

Annual Meeting

17 November 2008



The Faculty of Pharmaceutical Medicine

Advancing the science and practice of pharmaceutical medicine for the benefit of the public



President's Address

Revalidation

Revalidation is again of great interest and concern for our members based in the United Kingdom. As I informed you last year, the Faculty has made good progress on a number of aspects of revalidation. In particular I referred to appraisal and multi-source feedback. This progress took into account the very varied needs of our physicians from those who work within structured organisations or managed environments as they are called in revalidation terminology – such as big and medium size pharma or larger CROs or the Medicines and Healthcare products Regulatory Agency (MHRA), to those who work as independent consultants or in small organisations where that person may be the only physician. At that time the Faculty assumed that it would be addressing standards for specialty specific

issues only for those wanting to recertify onto the specialist register. However during the course of the year the General Medical Council (GMC) stance has been clearly spelt out as revalidation being 'one process, two outcomes', that is one process which results in relicensing for those not on the specialist register and relicensing plus recertification for those on the specialist register. The Faculty is not yet fully aware of the implications of this shift of emphasis for those seeking only to be relicensed. But it does seem apparent and logical that the appraisal for these physicians will also need to contain validated and auditable evidence of their ability to reach standards set by the Faculty. These standards must be at the same level as any branch of medicine, but tailored to our specialty of course.

The Faculty has preliminary concepts on how the required roles of Local Responsible Officer and GMC Affiliate can be made to work for our speciality despite the many differences from our clinical colleagues, and particularly within a managed environment this may not be too problematic. But many of our physicians work as independent consultants or within small companies where they may be the only physician. These factors raise particular challenges in respect of ensuring satisfactory, high quality, annual appraisals which must include the tenets of Good Pharmaceutical Medical Practice. The complexities are compounded by issues of commercial confidentiality of evidence if the person has changed company or if the appraiser or Responsible Officer should be external to the physician's organisation. Evidence will have to be validated, portable and auditable. The Faculty also has, 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. All these factors must be catered for in our final plans for revalidation.

The Faculty has managed to address these issues within the context of Higher Medical Training, although the challenges there are not as potentially convoluted, and it is committed to finding solutions in respect of revalidation. Another issue which is being considered by the Revalidation Committee is the recent comment by the GMC that one can only recertify

President's Address *continued*

in the speciality in which one certified in the first place – logical but has implications for the considerable number of our physicians who are on the specialist register from another specialty. The GMC informed us that currently they do not have the answers to this thorny question, which affects a large number of doctors in the NHS too. The Faculty will continue to keep this issue on our agenda in our discussions with the GMC and will keep the membership informed.

The Academy of Medical Royal Colleges of which the Faculty is a member, has been given by the UK Department of Health (DoH) and the GMC, the task of ensuring similar standards are set across all medical and surgical disciplines for revalidation. It is also through the Academy that the DoH is making available to the colleges and faculties its financial support for revalidation. 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. The Faculty participates in the main revalidation group and also other groups set up to address issues relating to those undertaking non-clinical work and e-portfolios as well as continuing to be involved with the CPD group. The Faculty has been very grateful this year to receive along with other Academy members a grant to undertake a survey of our members in connection with revalidation. The response was staggering but perhaps not surprising. The Faculty sent the questionnaire to our 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. Two short quotations from the free text section, which almost everyone used, perhaps sum up the views of our membership.

'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'*

Our work on standard setting for both relicensing and recertification has now begun in earnest and the results from the survey will feed particularly into this work. It is quite clear that standard setting is to be the responsibility of each college and faculty but that those standards will have to be approved by the GMC. There is a very great deal of work to be done in this area.

The numbers of physicians who will need to recertify to remain on the specialist register parallels those completing higher medical training successfully and increases very satisfactorily each year. Our higher medical training programme – now called PMST (Pharmaceutical Medical Specialty Training) – continues to attract a very substantial proportion of those entering pharmaceutical medicine. This year about 40 signed up to PMST and they continue to be supported by a large cohort of educational and specialty specific supervisors. The Faculty is very grateful to all those members who support our training programme from behind the scenes – and so of course are our trainees. I would like to encourage all our trainees to participate in the pilot study on methods of assessment for work-based competencies. The Faculty has continued to receive essential and valued support from our colleagues in the Royal College of Physicians and of course our inestimable Lead Dean, Professor Huw Jones who sadly will be retiring from this role in April. Professor Jones has always been a fantastic support to the Faculty and will be greatly missed for his wisdom and understanding of the specialty.

Fellowship nominations

Last year the Faculty introduced new procedures for the nomination for Fellowship of the Faculty but they have proved to be too onerous for proposers and seconders. The Faculty realised it needed to encourage applications for Fellowship without altering the standards that have stood us in good stead for many years. A Faculty Working Group therefore undertook a major review of other college procedures and in particular our three parent colleges. The Working Group decided that the Faculty particularly wanted to recognise the hard work and commitment to this specialty that is demonstrated by those who achieve a CCT (Certificate of Completion of Training) or CESR (Certificate of Eligibility for Specialist Register). The proposal from the Working Group was approved by the Board of trustees on 25 November. It is that, in future, the Faculty will proactively write to all CCT and CESR holders two years after they achieve this recognition, inviting them to become Fellows of this Faculty. There are some other changes to the procedure such as writing individually to Members (MFPM) eight years after they have become Members inviting them to apply for Fellowship – thus preserving the minimum of ten years for non-CCT and CESR members. It is important to realise that the criteria currently applied when the Fellowship Committee review nominations



will be maintained. The new arrangements, including a flow chart, will be posted on the Faculty website in the coming months.

New governance arrangements

This end of this year sees the introduction of the new governance arrangements for the Faculty. These changes reflect current good governance practice and also recognise the increasing external pressures on those members who so willingly undertake Faculty responsibilities. The changes have inevitably been a while in gestation but eventually recently the Faculty received formal agreement from all three of our parent colleges – the Royal colleges of Physicians of London, Edinburgh and Glasgow for the changes. The Faculty is planning to change to a charitable company limited by guarantee, which is much more appropriate in order to protect the liability of the trustees. This change is expected to take place later in 2009. The new committee structures have also come into force in 2009 although there will need to be some overlap during a transitional phase. In addition to the smaller trustee board, committee chairs will no longer be expected to take on the mantle of trustee work in addition to their committee work. You will also be aware of the introduction this year of inviting applications, with interviews where appropriate, for the majority of Faculty roles rather than as it was previously, by elections. This has been highly successful and it was very gratifying to see a number of physicians previously not involved in Faculty work put their names forward, including some relatively new members. In fact nearly fifty applications were received. It is very necessary for any organisation to ensure its newer members are involved as they have so much to offer and they are the future of the Faculty.

Innovative Medicines Initiative

Education is of course the pivot of the work of the Faculty. Some new initiatives have occurred during the year. One of these is the Innovative Medicines Initiative (IMI). This is a new research fund characterised by a matched funding partnership with the European Commission to enhance Europe as a base for medicines development. The European Commission's financial contribution is matched in kind from the pharmaceutical industry in the form of personal time etc – but not money. The Faculty has been involved in the training work stream, supporting a bid by the European Federation of Courses in Pharmaceutical Medicine in respect of courses and examinations throughout Europe. Our

main involvement, should the bid be successful, will be in quality assurance of courses and examinations – an area where the Faculty has considerable expertise to contribute.

Diploma and Certificate in Human Pharmacology

Another new initiative for this year has been the development of the Diploma and Certificate in Human Pharmacology (DHP and CHP). The Diploma is intended for principal investigators in phase one units and the certificate for other doctors or scientists in these units. The Diploma will consist of two years of supervised practice, which will include attendance at two courses both of which will both be assessed, the compilation of a portfolio of evidence of competencies and completion of a life support course and a final examination. The Certificate will require attendance at the same two courses, again these will be assessed and an examination. Both modules are to run at Kings College London and the first examination will take place in January 2010. The Faculty was very fortunate to receive a substantial grant to underwrite the costs of setting up these exams from the Department of Health. It will of course take time for the DHP to gain full recognition across Europe, which is our aim, but the Faculty is off to a satisfactory start.

Clinical Research

Clinical research is at the heart of much of the work of pharmaceutical physicians and the Faculty has been very pleased to be the co-host with the Academy of Medical Royal Colleges of two meetings with college representatives from the majority of the medical disciplines and the pharmaceutical industry to look at the issues facing clinical research in the UK and to examine the reasons for the fact that the UK is losing the prime position it once held for being the country to do clinical trials. The UK is losing out due to high costs, poor patient recruitment and slow timelines. Work is moving now beyond Europe and the USA to India and China where the quality, costs and timescales are far more beneficial. This is not in the interest of pharmaceutical physicians or of our colleagues who find clinical research stimulating, but also it is not in the interests of patients. There is a body of evidence that demonstrates that patients in trials fare better than their counterparts who are not included in trials for a wide variety of reasons. As a consequence of these meetings the Academy has produced a consensus

President's Address *continued*

statement to be used to encourage Government and others of the real need to support the clinical research base in the UK before too much damage is done.

Relationships between pharmaceutical industry, academia and the NHS

The outputs from these meetings were also valuable to feed into the exciting and challenging initiative from a Royal College of Physicians London working party to look at relationships between industry, academia and the NHS, set up by Professor Ian Gilmore and chaired by Dr Richard Horton, editor of *The Lancet*. I represented the Faculty on this working party and it was very fascinating, taking oral evidence from a wide range of very eminent people and reading the written submissions. It is very pleasing that much of the submission from the Faculty has been incorporated into the final report. The report from this working party is to be published in February 2009 and contains a number of far-reaching recommendations which, if enacted, will enhance the ways in which the pharmaceutical industry and healthcare professionals, particularly doctors, can work together for the benefit of patients and the public. There has always been considerable criticism of the relationship whether that be of the industry offering too much largesse or of doctors who accept it. And there must be an evolutionary process that keeps up with the changing environment and alters the rules accordingly. It is the role of pharmaceutical physicians working in industry and the regulatory authorities to ensure that the rules are followed. Health economics and relationships with patient organisations are some of the new activities that have driven changes to the codes of practice in all countries and add to the complex and ever changing environments within which our clinical colleagues work, making the work of pharmaceutical physicians who operate alongside commercial colleagues ever more challenging. However, there will be actions from within the final recommendations of this report that the Faculty must address and it will be incumbent on us to find the resource to do so. This is why it is so important to have an active and participative membership who are prepared to be involved.

Counterfeit medicines

One of the factors impacting on this changing environment is the expanding use by patients of the internet bringing inevitable upsides and downsides; and one of the growing downsides is the relatively easy and growing illegal supply of counterfeit medicines. This is

of major concern to pharmaceutical physicians who see first hand the sometimes disastrous consequences of such supply – not so much in this country, but it is increasing here, particularly in the developing world where many of our members practise. The Faculty, through one of its Fellows, contributed an article to the RCP London's journal highlighting the dangers of lack of efficacy, different active ingredients or even substitution by toxic ingredients and pointing out the role our clinical colleagues can play in detection by reporting any unexpected lack of efficacy or adverse effects of even routine medicines.

Climate change

The Faculty will be working with Dr Richard Tiner, our new Vice President, in his capacity as Medical Director of the Association of British Pharmaceutical Industry (ABPI) and Dr Ian Roberts from the London School of Hygiene and Tropical Medicine on an initiative to review and make recommendations on the adverse effects on climate change of clinical trials. The Faculty is conscious that many of the activities that pharmaceutical physicians supervise are intensively environmentally unfriendly such as investigator meetings and on site inspections, even though the end result is for the benefit of patients and the public. The Faculty is also aware that companies are undertaking many initiatives to reduce their carbon footprints in these and other areas. However there is no forum for these practices to be shared by pharmaceutical physicians, investigators and the regulators and so the Faculty will be involved in setting up an initial workshop meeting in January 2009 with a wide range of stakeholders to review new and best practices and decide where and how best the group can contribute to this very major issue. It is an issue which must deeply concern us all in view of the huge impact climate change will have on health.

Dr Susan Bews, President, November 2008



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Elections and Awards

The Faculty Board

Dr Steve Hobigger completed his second two-year term as Vice President, and Dr Richard Tiner was appointed Vice-President for a one-year term from November 2008. Dr Oswald Morton and Dr Andrew Hockey left the Board in 2008.

Professor Geoffrey Barker and Dr David Gillen had been appointed as trustees under the new governance rules.

Annual Dinner

Dr Susan Bews took the Chair at the Annual Dinner at which the Guest of Honour was Professor Sir Graeme Catto, Chairman, General Medical Council.

Faculty Awards Ceremony

The President welcomed all the new Fellows and Members and congratulated those who had been awarded the Certificate of Completion of Training (CCT) or Certificate of Eligibility for Specialist Registration (CESR) by PMETB during the year.

Honorary Fellowship

Honorary Fellowship was presented to Professor Sir Graeme Catto

Professor Sir Graeme Catto is the President of the General Medical Council. The GMC registers doctors to practice in the United Kingdom and works to protect, promote and maintain the health and safety of the public by ensuring proper standards in the practice of medicine. He has held the Office of President since February 2002. He is also a current member of the Council for Healthcare Regulatory Excellence.

After graduating in Medicine, Sir Graeme obtained a Harkness Fellowship from the Commonwealth Fund of New York to study at Harvard University. He is Professor of Medicine at the University of Aberdeen and an honorary physician with a special interest in renal medicine. He has published widely on different aspects of nephrology and immunology.

Sir Graeme has held a variety of senior appointments connected to medical education and health. These include Vice-Principal at the University of Aberdeen, Chief Scientist at the Scottish Executive Health Department and Governor of the Science Technology Park in Qatar. Sir Graeme is currently Chairman of the Scottish Stem Cell Network. This network brings together scientists, clinicians, business and society

to enable advances in stem cell biology to be rapidly translated to deliver new treatments.

Sir Graeme was knighted in 2002 in recognition of his services to medicine and medical education.

Sir Graeme, in his capacity as President of the General Medical Council, has supported the work of the Faculty over many years. This includes his ongoing support in the development of systems for the revalidation of doctors working in pharmaceutical medicine.

Honorary Fellowship was presented to Dr Jeffrey Aronson

Dr Jeffrey Aronson is a Reader in Clinical Pharmacology at the University of Oxford and Honorary Consultant Clinical Pharmacologist and Physician at Oxford Radcliffe Hospital Trust. He is a highly distinguished clinical pharmacologist and physician, both in the UK and internationally.

He qualified in medicine at Glasgow University in 1970 and was awarded MRCP in 1973, a DPhil from Oxford University in 1977, an MA in 1984, FRCP in 1985 and Fellowship of the British Society of Pharmacology in 2004. Dr Aronson's numerous achievements and awards include three visiting professorships in Brazil, Sri Lanka and the United States.

His public service is outstanding and includes terms as a Member and as Vice Chairman of the Medicines Commission, Member of the Technology Appraisals Committee of NICE and Member of the Technology Assessment's Commissioning Board, Member of the Joint Formulary Committee of the British National Formulary and President of the British Pharmacological Society.

Dr Aronson has acted as an examiner at Undergraduate and Postgraduate level at many Universities, including London, Cardiff, Sheffield, Aberdeen, Liverpool, Cambridge, Leicester, Hong Kong and Otago. He has delivered numerous invited lectures, including national named lectures. Interestingly, he is also a member of several groups and committees relating to the history of medicine at the University of Oxford.

Dr Aronson has made significant contributions to medical literature with original articles, editorships of books and journals (including the British Journal of Clinical Pharmacology), over 100 book chapters and reviews and over 60 presentations to national and international learned bodies.

Elections and Awards *continued*

Honorary Membership

Honorary membership was awarded to Dr Robert Skinner

Dr Robert Skinner has made a major contribution to the art and science of pharmaceutical medicine, particularly in his involvement in the field of training and education. He has been committed to the development of the Faculty's specialty training curriculum, specifically the clinical development module.

Dr Skinner sat on the Higher Medical Training (HMT) working group to update the HMT curriculum from 2004 to 2006 and now sits on the new Curriculum and Assessment Working Group, co-leading the Clinical Development sub-group to review the curriculum and to consider and agree various assessment methodologies. With senior Faculty members, Dr Skinner established the Academy of Pharmaceutical Medicine at GlaxoSmithKline. Work included developing and launching a GSK Pharmaceutical Medicine Curriculum and developing educational modules to help educate R&D staff on various aspects of pharmaceutical medicine. He also organised Educational Supervisor meetings and training and implemented Diploma in Pharmaceutical Medicine revision sessions and Introduction to HMT sessions.

Dr Skinner has been involved in clinical development for 17 years, including five years in clinical operations and 10 years in clinical research training. Dr Skinner has trained clinical, clinical pharmacology, regulatory and statistics and data management staff on Good Clinical Practice and other pharmaceutical medicine topics. He has also been a trainer on various Interpersonal Skills courses.

Dr Skinner has attended and presented at previous International Conference on Pharmaceutical Medicine meetings and through his work in GSK and via the Faculty, has helped to internationalise Pharmaceutical Medicine.

Membership by Distinction

Membership by Distinction was awarded to Dr Pipasha Biswas

Dr Pipasha Biswas has made significant contributions, particularly in the field of pharmacovigilance and pharmacoepidemiology at international levels. She has worked in India, the UK and the USA and is currently working as an independent consultant. One of her recent achievements was to start the first ever Certificate course in pharmacovigilance and pharmacoepidemiology in India in 2007. The course, now in its second year, is helping raise awareness of the importance of drug safety in the region and is supported by government organisations in India. Dr Biswas has also been actively involved in starting a pharmaceutical medicine course in India and establishing the Indian Association of Pharmaceutical Physicians both of which will help to build a strong identity for pharmaceutical medicine in the country.

Ordinary Fellowship

The following Members of the Faculty were awarded Ordinary Fellowship of the Faculty:

- Dr Dereck Amakye
- Dr James Anderson
- Dr Andrzej Czarnecki
- Dr Sarah Daniels
- Dr David Gordon
- Dr Juliet Roberts
- Dr Graham Ross
- Dr Jörg Täubel
- Dr Julian Schofield
- Dr Rafe Suvarna
- Dr Jennifer Sykes

Ordinary Membership

The following doctors were granted Ordinary Membership (MFPM) in 2008.

*Via UK Diploma in
Pharmaceutical Medicine*

Dr Brihad Abhyankar
Dr Mohammed Ahmad
Dr Oluwakemi Bankole
Dr Dominic Beale
Dr Rajkumar Chetty
Dr Robert Chipperfield
Dr Audrey Koay
Dr Piotr Krzeski
Dr Wally Landsberg
Dr Nicola Lister
Dr Witold Malyszczak
Dr Mohammed Mannan
Dr Nithyanandan Nagercoil
Dr Shaw Sorooshian
Dr Jean Van Wyk
Dr Manel Wijayasinghe
Dr Andrew Yeates

*Via Diploma in Pharmaceutical Medicine, Free
University, Brussels*

Frank Ebert

Specialist Registration in Pharmaceutical Medicine

The following doctors had received their CCTs since the last AGM.

Dr Dereck Amakye
Dr Philip Ambery
Dr Robert Chan
Dr Joubert Gama
Dr Frank Gray
Dr Julian Howell
Dr Teresa Improta-Brears
Dr Stephen Jones
Dr Nandan Koppiker
Dr Wally Landsberg
Dr Simon Lowry
Dr Finnuala Lonsdale
Dr Ian Mills
Dr Amanda Oliver
Dr Kathryn Owen
Dr Hitan Patel
Dr Anthony Patrikios
Dr Berkeley Phillips
Dr Sheuli Porkess
Dr Gabrielle Silver
Dr Bernard Souberbielle
Dr Fredric Steinberg
Dr Kristina Strutt
Dr Robert Tansley
Dr Daniel Thurley
Dr Anissa Tse
Dr Anne-Ruth van Troostenburg de Bruyn
One member received a Certificate of Eligibility for the Specialist Register (CESR) since the last AGM.
Dr Paul Robinson

Amendments to the criteria and procedure for applications for Ordinary Fellowship

Amendments to the criteria and procedure for applications for Ordinary Fellowship were approved by the Faculty Board on 25 November 2008.

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Elections and Awards *continued*



Distinction and Honorary Awards: From the left Professor Sir Graeme Catto (Honorary Fellowship), Dr Susan Bews, Dr Pipasha Biswas (Member by Distinction) and Dr Jeffrey Aronson (Honorary Fellowship)

Ordinary Fellowship: From the left Dr Andrzej Czarnecki, Dr James Anderson Jr, Dr Juliet Roberts, Dr Susan Bews, Dr Sarah Daniels, Dr Paul Schofield, Dr Derek Amakye and Dr Graham Ross





Ordinary Membership: From the left Dr Jean van Wyk, Dr Nithyanandan Nagercoil, Dr Nicola Lister, Dr Susan Bews, Dr Wally Landsberg, Dr Brihad Abhyankar, Dr Dominic Beale and Dr Piotr Krzeski

Specialist Registration: From the left Dr Wally Landsberg, Dr Fredric Steinberg, Dr Bernard Souberbielle, Dr Joubert Gama, Dr Amanda Oliver, Dr Teresa Improta-Brears, Dr Stephen Jones, Dr Susan Bews, Dr Sheuli Porkess, Dr Anthony Patrikios, Dr Anissa Tse, Dr Kathryn Owen, Dr Paul Robinson, Dr Philip Ambery, Dr Derek Amakye and Dr Berkeley Philips



Revalidation Seminar 17 November 2008

President's Introduction

Revalidation is a reality for pharmaceutical physicians as with any other doctor who wants to retain a licence to practise, but a licence to practise will not in the future be the same as being on the medical register. Licences to practise 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 practise 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 practise a requirement under contracts of employment. For anyone with clinical responsibilities in a Phase 1 unit it is likely to be mandatory.

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.

Neither the Faculty nor the GMC has 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.

Revalidation will consist of two parts, relicensing for those who wish to retain a licence to practise 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 practise 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 it was thought that relicensing and recertification would be two rather separate processes, relicensing being generic to other branches of medicine but against the principles laid down in *Good Pharmaceutical Medical Practice*, and recertification against specialty specific standards. The GMC has stated that revalidation will comprise 'one process, two outcomes' i.e. one process which results in relicensing for those not on the specialist register and relicensing plus recertification for those on the specialist register. This will have not yet fully known implications for those doctors seeking only to be relicensed, but it is apparent that the annual appraisals for all physicians will need to contain auditable evidence of their ability to reach standards at the same level as any branch of medicine. These standards will be set by the Faculty and 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 for pharmaceutical physicians 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 relicensing and for recertification will need to be. But it is clear that even if not identical there will be considerable overlap. The Faculty has, 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.

The Faculty has discussed its 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 principle that the proposals would be acceptable. There is however a great deal of work to formulate these proposals in detail but the Faculty is 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 the Faculty has a work force that moves 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. The Faculty has 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 the Faculty is committed to finding solutions in respect of revalidation. The GMC has recently stated that a doctor can only recertify back into the speciality in which one certified in the first place; this is logical but has considerable implications for the considerable number of our physicians who are on the specialist register from another speciality. This would affect a large number of doctors in the NHS as well, and the Faculty will keep this on its revalidation agenda.

The Faculty is working alongside the other colleges and faculties through the auspices of the Academy of Medical Royal Colleges and is involved in a number of the groups including not only the main Revalidation group which includes standard setting, but also 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

As noted in my address at the AGM, the Faculty recently conducted a survey of its membership in connection with revalidation. 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' the Faculty considered it would also be able to use the information to inform the standard setting for relicensing 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 the Faculty can set the requisite standards. The survey was also designed to collect additional information and provided a section for free text. The Faculty also asked participants if they would be willing to assist the Faculty for example by participating in focus groups. The Faculty 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 registered 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 relicensing 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, 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 the Faculty refines its standards for revalidation, both relicensing and recertification.

*Dr Susan Bews, President
November 2008*

Any pharmaceutical physician who would be interested in joining a focus group or participating in a pilot study in connection with revalidation, please contact Konrad Obiora, Professional Standards Administrator, email K.Obiora@fpm.org.uk

ARE YOU INVOLVED IN THE CONDUCT OF PHASE I STUDIES?

Human Pharmacology

Training programmes for all involved in Phase I

The Faculty of Pharmaceutical Medicine of the Royal Colleges of Physicians of the United Kingdom is enrolling trainees in its established training programmes in Human Pharmacology.

The Diploma in Human Pharmacology is a two-year programme of structured training in the workplace and courses followed by an examination for doctors intending to work as investigators for studies involving the first administrations of potential new medicines to humans.

The Certificate in Human Pharmacology is a one-year part-time programme of courses and an examination for scientists in the pharmaceutical industry, universities and regulatory authorities who have an interest in early clinical drug development.

Enquiries for the Diploma in Human Pharmacology and Certificate in Human Pharmacology should be made to Laura Cooper.

The 2009 Annual Meeting will take place on Friday, 20 November, at the Royal College of Physicians London.

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If you have recently moved or are planning to move, please notify the Faculty by telephone, post or e-mail (fpm@fpm.org.uk) of all changes of address.

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