FACULTY OF PHARMACEUTICAL MEDICINE
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From the President
Dr Keith Bragman MD (Lond) FRCP FRCPath PFPM
president@fpm.org.uk

Re: PMCPA proposals to amend the ABPI Code of Practice for the Pharmaceutical Industry

5th September 2013

Dear Ms Simmonds,

1 The Faculty welcomes the opportunity to submit evidence to this important consultation regarding changes to the ABPI Code of Practice. Many of our members would be directly affected by the proposed amendments. However, our comments are based on the Faculty's over-riding duty to ensure the highest standards of care and safety to patients.

2 The Faculty has sought input into this consultation response from our membership and I have taken into account their views in composing this letter. We received comments and suggestions from a wide variety of Faculty members, representing a cross-section of standpoints – from senior medical directors to those relatively new into pharmaceutical medicine, and from large, medium and small companies, as well as independent pharmaceutical physicians.

3 The Faculty is in broad agreement with the majority of the changes proposed in the PMCPA consultation. However, we have particular concerns regarding Amendment 6, which proposes the removal of the following paragraph from the Code of Practice:

4 *"Material referred to in Clause 14.3 below must be certified by two persons one of whom must be a registered medical practitioner or, in the case of a product for dental use only, a registered medical practitioner or a dentist."*

5 The rationale behind the proposed change being:

6 *"Deleting the second paragraph will extend the remit of pharmacists in relation to materials that currently have to be certified by a registered medical practitioner. The Authority is not aware of any problems which have arisen as a result of changes to the remit of pharmacists in this regard. Allowing pharmacists to certify, instead of a registered medical practitioner, items covered by Clause 14.3 is a logical next step which will mean that pharmacists will be able to certify all materials that previously needed a medical signatory. This*

facility has been requested by a number of companies."

7 The Faculty is very concerned that medical oversight of such materials and activities should be retained. In all other key areas of medicines development there is a clear requirement for medical input, and we do not believe that this area – where ethics and the welfare of the patient are just as important – should be overlooked by physicians. The kinds of materials outlined in clause 14.3 must be appropriate and useful, clinically relevant and ultimately beneficial for use by and for patients. We believe that this can only be assured by having a physician's input.

8 A medical degree provides a comprehensive understanding of all therapeutic areas as well as an understanding of how clinical data is interpreted, both on a statistical level but also with respect to clinical relevance. Non-promotional materials and activities often have nothing to do with medicinal products and may often be related to other aspects of healthcare delivery or patient care such as disease awareness, recognition, diagnosis and non-pharmacological treatment approaches. A very wide understanding of the patient and the disease process is required in order to ensure high quality materials. The extent of a pharmacist's training and experience in matters relating to non-pharmacological management of medical and surgical conditions can in no way be compared either in extent or depth to that of a medically qualified pharmaceutical physician.

9 Pharmacy and medical training are very different and it requires a trained pharmaceutical physician to fully appraise promotional materials from a benefit: risk perspective. Almost all doctors will now have had a minimum of four years of experience of clinical medicine before entering the pharmaceutical industry. An increasing number have completed Pharmaceutical Medicine Specialty Training and have become accredited specialists. Additionally, under the requirements of revalidation, the satisfactory signing off of material covered by clause 14.3 will now be reviewed as part of appraisal. This is not a statutory requirement for pharmacists, who generally do not undergo the same rigorous continuing professional development that pharmaceutical physicians undertake.

10 We believe that the proposed amendment could have serious implications for patient care and safety. In the explanatory paragraph for the proposed change it is stated "*The Authority is not aware of any problems which have arisen as a result of any changes to the remit of pharmacists in this regard*". Based on our initial enquiries, it seems that the PMCPA has not proactively conducted any research into or audit of issues of safety comparing pharmacist or physician sign-off. We believe that the safety implications of such a change must be thoroughly analysed before any change in policy is implemented.

11 The Faculty is also concerned that a large amount of potentially useful information on physician or pharmacist sign-off is being 'lost' due to the large number of complaints that are now settled at a company level, with the PMCPA unaware of the outcome. We are therefore concerned that the PMCPA may be proposing this change without access to any evidence that would ensure patient safety would not be affected by the changes.

12 We are concerned by the inclusion of the phrase "*This facility has been requested by a number of companies."* as we believe that the Code's ultimate responsibility is to patients, and that it should not be altered purely on the basis of requests coming from companies. The Faculty has informally surveyed a number of our members in senior medical positions in companies and we have not, to date, been made aware of our members making or being involved in making such a request to the PMCPA. Indeed, several medical directors have stated that they intend to retain medical sign-off of educational materials for the foreseeable future, regardless of the outcome of this consultation.

13 The Faculty does not consider a request by companies as a valid reason, on its own, for removing the absolute requirement for medically qualified certification of such materials and activities. It is unclear precisely why companies have 'requested' this change and the PMCPA do not state the reason(s) anywhere in their accompanying material. This lack of information has led us to conclude

that, in part, this request has been made on the basis of cost-savings and we would argue that this is not a legitimate reason to further modify these requirements in isolation of a thorough understanding of the implications.

14 The vast majority of Faculty members with whom we have had contact about the proposed changes have expressed serious concern about the proposals and their implications for patient safety. A very small minority have supported the changes, recognising the more clinically orientated training pharmacists receive now and their wider responsibilities and involvement in patient care in the NHS, though they also admit that cost is a factor. However, to maintain high standards in the development and approval of materials outlined in clause 14.3, the content must be appropriate and useful, clinically relevant and ultimately beneficial and safe for use with patients. The Faculty believes that it is essential that medically qualified individuals remain responsible, as a minimum, for the purpose of certification.

15 Considering all of the above, the Faculty opposes the proposed changes outlined in Amendment 6 and would seek reassurances from the PMCPA that these proposals are revisited and that the requirement for a physician to sign-off these materials not be removed from the ABPI Code of Practice. The provision of educational materials at the industry/clinician/patient boundary is a very high profile area and it is vital that rigorous standards are maintained. Quite apart from the potential safety implications, there are huge implications for further reputational damage if these processes are not handled effectively and appropriately, and clinician/patient trust in the industry could drop even further. At the very least, we would ask that the PMCPA provide more evidence for the rationale behind the proposed changes and provide an opportunity for a more public debate on the implications that such an important change would have on the efficacy and delivery of treatments and the safety of patients.

Please do not hesitate to contact me or the Faculty office if you have any questions about our comments, or would like to further discuss our concerns.

With kind regards,

Keith Bragman
President
Faculty of Pharmaceutical Medicine

About the Faculty of Pharmaceutical Medicine

The Faculty of Pharmaceutical Medicine ('The Faculty') is a professional membership organisation and standard-setting body. The Faculty has 1,500 members, who are practising pharmaceutical physicians or those with a professional interest in the speciality. It was founded in 1989, and is a Faculty of the Royal Colleges of Physicians of the UK.

Pharmaceutical medicine is a medical specialty concerned with the discovery, development, evaluation, licensing and monitoring of medicines and the medical aspects of their marketing. The Faculty's members work in diverse environments; from front line clinical trials, to medical affairs and medicines regulation.

Our mission is to advance the science and practice of pharmaceutical medicine by working to develop and maintain competence, ethics and integrity and the highest professional standards in the specialty for the benefit of the public. The Faculty seeks, through its activities, to bring about an improvement in the health of the public.