

PMCPA

Prescription Medicines
Code of Practice Authority

Code Awareness Campaign Examples and Best Practices

Heather Simmonds
Director

Prescription Medicines Code of Practice Authority
www.pmcpa.org.uk

1958
THE ABPI CODE 2008
FIFTY YEARS OF SELF-REGULATION OF THE
PROMOTION OF PRESCRIPTION MEDICINES

Prescription Medicines Code of Practice Authority

Director - Heather Simmonds
Secretary - Etta Logan
Deputy Secretary - Jane Landles

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



CODE OF PRACTICE

for the

PHARMACEUTICAL

INDUSTRY

2008

THE ABPI CODE **1958**
2008
FIFTY YEARS OF SELF-REGULATION OF THE
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PMCPA

Prescription Medicines
Code of Practice Authority

ABPI Code Of Practice

Established in 1958

Regularly updated

Reflects and extends beyond UK law, IFPMA,
EFPIA Codes

Drawn up in consultation with MHRA, BMA, RCN
and RPSGB

Promotion must be:

- in accordance with marketing authorization (*Clause 3*)
- accurate, balanced, up-to-date and must not mislead or exaggerate (*Clauses 7.2, 7.3 and 7.10*)
- substantiable (*Clauses 7.4 and 7.5*)

Promotion must also:

- be of a high standard (*Clause 9.1*)
- recognise special nature of medicines and professional standing of audience and not be likely to cause offence (*Clause 9.2*)
- be tailored to audience to whom it is directed (*Clause 11.1*)

Promotion must not:

- bring discredit upon or reduce confidence in the pharmaceutical industry (*Clause 2*)
- disparage competitors or health professionals (*Clause 8*)
- be disguised (*Clause 12*)

Code also covers:

- Non-interventional studies Clause 13
- Certification Clause 14
- Representatives Clause 15
- Training Clause 16
- Samples Clause 17
- Gifts and Inducements Clause 18

Code also covers:

- Hospitality and meetings Clause 19
- Use of consultants Clause 20
- Scientific Services Clause 21
- Relations with the Public Clause 22
- Relations with patient organisations Clause 23
- Internet Clause 24
- Compliance With Undertakings Clause 25

CHOCOLATE WILL SAVE YOUR LIFE

New bar staves off heart disease

By **Victoria Fletcher** Health Editor

A DAILY bar of chocolate could be given to patients to reduce their risk of heart disease, scientists will reveal today.

A British team has developed a bar packed with compounds that protect the heart from damage.

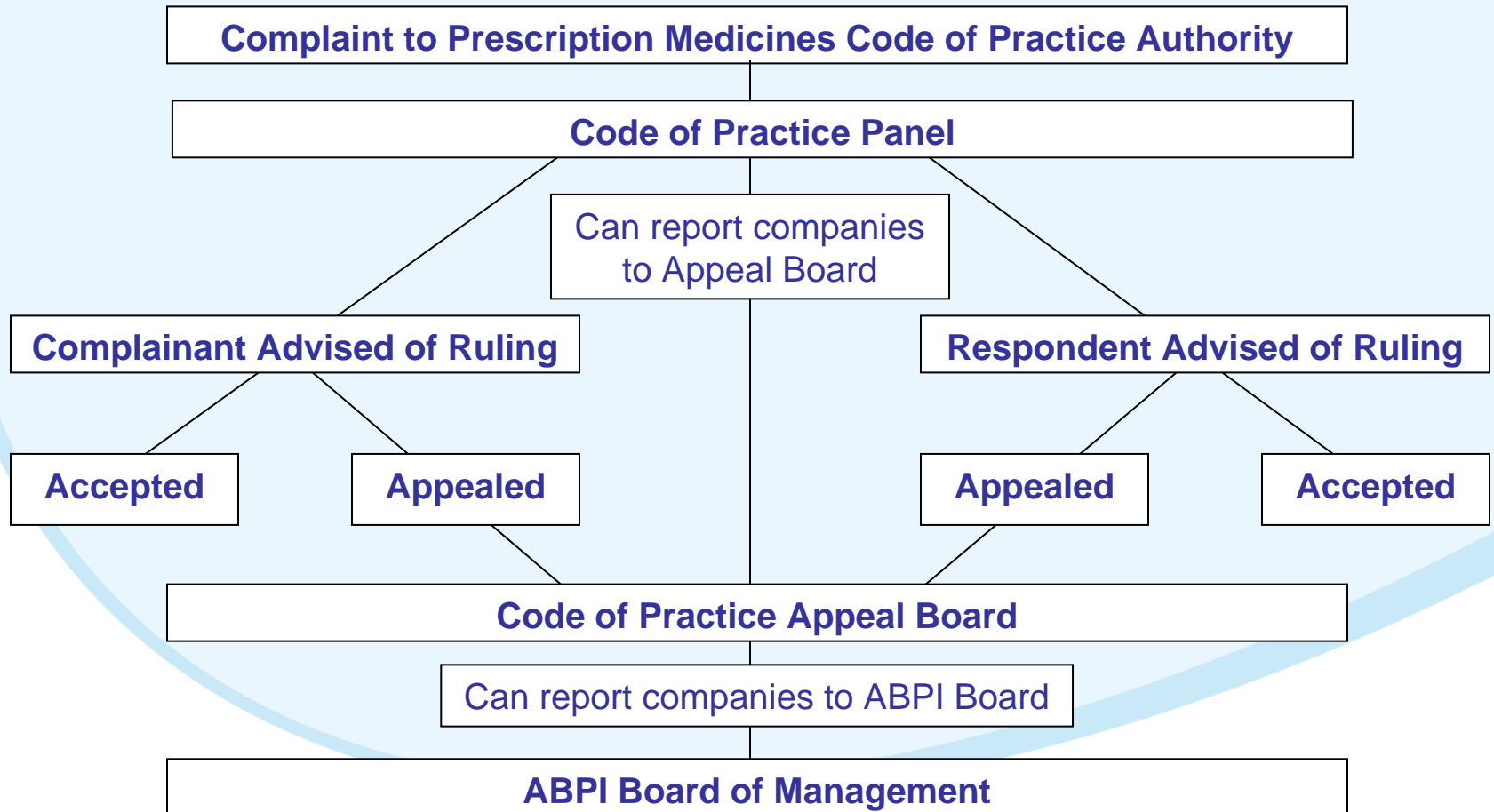
It will be tested on British volunteers in the first clinical trials of their kind.

The initial tests will be on women who have diabetes, but if the chocolate proves effective it could eventually be offered to millions of patients with heart problems.

Along with cholesterol-busting drugs called statins, it could prove a highly effective - and highly popular - medication.

Cocoa contains high levels of antioxidants thought to protect against heart disease. But the process of turning cocoa into chocolate often destroys these compounds so most of the beneficial effects are lost. The team at the

Complaints Procedure



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.

CODE OF PRACTICE REVIEW

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.

COMPLAINTS IN 2009 DOWN ON 2008

In 2009 the PMCPA received 92 complaints as compared with 112 in 2008. There were 127 complaints in 2007, 134 complaints in 2006, 101 in 2005 and 119 in 2004.

There were 87 cases to be considered in 2009, as compared with 103 in 2008. The number of cases usually differs from the number of complaints because some complaints involve more than one company and others do not become cases at all, often because they do not show that there may have been a breach of the Code.

The number of complaints from health professionals in 2009 (40) exceeded the number from pharmaceutical companies (both members and non-members of the

ABPI) (24). Complaints made by pharmaceutical companies are generally more complex than those from outside the industry, usually raising a number of issues.

Two complaints were made by members of the public and four by pharmaceutical company employees. There were seven anonymous complaints and one complaint was made by an organisation. Nine of the complaints from health professionals were also anonymous.

The remaining fourteen complaints were nominally made by the Director and arose from media criticism, voluntary admissions by companies and alleged breaches of undertakings.

HELP US TO HELP YOU - MAKING A COMPLAINT

The PMCPA aims to deal with all complaints under the Code in a timely manner. The following is intended to guide complainants so that their submissions will help the Authority in this regard.

Inter-company complaints will only be accepted if they are signed or authorized in writing by the company's managing director, chief executive or equivalent and if inter-company dialogue at a senior level has not been successful (Paragraph 5.2 of the Constitution and Procedure refers). The complainant company must submit a formal statement with its complaint detailing the actions taken. Complainants must state those clauses of the Code which are alleged to have been breached and must not go beyond the scope of the inter-company dialogue. If new matters and/or clauses are raised they will be referred back for

discussion between the parties in the first instance. Guidance on inter-company dialogue was published in the May 2009 Code of Practice Review and is also available on the Authority's website (www.pmcpa.org.uk).

When submitting a complaint brevity might not always be possible if complex matters are to be discussed but a clear and precise exposition of the facts should be provided. Repetition of the same point should be avoided. All points should be covered in the letter to the PMCPA. In inter-company complaints cross reference to previous correspondence between the parties should be avoided.

Cite only those clauses of the Code that are most relevant to specific aspects of your complaint. It is often the case that although a number of clauses are alleged to have been breached, some of those allegations

PUBLIC REPRIMAND FOR SOLVAY HEALTHCARE

Solvay Healthcare Limited has been publicly reprimanded by the Code of Practice Appeal Board for providing grants in the form of cheques via its representative to a GP on four separate occasions to conduct patient audits. The company had no processes to enable it to check that the money was used to pay a nurse to conduct an audit and how long that would take or that the audit itself was appropriate. The nurse employed to undertake the audits had not been assessed by the company with regard to her ability to carry out the task. There was a failure of management.

The Appeal Board noted that there appeared to be a marked consequential increase in the prescribing of Omacor by the GP concerned and it queried whether, as a result, patients had been put at risk.

In addition the Appeal Board required an audit and a subsequent re audit of Solvay's procedures.

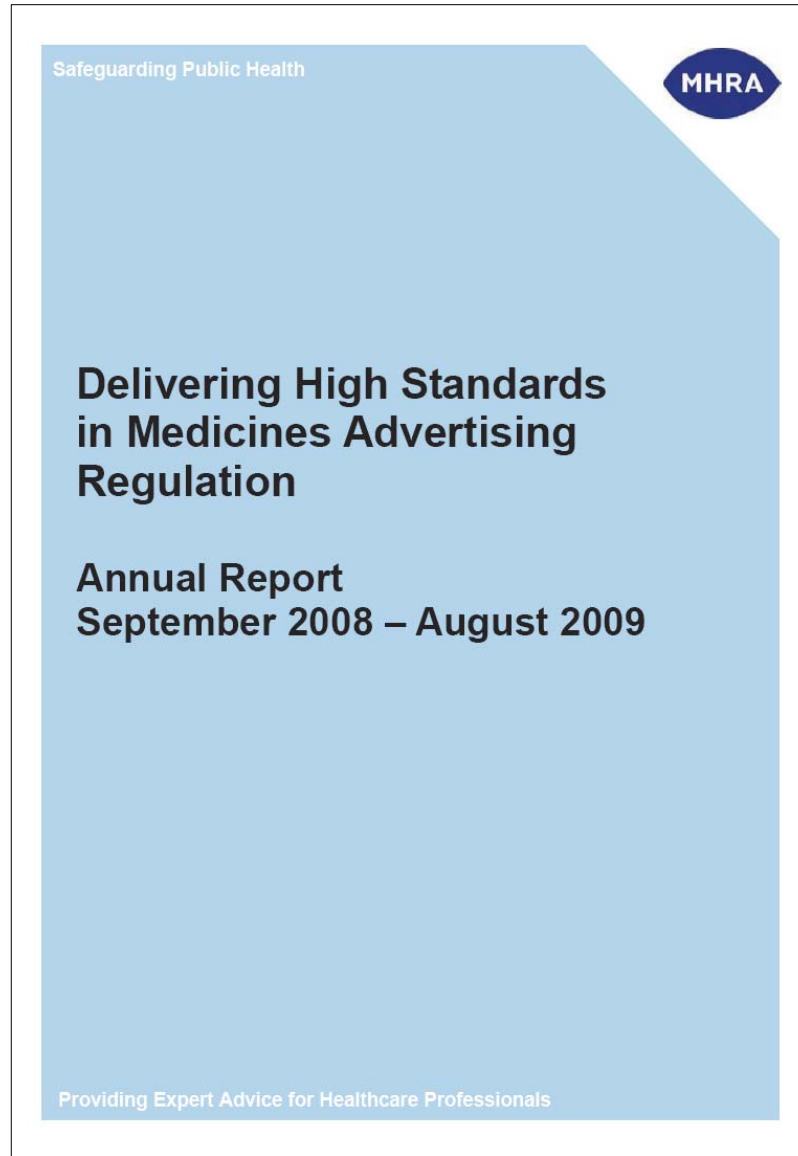
Full details can be found at page 3 of this issue of the Review in the Report for Case AUTH/2198/1/09.

PROPOSALS TO AMEND THE CONSTITUTION AND PROCEDURE FOR THE PRESCRIPTION MEDICINES CODE OF PRACTICE AUTHORITY

The consultation on the proposals to amend the Constitution and Procedure for the Prescription Medicines Code of Practice Authority has now closed. The proposed amendments and the explanatory memorandum are available on our website (www.pmcpa.org.uk).

The proposals were sent to the Medicines and Healthcare products Regulatory Agency (MHRA), the British Medical

Fourth Annual Report



Chief Executive, MHRA

‘... more generally, self regulation has been the cornerstone of control of medicines advertising for many years, predating any form of statutory control by the MHRA and its predecessors...

The Agency looks forward to working with these bodies for many more years to come to ensure that patients and health professionals receive high quality information from advertising to support the safe use of medicines.’

Annual Report September 2008 – August 2009

Other PMCPA activities

- Informal advice and guidance
- Training Seminars
- Code Awareness

Code Communications



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QUICK GUIDE TO THE CODE FOR HEALTH PROFESSIONALS

The ABPI Code of Practice controls how pharmaceutical companies can promote prescription medicines to health professionals in the UK and the information they can provide to patients and the public about prescription only medicines

The ABPI Code and Politicians

The Association of the British Pharmaceutical Industry (ABPI) Code of Practice for the Pharmaceutical Industry is 50 years old in 2008, marking 50 years of self-regulation of the promotion of prescription medicines in the UK.

The aim of the Code is to ensure that the promotion of medicines to health professionals is carried out in a responsible, ethical and professional manner that supports high quality patient care. For example, materials must be accurate, balanced, fair, objective, unambiguous and capable of substantiation, and all behaviour must be professional and beyond reproach. The Code also covers some non-promotional activities including the provision of information to the public. The Code reflects and extends beyond UK law. It is supported by the Medicines and Healthcare products Regulatory Agency (MHRA) which is responsible for administering UK law on behalf of UK health ministers.

HOW THE CODE AFFECTS YOU

Due to the requirements of the Code your constituents can be assured that they are being prescribed medication for the correct reasons and not because a health professional has been influenced by an inducement to prescribe.

The pharmaceutical industry is one of the most regulated industries in the world. The Code helps to ensure that prescribing remains free from any undue influence from pharmaceutical companies by setting out strict rules on what is permitted in terms of the promotion of prescription medicines and interactions with health professionals.

PMCPA Prescription Medicines
Code of Practice Authority

It is essential that health professionals are aware of the Code so that they can raise concerns if they feel that pharmaceutical companies are acting inappropriately. As a result of Code awareness activities undertaken by the industry amongst health professionals, nearly two thirds of doctors are now aware of the requirements of the Code.

Due to the requirements of the Code your constituents can be assured that information for patients produced by or sponsored by a pharmaceutical company is of a high standard.

Under the Code information about prescription only medicines must be factual, presented in a balanced way and must not encourage patients to ask their health professional to prescribe a specific prescription only medicine. The Code (and UK law) prohibit the advertising of prescription only medicines to the public. Disease awareness campaigns that comply with the Code are permitted.



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QUICK GUIDE TO THE CODE FOR PATIENT ORGANISATIONS

The ABPI Code of Practice controls how pharmaceutical companies can promote prescription medicines to health professionals in the UK and the information they can provide to patients and the public about prescription only medicines

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QUICK GUIDE TO THE CODE FOR THE PUBLIC

The ABPI Code of Practice controls how pharmaceutical companies can promote prescription medicines to health professionals in the UK and the information they can provide to patients and the public about prescription only medicines

Training Seminars/Presentations

- Full day seminars open to all (9 in 2009).
Syndicate sessions led by industry/agency personnel.
- In house seminars including pharmaceutical companies, public relations agencies, advertising agencies and university courses.

Code Awareness campaigns

25 April 2006 'Two to Tango' campaign

15 May 2007

29 September – 3 October 2008 – Still nifty at fifty?

25 – 29 January 2010 – Pilot project with NHS NW

Code Awareness Day 2006

- 52 companies took part which included over 10,000 of the 80,000 industry employees.
- Three key aspects to the campaign—
 - face to face contact with prescribers by industry personnel
 - building relationships with key professional bodies
 - media outreach.
- A cross party Parliamentary Motion supporting CODE Day and the Code of Practice was signed by 41 MPs.

Code Day 2006 Coverage

The

29 April 2006
 WJ 2716 No 7398 ISSN 0031-6873

Cover story

A News feature looks at some of the revisions to the Association of the British Pharmaceutical Industry's Code of Practice, which governs the promotion of prescription medicines to health care professionals

CPD

This week's Continuing professional development article looks at what pharmacists need to know about refractive errors, such as short-sightedness, the ways in which they can be treated with surgery and the drugs involved

Interventions

The Society has published guidance for pharmacists on the recording of interventions. It offers advice on what should be recorded and how intervention records can be used to improve efficiency and safety across the NHS

www.pjonline.com

News feature ■

2006: a tighter ABPI Code of Practice?

On 1 January a revised ABPI Code of Practice, which calls for changes to industry's marketing practices, came into operation. **Lin-Nam Wang** reports

The Government response agreed that "intensive marketing which encourages inappropriate prescribing of drugs must be curbed". Neither document blamed a particular marketing activity but, instead, found fault with the volume of activities. As a reflection of this, Mrs Simmonds explained that the code now specifies that, for a particular medicine, no more than eight mailings of promotional material may be sent to a health professional each year. Similarly, advertising in journals must be limited to two pages per issue.

The code itself reveals the ABPI's concern over the bad press that the industry has attracted and expressly states that one new direction — that particular care needs to be taken in terms of promotional materials released in the first six months following the launch of a medicine — is "to avoid criticism of the industry". The timing of the provision of medicines information was highlighted in the two parliamentary documents. The charge was that, in the first few months after a drug is launched, it was common practice for companies to embark on a mixture of "explosive marketing" (in order to establish market position for their product, encouraging wide early prescribing at a time when there is insufficient information about the use of a new drug in the community).

Promotional aids

The changes in the ABPI code relating to gifts and inducements have been extensively revised. In some places where the word "gift" was previously used, "promotional aid" has been substituted, emphasising the distinction between the two. Although the acceptable cost of a promotional aid remains the same (no more than £20), the definition of the type of items allowed has been updated. In the 2003 code, objects that could be used in the practice of health care were all right. However, the 2006 code now disallows of all items for use in the home or car. The list of examples that are not permitted has been expanded and now includes: coasters, clocks (previously an example of an acceptable promotional aid), desk thermometers, fire extinguishers, rug, thermos flasks, tea or coffee pots, lamps, travel adapters, toothbrushes and umbrellas. The code implies that anything more than a coffee mug is not allowed.

In addition, the previously authorised practice of using competitions or quizzes and giving prizes to promote products is now deemed unacceptable. "The industry looked at itself long and hard and it was thought that some forms of promotion were not acceptable for the type of product," Mrs Simmonds explained.

29 April 2006 The Pharmaceutical Journal (No 210) 499

Are "freebies" a thing of the past?

www.pharmacy.com

CMP United Kingdom Member

Chemist&Druggist The Newsweekly for Pharmacy

univadis medical and more

pulse

bmj.com

BMA

SCRIP

PharmaTimes

PMLive.com

HOSPITAL DOCTOR

Requests from health professionals

Usually doctors asking for unacceptable payments.

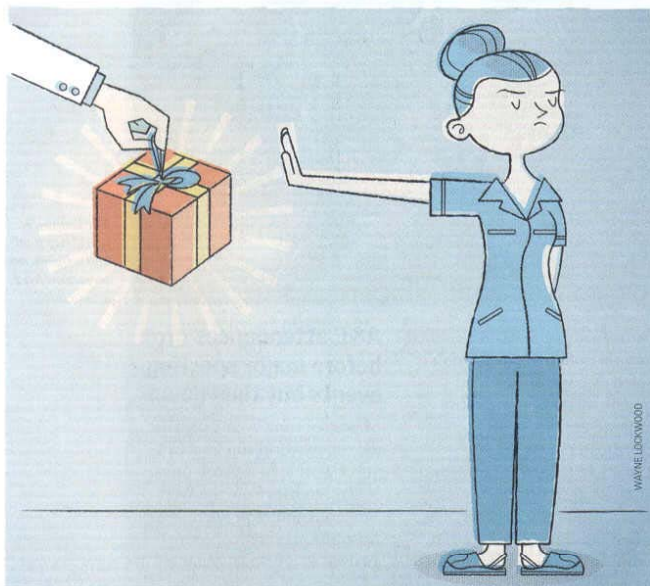
Write to draw attention to ABPI Code and UK law and GMC guidance.

Generally point well taken and arrangements changed.

Code Awareness Day May 2007

- 54 companies took part which included over 10,000 of the 80,000 industry employees.
- Key aspects –
 - face to face contact with prescribers by industry personnel
 - building relationships with key professional bodies
 - media outreach, 20 placed features
 - briefings sent to NHS employees
 - information sent to about 90 MPs.

Taking and giving



The pharmaceutical industry is targeting nurses next week as part of its Code Awareness Day

More than 10,000 nurses are now able to prescribe and the pharmaceutical industry is becoming increasingly aware of the need to make contact with them. So nurses must face the challenges of working with these companies.

To develop productive and ethical relationships, prescribers need to be aware of how pharmaceutical companies are

permitted to operate and what sort of support it is appropriate to receive, expect or solicit.

The Association of the British Pharmaceutical Industry (ABPI) code of practice sets out how pharmaceutical companies can promote medicines to health professionals and give information about prescription-only medicines to the public. The code is administered by the Prescription Medicines Code of Practice Authority (PMCPA).

The PMCPA's initial research found that 61 per cent of nurses are aware of the code, but only 24 per cent know how to make a complaint and 78 per cent would like to know more about it.

Nurses will be targeted, along with doctors and pharmacists, on Code Awareness Day – Tuesday May 15. On this day the industry will talk to health professionals

and distribute materials. Some of the provisions of the ABPI code are mirrored in clause seven of the Nursing and Midwifery Council's *Code of Professional Conduct* (NMC 2004). This sets out the rules concerning gifts, favours, hospitality and declaring any conflicts of interest.

Industry relations

Nurse-Industry Relations, a position statement from the International Council of Nurses, also covers industry-sponsored events, continuing professional development and research affiliations (ICN 2006).

The ABPI code includes the content of promotional material. Claims have to be accurate, balanced, fair and capable of substantiation. The code also puts restrictions on the provision of samples, promotional aids, meetings, hospitality and the conduct of representatives.

Pharmaceutical companies can sponsor meetings such as presentations at GP practices. Sponsorship must be disclosed in all relevant papers and prescribers may not be paid for the use of the rooms. Lavish venues must not be used, and there are strict requirements for meetings held outside the UK.

Hospitality can be provided only in association with scientific and promotional meetings. It must be limited to the main purpose of the event and remain secondary to it. Hospitality cannot be offered to spouses and companies can only offer delegates economy air travel.

No gift, benefit in kind or pecuniary advantage should be offered or given as an inducement to prescribe, supply, administer, recommend, buy or sell any medicine. Items must not be offered for personal benefit. Promotional aids must be inexpensive – the limit is £6 plus

SUMMARY

A code of practice sets out how pharmaceutical companies can promote medicines to health professionals and give information about prescription-only medicines to the public.

Keywords

Nurse prescribers • Pharmaceutical industry
• Association of the British Pharmaceutical Industry
• Prescription Medicines Code of Practice Authority

Impact Of Communications Activities

- In March 2007 awareness of the Code had improved amongst doctors – 73% of doctors aware of the Code compared to 52% in 2006.
- 61% of nurses aware of the Code.

Code Day Coverage 2007

IndependentNurse
The Authority on the profession

Opinion

Why nurses should be aware of the ABPI code

Nurses must know which activities pharmaceutical companies are permitted to undertake, says **Heather Simmonds**



Heather Simmonds is director of the Prescription Medicines Code of Practice Authority. Ms Simmonds has worked on the code for more than 17 years, including nearly 10 years as director. She is responsible for the day-to-day running of the organisation and chairs the Code of Practice Panel, which rules on all complaints submitted to the authority in the first instance.

What do you think? Email your views to independentnurse@haymarket.com

The Association of the British Pharmaceutical Industry's (ABPI) code of practice for the pharmaceutical industry covers the promotion of medicines for prescribing to health professionals as well as the provision of information about prescription-only medicines to the public.

It is important nurses are aware of the activities pharmaceutical companies are permitted to undertake to ensure that relationships remain productive and ethical, particularly given that nurses can now prescribe. Some provisions of the ABPI code are mirrored in the NMC Code of professional conduct.

20 • prescribing nurse

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Pharmaceutical company practice

By **Heather Simmonds**, director, Prescription Medicines Code of Practice Authority (PMCPA)

As more nurse prescribers qualify, it is increasingly important to be aware of what activities pharmaceutical companies are permitted to undertake if relationships with them are to remain productive and ethical

The Association of the British Pharmaceutical

question and take all possible steps to avoid a similar breach in the future. A

Received a gift? It's time to perk up

A meal out with pharmaceutical company representatives and a free road atlas to boot were once seen as the kind of harmless inducements that would oil a mutually beneficial relationship. No longer. A year after a new code of practice on the subject was introduced, many doctors are still unclear whether they are breaching regulations. Erin Dean reports

of the ABPI, the trade association for the pharmaceutical industry in the UK, to comply with the Code. Strong support is given to it by industry, even non-ABPI member companies have agreed to abide by its provisions.

Companies can also be publicly reprimanded through advertisements in the medical and pharmaceutical press or face being suspended or expelled from the ABPI.

The ABPI Code reflects and extends beyond UK level requirements for the

entific meetings, promotional meetings, scientific congresses and other such meetings. It must be strictly limited to the main purpose of the event and not exceed the level recipient would normally adopt when paying for themselves. It cannot be offered to spouses or other people unless they qualify as a delegate in their own right. Pharmaceutical company sponsorship must be disclosed.

Involvement of a company must always be made clear

Prescribing Nurse is for all of you, but especially for prescribers. This section of the journal keeps you up to date with everything you need to know about administering and prescribing medicines.

WHAT THE ABPI CODE MEANS FOR NURSES

Some of the provisions of the ABPI Code are mirrored in the NMC Code of Professional Conduct: standards for conduct, performance and ethics to which all nurses are required to adhere to (www.nmc-uk.org). Clause 7.2 states: 'You must ensure that your registration

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providing
services
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should be aware that they could be perceived by the patient or client to be endorsing the product. Clause 7.4 states: 'You must refuse any gift, favour or hospitality that might be interpreted, now or in the future, as an attempt to

www.conspiracymagazine.com

CMP
United Kingdom

Chemist&Druggist
The Newsweekly for Pharmacy

pulse

Prescriber
The Journal of Prescribing and Medicines Management

Volume 18 Issue 10 10 July 2007 www.prescriber.com

Drug review
Urinary tract infection

PM Live.com

univadis
medical and more

BMA

GP

bmj.com

PharmaTimes

Nurse Prescribing

Code Awareness Week 2008

42 companies took part

Key aspects

- face to face contact with customers
- building relationships
- emails to 53,000 clinicians
- electronic advertising on eBMJ, HSJ, Nursing Times and PJ
- Code busters visits

Code Awareness Week 2008

The ABPI Code –

Still nifty at 50 debate?

Issues raised included:

- future role of self-regulation
- information to patients
- sponsorship of meetings
- joint working with NHS and others



Other activities in 2008

All party pharmaceutical group meeting

Submission to Royal College of Physicians – Report urged PMCPA to continue Code Awareness Activities

INNOVATING FOR HEALTH

**Patients, physicians,
the pharmaceutical industry
and the NHS**

Report of a Working Party

February 2009



Royal College
of Physicians
Setting higher medical standards

Code Awareness Pilot Project in NHS North West January 2010

Joint project with NHS North West Medicines
Management Network

Offered Code Awareness Activities

Code Awareness 2010

Over 70 NHS staff attended various events

Emails sent to many more

Seminars included:

- introduction to Code
- interactive discussion activities
- presentation on joint working – as defined by DoH



**ABPI GUIDANCE NOTES ON
JOINT WORKING BETWEEN
PHARMACEUTICAL COMPANIES
AND THE NHS AND OTHERS
FOR THE BENEFIT OF PATIENTS**

**TAKING INTO CONSIDERATION THE 2008 ABPI CODE OF
PRACTICE FOR THE PHARMACEUTICAL INDUSTRY**

MARCH 2009



Feedback

Awareness of the Code and its operation would support better relationships.

Develop on-line learning for HPs.

Promotional material:

- wary of statistics, now more likely to ask for substantiation

Representatives:

- more focus on quality
- many wanted less pressure from representatives

Feedback

Education and training:

- medical information appreciated
- educational meetings welcomed

Working together:

- prefer to work with a group of companies
- needs to be done better – share best practice

Top tips for NHS employees

Know the regulations

What's in it for the patient?

Ask, ask and ask again

Be transparent

Seek out and share information

Have realistic expectations

Contact PMCPA if there is a problem.

PMCPA

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**The 2008
ABPI Code**

ABPI Code

The ABPI Code is fifty years old in 2008. **1958 2008**
[Click here to find out more...](#)

Welcome to the PMCPA website

The Prescription Medicines Code of Practice Authority (PMCPA) is responsible for administering The Association of the British Pharmaceutical Industry's (ABPI) [Code of Practice](#) for the Pharmaceutical Industry at arm's length from the ABPI.

The Code covers:

- o the promotion of medicines for prescribing to health professionals
- o the provision of information to the public about prescription only medicines in the UK.

PMCPA e-alerts

Sign up to receive the latest news and updates from the PMCPA. Find out how [here...](#)

Latest News

[Roche and Bayer Schering Pharma named in advertisements for breaches of the ABPI Code of Practice](#)
27 February 2009

Roche Products Limited and Bayer Schering Pharma are the subjects of advertisements in the medical, pharmaceutical and

Latest Advice

[Joint working and the ABPI Code of Practice for the Pharmaceutical Industry](#)

The ABPI has recently issued guidance notes on joint working between pharmaceutical companies and the NHS and others for the benefit of patients. T

SEARCH WEBSITE

Completed Cases

Reports for cases considered since 2006. [[more](#)]

Ongoing Cases

Information on the status of all ongoing cases. [[more](#)]

Advertisements

All public reprimands issued within the last twelve months. [[more](#)]

Training Seminars

The PMCPA holds regular training seminars on the requirements of the Code of Practice. These seminars are open to all. [[more](#)]

ABPI Website

The Association of the British Pharmaceutical Industry (ABPI) is the trade association for more than 75 companies in the UK producing prescription

PMCPA Learnings

Do not forget to communicate with companies – at all levels

Update website regularly

Vital to have good system for dealing with complaints

Win awards

Questions