

**MEMORANDUM OF UNDERSTANDING BETWEEN
THE ASSOCIATION OF THE BRITISH PHARMACEUTICAL INDUSTRY, THE PRESCRIPTION
MEDICINES CODE OF PRACTICE AUTHORITY AND
THE MEDICINES AND HEALTHCARE PRODUCTS REGULATORY AGENCY**

Introduction

The Association of the British Pharmaceutical Industry (ABPI), the Prescription Medicines Code of Practice Authority (PMCPA) and the Medicines and Healthcare products Regulatory Agency (MHRA) are committed to ensuring that patients and the public benefit from appropriate use of medicines as part of the provision of high quality healthcare. The promotion of medicines for prescribing to health professionals is carried out within a robust regulatory framework to maintain patient safety and public health.

This document sets out the arrangements in the United Kingdom for the regulation of the promotion of medicines for prescribing. There are two complementary systems of control, self regulation by the pharmaceutical industry by means of the ABPI Code of Practice for the Pharmaceutical Industry, administered by the PMCPA, and UK law, administered by the MHRA on behalf of the UK Health Ministers. The control of medicines advertising in the UK is thus based on the long established system of self regulation supported by the statutory role of the MHRA.

Efficient, stringent and transparent self regulation via the ABPI Code enables the Government to ensure that regulatory requirements are met by self regulation with intervention by the MHRA when there is a clear case for protection.

This memorandum of understanding covers those activities and materials subject to the ABPI Code.

Self Regulation

The ABPI Code sets out the requirements for the promotion of medicines for prescribing to UK health professionals and appropriate administrative staff. The Code also includes detailed provisions for the supply of information about prescription only medicines to patients and the public. The Code was established in 1958 and extends beyond UK legal requirements. A new edition will come into operation in January 2006. The Code is administered by the Prescription Medicines Code of Practice Authority which operates separately from the day to day management of the ABPI. The Code is drawn up in consultation with the MHRA, the British Medical Association, The Royal Pharmaceutical Society of Great Britain and the Royal College of Nursing.

Compliance with the Code is a condition of membership of the ABPI and, in addition, about sixty pharmaceutical companies that are not members of the ABPI have agreed to comply with the Code and accept the jurisdiction of the PMCPA. Members of the ABPI and non member companies that have agreed to comply with the Code should send complaints to the PMCPA.

Self regulation should be the first means of dealing with complaints. Both the PMCPA and the MHRA deal with complaints whatever their source. However the MHRA focus is on pre-vetting, dealing with complaints other than intercompany complaints and dealing with complaints that are not covered by the ABPI Code or other self regulatory authority.

UK Law

Legal requirements were first introduced in the UK by the Medicines Act 1968. Current UK law is based on Directive 2001/83/EC on the community code relating to medicinal products for human use, as amended by Directive 2004/27/EC. European law is implemented in the UK by the Medicines

(Advertising) Regulations 1994 and the Medicines (Monitoring of Advertising) Regulations 1994, as amended (primarily by 1999, 2004 and 2005 Regulations).

UK law provides that where the Health Ministers and the complainant agree, the Health Ministers shall refer a complaint about an advertisement to a health professional to an appropriate self regulatory body for consideration. The Blue Guide, Advertising and Promotion of Medicines in the UK (2005), issued by the MHRA, includes guidance on the relevant UK law for advertising to health professionals as well as other matters not covered by this memorandum, such as advertising over-the-counter medicines to the public.

Role of the PMCPA and the ABPI Code

- 1 In accordance with its Constitution and Procedure, the PMCPA deals with complaints received from whatever source that relate to matters covered by the ABPI Code in a timely and fair manner.
- 2 If complaints are received by the PMCPA about matters not covered by the ABPI Code, or about companies that do not agree to accept the jurisdiction of the PMCPA, advice is given to the complainant about the available means of addressing their complaint, be it referral to another self regulatory system, such as that of the Proprietary Association of Great Britain (PAGB), or to the MHRA.
- 3 If a non member company fails to comply with the procedures in relation to a complaint and no longer wishes to accept the jurisdiction of the PMCPA, the MHRA will be advised that responsibility for that company under the Code will no longer be accepted. The position would be similar if an ABPI member was expelled from the ABPI. Any future complaints about such companies would be referred to the MHRA.
- 4 The PMCPA has an open and transparent process. Both the complainant and the respondent may appeal adverse rulings. Comprehensive details of completed cases are published on its website www.pmcpa.org.uk. Case reports are also published in printed form in the PMCPA's quarterly Code of Practice Review which is widely distributed and is freely available on request. From 1 January 2006 the PMCPA will publish brief details of ongoing complaints on its website as soon as the parties involved have been notified and will further publicise details of certain cases ruled in breach of the Code.
- 5 The sanctions available under the self regulatory system are broadly similar to those available to and routinely used by the MHRA.
- 6 The PMCPA undertakes routine scrutiny of journal advertisements and this will be expanded from 1 January 2006 to include other promotional material and activities such as detail aids, leavepieces and meetings.
- 7 The PMCPA provides detailed training and informal guidance about the Code. It will be increasing communication to raise awareness about the control of advertising of medicines.

Role of the MHRA and the UK legislation

- 1 The MHRA is responsible on behalf of the Health Ministers for protecting public health by promoting the safe use of medicines by ensuring that medicines advertising is fully compliant with UK medicines law.

- 2 The MHRA deals with complaints received from whatever source that relate to matters covered by UK legislation in a timely and fair manner. This might include, with the complainant's agreement, referral to an appropriate statutory regulator, such as the Office of Communications (Ofcom), or self regulatory systems such as the PMCPA, PAGB, and Advertising Standards Authority (ASA). The MHRA will routinely decline to investigate cases where it is aware that these are under investigation by a self regulatory body but reserves the right to take action if serious public health concerns are raised or if self regulation fails.
- 3 The MHRA publishes the outcomes of its decisions on its website.
- 4 The MHRA will also refer complaints about relevant matters not covered by UK law to the PMCPA for consideration under the ABPI Code.
- 5 The MHRA will pre-vet promotional material for new active substances. It is not intended that this should delay launch of a product. The MHRA also pre-vets other advertising according to criteria published in The Blue Guide, Advertising and Promotion of Medicines in the UK (2005).
- 6 The MHRA also monitors published advertising from a variety of sources.

Consistency of Decisions

The ABPI Code covers and extends beyond UK law and it is thus possible that material pre-vetted and approved by the MHRA might subsequently be ruled in breach of the ABPI Code. Material subject to the ABPI Code, considered by the MHRA as being potentially in breach of UK regulations, is very likely to also be in breach of the ABPI Code.

Co-operation

The MHRA and PMCPA cooperate through the Medicines Advertising Liaison Group (a forum where all the regulatory and self regulatory bodies involved in the control of medicines advertising meet to discuss issues of current concern) and through bilateral contacts where appropriate to promote a common understanding of the advertising legislation. The purpose of cooperation is also to promote efficient complaint procedures without compromising the independence of each party. To avoid unnecessary duplication of investigations the MHRA will regularly review information on the PMCPA website about the consideration of current cases.

Conclusion

The purpose of the two systems of advertising regulation, statutory and self regulation is to ensure that complementary and mutually synergistic arrangements are in place to control the promotion of medicines for prescribing to UK health professionals.

Further information

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