

**MEMORANDUM OF UNDERSTANDING BETWEEN**  
**THE ASSOCIATION OF THE BRITISH PHARMACEUTICAL INDUSTRY,**  
**THE PRESCRIPTION MEDICINES CODE OF PRACTICE AUTHORITY AND**  
**THE SERIOUS FRAUD OFFICE**

**Introduction**

The Association of the British Pharmaceutical Industry (ABPI) and the Prescription Medicines Code of Practice Authority (PMCPA) 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 and other interactions that the pharmaceutical industry undertakes that lead to, or are related to, the use of medicines are carried out within a robust regulatory framework to maintain patient safety and public health.

The arrangements in the United Kingdom for the regulation of the promotion of medicines for prescribing and interactions with health professionals are subject to 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. The advertising law is administered by the Medicines and Healthcare products Regulatory Agency (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. The relationship between the MHRA, ABPI and PMCPA is set out in a memorandum of understanding.

There are other relevant UK laws including the Bribery Act 2010. The Serious Fraud Office (SFO) is the lead agency in England, Wales and Northern Ireland for investigating and prosecuting serious or complex fraud and corruption – domestic and overseas. The SFO is responsible for enforcing the Bribery Act 2010. The police, Crown Prosecution Service and the courts also have enforcement roles.

Efficient, stringent and transparent self regulation via the ABPI Code has enabled 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 model is supported by the SFO which wishes to see similar arrangements for activities covered by the ABPI Code and the Bribery Act 2010. The SFO endorses the pharmaceutical industry commitment to ensuring appropriate use of medicines and shares this aim in relation to enforcement of the Bribery Act 2010.

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, and interactions with, UK health professionals and appropriate administrative staff. The Code was established in 1958 and extends beyond UK legal requirements. 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 and the Royal College of Nursing.

The next time the Constitution and Procedure is amended a proposal will be included to amend Paragraphs 13.5 and 19.2 to add the SFO to the list of organisations.

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 SFO deal with complaints whatever their source. The SFO focus is on dealing with complaints that are not covered by the ABPI Code or other self regulatory authorities and which meet its criteria of serious fraud.

### **UK Law**

Current European legal requirements are implemented in the UK by the Medicines (Advertising) Regulations 1994 and the Medicines (Monitoring of Advertising) Regulations 1994, each as amended. UK law provides that where Health Ministers and the complainant agree, the Health Ministers shall refer a complaint about an advertisement to an appropriate self regulatory body for consideration.

The Bribery Act 2010 reforms the criminal law to provide a new legal framework to combat bribery in the public or private sectors. It creates two general offences covering the offering, promising or giving of an advantage, and requesting, agreeing to receive or accepting of an advantage; a discrete offence of bribery of a foreign public official; a new offence of failure by a commercial organisation to prevent a bribe being paid for or on its behalf (it will be a defence to the latter if the organisation has adequate procedures in place to prevent bribery).

### **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 or to the SFO.
- 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 or to the SFO.

- 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](http://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. The PMCPA publishes brief details of ongoing complaints on its website as soon as the parties involved have been notified and further publicises 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 other promotional material and activities such as detail aids, leavepieces and meetings.
- 7 The PMCPA provides detailed training and informal guidance about the Code.

### **Role of the SFO and the UK Bribery Act**

A number of provisions of the ABPI Code of Practice have the potential to overlap with the requirements of the Bribery Act 2010. The approach of the SFO to implementation of the Bribery Act 2010, and in particular how it might engage on matters of overlap, such as activities covered by Clauses 18 and 19, is set out below.

- 1 The SFO takes a vigorous approach to those corporates which believe that corruption gives a business advantages over ethical competitors and will act appropriately to ensure compliance with the Bribery Act 2010.
- 2 The SFO will determine, dependent on the facts, whether enforcement is best achieved through seeking a criminal conviction, or working with the company to ensure future compliance.
- 3 The SFO values self regulation by the pharmaceutical industry. This self regulation has worked well to date and is supported both by legislation and the memorandum of understanding with the MHRA. Self regulation provides a number of advantages:-
  - It is a relatively quick, efficient and transparent means of resolving complaints and disputes and is influential in setting gold standards of behaviour;
  - Self-regulation permits companies to self-report, and the SFO would not wish to discourage companies from doing so;
  - Self-regulation under the ABPI Code prevents unnecessary duplication of effort. The PMCPA deals with the complaints that it receives with the MHRA able to take action in serious cases;
  - Changes to the ABPI Code are subject to consultation with regulatory authorities and others. The SFO will be consulted in future over prospective changes to the ABPI Code.

4 Like the MHRA the SFO will retain discretion at all times over which cases it chooses to pursue and when but unless there are good reasons for doing otherwise, the SFO's approach to matters which are covered by the ABPI Code is as follows:-

- Companies need to have in place robustly defined and implemented anti-bribery procedures with clear ownership from the top of the organisation;
- The SFO and others agree that sensible proportionate promotional expenditure is entirely legitimate and not outlawed by the Bribery Act 2010;
- The SFO will not routinely intervene in matters covered by the Code but reserves the right to take action if the issue is deemed serious enough to merit SFO investigation. It will submit complaints to the PMCPA when appropriate;
- The SFO will not seek to prosecute unless it considers this is in the public interest and in reaching such a decision the SFO will take into account relevant action taken by the PMCPA and the MHRA;
- The SFO is aware of the requirements of other industry codes including the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) Code of Pharmaceutical Marketing Practices.

### **Co-operation**

The SFO, PMCPA and ABPI co-operate through contacts where appropriate to promote a common understanding of mutual interests. The purpose of co-operation is also to promote efficient complaint procedures without compromising the independence of each party. To avoid unnecessary duplication of investigations the SFO will regularly review information on the PMCPA website about the consideration of current cases.

### **Further information**

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