The new ABPI code of practice — what are the implications for pharmacists?

On 1 January 2011, the Association of the British Pharmaceutical Industry’s new code of practice will come into effect. This will change how pharmaceutical companies operate and some of these changes will affect practising pharmacists. Rina Newton describes these changes and their likely impact.

The promotion of prescription medicines in the UK is self-regulated by the Association of the British Pharmaceutical Industry (ABPI), which has, for more than 50 years, published a code of practice. This aims to ensure that the promotion of medicines supports patient care through defining a robust framework. It also sets standards relating to the provision of information to patients and the public, and relationships with patient groups. Key changes to this code are discussed below.

Medical signatories

Undoubtedly, a key feature of the new code for pharmacists who work within operating companies of the pharmaceutical industry is the proposed expansion to their role. Medical and commercial signatories take accountability for the proper approval of promotional and non-promotional items generated by companies, certifying that, in their belief, the items comply with necessary codes, laws and regulations. As the name suggests, medical signatories have been required to be medically qualified and registered with the General Medical Council. But it is now proposed that pharmacists can act as medical signatories without any limitations.

Rakesh Kantaria, medical leader at AstraZeneca UK and one of the few industry pharmacists acting as a medical signatory (but with certain limitations), approves of the proposed expansion: “This is a reflection of the professional status of pharmacists, which is now in line with medically qualified colleagues.” In his estimation, AstraZeneca has benefited from improved efficiencies and increased engagement. Ultimately, he states that “there are clear benefits for patients and healthcare professionals [in knowing that company promotional activities will have been approved by those who understand best the needs of patients and the NHS”.

Pharmacist signatories have the potential to use their technical expertise to deliver both scientific and medical review of materials. With current recruitment issues in the UK for industry medical professionals and the obvious career opportunities this presents for individual pharmacists, companies could soon realise their pool of potential signatories may significantly increase.

Public disclosure

For some years there has been a real drive to encourage pharmaceutical companies to behave more transparently in order to foster better relationships with their customers and, ultimately, enhance their reputation. To this end, a series of amendments have been passed (see News p498) relating to transparency and public disclosure (see Panel).

Overall, the proposed disclosure amendments aim for greater transparency and greater trust. The group “No free lunch” campaigns in the UK for “complete transparency through a public register of all contact, hospitality and payments received by health professionals from the industry.” These measures would seem to be a step in the right direction as far as it is concerned. But what about the responsibility of healthcare professionals themselves?

Responsibilities of pharmacists

The 2008 code addressed responsibilities of both the medical profession and pharmacists and stated: “The Code of Ethics for Pharmacists and Pharmacy Technicians of the Royal Pharmaceutical Society of Great Britain states ‘Do not ask for or accept gifts, inducements, hospitality or referrals that may affect, or be perceived to affect, your professional judgement’. ‘This has been re-emphasised but not redefined in the new code. Although stories from pharmacy colleagues about industry’s bad behaviour are rife, a few examples of pharmacists behaving unethically are coming to light. This re-emphasis serves as a reminder for the industry that healthcare professionals are bound by the same ethical codes.

Joint working

Joint working requirements have been expanded and emphasised in the new code. The Department of Health defines joint working between the NHS and the pharmaceutical industry as situations where,
AMENDMENTS TO THE ABPI CODE OF PRACTICE RELATING TO TRANSPARENCY AND PUBLIC DISCLOSURES

Companies must make publicly available the amounts paid to consultants for certain services (e.g., chairing, speaking, training, advisory boards, etc.) by disclosing the total amount of money paid in the previous calendar year, the total number of consultants used and the average fee paid to each. Eli Lilly became the first major company to provide a detailed list of consultant fees, disclosing $22m in compensation paid to almost 3,400 US healthcare professionals in the first quarter of 2009.

Hospital pharmacists who have consulted for many companies should not be worried by this proposal because of existing trust policies on registering interests. For example, some state that employees must register any interest or role in an organisation that is a potential or actual supplier of the trust. A general rule is that any other paid employment outside the trust must be registered.

Companies must also disclose the financial details of sponsoring healthcare professionals to attend meetings (e.g., registration fees, accommodation and travel).

Patient groups often receive funding and support from the UK pharmaceutical industry and this is publicly declared on company websites. In July 2007 a Which? report concluded that not all companies or patient groups are open about the extent of funding and what it is used for. Companies have since strived to present a more complete picture and the new code proposes published information to include the monetary value of financial support or significant indirect or non-financial support provided to a patient organisation with a value to the organisation of £250 or more (excluding VAT).

In written agreements with consultants, companies must include provisions regarding the obligation of the consultant to declare his or her relationship when writing or speaking about the subject of the agreement or any other subject relating to that company. Simon Chapman, professor of public health, University of Sydney, Australia, wrote in the BMJ (2010;341:c3575) that “the risks of odium associated with declaring competing interests have become such that many researchers are now intimidated into refusing industry engagement”. But he compares healthcare professionals disengaging with the industry to dietitians refusing to have anything to do with the food industry, which supplies almost all of the items that dietitians urge be consumed more. He concludes this to be a peculiar kind of hypocrisy.

Outcome programmes
Of particular interest to pharmacists may be the issue around outcome or risk-sharing agreements. This is when a full or partial refund of the price paid for a medicine or some other form of recompense is due if the outcome of the use of the medicine in a patient fails to meet certain predefined therapeutic criteria. Clear criteria as to when a refund or other recompense would be due must be settled in advance and set out in a written agreement.

Promotional aids
In January 2009, the US Pharmaceutical Research and Manufacturers of America’s code banned all promotional aids, claiming these “may foster misperceptions that company interactions with healthcare professionals are not based on informing them about medical and scientific issues”. The 2008 ABPI code limited the definition of promotional aids and it was widely expected that the 2011 UK code would follow the US in a ban. Instead, the new code states that healthcare professionals may only receive promotional aids when attending scientific meetings, promotional meetings and conferences. And these may consist only of inexpensive notebooks, pens and pencils for use at such meetings. These items cannot state the name of any medicine or any information about medicines, but they can bear the name of the company providing them. One central London community pharmacist laughed out loud when asked the value of such items to him, declaring: “Mugs are just mugs at the end of the day, we don’t read what’s on them.”

Based on this response, one could assume the impact of this particular proposal on the average community pharmacist is likely to be negligible.

The proposed amendments were issued for public consultation in two phases. After receiving comments from the public, pharmaceutical companies, the Medicines and Healthcare products Regulatory Agency, British Medical Association, Royal Pharmaceutical Society and the Royal College of Nursing, the final proposals were approved by the ABPI membership this week, and will come into effect on 1 January 2011. Newly introduced requirements will come into effect on 1 May 2011.