

The ABPI code of practice: controls on the promotion of prescription medicines

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The Department of Health has issued new guidance for joint working between the NHS and the pharmaceutical industry and other commercial organisations:

*NHS organisations and staff are encouraged to consider the opportunities for joint working with the pharmaceutical industry, where the benefits that this could bring to patient care and the difference it can make to their health and well-being are clearly advantageous.*¹

This in part reflects public concern about the probity of the relationships between doctors and the pharmaceutical industry,² and many doctors share this concern.³ The perception is one of cosy deals and greed to the advantage of doctors and companies at the expense of patients.^{4,5} This state of affairs risks the reputations of both doctors and companies.⁶

The professional behaviour of physicians and surgeons has never been under greater public scrutiny and subject to greater independent regulation.⁷ This extends to all areas of professional practice, including consultancy to commercial organisations. While clinical and research practice have robust governance requirements, including specified training, appraisal and peer review, they appear to be almost absent in respect of consultancy to the pharmaceutical industry.⁸ Few medical professional guidelines on best practice exist and those that do remain at the level of principle rather than practice.⁹

The pharmaceutical industries in the UK, through their trade association the Association of the British Pharmaceutical Industry (ABPI), have recognised this problem and are taking action. They invited revised guidance on promotional practice from the Prescription Medicines Code of Practice Authority (PMCPA), an independent regulatory group set up to self-regulate ABPI members' promotional behaviour. This places good promotional practice requirements on ABPI members beyond that required by the regulator, the Medicines and Healthcare products Regulatory Agency (MHRA).¹⁰

The problem is that guidance developed by the ABPI has not been widely known or accessed by physicians. Their Code Awareness Day 2006 focused mainly on raising awareness of the code among doctors and between 2006 and 2007 this rose from 52% to 73%.¹¹ Nurses, pharmacists and NHS management will continue to be targeted.

The revised ABPI guidance issued in April 2006 responded to the challenge and further restricts the range of benefits that can be offered in the context of promotion to healthcare professionals. Industry additionally recognised the extension of prescribing roles in nursing and pharmacy. The guidance originally designed for pharmaceutical physicians has been summarised in a version for health professionals. The focus and the responsibilities, however, still lie with the pharmaceutical side of the partnership.¹²

The *ABPI code of practice for the pharmaceutical industry 2006* and its guidance notes for health professionals entitled *Understanding the ABPI code of practice for the pharmaceutical industry, controls on the promotion of prescription medicines in the UK*,¹³ are freely available to download on the ABPI website (www.abpi.org.uk).

The code is based on principles. Promotion should:

- be overt, not covert
- follow licence
- inform prescribing decisions
- be rational ethical and professional
- have 'no strings attached'
- offer 'no free lunch'
- not be to the public.

These principles underpin guidance in respect to all aspects of promotional work. The main provisions in the code are as follows.

- It guides in respect of the promotion of prescription medicines to health professionals and NHS managers, not over-the-counter medicines.
- Promotion to the public is not allowed except in the instance of vaccination campaigns with ministerial approval.
- Promotion must not be disguised and any sponsorship by a pharmaceutical company must be declared.
- Promotion before regulatory approval of a medicine for use in the UK is not allowed. Relevant factual information can be shared with policymakers and senior health planners where there are significant financial implications of a new medicine or indication. International conferences held in the UK may see

promotional materials for medicines with regulatory authorisation overseas provided the meeting is attended by a significant proportion of non-UK delegates.

- The accuracy, balance and fairness of all promotional claims must be certified by two senior officials of the company, one of whom must be a registered medical practitioner.
- Sales forces must receive training in the code and pass the ABPI medical representatives examination. The code applies every bit as much to what they say as the materials they provide.
- Goods, services and promotional aids may be presented to health professionals provided they enhance patient care or benefit the NHS. They must not act as an inducement to prescribe. Promotional aids must be of low monetary value and relevant to professional practice.
- Hospitality can be provided to health professionals in the context of scientific and promotional meetings but must be of secondary importance to the value of meetings, and of an appropriate standard. Only economy air travel can be provided.
- Samples can only be provided in response to written request and no more than 10 samples can be provided in a calendar year.
- Prescribing information must be provided in all promotional materials, with the exception of abbreviated advertisements and promotional aids containing only the brand or non-proprietary name of the product, or the name of the company.
- Complaints on breaches of the guidance can be made to the PMCPA. It has the power to require members to withdraw promotional material, retrain sales forces, audit process for compliance, pay fines or by expulsion regulation by the MHRA.

The relationship between the PMCPA and the MHRA as the agency responsible for administering UK law is set out in a memorandum of understanding.

Making physicians and health professionals aware of the pharmaceutical industries' promotional practice guidelines can only be part of the solution. It is imperative that professional groups and their representative bodies develop complementary guidance to their members on best practice when working with commercial partners. The pharmaceutical and biotechnology industries are a key part of the UK knowledge economy and health delivery. They provide physicians with the only route to drug discovery. Working in and with the pharmaceutical industry can be a rewarding and challenging experience.¹⁴ There is a recognised need to strengthen professional training for this work at undergraduate and postgraduate levels.¹⁵ In common with other areas of medical practice it would be wise to work within a framework endorsed by peers, subject to an evidence base and amenable to assessment. This should extend to trans-

parent fee structures and financial disclosure. Some of the major pharmaceutical companies are leading this agenda by publishing details of payments to investigators and consultants. There is still some way to go to make sure our professional house is in order.

Conflict of interest

Peter Aitken is employed by the NHS and prescribes prescription medicines. He is Medical Director of Arbor Vitae Education Limited which stands to gain if more health professionals undertake training in partnership working. He has previously worked as a clinical research physician in the pharmaceutical industry.

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