



FACULTY OF PHARMACEUTICAL MEDICINE

OF THE ROYAL COLLEGES OF PHYSICIANS OF THE UNITED KINGDOM
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Responses to Questions submitted at the Revalidation Webcast held on 5th November 2009

Many of the questions asked in writing during the webcast were in fact answered during latter parts of the webcast and therefore can be found from the recording, which is currently on the Faculty web site.

Additionally, many of the questions overlap so I decided it would be easier to write a brief narrative addressing the questions. If you do still have further questions, please email them to Konrad Obiora at fpm@fpm.org.uk.

General

Revalidation only applies to doctors registered with the GMC with a licence to practise. It will be up to individual employers as to whether they use the same/ similar appraisal processes and Faculty standards for non-GMC registered physicians or those without a licence to practise.

Although licences to practise have been issued this year, definitive timelines for revalidation have not been set. It is currently envisaged that pilots will start in 2010 and full revalidation in 2012, for some doctors. It will not be a big bang approach and is not yet known how it will be rolled out.

One of the key aims of the Faculty of Pharmaceutical Medicine is to set and maintain the highest standards within the specialty for the benefit of the public. Revalidation is one method by which this can be attained.

The Faculty supports the concept of revalidation, and will work to ensure that the underlying process reflects the activities of, and is relevant to, pharmaceutical physicians. The mechanism for the revalidation of medical practitioners in the United Kingdom is currently under review by the Department of Health (DH) and GMC.

There are two circumstances under which doctors will need a GMC licence to practise. These are if they are undertaking any form of medical practice which under UK law currently requires GMC registration or if it is written into their terms of employment.

Whether or not there is a legal or contractual reason for doing so, maintaining a GMC licence to practise may be important to you and those who you work for if the demonstration of your medical credibility is a key requirement of your job or role. The Faculty understands that the MHRA will require those it employs as doctors to maintain a licence to practise. It is anticipated that other employers for whom pharmaceutical physicians work will also require

this. Therefore maintaining a licence to practise may also be important to individuals in the future if they change employer.

The Faculty of Pharmaceutical Medicine recommends that practising pharmaceutical physicians take up and maintain a GMC licence to practise.

Doctors with a licence to practise will be entitled to sign documents, including prescriptions as at present, within their area of competence. The ABPI/PMCPA have not yet decided whether the current requirement for promotional material of registered medical practitioner will be changed to “licensed”.

However, as the purpose of revalidation is patient protection, it may well be they decide that this would be in the public interest. In respect of any other documents that pharmaceutical physicians sign in their capacity as a physician, then the same argument is likely to apply – patient/public protection. It is worth noting that the MHRA have stated that they expect their doctors to maintain a licence to practise. Those who do not will not be able to publicly claim their medical competencies in the way that their counterparts with licences will be able to.

The Faculty has just started investigating the feasibility of running pilots starting in 2010. We will keep you informed about this as we shall want a representative cross-section of volunteers.

Trainees

The Academy’s proposal for trainees is that they will also need to revalidate but the ARCP/RITA process should provide the basis for appraisal, and their Postgraduate Dean will be the Responsible Officer.

Appraisal

The appraisal process that we intend to set up is likely to be similar to our Educational Supervisor system for trainees. There will be mandatory training for those who apply and the appraisers themselves will have to be regularly appraised to ensure they are and remain competent to appraise, as well as demonstrate their other competencies to retain a licence to practise. It is likely, but not yet decided that appraisers will have to be GMC registered with a licence to practise. This will be a GMC decision.

The Faculty appraisal system will be available to all pharmaceutical physicians who wish to use it. We envisage that the cost (as yet undefined) will be met by those who use it, not from subscriptions. Appraisers are likely to be paid as they will be expected to undertake a minimum number of appraisals per annum, which with the paperwork involved, will be quite time-consuming. We envisage those most likely to have Faculty appraisals are independents and those from small/medium-sized companies.

It is worth starting to collect your appraisal evidence now, even though you do not know when your first revalidation appraisal will be.

Responsible Officers

There are still a number of logistical issues that have to be resolved in respect of Responsible Officers (RO), but the principles have been established. Issues still to be resolved are, for example, companies that will have their own RO, the need for the RO and appraiser to be different, who will be the appraiser for the RO, who will be the RO for the RO. These and other unanswered questions are not unique to our speciality and are being investigated through the Academy of Medical Royal Colleges (AoMRC) Revalidation Group.

The requirements for the RO are many, but include that the person is GMC registered with a licence to practise and has the ability to influence the governance systems of the organisation over which s/he has jurisdiction.

The draft legislation requires the Faculty RO to be in place by October 2010. The timeline for organisations not named in the statute has not yet been defined. We circulated the consultation documents regarding ROs widely – to all members and the ABPI – with advice that companies needed to be made aware of the RO proposals and we hope they have given it due consideration and responded to the consultation.

In respect of an individual pharmaceutical physician, the RO is only likely to be involved in the 5-year cycle either at the end, or in between if problems arise, or appear to be arising, at the annual appraisals. The RO would also be involved in any required remediation.

The basic role of the RO is to ensure proper governance processes within the organisation, including a proper and robust appraisal process, such that they are prepared to endorse recommendations from the appraisers within their jurisdiction. The AoMRC is investigating the legal implications of these recommendations by the RO; the AoMRC is taking legal advice on this and other aspects of revalidation.

At the moment, we are uncertain as to what would be the minimal size for an organisation to have its own RO, but it is likely to be between 5 and 10 medics. However, those over the minimum number could still use the Faculty RO system if they chose to do so.

Each doctor can only have one RO and that will be either the Faculty RO or the RO where you spend the majority of your time; if, for example you do both industry and NHS work. Of course, your RO will change if you change company. If your organisation has its own RO, that person will be your RO whether you work in this country or abroad.

For those who work across two specialities, you will need to demonstrate your competencies in the work you undertake in both. You will only have one RO, but it may be that you will have two appraisals – this latter aspect is still not yet clarified and is a generic issue across other colleges and Faculties. So is the situation regarding specialist registration for those who are on a specialist register, but working in another specialty. We are still awaiting guidance from the GMC and DH as to how this will work.

Specialty Standards

We received a number of questions asking if supporting information should be collected retrospectively. Our view at this stage is that this is probably unnecessary, however the collection of supporting information from past experience/training may need to be given due consideration in seeking to demonstrate competence / keeping up-to-date / meeting the revalidation Standards in the selected Frameworks and Attributes.

Whilst the principles and processes of revalidation are essentially prospective, some retrospective supporting information might be relevant:

- a) if the past project / supporting information can be 'bridged' / linked to contemporary active work, or
- b) if the past project / supporting information was a 'one-off' and had relevant impact or influence on contemporary competence / meeting standards.

It will be up to the individual pharmaceutical physician to acquire supporting information from a former employer, and this will depend on a number of different factors and agreements.

Retrospective supporting information, like all supporting information, should be appropriately annotated (put in context; reflective comments), authenticated and validated.

It is to be expected that the Faculty (or sections of its membership) will be able to offer guidance and advice, *without prejudice*, to pharmaceutical physicians on revalidation 'programmes' and on the approach to meeting the requirements of the programmes.

With respect to meeting the requirements of Standards, for example demonstrating competency / keeping up-to-date in a process within the Pharmaceutical Medicine Framework, the Faculty will acquire examples, through custom and practice, and will be able to offer guidance, *without prejudice*, on general requirements and providing examples of 'generic' processes.

It is likely that there will be many bodies offering guidance and advice on revalidation, especially in keeping with their relative expertise and involvement in the Standards Frameworks for revalidation.

In relation to how much evidence should be collected, there is such enormous variance between each job, each doctor, each Attribute and Standard, each approach to meeting a Standard, and thus in the amount of supporting information that might be collected, that it is only possible, at this stage, to offer a general guide as to what might be considered 'normal'.

It is expected that to demonstrate meeting each Standard (cf. topic) 3-6 pieces of supporting information would be required. These would comprise, usually, 1-2 documents relating to the competency (e.g. protocol, report, presentation made, outcome record), 1-2 documents related to learning (e.g. meeting report, lecture/presentation received, discussion, summary of materials studied), 1-2 documents relating to engagement in the activity (e.g. emails, letters, feedback).

Each piece of supporting information might satisfy the requirements of more than one Standard and thus be cross-referenced across several Standards.

It is advisable to collect and collate supporting information on a regular basis e.g. weekly rather than just before an annual review or appraisal.

Audit

Auditing is a responsibility that has, currently, been allocated to all Colleges and Faculties and will apply to all organisations with a RO. The mechanisms for this still have to be worked out at an Academy level. The Faculty itself, having its own RO (unlike the Colleges), will also have to be subject to independent audit.

Finally, there remains concern across the whole profession about how much time revalidation will take. We shall be able to quantify this from the planned pilots, but will be endeavouring to reduce the bureaucracy wherever we can.

Dr Susan Bews
Chair of Revalidation Steering Committee
December 2009