



FACULTY NEWSLETTER SPRING 2011

Welcome to the new-look Spring 2011 Faculty Newsletter!

Following feedback from the membership survey reported in the last Newsletter, we have made some changes in the format, which we hope will make the newsletter of more value amidst the volume of online bulletins and notices.

The last few months have been busy ones in most Code compliance circles, with the publication of the 2011 ABPI Code in January, the MHRA Annual Report on Advertising regulation in February, and the extension of the Advertising Standards Association remit to digital media at the start of March. Whether you work at the commercial end of the spectrum or not, you are unlikely to find yourself unaffected by the ABPI Code changes – Asad Khan's article, to which we have devoted the major part of this newsletter, will tell you why.

You will also find updates of activities ongoing at the Faculty. Ben Cottam, the Faculty's Policy and Communications Coordinator, is perfectly placed as our 'man on the ground' to make sure that you, the members are as well informed about Faculty activities as possible. We hope you enjoy this edition; please let us know what you think of the changes and let us have any other feedback; only by so doing can we continue to improve our offering.

Dr Liz Clark MFPM and Dr Jit Solanki FFPM

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

In My Country

The International Committee of the Faculty has drafted a document entitled “In My Country” (please visit the Faculty website to view the document <http://www.fpm.org.uk/committees/internationalcommittee>) which reflects some major information on the current status of our speciality in the countries currently represented on the Committee. The document is intended to be a living one, therefore we



would urge all international members to read the document and get in touch with us if you spot any amendments, modifications or

additions that need to be made. Please let us know of any developments at your earliest convenience, so that we can update it at least once a year as things evolve. We would also like to invite other members, whose countries are not included, to take the time to send similar responses to the depicted questions and these will be added periodically to the document. Please contact Ibrahim Farr, Chairman of the International Committee, either via the Faculty's office fpm@fpm.org.uk or directly by e-mail at ibrahim.farr@pivotal.es with any additions or updates.

Consultations responded to

The Faculty has submitted responses to several major consultations in the last 6 months. To read the Faculty's submissions please visit the website <http://www.fpm.org.uk/faculty/consultations>.

- Department of Health – A new value-based approach to the pricing of branded medicines (Mar 2011)
- Department of Health – Cancer Drugs Fund (Jan 2011)
- Department of Health – Liberating the NHS: An Information Revolution (Dec 2010)
- Department of Health – Liberating the NHS: Greater Choice and Control (Dec 2010)
- House of Commons Health Select Committee – Inquiry into the Revalidation of Doctors (Nov 2010)
- Department of Health – Transparency in Outcomes: A Framework for the NHS (Oct 2010)

External News

Delivering High Standards in Medicines Advertising Regulation, 5th Annual Report, Advertising Standards Unit, MHRA

Published in February, this report covers September 2009 – December 2010, reviewing the unit's activity in the perspective of the five years since the Government's response to the Select Committee report, *The influence of the pharmaceutical industry*, during which time there have been a number of changes in advertising and its regulation, not least the increased use of the Internet, and pre-vetting of promotional materials for new products. There follows a detailed review of action on complaints, which have shown a steady increase since 2007. Sections on vetting of advertising prior to issue and collaboration with other agencies and the activities of the Medicines Advertising Liaison Group follow. The document concludes with a section on the legal perspective, describing progress with the MHRA's project to consolidate the Medicines Act 1968 and over 80 statutory instruments into a single piece of legislation, and a review of the Blue Guide. Look out for the formal public consultation on this later in the Spring.

The report can be accessed on the MHRA website (<http://www.mhra.gov.uk/Howweregulate/Medicines/Advertisingofmedicines/index.htm>).

Digital Media Now Under the Remit of the CAP Code

From March 1st 2011, the Advertising Standards Authority's remit now extends to cover companies' own marketing claims on their own websites and other non-paid spaces under their control. This is implemented through the Committee of Advertising Practice Code. Whilst its scope has recently been updated to state that it does not apply to claims addressed only to medical, dental, veterinary or allied practitioners, that relate to those practitioners' expertise, this will nevertheless be of relevance to members working with OTC brands.

Further information on the ASA and CAP code can be found on the ASA website (<http://www.asa.org.uk/sitecore/content/Home/CAP.aspx>).

UK Code of Practice Update Reflects Desire for Transparent Partnerships

Dr Asad Khan MFPM



The age-old Chinese proverb, ‘*may you live in interesting times*’, was perhaps written with the Pharmaceutical Industry in mind; because there is hardly a dull or boring moment in this interesting and exciting industry. Pharmaceutical physicians, in particular, quite regularly find themselves attempting to decipher and demystify complex new regulations, directives, guidelines, codes, procedures and processes; and not to forget, surviving ever increasing mergers, acquisitions, takeovers and work & other professional pressures!

The 2009 report of the Royal College of Physicians *Innovating for Health*¹ gave a clear indication that the relationship between the Pharma Industry and healthcare professionals is set to change. The report, on one hand, acknowledged the importance and diversity of this relationship but on the other hand, also raised concerns and questions about the strength and integrity of these relationships. It talked about rewriting the relationship between medicine and the Pharmaceutical Industry; with transparency, more balance and open communication being the major themes. The report, among other recommendations, advised abolishing all gifts to doctors and their support staff, and publicly declaring any honorarium or fee, commercial or otherwise, paid to doctors arising out of this relationship.

The timing of the RCP report couldn’t have been more perfect, because the industry’s trade association, ABPI, by then had already identified ‘trust’ as one of its four key strategic objectives². As part of this

objective, ABPI’s aim was to establish the industry as a trusted partner in the UK healthcare system by building a new contract between industry and society based on integrity, honesty, knowledge, appropriate behaviours, transparency and openness. Several campaigns were developed under the ‘Trust Imperative’ and many industry working groups debated long and hard on strategies and tactics to achieve this objective. A public consultation of various recommendations was launched in the autumn of 2009, with the objective of formalizing the outcomes in the industry’s Code of Practice.

With this background in mind, let us have brief look at the history of the ABPI Code of Practice³. The Code celebrated its 50th anniversary in 2008 and represents the long established system of self-regulation of medicines advertising in the UK, supported by the statutory role of the Medicines and Healthcare products Regulatory Agency (MHRA). The Code is revised regularly every 2-3 years in consultation with the Pharma Industry, British Medical Association, the Royal Pharmaceutical Society, the Royal College of Nursing and the MHRA. In addition to the above stakeholders, technically anyone can contribute in the consultation process. The Code is accepted by virtually all pharmaceutical companies operating in the UK; by all ABPI member and affiliate companies as a condition of the trade association membership and by around 60 non-members of the ABPI who have given their formal agreement to abide by the Code.



¹ Royal College of Physicians. *Innovating for health: patients, physicians, the pharmaceutical industry and the NHS*. Report of a Working Party. London: RCP, 2009.

² Association of the British Pharmaceutical Industry (ABPI). *Annual Report 2009/10*

Regulation of medicines promotion is technically a very complex area and is governed at several levels.

³ Prescription Medicines Code of Practice Authority. *ABPI Code of Practice for the Pharmaceutical Industry, 2011*.

On a global scale, there are the WHO's 'Ethical Criteria' for Medicinal Drug Promotion and the International Federation of Pharmaceutical Manufacturers and Associations' (IFPMA) Code of Pharmaceutical Marketing Practices. On a European level, there are European Federation of Pharmaceutical Industries and Associations' (EFPIA) Code on the Promotion of Prescription-Only Medicines to, and Interactions with, Healthcare Professionals and EFPIA Code of Practice on Relationships between the Pharmaceutical Industry and Patient Organisations. EC Directive 2001/83/EC also has a section on medicines promotion. In the UK there are several laws and legislation related directly with the advertising and promotion of medicines. There is also a code for OTC medicines, the Proprietary Association of Great Britain (PAGB) Code, and the MHRA's Blue Guide on the advertising and promotion of medicines in the UK. The ABPI Code incorporates the principles set out in all of the above. It reflects and extends beyond the relevant UK law.

Many UK pharmaceutical physicians, especially those working within Medical Affairs, come across the Code almost on a daily basis. The new version of the Code (the 2011 ABPI Code) came into operation on the 1st January 2011⁴. The transition period ends on 30th April 2011 after which it will become fully operational. The new Code includes both of the recommendations made by the RCP report mentioned above. The key themes are transparency and openness and the major focus is on building trust. The two major changes in the 2011 Code are:

- ① Companies are now required to make public declarations in relation to certain activities that fall within the remit of the Code, for example:
 - When UK pharmaceutical companies work with patient organisations, they are already required to make yearly public declarations of the names of such organisations and brief details of the activity. From next year onwards, companies will be required to declare, in addition to the above, monetary value of financial or non-financial support provided (cut-off point £250 per project excluding VAT)
 - Donation and grant payments to UK healthcare and/or research organisations in 2012 (declaration to be made from 2013)

- Fee/honoraria payments made to UK healthcare professionals and appropriate administrative staff employed as chairpersons, speakers, advisory board members and trainers in 2012 (declaration to be made from 2013)
- Payments made (as registration fees, cost of accommodation both inside and outside the UK, and out of the UK travel) in relation to sponsoring UK health professionals and appropriate administrative staff to attend independently organised meetings (declaration to be made from 2013)
- Summary details and results of non-interventional studies of marketed medicines with which the UK company has had *any* involvement

The above is not a complete list of public declarations. For details, please refer to the 2011 ABPI Code³.

- ② The Code will bring an end to the gift culture mentioned and criticised in the RCP report. Many items given as promotional aids in the past are no longer acceptable; these include coffee mugs, stationery, computer accessories such as memory sticks, diaries, calendars and the like.



The only such items allowed for health professionals and appropriate administrative staff are non-branded (i.e. not carrying drug names) notebooks, pens and pencils, and then only for individuals attending scientific meetings and conferences, promotional meetings and other such meetings, and only for use at such meetings. These items may bear the company name but the total cost must not exceed £6, excluding VAT. They cannot be provided by representatives when calling upon health professionals.

⁴ Khan A. *The new ABPI Code 2011, changes, consequences and compliance. Pharmaceutical Physician 2011, Vol 21 (4), January, pages 19-22*



The 2011 Code also carries greater details on 'Joint Working Projects'; defined as projects where, for the benefit of patients, one or more pharmaceutical companies and the NHS pool skills, experience and/or resources for the joint development and implementation of patient-centred projects and share a commitment to successful delivery. Such projects usually will last for 6 months or more and generally involve resources (manpower, materials, funding etc) in the region of £15,000 - £20,000.

Another new development that would be of interest to pharmaceutical physicians working within Medical Affairs is the addition of UK-registered pharmacists as independent signatories for promotional materials only (i.e. not for promotional activities and non-promotional materials and activities).

Compliance with the ABPI Code and other advertising regulations is of utmost importance; as non-compliance may carry huge monetary and non-monetary consequences, both at the individual and at company levels⁵. The issue and sign-off of any non-compliant and illegal promotional material is a criminal offence under the Medicines Act (1968) and carries financial penalties and potential for a custodial sentence; conviction of such an offence may lead to erasure from the medical register by the GMC⁶. The Faculty of Pharmaceutical Medicine's Guiding Principles⁷ also acknowledge the work that

⁵ Khan A. *The cost of an ABPI case*. Pharmaceutical Physician 2010, Vol 20 (1), March, pages 6-9

⁶ Griffin, J.P. and O'Grady, J. Eds. (2006). *The textbook of pharmaceutical medicine*, 5th ed. Oxford: Blackwell publishing; extract from chapter 11, J H Young, page 353

⁷ Bragman K et al. *Guiding Principles for Pharmaceutical Physicians*. Ethical Issues Subcommittee of the Faculty of Pharmaceutical Medicine of the Royal Colleges of Physicians of the United Kingdom, November 2010

pharmaceutical physicians perform within marketing and states that the promotion of all medicines must be based on objective, ongoing assessment of all the available information, be in accordance with the labeling and not involve the use of undue pressure or inducements of any nature on healthcare workers to prescribe a product.

The ABPI Code is administered by the PMCPA which is responsible for the provision of advice, guidance and training on the Code as well as for the complaints procedure. Interesting ABPI case histories are available at the PMCPA website www.pmcpa.org.uk.

There is often a misconception that the ABPI Code of Practice applies only to those working within the commercial side of business or to activities carried out by these functions. However, this is a 'Code of Practice for the Pharmaceutical Industry'; and therefore any individual working within any department in the UK Pharmaceutical Industry is covered by the Code.

In short, by introducing new requirements, the ABPI Code has once again led the way in establishing norms of behaviour within the EU. This is a first step in the right direction which will hopefully establish the Industry as a trusted partner in the UK healthcare system.



Board Meeting Summary

26th January 2011

Appointments & Elections

The new Treasurer is Dr John Young. Elected to the Board of Examiners are the new Chairperson - Dr Steve Pawsey, the new Vice Chairperson - Dr Julian Howell and the new Secretary – Dr Ruth Dixon.

Relocation of Faculty Office

The relocation expected in December 2010 had not taken place. Two proposed sites had fallen through. A third option is currently being pursued close to Chancery Lane.

Prescribing without Evidence conference

In collaboration with the British Pharmacological Society, the Faculty is organising a major conference for the 27th September 2011 on the topic of 'Prescribing without Evidence'. Please see the enclosed flyer for more information.



Annual Meeting

The Annual Meeting including dinner will be held on 23rd November 2011.

New Faculty of Medical Leadership & Management

It was noted that the FPM is being invited to nominate a representative to join the foundation committee of the new Faculty.

'Sense about Science' booklet on evidence based medicine

It was noted that the FPM would be contributing to a joint project between 'Sense about Science' and the Academy of Medical Royal Colleges on evidence based medicine. Material relating to pharmaceutical medicine would be submitted for publication in a booklet.

FPM Position Statements

The Board agreed that it would review the current FPM position statements at its next meeting. A method of updating and adding to these in a pro-active way would make these statements the most useful as prompt responses to enquiries could then be given.

Strategic Plan 2011 – 2015

The updated strategic plan is to be based upon the following:

- a) Revalidation
- b) Increasing the numbers of members
- c) Supporting the ongoing work of the RCP Medicines Forum
- d) Longer term resource planning
- e) Advocacy work
- f) Exploring new initiatives in education, training and qualifications
- g) Maintaining and developing current exams and programmes
- h) Supporting the Innovative Medicines Initiative through 'Pharmatrain'
- i) Implementing a new digital strategy
- j) Increasing the involvement of members
- k) Raising the awareness of the importance of pharmaceutical medicine
- l) Collaborating with other organisations

President's update

Richard Tiner .

*Dr Richard Tiner
President of the Faculty*



Welcome to this new section of the Newsletter. From this edition onwards the Faculty President will highlight current important topics. For further information and to keep up to date with any of the chosen topics, please visit the website regularly.

Revalidation

Many thanks to those of you who have volunteered to take part in the Tri-Faculty pilot which is now underway. With our partners, the Faculties of Occupational Medicine and Public Health, the FPM will obtain a real understanding of the revalidation process and that ought to be of great benefit to all our members who have a GMC Licence to Practise. The evaluation will take place at the end of the year leaving about a year before revalidation officially begins (still scheduled for the end of 2012).

Pharmaceutical Medicine Specialist Training (PMST)

The GMC are just completing a consultation on National Postgraduate Professional Examinations and the FPM has responded to the consultation. In launching the consultation, the GMC have announced that “all doctors already in specialty training, or who enter specialty training by 31st October 2012 will be able to have any valid passes in previously approved national professional examinations counted towards a CCT, even if those passes were obtained outside approved training”. This means that any Pharmaceutical Physician with the Diploma and in PMST by 31st October 2012 will have that pass counted towards the final CCT. After that date it is likely that a time limit will be introduced. As soon as the FPM knows the detail an announcement will be made on the website and in a future Newsletter. In the meantime, if you are considering

entering PMST and you passed the Diploma some years ago, I would advise you to enrol by 31st October 2012.

Guiding Principles for Pharmaceutical Physicians

With this Newsletter you will have received a copy of the updated FPM Guiding Principles for Pharmaceutical Physicians. These have been updated following a recommendation in the Royal College of Physicians London (RCP) report “Innovating for Health: Patients, physicians, the pharmaceutical industry and the NHS” to update the guidelines in line with the Nolan Principles of Public Life as applied to doctors. These principles are: selflessness, integrity, objectivity, accountability, openness, honesty and leadership. The revised guidelines were launched at the FPM AGM 2010 and were made available to delegates at the RCP Medicines Forum Conference which was a follow-up conference to the original Innovating for Health report. I also presented them at a RCP conference on Fraud and Whistleblowing and there they were actively supported by Sir Iain Chalmers, the Editor of the James Lind Library.

Part of the original recommendation was that the guidelines should be promoted to the Academy of Medical Royal Colleges and I did that on 28th March with encouragement to Royal Colleges and Faculties to introduce or update similar guidelines for their members. The FPM will also be including them as part of their response to the current GMC consultation on updating Good Medical Practice.

I commend the guidelines to you and invite you to ensure that the principles are a normal part of your working lives. The document is short but the principles are not easy to follow but they are right.

Examiners

In 2011, there were 65 entrants for the Diploma and it is likely that that number will increase over the coming years. Also, the GCP exam is likely to have increased entrants in the future due to the FPM's agreement with the National Institute for Health Research in England. These welcome developments mean that the FPM needs more examiners. If you would like to consider becoming an examiner, please let us know via the FPM office. Training will be

provided and of course the work involved is subject to CPD points. This is a very positive way to help the Faculty.

Annual Meeting and Prescribing without Evidence Conference

Two important dates for your diaries: a conference entitled 'Prescribing without Evidence' is being organised in collaboration with the British Pharmacological Society for Tuesday, 27th September at the RCP London. A Flyer for this conference is enclosed and further details will appear on the website shortly. The AGM and Awards Ceremony and Annual Dinner will take place again at the RCP on Wednesday 23rd November. As yet the Coordination Committee has not decided whether to have a short symposium or a key lecture as part of the day but that will be announced on the website.

Finally, I would like to congratulate one of our Hon. Fellows – Prof. Sir Rory Collins – on the award of a Knighthood in the UK New Year's Honours List.

I wish you well in all your endeavours and please visit the website regularly for more information on Faculty activities throughout the year.

Faculty events 2011

April	12 th – Faculty Board Meeting
May	4 th – Deadline for the receipt of applications and nominations for Fellowship, Honorary Fellowship and Membership, Membership by Distinction and without Examination 5 th – Deadline for entries into the GCP examination 23 rd – National Trainees meeting (RCP)
June	6 th – GCP Examination 15 th – Trainees Sub-committee meeting 22 nd – Educational Supervisor Induction session
July	7 th – Faculty Board Meeting
Sept	27 th – Prescribing without Evidence conference
Nov	23 rd – Faculty Annual Meeting

Contact the Faculty:

We are keen to hear the views of Faculty members on any of the topics discussed in this newsletter. If your comments are related to the newsletter itself, Faculty policy or communications then please contact Ben Cottam (b.cottam@fpm.org.uk or 020 7224 0343 ext 25), otherwise please contact the Faculty office for more information:

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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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