



# FACULTY NEWSLETTER

## AUTUMN 2011

Welcome to the autumn newsletter. As the weather here in the UK oscillates between extremes, our lead article explores the equally diverse territories of emerging markets. In a fascinating article about these territories, Dr Macrae gives an insight into the complexities in these countries both at a country level and through the patient journey, and offers some possibilities for meeting the challenge. Equally mentally taxing, but in a completely different environment is the issue of prescribing without evidence, the subject of the Faculty's Annual symposium, and the recent Educational Supervisor training, both covered in the following pages.

For those of you who wish to write as well as read, Linked In now boasts a Faculty group, and an Educational Supervisors' forum in addition to the existing Trainees' group.

Our next issue features the challenge of raising awareness of Pharmaceutical Medicine as a career, currently being tackled by the Working Party chaired by Dr Jane Zuckerman. If you have a view on this, we'd like to hear from you.

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The Faculty of  
Pharmaceutical Medicine  
of the Royal Colleges of Physicians  
of the United Kingdom

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



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# Faculty News

*Prescribing without Evidence report – Website update – Effective Educational Supervision – Consultations update*

## Conference Report

*Prescribing without Evidence – 27<sup>th</sup> September 2011  
– Wolfson Theatre, RCP London*

The Faculty's Annual Symposium was this year co-hosted with the British Pharmacological Society, and members of both organisations and a number of other groups came together to discuss the issues around prescribing with an absence of data and how best to go about 'filling the gaps' in this data.

During the morning sessions the delegates enjoyed short 'scene-setting' presentations, which set out the research, legal and ethical landscape. During the afternoon there was the opportunity for more in-depth discussions in the breakout sessions, and the conference culminated in an engaging feedback session, deftly chaired by Dr Evan Harris.

The conference was a great success and we would like to thank all those Faculty members who attended for contributing their expertise and insight. The Faculty and the BPS are currently analysing the outputs from the conference and hope to put together a report in due course.

## New Faculty website

The new Faculty website is currently in development and is due to be officially launched at the AGM on the 23<sup>rd</sup> November 2011. It is expected that the new website will provide Faculty members with the opportunity to better interact with the Faculty's activities, and also present other healthcare professionals and stakeholders and members of the public with a more engaging interface to learn about the Faculty.

## 'Effective Educational Supervision'

*Dr Liz Clark*

RCP Accreditation programme for Educational Supervisors.

The Faculty ran its third training course for in-service Educational Supervisors in Pharmaceutical Medicine in

September this year. Designed to follow on from the basic training provided on appointment, this 2-day course 'Effective Educational Supervision' also enables Educational Supervisors to gain RCP accreditation for their role.

The course, jointly run by the RCP Education Department and the Faculty, and partly supported by a grant from the Medical Leadership Forum, was led by David Parry, Peter Stonier and Sharon McCullough. David, who may be less familiar to you than the rest of the trio, is Deputy Director of Education at the Royal College of Physicians. In addition to presenting specific elements of the course, David provided a useful insight into the role and evolution of the Educational Supervisor in the world of clinical medicine. Many training requirements are common across the board as are many of the issues experienced by Educational Supervisors.

The course, which is the taught component of the accreditation process for Educational Supervisors, was held over two days three weeks apart, and addressed the following areas: the curriculum; appraisal; assessing and documenting evidence and reflective practice; workplace-based assessments; the e-portfolio; medical leadership and skills used in Educational Supervision, including recognising and addressing trainees in difficulty.

Whilst firmly rooted in practicality, the course also featured discussions on a number of areas of soft skills, including giving feedback, the place of reflective commentary with practice in writing reflections, and recognising leadership qualities and activities in the trainee.

The structure of the course allowed for varied presentation of content and a number of practical exercises, not least the opportunity to explore the e-portfolio in a training environment. There was plenty of time for discussion of both the content in hand, and of real-life examples of evidence and reflections produced by trainees, and the mix of ESs attending also enabled sharing of much pertinent experience.

ESs attending the whole course are eligible for the Accreditation project, which is, in part, an account based on assessment, appraisal and review of a trainee.

So far about half of the Faculty's Educational Supervisors have attended the course, which is planned again for next year, once again supported by the Medical Leadership Forum. It is anticipated that within the next three years the GMC will require ESs to be fully trained and accredited, so in time such training is likely to become mandatory. That said, attending the course was a pleasure. Even the most experienced of the attendees in my group found it useful, so if you didn't attend on this occasion, look out for the flyers for next year's courses and reserve your place.

## Consultations update

The Faculty has submitted responses to several major consultations during the last three months. To read the Faculty's submission to these consultations please visit the website <http://www.fpm.org.uk/faculty/consultations>

DH: Changes to regulations Care Quality Commission registration (Oct 2011)

Home Office and UK Border Agency: Employment-related Settlement, Tier 5 and Overseas Domestic Workers (Sept 2011)

DH: UK Influenza Pandemic Preparedness Strategy 2011 (June 2011)

# External News

*Faculty of Medical Leadership and Management – Leadership framework*

## The Faculty of Medical Leadership and Management – Membership now open

The Membership of the Faculty of Medical Leadership and Management is now open.

Membership is open to doctors, secondary-care dentists and medical students. You can find out more about the package of benefits on offer and how to join by visiting the FMLM website <http://www.fmlm.ac.uk/membership>

## NHS Clinical Leadership Competency Framework – new Self Assessment Tool

A Self Assessment Tool, linked to the NHS Clinical Leadership Competency Framework (CLCF), is now available for anyone in health and care services who would like to review - quickly, easily and free of charge – their leadership skills.

Although the Self Assessment Tool has been designed primarily for doctors working in the NHS, it is thought

that there is also value in the tool for pharmaceutical physicians.

The CLCF is designed to ensure that all doctors can have the leadership knowledge, skills and behaviours we need to improve health and care.

The Self Assessment Tool can be downloaded here: <http://nhsleadershipframework.rightmanagement.co.uk/tracked/assets/x/50172>

It's an offline process, so results are private to the individual, and it shows where an individual's leadership strengths and weaknesses lie. After completing the Tool, individuals can choose to generate an action plan to develop their skills – guidance is given at the end of the Self Assessment Tool, and access is available to a range of materials to support the development of leadership skills such as the free e-learning modules available through LeAD, as well as the Leadership Development Module which signposts further development opportunities for each of the domains of the CLCF.

The CLCF sits at the heart of the new Leadership Framework - find out more at [www.nhsleadership.org/framework.asp](http://www.nhsleadership.org/framework.asp)

## Feature Article:

# The complexity of healthcare in the Emerging Markets

Sandy Macrae, SVP, GSK Emerging Market R&D

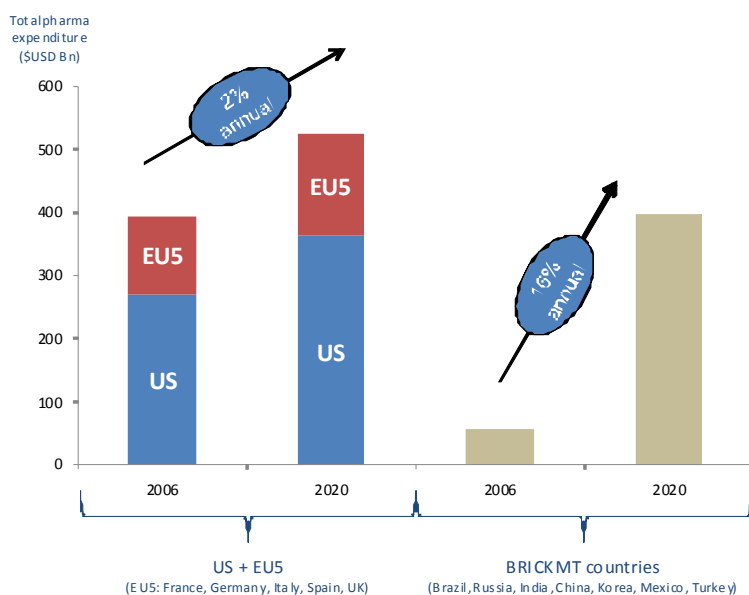
Phil Swanston, GSK Emerging Market R&D / Global Pharma Packaging



The potential for health care in emerging markets is frequently measured against numbers and contrasts. China's population expanding by a number equivalent to Australia's population each year; the growth of an overweight wealthy middle class in India facing an epidemic of diabetes; the challenge of bringing healthcare to the Favelas of Rio where malnutrition lives within sight of pockets of extreme wealth.

Behind this bewildering reality lies a complexity of healthcare systems, regulatory environments and government policy that prevents the description of a unified BRIC (Brazil, Russia, India, and China) block. Although the economic acronym BRIC reflects the major centres of growth, it does not capture the rise of medical demand complexity of the markets and in many other countries.

## Emerging Markets will rival developed markets by 2020



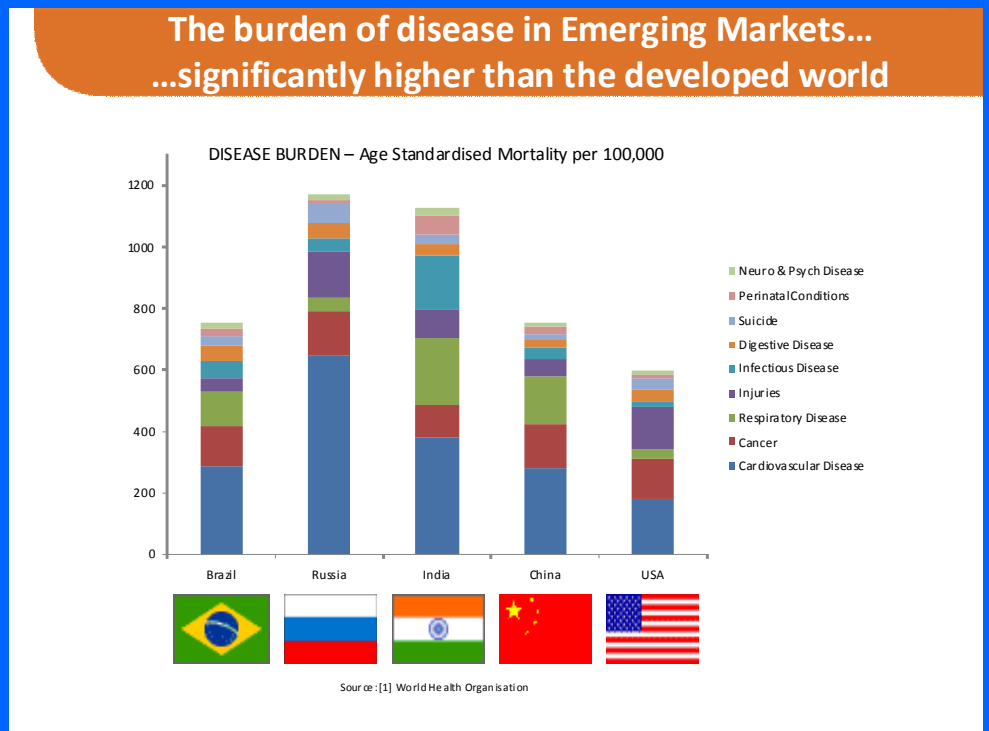
Source: [1] IMS MIDAS sale data, total pharmaceutical markets  
Note: [a] Extrapolation from 2006 to 2020 based on IMS projections and % of 2006 sales

It is estimated that by 2013 China will be second only to the United States in health spend, and that by 2020 the combined emerging markets will spend more on health than Europe and be comparable to the combined US and EU budgets today. The medicines that are currently being developed will be launched into a world of added complexity, where the particular and evolving needs of these diverse global patients must be baked into the development of our medicines, to ensure faster launches and deeper access.

What connects these countries is a common burden of Non-Communicable Diseases (NCD's) more commonly associated with western countries. The WHO recently highlighted that NCDs are increasing amongst patients from these countries fuelled by a relative increase in wealth, migration to the cities, smoking and a move towards less balanced higher-calorie western-like diets<sup>1</sup>. Thus, although there remains a medical challenge of infectious disease and regional specific disease, often in the very least developed countries and their poorest inhabitants; the rising challenge is for diseases such as COPD, diabetes, heart disease, strokes, and common cancers such as breast, lung and colon.

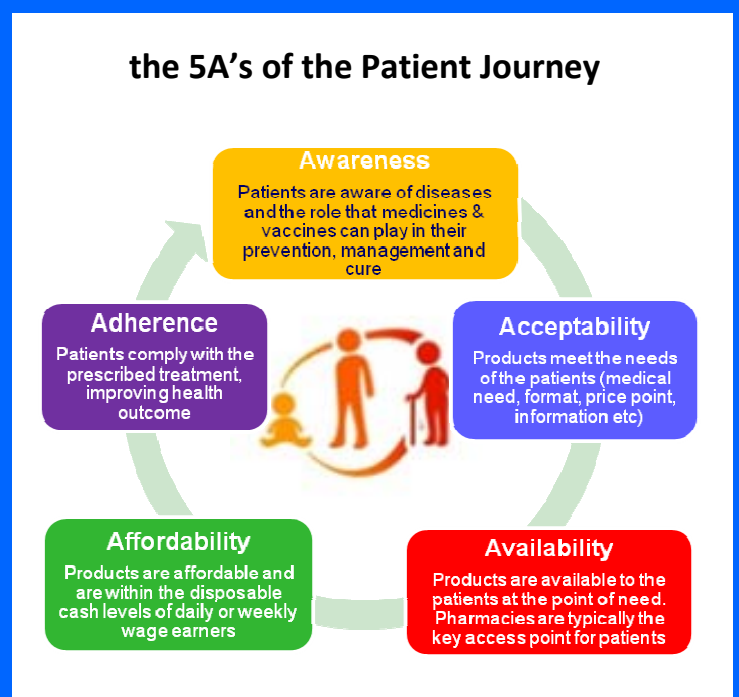
The WHO reports that 80% of cardiovascular / diabetes deaths and up to 90% of COPD deaths occur in low and middle income countries, and emphasise the disproportionate burden of disease in those on lower social or economic groupings. They recommend a move from hospital to primary care, treatment to prevention (similar to that seen in developed countries). They also describe sensible treatment of diabetes, affordable inhaled medicines for chronic respiratory care and good cancer care as “best buys”.

Three features are striking. Firstly the disease ranking is similar across the emerging markets and increasingly similar to that of the US and other developed countries. Secondly the relative disease burden is far greater in the emerging countries reflecting the availability of health care and the social burden. Thirdly this reflects a snapshot of the current situation and disease patterns from less developed times. The rate of fundamental change, urbanisation and industrialisation will add to the healthcare burden.



Another commonality that spans all of these emerging countries, is a population of patients referred to as the ‘have less’. The ‘have less’ often pay for their medicines out of pocket on a weekly or even daily basis and represent the majority of the population (about 60% are positioned in the C&D class socioeconomic groups).

Access is an emotive term and describes the full interaction between the patient and their medicine. The 5A's of the patient journey – Awareness, Acceptability, Availability, Affordability & Adherence - each speak to the barriers that need to be addressed before full patient / medicine access is achieved.

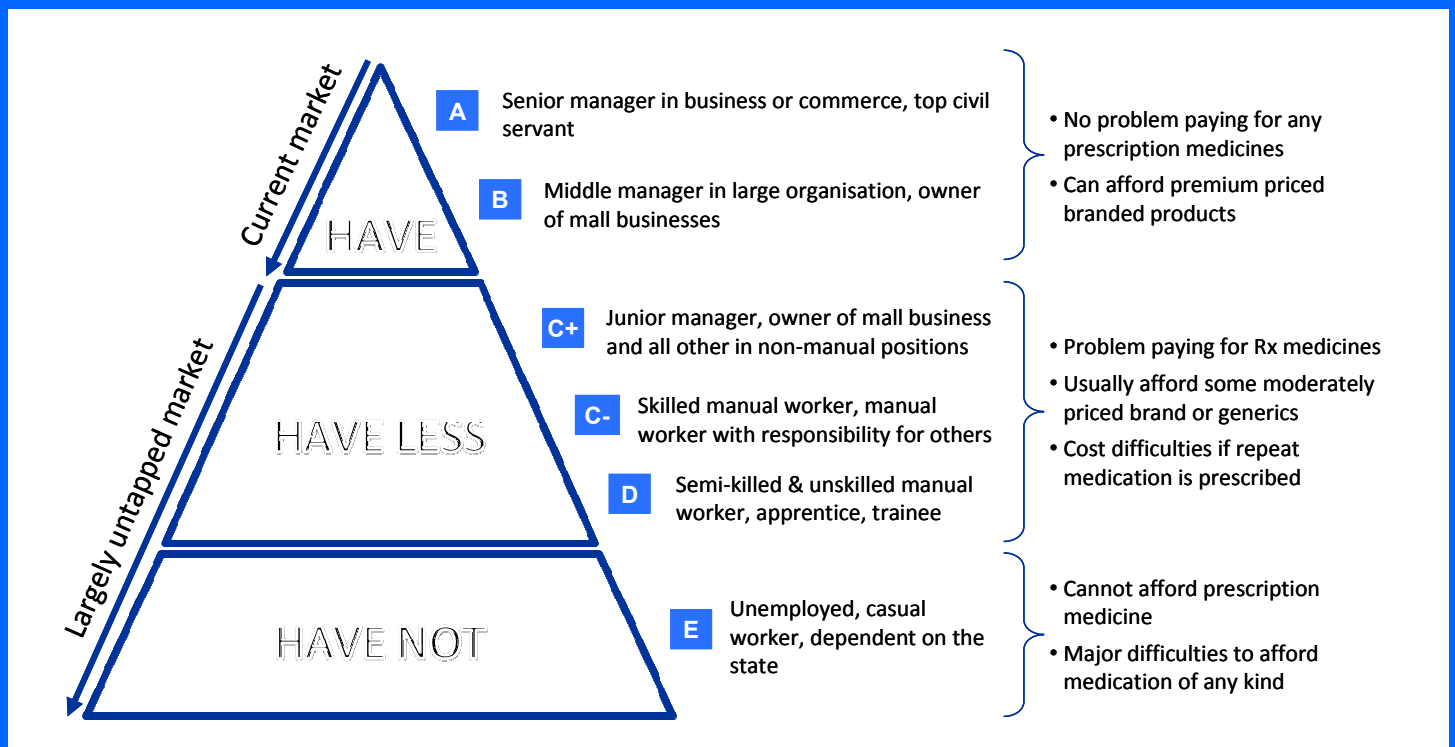


Historically, western medicines were affordable and accessible for only the wealthiest few percent of the population. The pharmaceutical industry continues to work hard to face the challenge of partnering not only with governments but also NGO's to provide healthcare to more people in the emerging markets.

From a pharmaceutical industry point of view access begins with a portfolio of medicines that are pertinent to the needs of the patient in emerging markets. This will span early availability of newer, IP-protected innovative medicines for the current patient populations, but now must also include medicines relevant to the have-less populations, addressing the chronic NCD's with those off-patent medicines that are the backbone of treatment algorithms. Companies

and affordability, and it is important to apply them on a case-by-case basis to these countries.

While the medical need has attracted great focus from pharmaceutical companies, there remains additional unique and significant challenges. As in the UK or US the governments in the emerging markets are facing a growing, aging population whose demand for modern health care places huge pressure on the national budget. The regulatory requirements continue to evolve and become more similar to that of the US or EU. However the national agency infrastructures were not conceived for the deluge of applications and will lead to inevitable delay. Finally, although IP has become less of an issue there remains an important and successful local generic



that are successful in the emerging markets will often also manufacture a vaccine portfolio emphasising the importance of primary prevention and national health care.

There are a number of approaches to access encapsulated in the 5 A's including for example supply chain infrastructure, capability and training and also affordability and appropriate pricing. To determine the right price to drive patient access in individual countries a flexible approach across the emerging markets, taking into consideration the affordability for patients, coupled with the governmental and market environment is required. There are a variety of models to increase accessibility

industry whose portfolios often address the common medical needs and have a closer understanding of the local situation.

By 2012 the world's population will have crept over 7 billion, the vast majority of whom live and work in the emerging markets. As these countries grow and develop so will their healthcare needs. Whether this is important to the pharmaceutical industry is no longer the question; how we address this is now the challenge.

1) World Health Organisation – Global status report on non-communicable diseases 2010  
[http://www.who.int/chp/ncd\\_global\\_status\\_report/en/](http://www.who.int/chp/ncd_global_status_report/en/)

# *Faculty Board summary*

*Board of Trustees Meeting Summary – 7<sup>th</sup> July 2011*

## **Welcome**

Mrs Suzie Hughes was welcomed as a new lay trustee. Mrs Hughes is also the Chairperson of the RCP Patient and Carer Network.

## **RCP Medicines Forum**

The Medicines Forum has now been discontinued but a new group has been established to take forward some of the work. This new group has been jointly set up by the RCP and the ABPI and is called 'evolving the relationship between the medical community and the pharmaceutical industry'. The President represents the Faculty on this group. The group will focus on three main areas: sponsorship of medical education, clinical pharmacology and the next version of the ABPI Code of Practice in 2013.

The President reported that the FPM publication 'Guiding Principles for Pharmaceutical Physicians' was to be submitted to the RCP London Ethics Committee to consider production of a similar document by the RCP.

## **Raising Awareness of Pharmaceutical Medicine**

The first meeting of the working group to explore this issue will be held on 21 July and will be chaired by the Vice President. The group will focus on raising awareness amongst medical students and foundation doctors.

## **Adherence Working Group**

This working group, set up by the Professional Standards Committee, is working to research, influence and potentially impact on policy regarding Patient Information Leaflets.

## **Revalidation**

The revalidation pilot is now underway. The Academy of Medical Royal Colleges are working with the GMC to develop guidance on revalidation which is expected to be more streamlined than earlier documents.

Through the Professional Standards Committee, the FPM will review how revalidation and CPD will work together.

## **Academy of Medical Royal Colleges**

The President reported that the single prescription chart recommended by the Academy had not yet been adopted by the DH England. This would be discussed further at the next Academy meeting.

## **Future Meetings**

The next Co-ordination Committee is on 5 October 2011 and the next Board Meeting is on 19 October 2011.

## *Contact the Faculty...*

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Charity number: 1130573

If you have recently moved or are planning to move, please notify the Faculty by phone, post or email of all changes of address.

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## *Upcoming Faculty events...*

### **November 2011**

23<sup>rd</sup> – Faculty Annual Meeting and Dinner

### **January 2012**

25<sup>th</sup> – Faculty Board meeting

26<sup>th</sup> – PFPM attending RCP Council

31<sup>st</sup> – CHP Revision day

### **March 2012**

1<sup>st</sup> – D/CHP examination

2<sup>nd</sup> – DHP examination

# *President's update*



*Dr Richard Tiner*  
*President of the Faculty*

## **Faculty Offices**

I am delighted to report that the new Faculty Offices at 30, Furnival Street are now open. Indeed, we had our first Board meeting in the new environment recently. I must say that having seen them as a shell earlier in the year, the office planners have done a splendid job and other than a few gremlins in the email system, everything has gone surprisingly well in the move. Much of that is down to Kathryn and the team.

## **Diploma in Human Pharmacology**

Prof. Sir Gordon Duff visited the Board to discuss the future of the Diploma in Human Pharmacology, which the Faculty established following his report on the TeGenero trial. Uptake has not been as good as we hoped, Sir Gordon is going to pursue a few avenues on our behalf but in the meantime the Board has agreed to reduce the current fee quite substantially. We hope that will encourage members working in Phase 1 to consider the Diploma as in time it is likely to become a qualifying exam for Principal Investigators.

## **Diploma in Pharmaceutical Medicine**

Recently a record number of candidates took the DPM and three sat it in Cape Town as a pilot to see if exporting the DPM is feasible. I should like to thank Steve Pawsey, the Chairman of the Board of Examiners, for going out to Cape Town for the exam on behalf of the Faculty, and Bernd Rosenkranz for all his efforts in getting the exam centre established.

## **Revalidation**

Following a recommendation from the Revalidation sub-committee, the Board has agreed that the Faculty is not likely to be in the vanguard of organisational readiness for the early stages of revalidation. However this does not mean that members with a GMC Licence to Practise should rest on their laurels but they should still undertake CPD and where possible have an annual appraisal. Fuller details on this will be available in my annual report which will appear in the next Newsletter but I thought you would like to have early information on this issue.

## **Prescribing Without Evidence**

This was the title of our very successful Annual Symposium held on 27<sup>th</sup> September with our partners the British Pharmacological Society. A full report will appear in a future Newsletter but I was delighted for the support for a recommendation for the Faculty and BPS to pursue the removal of an upper age limit as an exclusion criterion for clinical trials. There is no justification for such a criterion which is purely ageist. Elderly people are major users of the medicines that the industry develops and the more data that can be collected from the eventual users in RCTs then the better.

Finally, as this is likely to be the last Newsletter of 2011, please accept Seasons Greetings and my wishes to all of you for a Happy and Prosperous New Year.