

# NEW CODE OF PRACTICE FOR PHARMACEUTICAL INDUSTRY UNVEILED



Details of the revised and updated ABPI Code of Practice that governs the UK-based pharmaceutical industry's relations with healthcare professionals and other stakeholders were published recently. The new code comes into effect on January 1, 2006.

A major review of the code and its operation has taken place, and among key changes to the code are:

- Patient safety is being further promoted by a requirement for all printed, promotional material to include prominent information about reporting adverse drug reactions.
- Further definition and restrictions are being applied on what can be provided to health professionals in the way of promotional aids, hospitality, subsistence, travel, and accommodation.
- Relationships with patient groups and the provision of information to the public are covered in greater depth.
- A reduction in the permitted number of pages of medicines advertising and an outright ban on all promotional competitions are introduced.
- Moves to speed up the process of determining complaints so that decisions can be made more quickly and sanctions imposed faster.
- Materials or activities ruled in serious breach of the code may, under certain circumstances, be suspended, even if an appeal is intended, which will reduce the time such material remains in use.
- Results of some, more serious cases will be advertised in the medical and pharmaceutical press, thus strengthening the sanctions available.

"This has been a fundamental review of the code and follows a far-reaching public consultation exercise. We have listened to all these comments and taken action accordingly," said Vincent Lawton, President of the ABPI.

"As well as the changes to the code itself, we want to ensure that more people and organisations know about it, its provisions and understand how it works. With this in mind, we are planning to create a new communications post within the Prescription Medicines Code of Practice Authority (PMCPA), which administers the code, and there will be a major campaign in the new year to ensure that the code has as high a profile as possible."

Jeremy Mean, Senior Policy Manager at the Government regulator, the Medicines and Healthcare products Regulatory Agency (MHRA), said: "The control of medicines advertising in the UK is based on a long-established system of self-regulation supported by the statutory role of the MHRA.

"The MHRA warmly welcomes the new code, which includes positive changes to enhance patient safety to ensure that the code remains robust and rigorous."

The MHRA's backing for the new code coincides with the publication of a joint memorandum of understanding between the ABPI, PMCPA and the MHRA. The memorandum sets out the arrangements for the regulation of the promotion of medicines for prescribing in the UK, and is available on both the MHRA website ([www.mhra.gov.uk](http://www.mhra.gov.uk)) and that of the PMCPA ([www.pmcpa.org.uk](http://www.pmcpa.org.uk)).

The changes to the code have been agreed following a major consultation exercise with a wide variety of stakeholders, including professional bodies representing doctors, pharmacists and nurses; patient advocacy groups; and the MHRA. The process of considering complaints will be more transparent.

"The ABPI Code of Practice has been the gold standard for pharmaceutical industry regulation throughout the world for many years, and our aim was to ensure that it continued to be strong and effective as well as fully meeting all the changes and requirements that have occurred since the last review," said Andrew Hotchkiss, ABPI Board member and Managing Director of Lilly UK, who was in charge of the project.

"Self-regulation is by far the most effective means of ensuring that the industry's relationship with the NHS and others is conducted in a responsible and ethical manner. Given that branded medicines can make the difference between life and death, it is incumbent on all of us who work

in the pharmaceutical industry to ensure the highest standards when dealing with healthcare professionals and other stakeholders. The revised code is a strong message of intent but, ultimately, society will judge us on our actions and behaviour."

## Key changes to the ABPI Code of Practice Safety

To emphasise the pharmaceutical industry's commitment to safety, the new code requires companies to include prominent information about adverse event reporting mechanisms on all promotional material. This comes at a time when the Government is extending the 'Yellow Card' scheme so that patients across the country can report adverse effects, and will mean that all promotional material produced by companies will have to be changed.

## Relationships with health professionals

Existing rules that cover the provision of promotional aids, hospitality, travel and accommodation have been further defined. For example, it is now specifically stated that items must not be offered for the personal benefit of health professionals or administrative staff. It remains the case that items must be inexpensive - the limit is £6, excluding VAT - and relevant to the recipients' profession.

The new code makes it clear that promotional aids are more likely to be acceptable under the code if they benefit patient care, and gives more guidance on the types of items that are both acceptable and unacceptable. It also bans the use of promotional competitions and quizzes.

As far as meetings and seminars are concerned, subsistence must be strictly limited to the main purpose of the event and be secondary to the purpose of the meeting. Companies must only offer economy air travel to delegates sponsored to attend meetings. Lavish venues must not be used and companies should avoid using venues renowned for entertainment facilities.

Further clarification is also given on the circumstances under which meetings may be appropriately held outside the UK.

## Relationships with the public and patient groups

Definitions of what information can be supplied to the public have been improved to give more guidance and to clarify how companies may respond to patients' needs for reference information on medicines. Promotion of prescription-only medicines to the public remains strictly prohibited.

There is also an important new clause concerning relationships with patient advocacy groups. While companies are permitted to work with such groups, their involvement must be made clear, and rules on arrangements for meetings are the same as those for health professionals.

Companies must make public, by means of information on their website or annual report, a list of all patient organisations to which they provide financial support, and a written agreement must be in place with every organisation spelling out exactly the terms of the relationship and funding of every significant activity or ongoing co-operation.

## Complaints and sanctions

Various moves have been put in place to speed up the process of deciding a complaint and imposing sanctions. For example, a company accepting a ruling of the Code of Practice Panel has just five working days - instead of the current ten - to stop use of the material.

In addition, if the material or activity found in breach is likely to prejudice public health or safety, or is a serious breach of the code, the company will be required suspend use of it even if an appeal is planned.

Several different sanctions are already applied to companies found in breach, but the new code gives additional sanctions to the Appeal Board and also allows for details of certain cases, considered serious, to be advertised in pharmaceutical or medical press.

Brief details of ongoing cases will in future be available on the PMCPA's website. In the past, such details have only been provided when the case is completed.

**The new ABPI Code of Practice can be accessed at [www.pmcpa.org.uk](http://www.pmcpa.org.uk).**