

Faculty of Pharmaceutical Medicine

Revalidation Seminar 17 Nov 2008

President's Introduction

Good afternoon colleagues and friends

Welcome to this Revalidation Seminar. I know from the very rapid take up of places when we announced that we would be holding it, that we would have a packed and very interested audience who will be very interactive. As you will see from the agenda, we have therefore allowed plenty of time after the presentations for questions. In putting together the programme for this session I decided that, as there will be considerable overlap but not duplication between my introduction and the presentation from our speaker from the GMC, that it would be better to take questions on all aspects of revalidation together. We are immensely grateful to Mr Richard Marchant, Head of Regulation Development at the GMC for agreeing to come and address us this afternoon and to be prepared to answer what I suspect may be a barrage of questions. In my introduction I want to cover what the Faculty is doing in respect of revalidation, update you on our progress and give you top-line results from the survey we recently carried out. However, before doing this I want to make a few general points.

Firstly, revalidation is a reality for pharmaceutical physicians as with any other doctor who wants to retain a licence to practice, but a licence to practice will not in the future be the same as being on the medical register. Licences to practice will be issued next year to all of us who choose to request one and it spells the countdown to a fully implemented revalidation process. If you choose not to have a licence to practice

either next year or not to renew it through revalidation at any time in the future, then whilst you may remain on the medical register, you will lose the many legal privileges which we now enjoy, of which being able to prescribe is probably the one that first springs to mind. The choice for each and every one of us is a personal one

However having said that it may well be that employers whether pharma, CROs or the regulatory authorities may make the retention of a licence to practice a requirement under contracts of employment. For anyone with clinical responsibilities in a Phase 1 unit it is likely to be mandatory.

Secondly, I want to reassure that the Faculty is fully committed to ensuring a process whereby pharmaceutical physicians can revalidate. We shall ensure our processes can cater for physicians wherever their place of work so it will cover those working for big and medium size pharma and CROs and the regulatory authorities— organisations which are likely to fit the definition of a ‘managed environment’ to use revalidation terminology but will also cater for those working in small organisations where there may be only one medic and our large cohort of independent consultants. We have also made a commitment that it will also be available for physicians who are not members of this Faculty.

Thirdly, neither we nor the GMC have all the answers. Whilst the general arrangements are taking place satisfactorily, the devil is often in the detail and there is still a very great deal to do to work out how our outline principals and proposals will work in the many and varied situations you are working in. There will always be some exceptions who do not fit the normal pattern but as we learn more about those individuals or groups the more likely we are to be able to accommodate them.

In addressing you on revalidation it is difficult to know where to start as there are many strands that have to be woven together in an evolving environment

Revalidation will consist of two parts, relicencing for those who wish to retain a licence to practice and recertification for those who are on and wish to remain on the GMC specialist register. Relicensing will comprise three parts, annual appraisal which is where CPD fits in, multi-source feedback and a process whereby any concerns about the individual's fitness to practice can be raised with a nominated Responsible Officer, who is the person locally for ensuring a robust appraisal system and either through that person or directly with a local GMC person – the GMC Affiliate. Originally we thought we relicencing and recertification would be two rather separate processes, relicencing being generic to other branches of medicine too but against the principles laid down in Good Pharmaceutical Medical Practice. Recertification would be against specialty specific standards. However during the course of the year the GMC stance has been clearly spelt out as revalidation being 'one process, two outcomes' i.e. one process which results in relicencing for those not on the specialist register and relicencing plus recertification for those on the specialist register. We are not yet fully aware of the implications of this shift of emphasis for those seeking only to be relicenced. But it is apparent that the annual appraisals for all physicians will also need to contain auditable evidence of their ability to reach standards which will be set by the Faculty and which are at the same level as, but tailored of course, any branch of medicine and which will have to be approved by the GMC.

Those applying for recertification which will be through the relevant colleges of faculties in all branches of medicine will be assessed against standards set by the

Faculty and approved by the GMC. What is not clear to us at the moment is how similar or different the standards for relicencing and for recertification will need to be. But it is clear that even if not identical there will be considerable overlap otherwise it cannot be 'one process, two outcomes'. We also have, in common with the other colleges and Faculties, a very broad platform of activities that our physicians may be undertaking from Phase 1 work, pure clinical research, work within the regulatory authorities, health economics and the commercial healthcare market place to name but a few sub-specialities. All these factors must be catered for in our final plans for revalidation.

We have discussed our proposals for processes for appraisals, multisource feedback and responsible officers for those within and those not within managed environments with the GMC and have agreement in principal that are proposals would be acceptable. There is however a great deal of work to formulate these proposals in detail but we are confident that it can be done.

However it is obvious that particularly with the move to 'one process, two outcomes' validated and auditable evidence as the basis of appraisals as well as recertification becomes paramount and starts to raise a number of issues - not insurmountable but which will need carefully devised solutions. Within a managed environment this may not be too problematic but we have a work force that move to competitor companies quite regularly so that evidence must be portable and also for those for example working as independents it has to be accessible to their appraiser who may work for a competitor company or companies if themselves independents. We have managed to address these issues of commercial confidentiality of evidence within the context of Higher Medical Training although the challenges there are not as potentially

convoluted but we are committed to finding solutions in respect of revalidation. Another issue which is taxing the Revalidation Committee is the very recent comment by the GMC that one can only recertify back into the speciality in which one certified in the first place – logical but has considerable implications for the considerable number of our physicians who are on the specialist register from another specialty. At that time the GMC did not have the answer to this thorny question which affects a large number of doctors in the NHS too but informed us that a solution has to be found. We will obviously keep this on our agenda in our discussions with the GMC and will keep you informed.

It has therefore been very reassuring and very instructive to work alongside the other colleges and faculties through the auspices of the Academy of Medical Royal Colleges and to realise that although some of our peculiarities are unique, each group has its own challenges. We are involved in a number of the groups including the main Revalidation group which includes standard setting, the non-clinical and the e-portfolio groups. It is essential that colleges and faculties do work together so as to share learnings and experiences and also to ensure that the standards set are similar across all branches of medicine - an absolute requirement of both the DoH and the GMC

Our Revalidation Committee are now starting to look in detail at how to set appropriate standards and this is where the survey we undertook comes in. We received a grant from the Academy to undertake this survey. The response was staggering. We sent the questionnaire to the about 800 UK based members and received almost 500 responses. A response of over 60% is indicative of the interest in

and concern about revalidation by our physicians and two short quotes perhaps sum up the views of our respondents.

'It will come. The Faculty must embrace it and stay ahead of the game as it is doing'
and

'I don't really understand this process or practical implications'

The aim of the survey was to gather information on the scope of practice of pharmaceutical physicians in order to assess the viability of the recertification model proposed by our Revalidation committee. In the light of the move to 'one process, two outcomes' we considered we would also be able to use the information to inform the standard setting for relicencing too. Fundamental to the need to collect this information is the revalidation principle that doctors will be revalidated within their fields of practice – i.e. they must demonstrate competence within their field of practice. So the Faculty needs to know how broad or narrow those fields are before we can set the requisite standards. The survey was also designed to collect additional information and provided a section for free text. We also asked participants if they would be willing to assist the Faculty for example by participating in work shops. We used as the basis of fields of practice the seven modules in the higher medical training curriculum.

About 45% of respondents were from large pharma, about 16% from small pharma, 10% from CROs, 5% from the regulatory agency and 12% were self employed.

About 50% said they were on a specialist register but only half gave their specialism. Of those that did 57 were on through pharmaceutical medicine, 32 from general

practice, 9 from clinical pharmacology and the others were across almost the full range of specialties. Nearly a quarter of respondents were trainees. . In response to the question as to whether relicencing would be sought, 60% said yes and 25% said they do not know.

I think these demographics are probably fairly representative of UK based pharmaceutical physicians.

So returning to the model for standard setting proposed by the Revalidation Committee. It was agreed that the management module would not count towards the medical competencies required. So the six modules as detailed in the survey would form the basis for the competencies that would need to be demonstrated. We were aware that the work of pharmaceutical physicians could be very varied and for some could be quite general across most or all of the fields covered by our specialty and for others could be relatively narrow and highly specialised. The model was based on these six medical modules from the specialist training programme, each of which has around eight to ten items, so something over fifty items in total. The premise for our model that pharmaceutical physicians would be able to produce evidence of ‘comprehensive cover’ for all items within a minimum of one module, that is, they would be fully competent to perform the all the activities unaided or as part of a team. Additionally, we anticipated that physicians would be able to produce similar levels of evidence of competencies in ten other items taken from any other of the modules. For the purpose of the survey we therefore required comprehensive cover for one module and used ‘good’ or ‘comprehensive involvement’ in a further three modules as a surrogate marker to determine whether the job of the respondent would comply with requirements of the proposed model. We recognised that this is subjective but it

would be a reasonable starting point for us. We also were aware that with the breadth and growth of functions you do, we would need to be flexible when the time comes and, with appropriate quality assured procedures, would be able to include major job items which are not currently picked up within specialist training.

Around 90% of respondents considered that their roles covered one module comprehensively. Our results indicate that around 60% of respondents' roles could comply with the proposed rectification model of 'comprehensive involvement' in one complete module and 'good or comprehensive involvement' in ten items from a further three modules. Twenty percent appeared marginal as to whether they could achieve this, but it appeared that 20% of jobs may not be able to achieve the combination proposed. We thus need to explore the results from this 20% in more detail and probably hold a series of focus groups with those respondents affected, and others, to ascertain the reality of the situation and determine what model for recertification would be appropriate. As the aspect of 'one process, two outcomes' becomes clearer then we can use the information gained from this survey to set the standards for relicencing too. So, thank you to all who completed the survey, the results and your comments are extremely informative and will give us guidance over the next year as we refine our standards for revalidation, both relicencing and recertification.

In fact it was as a result of the level of concern expressed in the free text that made us decide to alter this symposium day and have this session on revalidation. So we do listen and will continue to do so as we go forward with our proposals. Thank you too to those who offered to continue to help us – we shall as I said be calling soon many

of you. However now I would like to hand over to Richard Marchant our speaker from the GMC who will give more detail on a number of aspects of revalidation.

Dr Susan Bews

President

Faculty of Pharmaceutical Medicine