PMCPA | Prescription Medicines Code of Practice Authority

Opportunities, challenges and learnings in running a Code enforcement body
ABPI Code of Practice for the Pharmaceutical Industry

Tuesday, 26 March 2013

Heather Simmonds
Director
Prescription Medicines Code of Practice Authority
www.pmcpa.org.uk

…. or how did we get to where we are and how does the future look?

Prescription Medicines Code of Practice Authority

Heather Simmonds, Director
Etta Logan, Deputy Director
Jane Landles, Secretary
A N Other, Deputy Secretary

Appointed by and reports to ABPI Board of Management.

ROLE:

Responsible for administration of the Code and complaints procedure including provision of advice, guidance and training.

Arranging the scrutiny of advertising and meetings.

Arranging conciliation.

ABPI Code Of Practice

Agreed on 2 October 1958 – before any UK legislation.

Regularly updated.

Reflects and extends beyond UK law, IFPMA, EFPIA Codes, WHO ethical criteria.

Drawn up in consultation with MHRA, BMA, RCN and RPS.

Confidential **Not for Publication**

CODE OF SALES PROMOTION PRACTICE FOR MEDICAL SPECIALITIES IN THE UNITED KINGDOM

October, 1958

THE ASSOCIATION OF BRITISH PHARMACEUTICAL INDUSTRY

Tavistock House South
Tavistock Square
London W.C.1
EUSton 2531/3

CODE OF PRACTICE

for the

PHARMACEUTICAL INDUSTRY

SECOND 2012 EDITION

PMCPA | Prescription Medicines Code of Practice Authority

ABPI Code applies to

- The promotion of medicines to members of the UK health professions and to appropriate administrative staff
- Interactions with health professionals and certain non promotional activities
- Information made available to the public about prescription only medicines
- Relationships with patient organisations

UK Statutory control

MHRA Acts on behalf of health ministers but supports self-regulation

The Blue Guide

Memorandum of understanding

SFO Memorandum of understanding

UK & EU Legislation

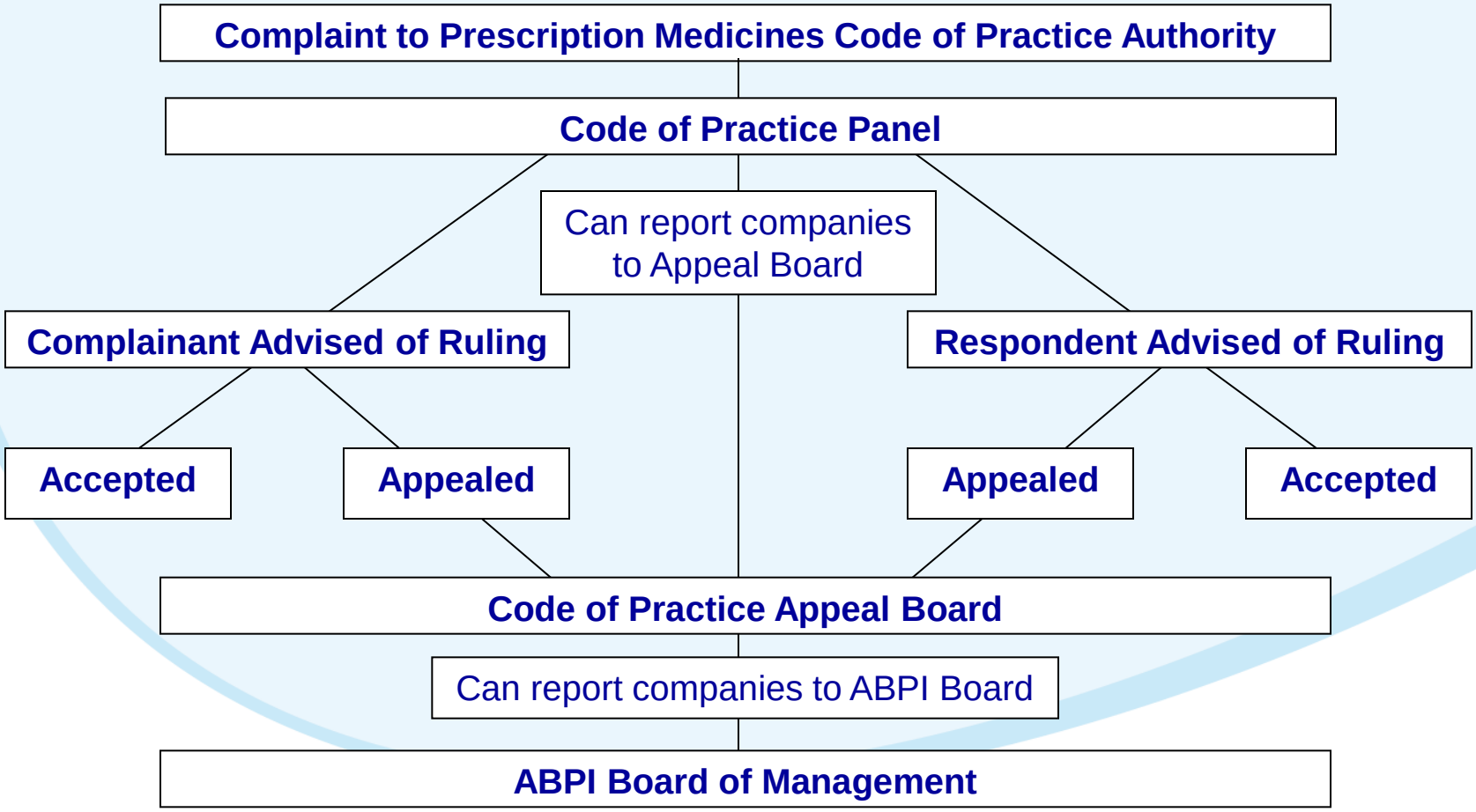
The Human Medicines Regulations 2012 (2012 No. 1916)

Council Directive 2001/83/EC of 26 November 2001 on the Community Code relating to medicinal products for human use

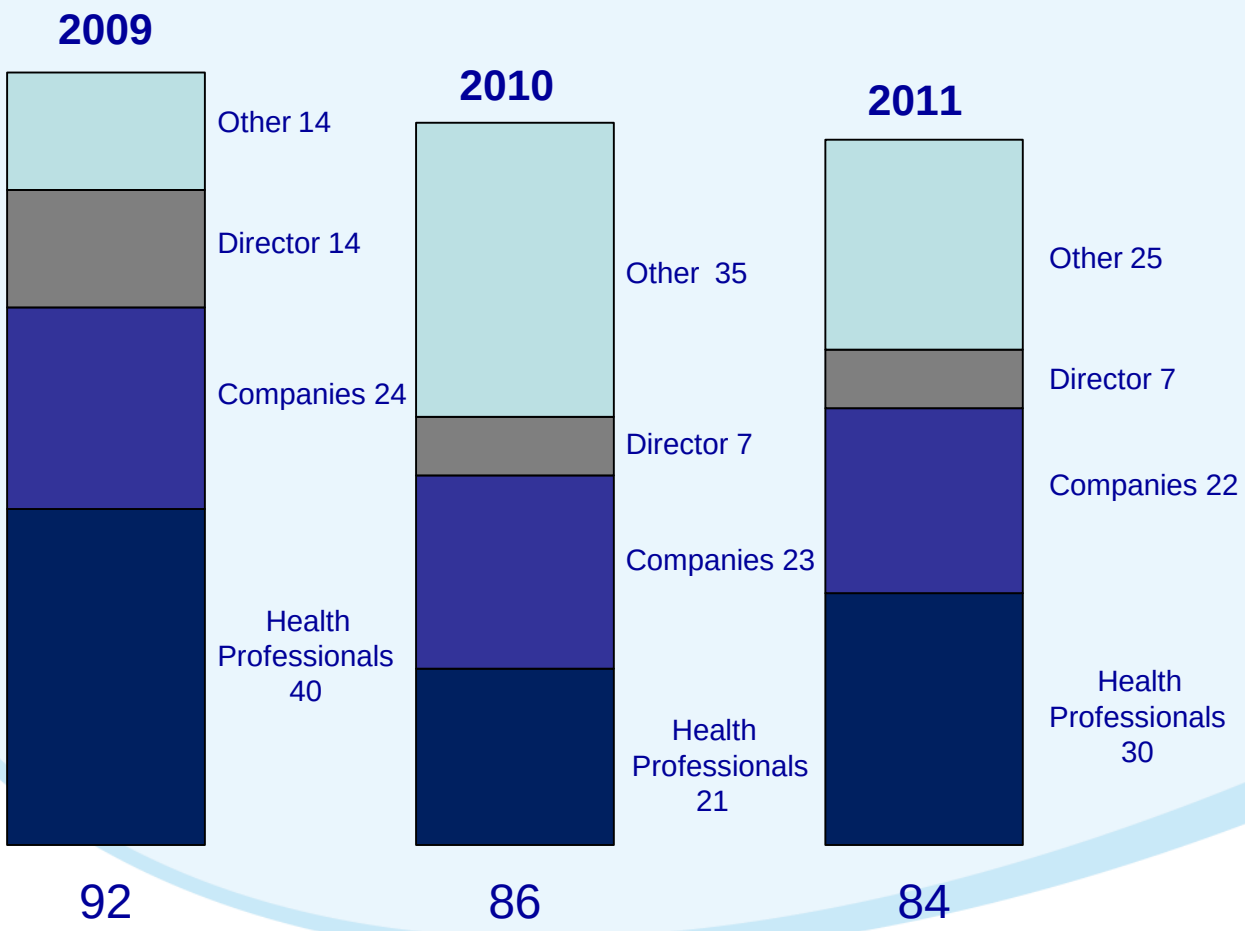
Articles 86 → 100

Council Directive 2004/27/EC of 31 March 2004

Complaints Procedure

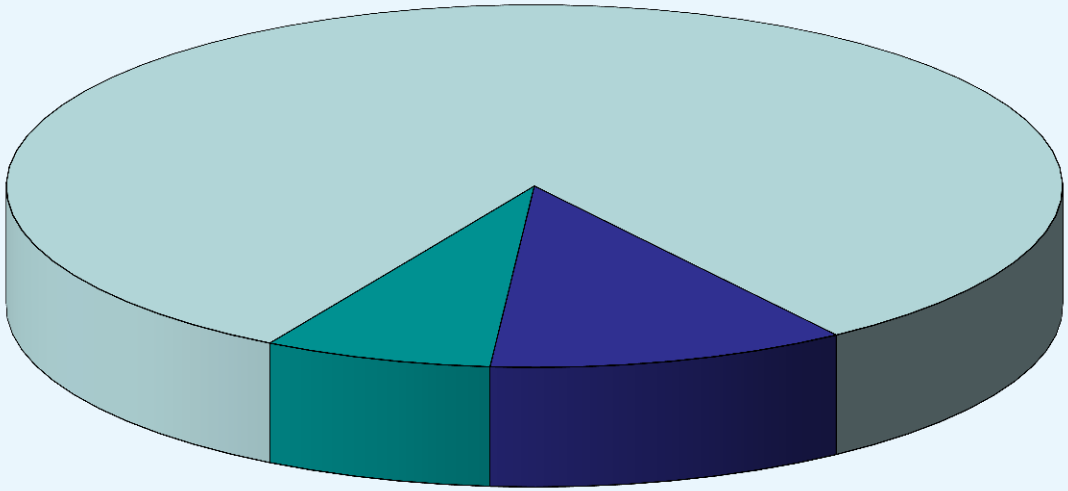


Complaints received



Code of Practice Panel Rulings 2011

- 223 (86%) rulings accepted
- 15 (6%) rulings unsuccessfully appealed
- 21 (8%) rulings successfully appealed



Number of matters	259
Ruled in breach	94
Ruled not in breach	165

Sanctions

- Rapid cessation of promotion
- Publication of case reports
- Recovery of items
- Audit of company's procedures can be followed by pre-vetting
- Public reprimand
- Corrective statements
- Advertising of certain cases in medical, pharmaceutical and nursing press
- Suspension/expulsion by ABPI Board of Management

PMCPA | Prescription Medicines Code of Practice Authority

The ABPI Code of Practice for the Pharmaceutical Industry sets standards for the promotion of medicines for prescribing to health professionals and the provision of information to the public about prescription only medicines. Publicity is the main sanction when breaches of the Code are ruled. The latest case ruled in breach of Clause 2 of the Code (a sign of particular censure) is highlighted below.

Bayer HealthCare has breached the ABPI Code of Practice for the Pharmaceutical Industry and brought discredit upon, and reduced confidence in, the pharmaceutical industry.

Voluntary admission by Bayer – Case AUTH/2490/3/12
Bayer made a voluntary admission in relation to the distribution of unapproved documents associated with a proposed joint working project. Bayer was ruled in breach of the following clauses of the Code:

Clause 2 - Bringing discredit upon, and reducing confidence in, the pharmaceutical industry.
Clause 3.1 - Promoting a medicine for an indication for which it had no marketing authorization.
Clause 4.1 - Failing to include prescribing information in promotional material.
Clause 4.10 - Failing to include a statement in relation to adverse event reporting in promotional material.
Clause 4.11 - Failing to include an inverted black triangle on promotional material to denote that special reporting requirements were required in relation to adverse events.
Clause 7.2 - Making inaccurate and misleading claims.
Clause 7.3 - Making a misleading comparison with another medicine.
Clause 7.4 - Making unsubstantiated claims.
Clause 9.1 - Failing to maintain high standards.
Clause 12.1 - Disguising promotional materials.
Clause 14.1 - Failing to certify promotional material before issue.
Clause 15.2 - A representative failing to maintain high standards of ethical conduct.

The full case report was published in the PMCPA August Code of Practice Review and is also available at **www.pmcpa.org.uk**

The Prescription Medicines Code of Practice Authority (PMCPA) administers The Association of the British Pharmaceutical Industry's (ABPI) Code of Practice for the Pharmaceutical Industry at arm's length from the Association itself. The Code covers the promotion of medicines for prescribing to health professionals and the provision of information to the public about prescription only medicines.

If you have any concerns about the activities of pharmaceutical companies in this regard, please contact the **PMCPA at 7th Floor, Southside, 105 Victoria Street, London, SW1E 6QT** or **complaints@pmcpa.org.uk**.

The Code and other information, including details about ongoing cases, can be found on the PMCPA website.

NUMBER 79 February 2013

CODE OF PRACTICE REVIEW

PMCPA | Prescription Medicines Code of Practice Authority

The Prescription Medicines Code of Practice Authority was established by The Association of the British Pharmaceutical Industry (ABPI) in 1993 to operate the ABPI Code of Practice for the Pharmaceutical Industry independently of the Association itself.

ETHICAL STANDARDS IN HEALTH AND LIFE SCIENCES GROUP CONSULTATION ON PAYMENTS TO HEALTHCARE PROFESSIONALS

The Ethical Standards in Health and Life Sciences Group (ESHLSG), the multi stakeholder group of healthcare organisations, is currently running a survey to look at the public disclosure of payments to healthcare professionals. The consultation is intended to establish whether there is support in principle for a system of public declaration of payments. The survey together with further details about the group's membership and its activities can be found at eshlsg.org.

MHRA ANNUAL MEETING AND REPORT

The Medicines and Healthcare products Regulatory Agency has published its annual report for 2012. There were fewer than ten complaints about prescription medicines, four cases were upheld of which three cases concerned advertising by companies holding manufacturing licences but not marketing authorizations for the products (specials manufacturers). The long term downward trend in the number of advertising cases in this sector continued in 2012. The MHRA will continue to work proactively with self regulatory bodies and others to maintain high standards. At its annual meeting the MHRA strongly supported self regulation which had been shown time and again to be effective.

NEW INDEPENDENT MEMBERS OF THE APPEAL BOARD

Mrs Gillian Hawken and Dr Howard Freeman have recently been appointed to the Code of Practice Appeal Board as independent members. Both are welcomed by the Authority. Mrs Hawken is a solicitor with her own practice and joins as the lay member. Dr Freeman joins as a medical member. He is the senior partner in a GP practice and has worked in a number of senior NHS management roles, most recently as Associate Medical Director at the London Strategic Health Authority.

PUBLIC REPRIMAND FOR CHIESI

Chiesi Limited has been publicly reprimanded by the Code of Practice Appeal Board for failing to provide the Code of Practice Panel with complete and accurate information at the outset in response to a complaint (Case AUTH/2435/8/11).

In 2011 the Panel ruled breaches of the Code in relation to the promotion of Fostair (beclomethasone and formoterol) for an unlicensed indication. In order to make its rulings, however, the Panel had to repeatedly ask Chiesi for further information. Chiesi's submission in this case was inconsistent with its submission in a previous similar case.

The Panel reported Chiesi to the Appeal Board. On consideration of that report in December 2011, the Appeal Board considered that it was vital that responses to the Authority were comprehensive and not misleading. Chiesi's failure to provide complete and accurate information was unacceptable. The Appeal Board required an audit of Chiesi's procedures in relation to the Code and a subsequent re-audit.

The first audit was conducted in March 2012 and upon consideration of the second audit report in November 2012 the Appeal Board noted that progress had been made but requested that the Authority review the company's revised standard operating procedures (SOPs). Following the Authority's assessment of the SOPs, the Appeal Board decided in January 2013 that sufficient progress had been made and on the basis that this was maintained, no further action was required.

Full details of Case AUTH/2435/8/11 can be found at page 15 of this issue of the Review.

CASE AUTH/2411/6/11

PHARMACOSMOS v VIFOR

Ferinject video

Pharmacosmos A/S complained about a video issued by Vifor Pharma UK which referred to Ferinject (ferric carboxymaltose) solution for injection/infusion. Ferinject was indicated for the treatment of iron deficiency when oral iron preparations were ineffective or could not be used.

Pharmacosmos understood that Vifor agreed with the NHS Alliance to contribute to NHS Alliance TV news, an hour-long video which was to be shown at the NHS Alliance conference and posted on the NHS Alliance website. The theme of the conference was to focus on the Quality, Innovation, Productivity and Prevention (QIPP) initiative. The title of the video was 'Delivering QIPP by redesigning iron services'. Vifor provided speakers and allowed filming at its premises. The script was reviewed internally and the video was signed off according to Vifor's procedures.

Pharmacosmos stated that Vifor did not regard its involvement in the video or its content as being promotional and this was at the crux of this case.

Pharmacosmos stated that its complaint was about the video being made available to health professionals in the first place as part of the NHS Alliance conference. Pharmacosmos alleged that it was not clear to the intended audience that the video constituted a promotional presentation from Vifor, in breach of the Code.

The claim 'for patients it would mean a speedier recovery' appeared immediately following a statement that 'Iron treatment protocols are placing a burden on the NHS'. Taken in context with later comments in the video about Ferinject, the clear inference was that Ferinject could speed recovery by allowing the iron services to be redesigned, which was misleading, in breach of the Code.

The first time the brand name was used meant that the generic name and an indication that the product was under intensive monitoring from the Committee on the Safety of Medicine (CSM) was needed. In the absence of a visual indication on screen, this should be stated in the commentary. In addition, the failure to provide prescribing information was in breach of the Code.

Pharmacosmos alleged that the claim 'Ferinject provides ... all the iron they need in just one 30 minute visit' was misleading as not all patients treated with Ferinject could be given all the iron they needed in a single infusion. The maximum dose of Ferinject per treatment was 1000mg and 15mg/kg.

Pharmacosmos stated that it had serious concerns about Vifor's approach to the project as exhibited in the inter-company dialogue. The combined effect of disguised promotion, misleading claims and missing obligatory information constituted a considerable failure to maintain controls and standards.
The detailed response from Vifor is given below.

The Panel noted that the video opened with a sequence which featured the Vifor company name and logo in the centre of the screen together with the title 'Delivering QIPP by redesigning iron services'. In this regard the Panel considered that there was no doubt that the video had been sponsored by Vifor; the company's involvement was clear from the outset. No breach of the Code was ruled.

The Panel considered that although the title of the video was not product related its content was such that most viewers would consider that it promoted Ferinject. The first two minutes of the 3:44 minute video were about general issues but then the information was specifically about Ferinject. The Panel considered that the video was clearly promotional and in that regard its nature was not disguised. No breach of the Code was ruled.

The Panel noted that the video had been filmed at Vifor's offices, Vifor had suggested speakers; its general manager had spoken on the video. The draft script had been reviewed internally and signed off according to company procedure. Vifor had submitted that its input into the video stopped at this stage. The Panel noted that a document provided by Vifor, entitled 'Story Outline', appeared to be a written agreement between the NHS Alliance, the film company and Vifor. The document listed three key messages: 'Vifor Pharma want to raise awareness of their product, Ferinject'; 'Vifor Pharma want to raise awareness of iron deficiency, its symptoms, how anaemia could be better treated now and for patients in the future' and 'Vifor Pharma want to start a conversation among doctors about how this illness is best treated and help them discuss the best funding options with the NHS'. In the Panel's view there was thus no doubt that, at the outset and contrary to the company's response, Vifor knew that the video would promote Ferinject; to consider otherwise demonstrated a fundamental lack of understanding of the Code and its requirements. In this regard the Panel noted the definition of promotion was any activity undertaken by a pharmaceutical company or with its authority which promoted the prescription, supply, sale or administration of its medicines. The Panel considered that Vifor's submission that its intention was simply to help the debate around the practicality of QIPP by giving a practical example was disingenuous. The Panel considered that the video should have contained prescribing information and other obligatory information for Ferinject which it did not. A breach of the Code was ruled.

Code of Practice Committee

Case Reports

Volume I
1979 and 1980

abpi

It was alleged that the claims in the advertisement were misleading and that there had thus been a breach of Clause 4.1 of the Code.

The position of the advertisement, being adjacent to an editorial article pertinent to the product was also alleged to be contrary to the Code.

In response, the company stated, and justified to the satisfaction of the Committee, that the juxtaposition with the relevant editorial material was purely fortuitous. The company also refuted the allegations concerning the claims made and produced evidence in support.

The Committee decided that the complaints had not been substantiated and accordingly ruled that the Code had not been breached.

Case 295/4/79

Promotional folder – gift of seeds included.

Alleged – not relevant as required by Clause 13.2 (4th edition). Allegation upheld.

Ruled Clause 13.2 contravened. (Clause 17.2, 5th Edition).

A company complained about a promotional folder issued by another which included a gift of seeds and thus contravened Clause 13.2 of the Code of Practice. (Clause 17.2, 5th Edition).

The Committee decided that, although the gift of the packet of seeds was of negligible value, it bore no relation to the practice of medicine or pharmacy.

The Committee accordingly ruled that there had been a contravention of Clause 13.2 of the Fourth Edition of the Code.

Case 296/4/79

Promotional mailing incorporating comparative histogram of products.

Alleged data presented unfair and unsubstantiated.

Allegations upheld – ruled contravention of Clause 4.5 and 5.1 (4th edition) of Code.

A company complained about a promotional mailing issued by another, alleging that data presented in the form of a histogram incorporating a comparison which included a reference to one of the complainant's products was not factual, fair and capable of substantiation and thus contravened Clauses 4.5 and 5.1 of the Code.

The Committee decided that the histogram did not truly reflect the scientific evidence adduced by the company as supportive evidence. Taken as a whole the histogoram was likely to prove misleading.

The Committee ruled that there had been breaches of Clauses 4.5 and 5.1 of the Fourth Edition of the Code.

Home | Contact us | Site map

Search this site Search... Advanced Search

PMCPA Prescription Medicines Code of Practice Authority

About us | The Code | Advice | Cases | Media | Training

Try the Interactive Code
Read more

Take the e-learning module for health professionals
Read more

Attend a PMCPA Training Seminar
Read more

CONTACT US

Welcome

The Prescription Medicines Code of Practice Authority (PMCPA) administers The Association of the British Pharmaceutical Industry's (ABPI) Code of Practice at arm's length from the ABPI itself.

The ABPI Code covers the promotion of medicines for prescribing to health professionals and the provision of information to the public about prescription only medicines. The ABPI Code also sets standards for information made available to the public about prescription medicine. Advertising or promoting prescription only medicines to the public is prohibited under the ABPI Code and UK law.

Code of Practice | Make a complaint | View cases

Latest news

ABPI Code of Practice for the Pharmaceutical Industry Second 2012 Edition

Pre-licence activity

View more news articles

Other PMCPA activities

Code Awareness

Informal guidance

Interactions with stakeholders such as Ethical Standards in Health and Life Sciences Group

Next edition of the Code?

PMCPA | Prescription Medicines Code of Practice Authority

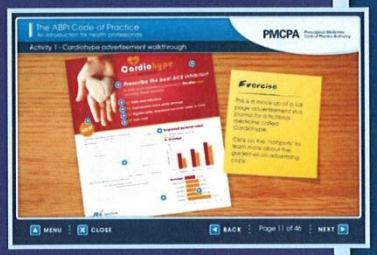
The ABPI Code of Practice
New online learning module

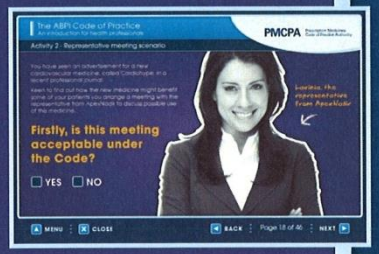
The ABPI Code of Practice for the Pharmaceutical Industry has been updated this year, but are you familiar with what this means to you?

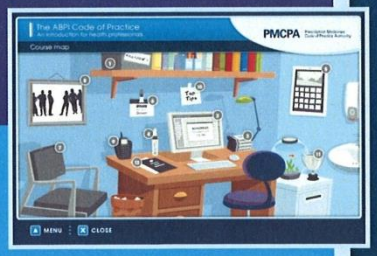
The PMCPA has developed a free online learning module for health professionals to update them on the Code.

The Code is relevant to all people who come into contact with the pharmaceutical industry. The interactive online module has been developed to introduce health professionals to the rules that govern the promotion of medicines.

The resource lets you easily navigate through the different sections of the Code, testing your knowledge as you go. Once you've looked at all sections you can complete a short assessment. The module has been certified as conforming to continuing professional development guidelines by the CPD Certification Service.







CPD CERTIFIED The CPD Certification Service

Access the module at
www.pmcpa.org.uk

PMCPA published guidance

- Clause 3
- Digital Communications

PMCPA | Prescription Medicines Code of Practice Authority

GUIDANCE ABOUT CLAUSE 3

Following a number of recent cases the Code of Practice Appeal Board considered it would be helpful to provide guidance on the application of Clause 3 to various activities. The ABPI Code of Practice for the Pharmaceutical Industry reflects and extends beyond UK law. It covers promotional and non-promotional materials and activities.

Clause 3 prohibits the promotion of a medicine prior to the grant of its marketing authorization. It also requires that promotion must be in accordance with the marketing authorization and not be inconsistent with the summary of product characteristics.

The supplementary information to Clause 3 provides additional detail, including a clear statement that the legitimate exchange of medical and scientific information during the development of a medicine is not prohibited provided that this does not constitute promotion which is prohibited by Clause 3 or any other clause in the Code.

Clause 1.2 defines 'promotion' as 'any activity undertaken by a pharmaceutical company or with its authority which promotes the prescription, supply, sale or administration of its medicines'. This is followed by a list of materials and activities that come within that definition and a number that do not.

Companies need to start by considering two aspects. Firstly, whether the activity itself is promotional and secondly the role of employees carrying out that activity.

The Medicines and Healthcare products Regulatory Agency (MHRA) is responsible for administering the relevant UK law and gives strong support to the ABPI Code. It is consulted on any changes to the ABPI Code and its operation.

The PMCPA can only give informal advice and in the event of a complaint being received it would be considered in the usual way. This paper focuses on Clause 3 but other clauses of the Code might also be relevant including Clauses 7 and 9.10. Companies should always bear in mind the overall impression created by activities, materials, etc.

PMCPA | Prescription Medicines Code of Practice Authority

DIGITAL COMMUNICATIONS

INTRODUCTION

In the UK, the promotion of prescription medicines to health professionals is carried out within a robust regulatory framework to support high quality patient care. The pharmaceutical industry is highly regulated. The ABPI Code of Practice for the Pharmaceutical Industry, administered by the Prescription Medicines Code of Practice Authority (PMCPA), is the self-regulatory code which applies, *inter alia*, to the promotion of prescription medicines to health professionals and to the provision of information about prescription only medicines to the public. The Code reflects and extends beyond UK law.

In stark contrast, digital communication such as social networking sites, twitter, blogs, discussion forums, user generated copy and Wikipedia are largely seen as unregulated. Indeed, for many other industries this can be part of the attraction for engaging in this way. The challenge is how these tools can be used by the pharmaceutical industry.

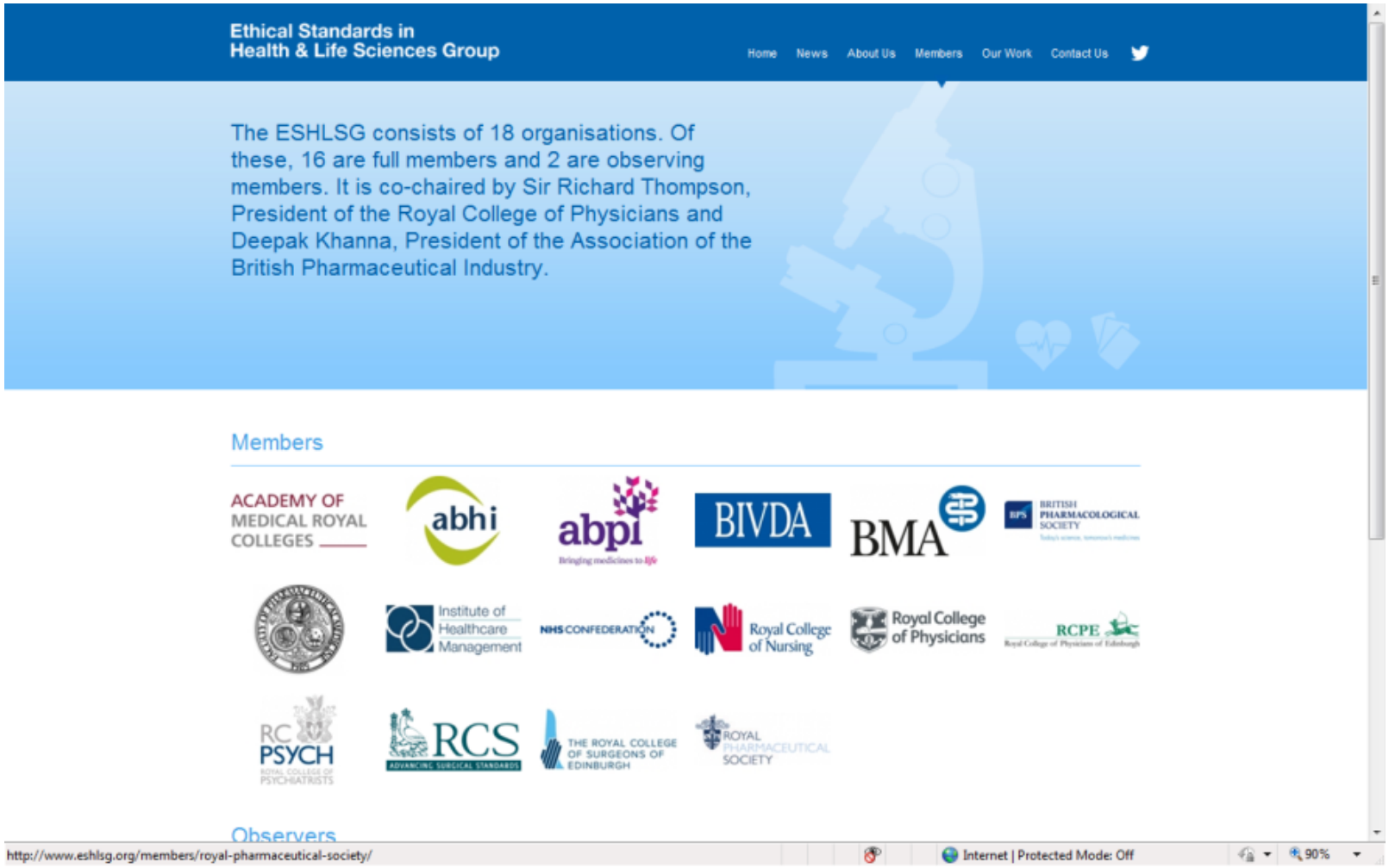
Pharmaceutical companies want, and indeed should be able to use digital media. However, unlike other industries which can promote their products to all, pharmaceutical companies are prohibited from promoting prescription only medicines to the public. Therefore, pharmaceutical companies need to identify ways of utilising digital communications whilst complying with this restriction.

Companies can use any method of communicating to any audience provided relevant requirements of the Code are followed.

Transparency

- Code already has general requirements re aggregated disclosure
- Proposed new EFPIA Code on disclosure of transfers of value from pharmaceutical companies to healthcare professionals and healthcare organisations
- Ethical Standards in Health and Life Sciences Group consulting on method of disclosure

ESHLSG


Ethical Standards in
Health & Life Sciences Group
Home
News
About Us
Members
Our Work
Contact Us
The ESHLSG consists of 18 organisations. Of these, 16 are full members and 2 are observing members. It is co-chaired by Sir Richard Thompson, President of the Royal College of Physicians and Deepak Khanna, President of the Association of the British Pharmaceutical Industry.
Members
ACADEMY OF MEDICAL ROYAL COLLEGES
abhi
abpi
BIVDA
BMA
BRITISH PHARMACOLOGICAL SOCIETY
Institute of Healthcare Management
NHS CONFEDERATION
Royal College of Nursing
Royal College of Physicians
RCPE
RC PSYCH
RCS
THE ROYAL COLLEGE OF SURGEONS OF EDINBURGH
ROYAL PHARMACEUTICAL SOCIETY
Observers
http://www.eshlsg.org/members/royal-pharmaceutical-society/
Internet | Protected Mode: Off
90%

Ethical Standards in Health & Life Sciences Group

Guidance on collaboration between healthcare professionals and the pharmaceutical industry

Ethics, transparency, partnership

This document has been jointly produced by senior representatives of the pharmaceutical industry and the healthcare community with the aim of promoting positive collaboration between industry and healthcare professionals to support high quality patient care.

The document is based on the following core principles:

- Collaboration between industry and healthcare professionals has the potential to deliver significant patient benefit above and beyond what may be delivered by any party in isolation.
- Healthcare and industry professionals are able to manage their relationships with each other without compromising clinical decision making.
- A comprehensive and robust set of regulations, including UK law, health professionals' codes and standards and the ABPI Code of Practice for the Pharmaceutical Industry ensure professional and ethical standards are upheld.

THE TIMES

Letters to the Editor

Drug companies must come clean

Sir, Last week Lord Howe stated on the *Today* programme that drug companies are obliged, by law, to report both positive and negative results from clinical trials.

We wish that drug companies truly were compelled to be transparent. In reality, vitally important information about drug trials continues to be withheld from doctors and the public, meaning that patients are harmed, and money is wasted. The public remain largely unaware of this issue.

The current best estimate is that half of all drug trials are never published in academic journals, but this is not the only issue. The UK has spent £500m on stockpiling Tamiflu, and yet Roche continues to withhold information about trials on this drug from the widely respected Cochrane Collaboration, which produces summaries of evidence for doctors and patients.

Politicians have neglected this problem for too long. New legislation passing through the European Parliament is weak, and US legislation has been widely ignored. In an age of increasing transparency, and open access to knowledge, there is no justification for this ongoing secrecy.

We are pleased that a Health Minister has now agreed to meet with us. The government must publicly acknowledge the harm done to patients when information on trials is withheld, and commit to specific remedial steps. All information affecting patient care, from all clinical trials, new and old, on all drugs in current use, must be made available to healthcare professionals. Until that happens, patients will continue to suffer unnecessarily.

DR BEN GOLDACRE
author of *Bad Pharma*
DR FIONA GODLEE
British Medical Journal
DR RICHARD HORTON
The Lancet
DR VIRGINIA BARBOUR
PLOS Medicine
DR CLARE GERADA
Royal College of General Practitioners
SIR IAIN CHALMERS
co-founder, Cochrane Collaboration
Plus 22 signatories whose names can be seen at thetimes.co.uk/letters

THE TIMES

Letters to the Editor

Ethical standards and clinical trials

Sir, *The Times* has done patients and the public a great service by highlighting the campaign for transparency in clinical trials. We hope you and other newspapers will also be willing to continue to highlight the important work that the healthcare professions are doing with the life sciences industry to address this complex problem. An ethical standards group (ESHLSG.org), formed by a number of medical royal colleges and professional societies, together with relevant industry bodies, has come together in support of transparency and higher standards for the benefit of patients.

The Ethical Standards in Health and Life Sciences Group (ESHLSG) has already published a set of best practice principles and facts on the transparency of clinical trials. We are currently seeking the views of healthcare professionals on medical education sponsored by the pharmaceutical industry and will shortly consult on the disclosure of financial relationships between healthcare professionals and commercial organisations. The outcomes will inform our future work to bring transparency to these relationships. Healthcare professionals, pharmaceutical companies and others within the life sciences industry are committed to ethical behaviour, and progress has already been made.

It is only by working together that we can most effectively deliver further improvements in transparency. We shall continue to do this, including work on the complex issue of increasing disclosure of clinical trials data.

SIR RICHARD THOMPSON
President, Royal College of Physicians and co-chair, ESHLSG
DEEPAK KHANNA
President, Association of the British Pharmaceutical Industry and co-chair, ESHLSG
plus a further 14 signatories whose names can be seen at thetimes.co.uk/letters

Conclusions

Factors relevant to the development of the UK Code

transparency

regularly updated code

robust complaints procedure

good relationships with stakeholders

confidence to challenge critics to submit a complaint

informal guidance

training

support for and from companies