. Depending on progress made, and the findings of the accreditation team at Step 3a, the accreditation team will agree whether a further event to review progress (Step 3b) is necessary.



Tracking progress across all steps

The GPhC will retain a record across all steps about what assurance has been received against each standard. This will be updated and published on our website following each assurance activity.

When should this be achieved?

- Foundation Training Year providers must complete the process and receive approval before the start of the foundation programme intake 2025/26. Step 1 will take place during 2021/22 and the remaining steps will take place in the following academic years in the lead up to 2025/26 (See Table 1).
- The initial steps (statement of intent and self-assessment) must be completed and submitted by **31 March 2023** so that further activity can be scheduled at the appropriate point.
- The remaining steps will be flexible to reflect the different approaches of Foundation Training Year providers. We have set some deadlines to when the final steps can take place to ensure issues can be resolved before the 2025/26 deadline and to manage logistics but otherwise, we aim to tailor its approach to the needs of Foundation Training Year providers.

Table 1: Summary of accreditation activity in each academic year:

Academic year	Activity
2021/22	Step 1
2022/23	Step 2
2023/24	Step 3a
2024/25	Step 3b (if required)
2025/26	Start of full implementation of accredited foundation training programme

Step 1: confirmation of intent

Purpose

This step is intended to establish the administrative relationship between the GPhC and the Provider to approve the Foundation Training Year programme.

Content/format

Format

This step will be delivered entirely through a short self-declaration form.

Content

The Foundation Training Year provider to provide factual information on:

- The anticipated date to meet the standards in full, either by the start of the academic year 2025/26 or earlier

- How the Foundation Training Year provider meets/will meet the requirement that it has responsibility for the totality of the Foundation Training Year within its jurisdiction³ through:
 - confirming there is an MoU between the provider and the GPhC covering the delegation of approval functions to the SEB, in the Foundation Training Year, and that the MoU is active or will come into force on or before 2025/26, or
 - completing an additional Step 1a
- Key contact details for the programme: The Dean (or equivalent) and a quality management contact
- Narrative on how regional variations, if any, in the programmes will be managed
- The approach to partnership arrangements around Foundation Training Year delivery (both employers and providers of FTY programmes)

Timing

Foundation Training Year provider should confirm their intentions and contacts to the GPhC by the end of January 2022.

Delegation of approval functions

Where the Provider does not have control or funding for the totality of training, they should set out the steps by which they will acquire responsibility for the totality of foundation training in their jurisdiction. This should happen before the planned date to meet the standards in full. Providers will need to:

- Confirm intention to have such an arrangement in place
- Identify target date to complete an MoU with the GPhC to govern the arrangement
- Provide a short narrative on how this will be achieved

This step should result in the eventual completion of an MoU between the GPhC and the provider, covering delegation of function in the Foundation Training Year.

Data sharing

The MoU will need to include agreements to share the administrative data required to effectively manage and assure the Foundation Training Year programme.

Outcome

Foundation Training Year providers will be notified of their Step 1 outcome by e-mail and progress will be published on our website.

Step 2: self-assessment

Purpose

The purpose of this step is to:

- Receive assurance that the Foundation Training Year provider is designing its programme to meet GPhC standards for the Foundation Training Year

³ Other than those delivered as part of an integrated MPharm degree programme. This does not preclude the SEB from being involved in such a programme.

- To demonstrate that the Foundation Training Year provider has a credible plan and arrangements in place to meet their intended deadline
- To provide a steer for the timing and format of the final steps of the review

Timing

Foundation Training Year providers may complete the self-assessment template at any time for their own purposes but should only submit to the GPhC **during March 2023**. The final deadline for Step 2 submission is **31 March 2023**.

Content/format

Format

The Foundation Training Year provider will complete a templated self-assessment against each criterion and provide supporting commentary.

Content

FTY providers will need to submit:

- Updated narrative on plans for programme management and partnership arrangements
- A self-assessment of the extent to which they feel that their existing arrangements meet the accreditation criteria against the standards:
 - Fully
 - Partially (requires some work), or
 - Minimally (requires significant work)
- Supporting documents relating to the key aspects of the programme (curriculum, assessment, quality management, trainee support and concerns processes, requirements and support for/training of supervisors, and agreements to provide training places)
- An assessment of current capacity against that required to deliver the programme (placements and supervisors)

Outcome

Analysis and publication

Self-assessment outcomes would be summarised into:

- Confirmation that the GPhC has received self-assessment and key supporting documents and information from the FTY provider
- Indication of progress towards meeting the standards shown by the self-assessment against each criterion (fully/partially/minimally)
- Key themes in terms of challenges and barriers

Foundation Training Year providers will be notified of their Step 2 outcome by e-mail, summarising the status of the programme and progress will be published on our website.

Discussion with providers

GPhC staff will review the submission to:

- Identify any early concerns or issues about progress identified
- Set out arrangements and timing for the Step 3 event (review by accreditation team)

Step 3: accreditation event (review by GPhC accreditation team)

The final step will be to discuss and triangulate information through peer review, meaning a discussion with a GPhC accreditation team. We have suggested that this step may take place through two activities some time apart, reflecting that the arrangements for implementation may evolve as 2025/26 approaches.

In line with our intention to deliver flexible and proportionate assurance processes, we will consider a degree of flexibility at this step. For example, in some cases, Step 3b may not be required if the accreditation team has sufficient assurance at the Step 3a event. Any such decision will be at the discretion of the GPhC based on the recommendation of the accreditation team.

Step 3a: formal review by GPhC accreditation team

Purpose

The purpose of this step is to receive assurance that the programme meets all aspects of the standards, including a review of:

- Selection and admission arrangements
- Curricula and assessment strategies
- Policies and systems to underpin training and support
- Establishment of quality management systems to govern the programme
- Arrangements for partnership working
- Mechanisms for monitoring of trainee progression and managing fitness to practise issues
- Processes in place for the approval of training sites
- Processes in place for the approval and training of designated supervisors and Designated Prescribing Practitioners (DPPs)⁴

As well as:

- Transition arrangements for trainees completing foundation training to the 2011 standards and interim learning outcomes

Timing

For providers intending to meet the standards for implementation in the 2025/26 academic year, Step 3a must take place during the 2023/24 academic year. The timing of activities during this year will be flexible and we will endeavour to accommodate the preference of the FTY provider. If Step 3b is required, it should

⁴ The designated supervisor and the Designated Prescribing Practitioner (DPP) can be the same person. Designated Prescribing Practitioners must be fit to carry out that role and must have appropriate training and experience in line with the Standards for the education and training of pharmacist independent prescribers.

take place no later than the 2024/25 academic year and at least 3 months in advance of the intended start date of the foundation training programme (April 2025 at the latest).

Content/format

Format

Step 3a events will be primarily remote, but may additionally include some face-to-face elements/on-site visits depending on the assessment of the accreditation team.

Measurable components

The FTY provider will be required to demonstrate that:

- The numbers of available placements, designated supervisors and Designated Prescribing Practitioners (DPPs) are adequate to support the programme for the anticipated numbers of trainees
- It has systems in place to collect data to support the quality management of the Foundation Training Year placements, such as:
 - The names of trainees
 - Trainee equality and diversity data
 - The location of placements/planned placements
 - Monitoring and tracking of trainees' progression
 - Registration and training status of designated supervisors (have they completed the Foundation Training Year providers' requirements for their role such as training and induction)
 - Approval and training of Designated Prescribing Practitioners (DPPs)

Dialogue components

An accreditation team, drawn from members of the Accreditation and Recognition Panel, will review the submission documentation and supporting evidence provided by the FTY provider. The template for Step 3 submission documentation will be made available to FTY providers during September 2023.

The accreditation team will plan questions based on the scrutiny of the documentary evidence but may focus on the following areas:

- Progress/project management towards implementing systems to achieve full compliance with the standards for the Foundation Training Year
- Development of quality management systems and processes, including partnership arrangements to deliver the Foundation Training Year programme; the provider should be able to demonstrate progress towards a quality management system that can identify, track and resolve quality issues in all training sites
- Supervision, including the recruitment of supervisors, training, and support
- Curriculum and assessment
- Tracking trainee progression and providing remediation where appropriate

- That partnership arrangements to manage the transition from MPharm to Foundation Training Year are in place and demonstrate that the student/trainee's journey through from MPharm to Foundation Training Year is reflected in the design of the Foundation Training Year programme (years 1-4 will be covered in MPharm accreditation)

Indicative schedule of activities leading up to Step 3a event:

When	Activity
By September 2023	Agree Step 3a event date and event format.
8 weeks before event	FTY provider submits Step 3 documentation.
3 weeks before event	Pre-event meeting takes place: <ul style="list-style-type: none"> • Key lines of enquiry shared with FTY provider • Further information/documentation requested if necessary • Event schedule agreed
1 week before event	<ul style="list-style-type: none"> • FTY provider responds to further requests for evidence • FTY provider confirms event attendees
Event	<p>Event is likely to include:</p> <ul style="list-style-type: none"> • Update on management of programme/ progression: <ul style="list-style-type: none"> ○ Progression against plans ○ Risks and challenges to implementation ○ Development of partnership arrangements • Curricula and assessment development • Quality management processes • Supervision arrangements, policies and processes • Discussion with sample of supervisors and employers covering: <ul style="list-style-type: none"> ○ Involvement in programme development ○ Development of agreements and quality management structures in respect of local placements ○ Support and training from the FTY provider • Triangulation of evidence with employers, training placement providers and other partners
Event	Event will conclude with the accreditation team agreeing a recommendation to the GPhC Registrar on the approval of the programme (See Step 3a outcome).
Post event	Provider submits a response to any conditions of accreditation, to meet the deadline set by the accreditation team.
Post event 6 weeks	Report of event submitted to FTY provider to check factual accuracy.

When	Activity
Post event 6 weeks+	Report finalised and accreditation team's recommendation for approval considered by Registrar.
Post event 8 weeks+	<ul style="list-style-type: none"> Formal notification of Registrar's decision shared with FTY provider GPhC website updated accordingly If a Step 3b event is not required and approval is granted, trainees may begin the accredited FTY programme once any conditions have been met satisfactorily
By September 2024	Agree Step 3b event date, where one is required.

Step 3a Outcome

The outcomes available to the accreditation team will be a recommendation to the Registrar to:

- Approve the Foundation Training Year programme. This may be subject to conditions.
- Approve the Foundation Training Year programme, subject to a satisfactory Step 3b event. This may also be subject to conditions.
- Decline to approve:
 - We do not anticipate this scenario taking place as we would work with providers to resolve any concerns earlier in the process. However, if significant gaps in the ability to meet the standards remain, and there is little prospect of their resolution for the 2025/26 cohort, we will consider the implications of a decision to decline approval.
 - A repeat Step 3a event will be scheduled, allowing sufficient time for the FTY provider to make progress to address any area(s) of concern.

Reporting and feedback

Quality Assurance is undertaken on the principles of transparency and as a requirement of the Pharmacy Order 2010, all accreditation reports are made available publicly. The accreditation report will take the form of:

- Factual narrative summarising the provision in place.
- Summary of areas probed by the accreditation team and additional evidence gathered during the event. Justification for the setting of any conditions, recommendations, or minor amendments.
- Outcome of the event - the accreditation team's recommendation to the Registrar.

If a Step 3b is required, the Step 3a report will also detail:

- Remaining areas in which further assurance is required
- Any further evidence required to gain this assurance
- Key lines of enquiry to explore at Step 3b

Step 3b: progress review by GPhC accreditation team

Purpose

The purpose of Step 3b is to:

- Check progress against targets, issues or concerns identified at Step 3a

- Provide a final check of in-practice arrangements and overall readiness to deliver the Foundation Training Year programme

Timing

Step 3b is intended to provide a final check before accreditation can be confirmed. It should take place in sufficient time before the planned full implementation date to allow time to act on any concerns, and no later than three months before the start of the academic year in which the training would be delivered against the standards in full for the first time (2025/26).

Content/format

Content

The content of Step 3b will largely be shaped by the outcome of the Step 3a event and the areas in which the accreditation team wishes to seek further evidence and receive an update on progress in order to have assurance of the training provision. In most cases it will involve the following components:

- Update on progress and any key developments since Step 3a
- Update on the numbers of placements, designated supervisors and Designated Prescribing Practitioners (DPPs) required and secured, and the status of the supervisors in terms of mandatory training and inductions
- Updates on any issues or concerns identified at Step 3a
- Exploration of readiness to roll out the new programme in full the following academic year
- Exploration of partnership arrangements for delivery of the Foundation Training Year

Other assurance - focussing on triangulation and testing arrangements.

The team may seek further assurance through other means. We will discuss with Foundation Training Year providers on what this is likely to be, but we anticipate that in addition to seeking evidence from the provider from discussion and reporting updates, the team would consider whether assurance should be triangulated from employer and supervisors locally.

Step 3b Outcome

The outcomes available to the accreditation team will be a recommendation to the Registrar to:

- Approve the Foundation Training Year programme. This may be subject to conditions.
- Decline to approve:
 - We do not anticipate this scenario taking place as we would work with providers to resolve any concerns earlier in the process. However, if significant gaps in the ability to meet the standards remain, and there is little prospect of their resolution for the 2025/26 cohort, we will consider the implications of a decision to decline approval. A repeat Step 3b event will be scheduled, allowing sufficient time for the FTY provider to make progress to address any area(s) of concern.

Submission documentation

Submission documentation will normally be required 8 weeks before the event. The exact date will be specified when a mutually convenient event date is agreed.

Step 3 submission templates will be made available in September for events in the coming academic year at: <https://www.pharmacyregulation.org/education/approval-courses/accreditation-guidance>

Reference links

Standards for the initial education and training of pharmacists, Jan 2021

Guidance to support implementation of the IETP standards

Standards for the education and training of pharmacist independent prescribers

Accredited pharmacist foundation training year programmes homepage