

GENERAL INFORMATION LEAFLET 2016

The Authority

The Prescription Medicines Code of Practice Authority (PMCPA) was established by the Association of the British Pharmaceutical Industry (ABPI) in 1993 to administer the ABPI Code of Practice at arm's length from the ABPI itself.

The Authority is responsible for the provision of advice, guidance and training on the Code of Practice, as well as for the operation of the complaints procedure whereby complaints about a pharmaceutical company's materials or activities are considered in relation to the requirements of the Code.

It is also responsible for arranging conciliation between companies when requested to do so and for arranging for the scrutiny of samples of advertising and meetings to check their compliance with the Code.

The Constitution and Procedure for the Prescription Medicines Code of Practice Authority, which is included in the Code of Practice booklet, provides detailed information about the Authority and the complaints procedure.

The Code

The Code covers the advertising of medicines to health professionals and other relevant decision makers.

This includes:

- journal and direct mail advertising
- the activities of representatives, including electronic and printed material used by them
- the supply of samples
- the provision of inducements in connection with the promotion of medicines and inducements to prescribe, supply, administer, recommend, buy or sell medicines by the gift, offer or promise of any benefit or bonus, whether in money or in kind
- the provision of hospitality
- the organisation of promotional meetings
- the sponsorship of scientific and other meetings, including payment of travelling and accommodation expenses
- the sponsorship of attendance at meetings organised by third parties
- all other sales promotion in whatever form, such as participation in exhibitions, the use of audio or video recordings in any format, broadcast media, non-print media, the Internet, interactive data systems, social media and the like.

The Code also covers:

- the provision of information on prescription only medicines to the public either directly or indirectly, including by means of the Internet
- relationships between pharmaceutical companies and patient organisations
- disclosure of transfers of value to health professionals and organisations
- joint working between the NHS and pharmaceutical companies

- non-interventional studies of marketed medicines
- the use of consultants by pharmaceutical companies
- the provision of items for patients
- the provision of medical and educational goods and services
- grants, donations and benefits-in-kind to institutions.

Compliance with the Code is obligatory for ABPI member companies and, in addition, over sixty non-member companies have voluntarily agreed to comply with the Code and to accept the jurisdiction of the Authority.

Complaints

Complaints submitted under the Code of Practice are considered in the first instance by the Code of Practice Panel which consists of the Director, Deputy Director, Secretary and Deputy Secretary of the Authority, acting with the assistance of independent expert advisers where appropriate. One member of the Panel acts as case preparation manager for a particular case and that member does not participate and is not present when the Panel considers it.

Both complainants and respondents can appeal to the Code of Practice Appeal Board against rulings made by the Panel. The Appeal Board is chaired by an independent legally qualified chairman and includes eight independent members from outside the industry. Details of its composition can be found in the Constitution and Procedure. Independent members, including the Chairman, are always in a majority when matters are considered by the Appeal Board.

Complaints should be sent to:

The Director, Prescription Medicines Code of Practice Authority, 7th Floor Southside, 105 Victoria Street, London SW1E 6QT
020 7747 8880 complaints@pmcpa.org.uk.

Sanctions

In each case where a breach of the Code is ruled, the company concerned must give an

undertaking that the practice in question has ceased forthwith and that all possible steps have been taken to avoid a similar breach in the future. An undertaking must be accompanied by details of the action taken to implement the ruling.

Additional sanctions are imposed in serious cases. These can include:

- the carrying out by the Authority of an audit of a company's procedures to comply with the Code, possibly followed by a requirement that promotional material be submitted to the Authority for pre-vetting for a specified period
- requiring the recovery of a promotional item from those to whom it has been given
- requiring the publication of a corrective statement
- a public reprimand
- suspension or expulsion of a member company from the ABPI.

The Authority advertises in the medical, pharmaceutical and nursing press brief details of cases in which companies were ruled in breach of Clause 2, were required to issue a corrective statement or were the subject of a public reprimand. Such advertisements also appear on the Authority's website www.pmcpa.org.uk.

Charges

Levy

All members of the ABPI are required to pay an annual Code of Practice levy (in addition to their ABPI subscriptions) to fund the Authority.

The levy is £1,000 to £32,000 per annum according to the size of the company concerned.

Administrative Charges

Administrative charges are payable by pharmaceutical companies (both members and

non-members of the ABPI) in relation to complaints made under the Code of Practice.

No charges whatsoever are payable by complainants from outside the pharmaceutical industry.

Charges are paid either by the company ruled in breach of the Code or, where there is no breach of the Code, by the complainant where the complainant is a pharmaceutical company.

The charges are assessed per matter ruled upon. A number of matters may arise in a particular case.

A charge of £3,500 per matter is payable where an ABPI member company accepts the Code of Practice Panel's ruling that it had breached the Code or where an ABPI member company complainant accepts the Panel's ruling that there had been no breach.

A charge of £12,000 per matter is payable where an ABPI member company ruled in breach of the Code by the Panel appeals that ruling and its appeal is rejected by the Code of Practice Appeal Board, or where an ABPI member company complainant appeals against a ruling of no breach by the Panel and its appeal is rejected by the Appeal Board.

Where a complainant appeals against a ruling of no breach and the appeal is upheld by the Appeal Board, an ABPI member company then ruled in breach pays £3,500 per matter.

Where a company ruled in breach appeals and its appeal is upheld by the Appeal Board, then an ABPI member company complainant pays £3,500 per matter.

Companies that are not members of the ABPI do not pay the levy and the administrative charges for them are consequently higher, being £4,500 and £13,000.

Further Information

Reports on completed cases and comments on matters of current concern are published quarterly in the Code of Practice Review which

is freely available and on the Authority's website, www.pmcpa.org.uk, which, in addition, provides brief information about cases currently under consideration and about the administration and application of the Code.

Seminars on the Code of Practice are held by the Authority on a regular basis and are open to all. Details are on the Authority's website.

Copies of the Code of Practice for the Pharmaceutical Industry, the Code of Practice Review and the Authority's Annual Report are available to download from the website and hard copies are available on request from the Prescription Medicines Code of Practice Authority 7th Floor Southside, 105 Victoria St, London SW1E 6QT Tel: 020 7747 8880 www.pmcpa.org.uk