PMCPA | Prescription Medicines Code of Practice Authority

ANNUAL REPORT 2008

1958 2008

THE ABPI CODE

FIFTY YEARS OF SELF-REGULATION OF THE PROMOTION OF PRESCRIPTION MEDICINES

The Prescription Medicines Code of Practice Authority (PMCPA) was established on 1 January 1993 by The Association of the British Pharmaceutical Industry (ABPI) to be responsible for all matters relating to the Code of Practice for the Pharmaceutical Industry.

The PMCPA operates independently of the ABPI, has its own staff and reports directly to the ABPI Board of Management. The PMCPA operates impartially between complainants and respondents and between members of the ABPI and companies which are not members of the ABPI.

Contents

"I am delighted to contribute to the Annual Report for 2008 of the Prescription Medicines Code of Practice Authority."

Foreword

I am delighted to contribute to the Annual Report for 2008 of the Prescription Medicines Code of Practice Authority.

I was very pleased to participate in the debate arranged to celebrate the 50th anniversary of the ABPI Code. It was an excellent opportunity to note the achievements of the first 50 years of the Code as well as discussing current concerns and what could be done to enhance further the effectiveness of self-regulation.

The number of complaints to the PMCPA in 2008 was 112 – slightly less than in 2007 when 127 complaints were received. The number of cases (103) was also less than those considered in 2007 (122), as was the number of individual allegations considered in 2008 (280) compared with 2007

(295). Fewer matters were appealed in 2008 (32) than in 2007 (52). The number of matters successfully appealed in 2008 was 9 which was a decrease on the 12 issues successfully appealed in 2007. Of the 32 decisions appealed, 28% were successfully appealed and 72% were unsuccessfully appealed. The proportion of the Code of Practice Panel's rulings successfully appealed decreased to 3% (9/280) in 2008 compared with 4% (12/295) in 2007. The parties accepted without appeal 89% of the Panel's rulings compared with 82% in 2007. The statistics support the claim that the Panel reaches the correct decision in the overwhelming majority of cases. I should stress that the Appeal Board has no hesitation in overturning the Panel's rulings where appropriate.

One of the strengths of the current procedure is that cases are resolved relatively speedily. That is as it should be; justice delayed is justice denied. The average time taken to complete consideration of a case which was the subject of appeal was less in 2008 (17 weeks) than in 2007 (18.6 weeks). Every effort is made to complete consideration of cases as quickly as possible and publish the outcomes. Transparency and openness are key requirements to maintain confidence. The detail given in the published case reports serves the industry well and demonstrates that the system operates without fear or favour.

The Appeal Board required a number of audits and follow-up audits. The Appeal Board also reported a company to the ABPI Board of Management and the ABPI Board suspended that company from membership of the ABPI with readmittance conditional upon a satisfactory audit. The company was readmitted to membership in 2009.

Each case is considered entirely on its own merits. The Authority is not an investigatory body as such. There is essentially an adversarial process in which the evidence to be taken into account comes from the complainant and the respondent company. Anonymous complaints are accepted but I would encourage complainants to give their identity, or at least a means of contact, so that they can participate fully in the process including appealing no breach rulings where there is reason to do so. The names of individuals complaining from outside the pharmaceutical industry are kept confidential. Occasionally it may be necessary for a company to know the identity of a complainant in order to investigate properly, for example, a complaint about what a representative has said to a health professional. Even in these instances the name of the complainant is only disclosed with permission.

Members and co-opted members of the Appeal Board take their responsibilities extremely seriously and devote a significant amount of time to preparing for and attending meetings. I admire their diligence and commitment. I am grateful for their support and contributions.

William Harbage QC
Chairman, Code of Practice Appeal Board

Director's Report

The year was again an extremely busy one, not just in dealing with complaints. A new ABPI Code came into effect on 1 July 2008. The new Code reflected comments made by a number of companies and organisations as well as ensuring that the requirements of the revised European Federation of Pharmaceutical Industries and Associations' (EFPIA) Code, the EFPIA Code on the Promotion of Prescription-Only Medicines to, and Interactions with, Healthcare Professionals, and the new EFPIA Code of Practice on Relationships between the Pharmaceutical Industry and Patient Organisations, were added to the ABPI Code.

The ABPI Code reached its 50th anniversary on 2 October 2008 and much of the focus of the year was on the anniversary. It was an opportunity to look to the future as well as acknowledge the successes of self regulation. The theme of the year was 'The ABPI Code – Still Nifty at 50?' A debate chaired by John Humphrys was an enjoyable evening held at the Royal College of Physicians when a distinguished panel responded to questions and challenges from an invited audience. My thanks to all those who participated. The response from the debate showed that this was a useful way to raise issues and look to the future. Some of the issues raised will be considered for the next version of the Code.

Code Awareness Week 2008 was an opportunity to promote the Code to as many health professionals and others that work with the industry as possible. Visits to companies to run 'Code Busters!' sessions were greatly enjoyed with a quiz leading to serious competitiveness in demonstrating knowledge of the Code and its operation. A history of the first 50 years was produced and is available on the website (www.pmcpa.org.uk).

The main focus of the PMCPA is of course the administration of the complaints procedure. The number of complaints from pharmaceutical companies increased (33 out of 112 in 2008 and 28 out of 127 in 2007) whereas the number from health professionals decreased (44 in 2008 and 57 in 2007). The PMCPA usually receives more complaints from health professionals than from companies. This was still so in 2008.

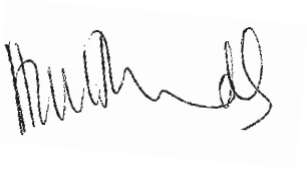
Complaints nominally attributed to the Director decreased (6 in 2008 compared to 13 in 2007).

A slightly larger percentage of complaints were ruled in breach in 2008 (67%) compared with 2007 (61%). If this is looked at on the basis of individual matters, 52% (134/280) were ruled in breach in 2008 compared to 48% in 2007 (143/295).

Details of the Panel's and Appeal Board's rulings are given elsewhere. The Panel has a good record with 97% (271/280) of its rulings in 2008 being accepted by the parties or upheld on appeal; the figure in 2007 was 96% (283/295). Since the Panel was established in 1993 this figure has ranged from 92% to 97% (mean 95%, mode 96%). The time taken to complete cases settled at Panel level decreased in 2008 to 7.2 weeks compared to 7.9 weeks in 2007. The Panel has worked hard in this area as it is extremely aware of the need to deal with cases as quickly and efficiently as possible. Some cases however require additional information before the Panel can reach a conclusion.

The implementation of the 2008 Code reinforced the industry's commitment to, and support of, self regulation. Successful self regulation depends on transparency and meaningful sanctions. The swifter publication of detailed reports on completed cases and the disclosure of brief details about ongoing cases are important factors and continue to be remarked upon and widely used.

The PMCPA has been able to carry out its functions successfully, independently of the ABPI. I would like to thank the staff of the PMCPA for all their hard work throughout this golden anniversary year. The team has a difficult role which it carries out professionally. The PMCPA intends to continue to build on the successes of the first 50 years of self regulation.



Heather Simmonds
Director, PMCPA

Complaints

Complaints in 2008

One hundred and twelve complaints were received in 2008 compared with one hundred and twenty seven in 2007. There were 103 cases for the PMCPA to deal with. The number of individual allegations to be considered within these cases, at 280, was less than the corresponding figure for 2007 which was 295.

The largest number of complaints in 2008 came from health professionals.

Time to deal with complaints

There was a decrease in the overall time taken to deal with complaints. The figure for 2008 was 8.6 weeks compared to 2007 at 10 weeks. There was a decrease in the time taken to complete cases finalised at Panel level from 7.9 weeks in 2007 to 7.2 weeks in 2008. The majority of cases complete at the Panel level. The time taken to complete cases that went to appeal at 17 weeks was less in 2008 than in 2007 (18.6 weeks).

Reports to the Code of Practice Appeal Board from the Panel

Three formal reports were made by the Code of Practice Panel to the Code of Practice Appeal Board in relation to four complaints received in 2008.

One report concerned a scheme related to the prescription of a medicine. The Panel ruled a breach of the Code. The Panel reported the respondent company to the Appeal Board and required the company concerned to suspend the scheme pending the final outcome of the case. The Appeal Board overturned the Panel's ruling following an appeal from the respondent company. It also decided to take no further action in relation to the report from the Panel.

The second report concerned two cases which related to similar matters. These being the inappropriate supply of a prescription only medicine to a bogus health professional and the funding of a new private clinic. The Appeal Board was extremely concerned, particularly with reference to the company's disregard for patient care. The Panel ruled breaches of the Code. The Appeal Board upheld the Panel's rulings, publicly reprimanded the company and reported it to the ABPI Board of Management. The Appeal Board also required an audit and following that audit a further audit was required in 2008. In 2009 the Appeal Board required another audit to be carried out later that year.

The third report concerned a company's provision of vouchers for high street stores to young patients as an incentive to use their medicine. The Panel ruled breaches of the Code and reported the company to the Appeal Board. The Appeal Board was extremely concerned about the arrangements. It noted that the company was currently suspended from membership of the ABPI and undergoing a series of audits. It decided that in the circumstances no further action was required in relation to possible further sanctions.

Report to the Code of Practice Appeal Board from the Authority

This report concerned the failure of a non member company that had previously agreed to comply with the Code and accept the jurisdiction of the PMCPA to provide the requisite undertaking and assurance in relation to a ruling of a breach of the Code. The Appeal Board had upheld the Panel's ruling. The requisite undertaking and assurance was received just before the Appeal Board considered the report. The Appeal Board noted that the company had stopped the activity in question and as the material in breach had not been used no action was taken at this stage. The Appeal Board expected the company to comply with the Constitution and Procedure in future as otherwise it could not remain on the list of non member companies that complied with the Code.

Report to the ABPI Board of Management from the Appeal Board

A report was made by the Code of Practice Appeal Board to the ABPI Board of Management in relation to two complaints made in 2008. In July 2008 the company was suspended from membership of the ABPI for a minimum of 6 months. The ABPI Board required sight of the two further audits required by the Appeal Board in 2008. The company was readmitted to membership of the ABPI in February 2009 and required to undergo another audit late in 2009.

Audits by the PMCPA

Two complaints about the same company received in 2008 resulted in an audit of that company's procedures and a further audit.

These audits were required by the Code of Practice Appeal Board. This company was already undergoing a series of audits.

Two re-audits were carried out in 2008. Both were in relation to complaints received in 2006. These re-audits were required by the Appeal Board.

The ABPI Board of Management required sight of the report of one of the re-audits.

Four audits and re-audits were carried out in 2008 in total.

ABPI members and non members

Compliance with the Code is obligatory for members of the ABPI and, in addition, about fifty non member companies have voluntarily agreed to comply with the Code and to accept the jurisdiction of the PMCPA. Nearly every relevant company is thus covered.

Complaints involving non member companies are dealt with on the same basis as those involving members.

If a complaint is received about a company which is neither a member of the ABPI nor one that has previously agreed to comply with the Code and accept the jurisdiction of the PMCPA, in the first instance the company is encouraged to agree to comply with the Code and respond to the complaint. Many companies in this situation do just that. It is extremely rare for a company when approached to decline to respond to a complaint. In such circumstances, and if it was a matter covered by UK law, the complainant would be advised to take the matter up with the Medicines and Healthcare products Regulatory Agency (MHRA) which administers UK law in this area. One company declined to agree to comply with the ABPI Code and the five complainants were advised to contact the MHRA about the matter. The MHRA fully supports the Code. It encourages companies to comply with it and send senior management to attend PMCPA training seminars.

The Code of Practice 2008 and its operation

Following agreement on the two European Federation of Pharmaceutical Industries and Associations' (EFPIA) Codes, the EFPIA Code on the Promotion of Prescription-Only Medicines to, and Interactions with, Healthcare Professionals (an update of the 2006 EFPIA Code) and the EFPIA Code of Practice on Relationships between the Pharmaceutical Industry and Patient Organisations (a new Code) in October 2007, work started on proposals to amend the ABPI Code to implement the EFPIA changes. It was also an opportunity to make other amendments both to the Code and to the PMCPA Constitution and Procedure.

Comments and suggestions for changes from anyone were invited via the PMCPA website and other communication channels. The proposals were agreed by ABPI member companies at the ABPI Annual General Meeting on 30 April 2008.

The new ABPI Code came into operation on 1 July 2008 with a transition period until 31 October 2008 for the majority of the provisions and a longer transition period for two specific provisions.

Many of the changes ensure even greater transparency by requiring companies to:

- Make publicly available a short description of their support for patient organisations for both financial and significant indirect support.
- Ensure that sponsorship declarations accurately reflect the nature of the involvement.
- Disclose details of ongoing clinical trials.
- Have contracts with health professionals and others employed as consultants; companies are strongly encouraged to require consultants to declare these as an interest.
- Seriously consider making publicly available information about donations and grants to institutions etc that support healthcare and research.

Other changes include:

- Increased awareness of the need to report adverse drug reactions (ADRs).
- More guidance about meetings and hospitality.
- Additional limitations on the supply of samples.
- The publication of interim case reports when publication of the final report is delayed because an audit is required.
- Advertisements of the outcome of certain cases will now appear in the nursing media as well as in medical and pharmaceutical journals.

Advice and training on the Code

Informal advice on the Code

Many requests for informal guidance and advice on the operation of the Code were received in 2008 from various sources including pharmaceutical companies, health professionals, public relations agencies and patients. A number of enquiries were also received from newspapers, radio and television about the Code and the complaints made under it.

All published advice is searchable in the 'Latest advice on the Code' section of the PMCPA website (www.pmcpa.org.uk).

Anyone can call the PMCPA for informal advice on the Code on 020 7747 8880.

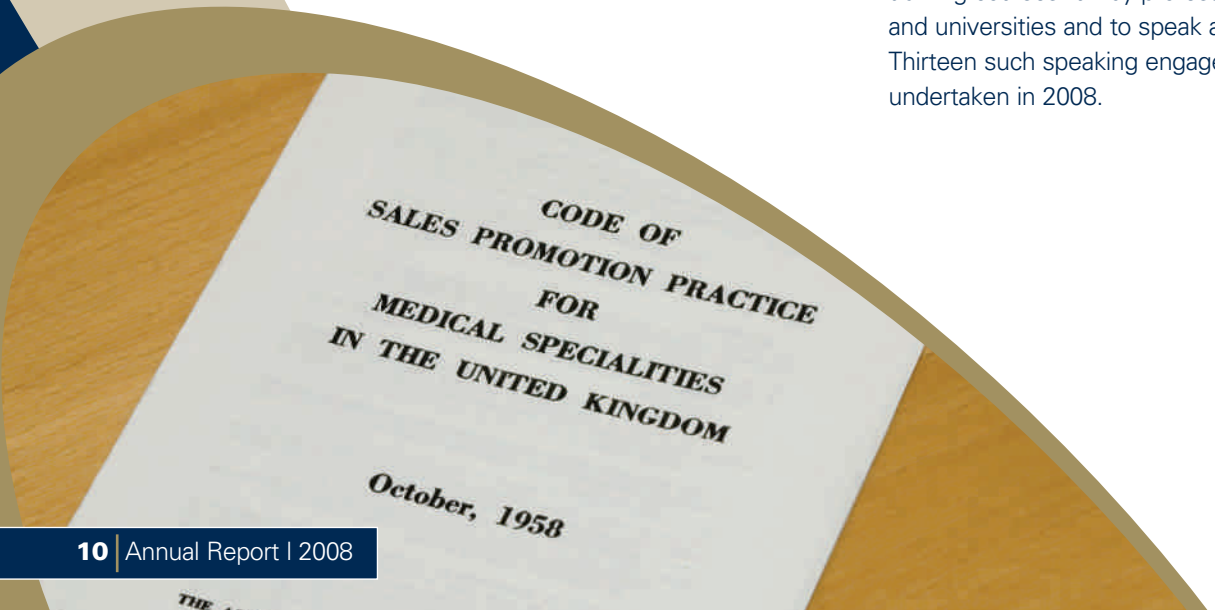
Training on the Code

Seminars designed to explain the requirements of the Code are held by the PMCPA in central London on a regular basis. These seminars are open to all. Six such seminars were held in 2008. Places can be booked via the PMCPA website (www.pmcpa.org.uk) using the online booking system. One of the key elements in the seminars is the syndicate work which is highly valued by delegates. The PMCPA thanks all those who act as syndicate leaders.

In addition, over 30 presentations on the Code were made for individual companies and other organisations, such as public relations companies and advertising agencies. These included 'Code Busters!' sessions.

The PMCPA also ran two meetings specifically for patient organisations and others to highlight relevant changes in the 2008 Code.

The PMCPA is regularly invited to lecture on training courses run by professional organisations and universities and to speak at conferences. Thirteen such speaking engagements were undertaken in 2008.



50th anniversary of the Code

Early in 2008, the PMCPA launched 'The ABPI Code: Still nifty at fifty?' campaign to mark the 50th anniversary of the ABPI Code. The campaign targeted the pharmaceutical industry, MPs, health professionals, patient organisations and PR and marketing professionals.

As part of this, a 'Question Time' style debate chaired by John Humphrys and entitled 'The ABPI Code: Still nifty at fifty?' took place on the evening of 2 October at the Royal College of Physicians, London. The debate examined what impact the ABPI Code has had on relationships between the industry and health professionals, how these interactions had changed over the past 50 years and what the future might hold.

The panel consisted of:

- **Chris Brinsmead** (President of the ABPI)
- **William Harbage QC** (Chairman of the Code of Practice Appeal Board)
- **Andrew Jack** (Journalist, The Financial Times)
- **Dr June Raine** (Director of Post-Licensing, MHRA)
- **Dr Des Spence** (GP and regular contributor to the BMJ)

The audience, of approximately 200, was made up of key industry personnel, health professionals, patient representatives, the media, political and other relevant stakeholders.

Topics covered during the evening included:

- Whether publicity was the most powerful sanction for Code violations.
- Whether it was appropriate for joint working to take place between the industry and the NHS
- The future of industry support for medical education.
- What information industry should be able to provide to patients.

An audio recording and transcript of the debate can be found in the 50th anniversary section of the PMCPA website along with more details about the anniversary of the Code.

Some milestones from the past 50 years

2 October 1958
The first edition of the Code of Practice took effect called the Code of Sales Promotion Practice for Medical Specialities in the United Kingdom. It was only two pages long!

14 October 1958
The first complaint was received under the Code.

April 1959
Agreement was reached at the ABPI's AGM that that the existence of the Code should be made public – more than six months after it was first introduced!

1967
The ABPI appointed an independent legally qualified Chairman, Sir Joseph Molony QC. Until that time the Committee that ruled upon complaints had always been chaired by industry executives. Company names and products were also named for the first time in Committee papers.

1968
The Medicines Act provided the power to make regulations controlling the promotion of prescription medicines.

1979
Brief case reports were published as printed booklets for the first time.

31 March 1992
The EC Directive on the advertising of medicinal products for human use was adopted. It was implemented in the UK on 1 January 1993 by an updated Code and by updated UK Regulations in 1994.

1993
The Prescription Medicines Code of Practice Authority (PMCPA) was established to administer the Code at arm's length from the ABPI and detailed case reports began to be published quarterly in the Code of Practice Review. An independent pharmacist and an independent member from an organisation providing information on medicines were added to the Appeal Board.

2004
Case reports were published on the PMCPA website for the first time.

2005
The Health Select Committee Inquiry into 'The Influence of the Pharmaceutical Industry' took place.

1 January 2006
A revised Code was introduced with many areas significantly strengthened.

25 April 2006
The first Code Awareness Day took place when more than 8000 sales representatives from 50 pharmaceutical companies across the UK talked to health professionals about the Code. This was part of an award winning awareness campaign, 'It Takes Two to Tango', run in 2006 by the ABPI and PMCPA.

2 October 2008
The ABPI Code is 50 years old.

Communicating the Code

The campaign to inform health professionals and others about the Code continued in 2008 with efforts being made to ensure that a wider audience is aware of the Code and how it works.

Code Awareness Week

Code Awareness Week 2008 took place from 29 September – 3 October to coincide with the 50th anniversary of the Code on 2 October.

The feedback from the Code Awareness Days held in 2006 and 2007 was that companies wanted more flexibility with arranging events and activities to promote the high standards required by the Code.

During Code Awareness Week, employees from more than 40 companies across the industry talked to doctors, nurses, pharmacists and other stakeholders about how the industry can work ethically with the NHS in accordance with the Code.

Code Awareness Week is part of an ongoing campaign to increase understanding of the ethical standards that the industry must meet when dealing with health professionals and others. The aim of the week was to help ensure that as many people as possible know about the Code and its provisions.

During the week health professionals were offered copies of 'The ABPI Code and Healthcare Professionals' leaflet and the 'Quick Guide to the Code for Health Professionals'. In addition, industry representatives distributed copies of the 50th anniversary leaflet. Copies of all of these documents are available at www.pmcpa.org.uk.

The PMCPA also conducted a targeted media campaign around Code Awareness Week 2008. The story was generally covered alongside the debate in the trade press.

In addition an e-alert about the Code was sent to 53,000 clinicians in the week starting 22 September and a second one, about the 50th anniversary, was sent on 2 October. Approximately 48,000 clinicians viewed these emails and initial figures suggest that about 7% clicked through to the PMCPA website with many others 'bookmarking' the email for future reference. Online advertisements also ran on the BMJ, HSJ, The Pharmaceutical Journal and Nursing Times websites from Monday, 22 September to Friday, 3 October.

A leaflet entitled 'The ABPI Code and Politicians' was sent to MPs and other political stakeholders in advance of the week.

In response to a survey participating companies gave very positive feedback. Code Awareness Week was seen as an effective way of communicating the industry's commitment to high ethical standards and the messages were received favourably by stakeholders.

Code Busters!

During Code Awareness Week (and throughout the final quarter of 2008), PMCPA staff ran 'Code Busters!' sessions at pharmaceutical companies. These sessions involved a presentation of the history of the Code and the benefits of self regulation and a team quiz about the Code as well as offering attendees the opportunity to ask questions during a 'myth-busting' surgery session.

Joint working with the NHS and other organisations

During 2008 the PMCPA contributed to an ABPI group which looked at providing guidance about joint working between pharmaceutical companies and the NHS and other organisations. The guidance was published in 2009. It refers to matters covered by the Code as well as to matters not covered by the Code. The ABPI guidance followed publication of best practice guidance by the Department of Health and an interactive toolkit 'moving beyond sponsorship'. The prime purpose of joint working is to benefit patient care.

Physicians and the Pharmaceutical Industry – Royal College of Physicians' Working Party

In 2008 the PMCPA submitted written evidence to the Royal College of Physicians' Working Party. The report 'Innovating for Health – Patients, physicians, the pharmaceutical industry and the NHS' was published in February 2009. The PMCPA will be looking carefully at its recommendations.

Advertisements in the medical, pharmaceutical and nursing press

In accordance with the Constitution and Procedure, the PMCPA advertises brief details of all cases where companies are ruled in breach of Clause 2 of the Code, are required to issue a corrective statement or are the subject of a public reprimand. These advertisements both act as a sanction and highlight what constitutes a breach of the Code.

Four advertisements were placed in the BMJ and The Pharmaceutical Journal in 2008. One advertisement was placed in the Nursing Standard as required by the 2008 Constitution and Procedure. The advertisements are also published on the PMCPA website.

Code of Practice Review

Detailed reports of all completed cases are published in the Code of Practice Review on a quarterly basis. The Review is available from the PMCPA's website and individuals can sign up to be alerted when a new Review is added to the site. Case reports from all complaints received from 1 January 2006 onwards are also available to download individually from the website.

The Review also carries comment on matters of current interest for the benefit of companies and others.

A selection of some of the PMCPA's press releases in 2008

Consultation on the proposed changes to the Code and its operation *18/02/08*
An updated set of the proposed changes have now been sent to chief executives of all ABPI member companies and those non member companies that have agreed to comply with the Code for response by Friday, 14 March 2008. Other stakeholders, such as the MHRA, BMA, RPSGB and RCN have also been sent the latest changes.

The ABPI Code: Still nifty at fifty? *07/04/08*
'The ABPI Code: Still nifty at fifty?' campaign is launched today to mark the 50th anniversary of the ABPI Code later this year. The campaign will run throughout 2008 and will target the pharmaceutical industry, MPs, health professionals, patient organisations and PR and marketing professionals.

ABPI Code introduces new requirements for working with health professionals and patient groups *08/05/08*
More detailed requirements for pharmaceutical companies' relationships with patient groups and health professionals will be included in the revised ABPI Code of Practice which comes into effect on July 1.

Complaints from health professionals continue to exceed those from pharmaceutical companies *09/07/08*
Complaints about the promotion of prescription medicines continue to come from health professionals according to new figures from the Prescription Medicines Code of Practice Authority (PMCPA). Fifty-seven complaints out of a total of 127 were received from health professionals in 2007 compared to just 28 from pharmaceutical companies.

Industry joins together to promote ethical working with the NHS in the 50th year of the ABPI Code *26/09/08*
Employees from across the pharmaceutical industry in the UK will unite during Code Awareness Week – 29 September- 3 October 2008 – to talk to doctors, nurses, pharmacists and other stakeholders about how the industry can work ethically with the NHS in accordance with the Association of the British Pharmaceutical Industry (ABPI) Code of Practice for the Pharmaceutical Industry.

European and International Codes

European Federation of Pharmaceutical Industries and Associations

In 2008 the European Federation of Pharmaceutical Industries and Associations' (EFPIA) Code of Practice on the Promotion of Prescription-Only Medicines to, and Interactions with, Healthcare Professionals and the EFPIA Code of Practice on Relationships between the Pharmaceutical Industry and Patient Organisations were required to be implemented by no later than 1 July. The Director of the PMCPA was a member of the EFPIA group that worked on the EFPIA Codes and was involved in a training day with regard to the new EFPIA Code on relationships with patient organisations.

International Federation of Pharmaceutical Manufacturers and Associations

The Director of the PMCPA was appointed as a member of an ad hoc group to adjudicate on complaints covered by the IFPMA Code complaints procedure which operates only in relation to countries that do not have local arrangements, be that by self regulation or external regulation. In 2008 this group had a number of complaints to consider – the first under the new arrangements.

The IFPMA Code Compliance Network (CCN) continued its work in 2008. Members include national associations and member companies of the IFPMA. It is an opportunity to share best practice. The Director of the PMCPA is a member of the CCN.

As part of the CCN the Director of the PMCPA and others were invited to present at a World Health Organisation (WHO) consultation on the role of the private sector in promoting good governance. The meeting was part of the WHO Good Governance for Medicines Programme.

EU Directive

A proposal for a Directive of the European Parliament and of the Council amending, as regards information to the general public on medicinal products subject to medical prescription, Directive 2001/83/EC on the Community Code relating to medicinal products for human use, was published on 10 December 2008.

The Directive includes proposals for the provision of information about prescription only medicines to the public. The ABPI Code in the UK and European law prohibits the advertising of prescription only medicines to the public. The provision of information is allowed provided the requirements of the Code are followed. It is important to the UK that changes in European law do not make the UK more restrictive than the current position.

The Code of Practice Panel

The Code of Practice Panel consists of the Director, Secretary and Deputy Secretary of the PMCPA. The Panel considers all complaints made under the Code with the benefit of independent medical and other such expert advice as appropriate.

The Panel met 73 times in 2008 (compared with 69 times in 2007). As its members are full-time staff, the Panel can meet at short notice when required.

Heather Simmonds is the Director of the PMCPA.

Heather chairs the Code of Practice Panel and is responsible for the overall running of the organisation. Heather also works with the IFPMA and EFPIA in relation to their codes of practice.

Heather has a degree in pharmacology and joined the ABPI in 1984. She has worked full time on the Code of Practice since 1989 and has been Director of the PMCPA since 1997.

Etta Logan is the Secretary of the PMCPA.

Etta is a solicitor and joined the PMCPA in 1997 from private practice in London where she specialised in medical negligence and professional indemnity litigation.

Jane Landles is the Deputy Secretary of the PMCPA.

Jane is a pharmacist and spent the early part of her career in hospital pharmacy. Jane then spent 10 years in the pharmaceutical industry, first as a medical information officer, later moving into the area of promotional affairs and was ultimately a nominated signatory. She joined in 1996.

The Code of Practice Appeal Board

A complainant whose complaint has been rejected or a company ruled to be in breach of the Code may appeal the Panel's ruling to the Code of Practice Appeal Board. In serious cases a company may be required by the Panel to suspend the material or activity at issue pending the outcome of an appeal.

The Appeal Board has an independent chairman and eight other independent members. There are also twelve senior executives from pharmaceutical companies on the Appeal Board. In addition to its role in relation to appeals, the Appeal Board receives reports on all cases considered by the Panel and oversees the work of the PMCPA.

The Appeal Board met 9 times in 2008 the same number as in 2007 and considered appeals in 15 cases in 2008 (compared with 24 cases in 2007).

Membership and Attendance During 2008

Chairman

Mr William Harbage QC (9/9)

Independent Members

Mrs Mary Baker MBE (Representing patients' interests) (8/9)

Professor Steve Chapman (Member from an independent body involved in providing information on medicines) (8/9)

Professor Richard Hobbs (University Academic/General Practitioner) (2/9)

Professor Peter Hutton (Hospital Consultant) (8/9)

Mrs Aileen Palanisamy (Nurse Prescriber) (9/9)

Mr Andrew Reid (Lay Member) (7/9)

Mrs Linda Stone OBE (Pharmacist) (7/9)

Dr Michael Wilson (General Practitioner) (8/9)

Industry Members

Mr Gary Bowler (Director of Sales, Servier Laboratories Ltd) (until February 2008) (1/1)

Dr Susan Bews (Previously Medical Director, Astellas Pharma Ltd) (8/9)

Dr Stuart Dollow (Vice President - Medical, GlaxoSmithKline UK Limited) (until March 2008) (1/2)

Dr Mike Geraint (Medical Director, Norgine Limited) (9/9)

Mr Stephen Miles (Respiratory Business Unit Director, Trinity-Chiesi Pharmaceuticals Ltd) (from April 2008) (5/6)

Ms Helen Roberts (Legal Director and Company Secretary, Sanofi-Aventis) (until February 2008) (UK & Ireland Legal Director, Novartis Pharmaceuticals UK Limited) (from March 2008) (5/9)

Dr Rhiannon Rowsell (Director of Corporate Responsibility, AstraZeneca PLC) (7/9)

Mr John Russell (Sales Director, Eli Lilly and Company Limited) (1/9)

Dr Mark Sampson (Senior Director, Medical Affairs - Europe, Gilead Sciences Europe Limited) (2/9)

Mr John Simmons (Head of Marketing, A Menarini Pharma UK SRL) (from April until July 2008) (2/2)

Mr Philip Watts (Customer Marketing Director, Pfizer Limited) (4/9)

Co-opted Members

The Chairman can co-opt members for meetings of the Appeal Board so as to enable a quorum to be achieved. During 2008, the following were each co-opted for at least one meeting:

Dr David Farrow (Independent General Practitioner)

Mr Grant Geddes (Managing Director, Otsuka Pharmaceuticals UK Limited)

Dr Gillian Shepherd (Medical Director, Merck Serono)

Statistics on complaints

The complaints procedure

Complaints are ruled upon in the first instance by the Code of Practice Panel which is made up of the Director, Secretary and Deputy Secretary of the PMCPA, with the benefit of independent medical and other such expert advice as appropriate.

A complainant whose complaint has been rejected or a company ruled to be in breach of the Code may appeal the Panel's ruling to the Code of Practice Appeal Board. In serious cases a company may be required by the Panel to suspend the material or activity at issue pending the outcome of an appeal.

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.

The PMCPA publishes reports of all completed cases in its quarterly Code of Practice Review and on its website at www.pmcpa.org.uk. The website also carries brief details of complaints which are under consideration or, if resolved, details of those cases not yet published.

Additional sanctions can also be imposed. These include:

- an audit by the PMCPA of a company's procedures to comply with the Code; the principal elements of an audit are an examination of documentation and the questioning of appropriate members of staff; following an audit, a company can be required to submit its promotional material to the PMCPA for pre-vetting for a specified period;
- requiring the company to take steps to recover material from those to whom it has been given;
- the publication of a corrective statement;
- a public reprimand; or
- suspension or expulsion from membership of the ABPI for ABPI members. In the case of a non member company, the MHRA can be advised that responsibility for that company under the Code can no longer be accepted.

The PMCPA advertises in the medical, pharmaceutical and nursing press brief details of all cases where companies are ruled in breach of Clause 2 of the Code, are required to issue a corrective statement or are the subject of a public reprimand.

Complaints

Complaints received by the PMCPA

	2008	2007	2006
Complaints received	112	127	134
No prima facie case established*	7	13	15
Not within the scope of the Code	3	-	-
Covered by a previous case	-	1	-
Complaints withdrawn	-	-	1
Company declined to accept the PMCPA's jurisdiction before proceedings commenced	5**	1	1
No prior inter-company negotiation	1	1	-
Complaints considered	96	111	117
Cases arising from these complaints	103	122	128
Individual matters considered	280	295	272

* The power of the Director to decide that no prima facie case exists was removed from the Constitution and Procedure in the 2008 edition of the Code which came into operation on 1 July 2008.

** All involved the same company.

Some complaints involve a number of allegations. Some complaints give rise to more than one case as they involve more than one company. Each individual issue alleged to be in breach is one 'matter'.

Outcomes of complaints considered

	2008	2007	2006
Cases where a breach found	69	74	73
Cases where no breach found	34	48	55
Number of matters in these cases:			
- in breach	146	143	112
- no breach	134	152	160
Cases where the Code of Practice Panel required suspension of materials	1	2	-
Breaches of undertaking ruled	-	4	3
Breaches of Clause 2 ruled	7	10	11
Reports to the Code of Practice Appeal Board	4*	2	6
Reports to the ABPI Board of Management	1*	-	1

*One report related to two similar complaints

Sources of complaints

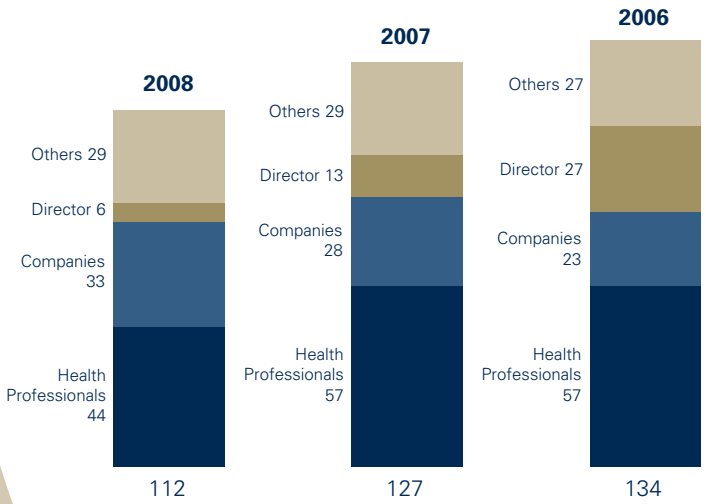
	2008	2007	2006
Health professionals			
General practitioners	16	18	22
Hospital doctors	4	6	2
Other doctors	3	1	5
Pharmacists	14	17	7
Medical/pharmaceutical advisers	1	4	18
Nurses	4	2	1
Managers	2	9	2
	44	**57**	**57**
Pharmaceutical companies			
ABPI members	27	26	21
Non members	6	2	2
	33	**28**	**23**
PMCPA Director			
Arising from media criticism	2	7	13
Arising from other complaints	-	-	4
Alleged breach of undertaking		1	1
Arising from voluntary admissions	4	5	8
Arising from scrutiny	-	-	1
	6	**13**	**27**
Organisations			
Medicines and Healthcare products Regulatory Agency	1	1	2
Myocardial Infarct National Audit Programme		1	-
Consumers International	1	-	-
Lifeblood the Thrombosis Charity	1	-	-
Other organisations	-	-	2
	3	**2**	**4**
Others			
Members of the public	6	6	3
Anonymous	15	15	13
Employees/ex employees	2	2	5
Anonymous employees	3	4	2
	26	**27**	**23**
Total	**112**	**127**	**134**

Appeals to the Code of Practice Appeal Board

	2008	2007	2006
Total number of matters ruled upon by the Code of Practice Panel	280	295	272
Rulings accepted by complainants and respondents involved	248	243	232
Rulings successfully appealed	9	12	15
Rulings unsuccessfully appealed	23	40	25
Panel rulings declared a nullity	-	2*	-
Number of cases appealed	15	25	22
Sources of appeals			
Cases appealed by complainants	3	4	5
Cases appealed by respondents	13	21	19
In one case in 2008 and two cases in 2006, both the complainant and respondent appealed.			
Appeals by complainants			
successful	-	-	1
partly successful	-	1	1
unsuccessful	3	3	3
	3	**4**	**5**
Appeals by respondents			
successful	2	6	7
partly successful	5	3	3
unsuccessful	6	12	9
	13	**21**	**19**
Rulings appealed by complainants			
successful	-	1	3
unsuccessful	3	7	10
	3	**8**	**13**
Rulings appealed by respondents			
successful	9	11	12
unsuccessful	20	33	15
	29	**44**	**27**

* In a case appealed by a respondent one Panel ruling was overturned. Two other Panel rulings were declared a nullity by the Appeal Board which decided that inter-company discussion had been successful and those aspects should not have proceeded. These are not included in the statistics.

Complaints received

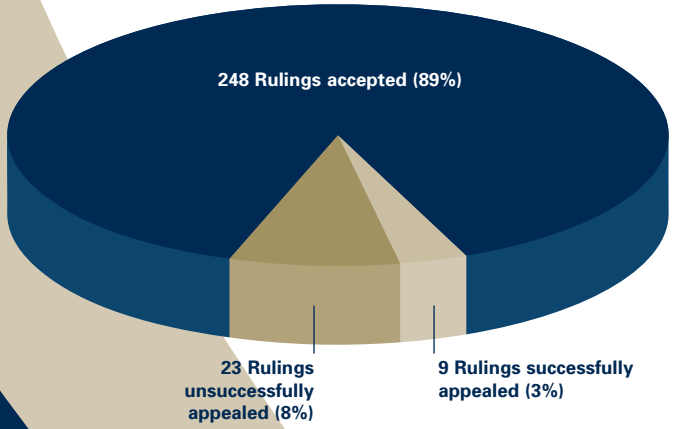


Complaints nominally made by the Director usually result from media criticism of the promotion of prescription medicines. Such criticism is always examined in relation to the Code.

Complaints nominally made by the Director can also arise as a result of:

- the routine scrutiny of advertisements;
- when it is alleged that a company has failed to comply with an earlier undertaking to cease a particular method of promotion; and
- from voluntary admissions.

Code of Practice Panel rulings



In 2008 the Code of Practice Panel made 280 rulings. Of these, 248 (89 per cent) were accepted by the complainants and respondents involved. A further 23 (8 per cent) were the subject of unsuccessful appeals to the Code of Practice Appeal Board. The remaining 9 (3 per cent) were successfully appealed to the Appeal Board.

Average time taken to complete cases (in weeks)

	2008	2007	2006
Cases settled at Code of Practice Panel level	7.2	7.9	9.2
Cases which were the subject of appeal	17	18.6	19
All cases	8.6	10	10.9

Scrutiny

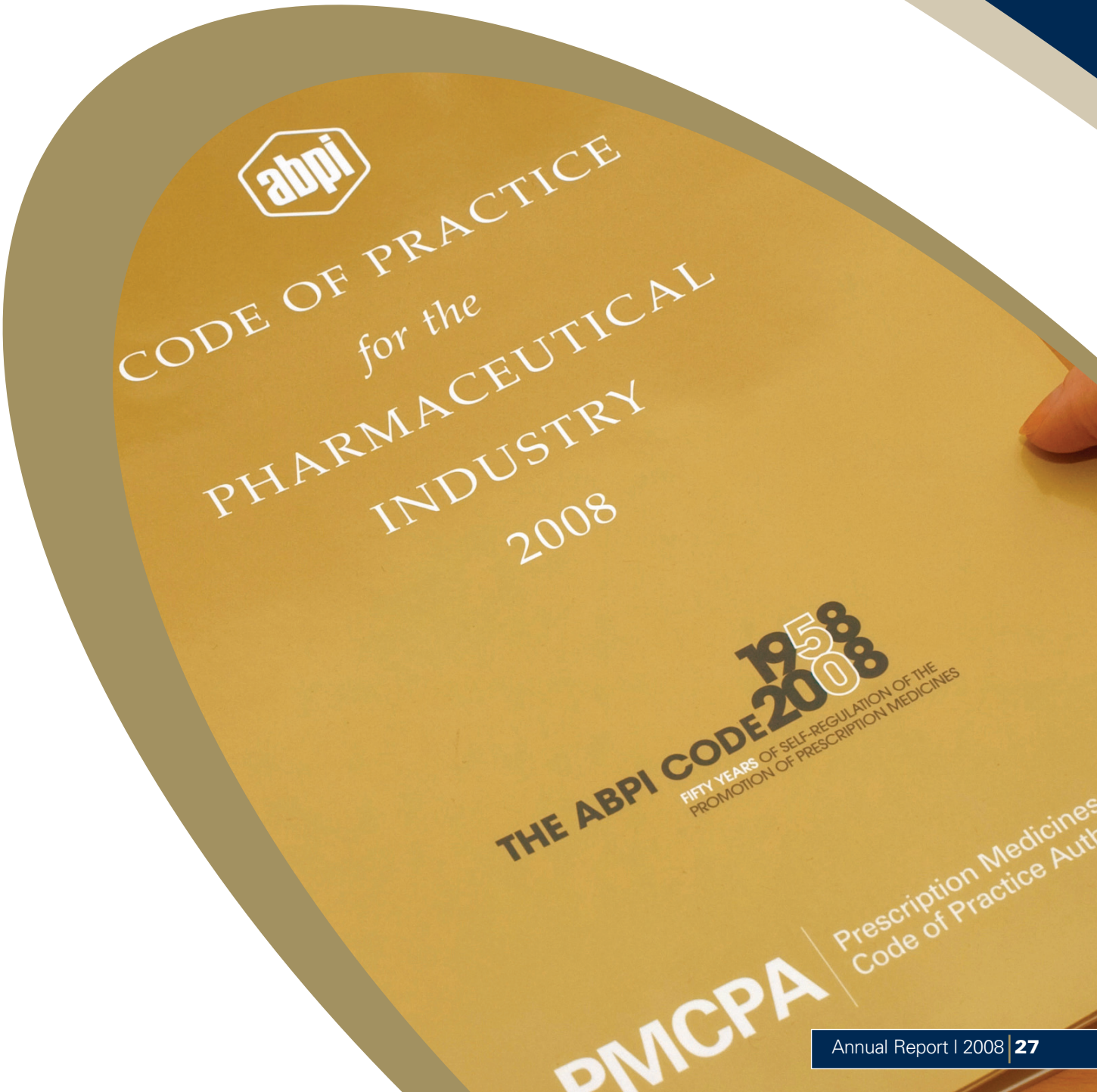
The PMCPA scrutinises a sample of all advertisements issued by pharmaceutical companies in accordance with the provisions of its Constitution and Procedure and takes up with the companies concerned any advertisements potentially in breach of the Code.

In 2008 11 advertisements were taken up as potentially being in breach of the Code. All were satisfactorily resolved with the companies concerned and none were taken up as formal complaints.

Companies ruled in breach of the Code (complaints received in 2008)

* In breach of Clause 2

Abbott Laboratories Limited
Allergan Ltd
AstraZeneca UK Limited
* Bayer Schering Pharma
Boehringer Ingelheim Limited
Bracco UK Ltd
Chemical Developments Ltd
Chugai Pharma UK Ltd
* Eli Lilly and Company Limited
Flynn Pharma Ltd
Galen Ltd
GlaxoSmithKline UK Ltd
Goldshield Pharmaceuticals UK
Grünenthal Ltd
Guerbet Laboratories Ltd
Janssen-Cilag Ltd
Johnson & Johnson Wound Management
Meda Pharmaceuticals Ltd
Merck Sharp & Dohme Limited
Merz Pharma UK Ltd
Novartis Pharmaceuticals UK Limited
Otsuka Pharmaceuticals (UK) Ltd
Pfizer Limited
Procter & Gamble Pharmaceuticals UK Limited
ProStrakan Group plc
Reckitt Benckiser Healthcare
Recordati Pharmaceuticals Ltd
* Roche Products Limited
Sanofi-Aventis
Sanofi Pasteur MSD Ltd
Schering-Plough Ltd
Servier Laboratories Ltd
Special Products Limited
Syner-Med Pharmaceutical Products Ltd
Takeda UK Ltd
* Takeda Pharmaceuticals Europe Limited
Teva UK Limited
Trinity-Chiesi Pharmaceuticals Ltd


abpi
CODE OF PRACTICE
for the
PHARMACEUTICAL
INDUSTRY
2008
THE ABPI CODE
1958
2008
FIFTY YEARS OF SELF-REGULATION OF THE
PROMOTION OF PRESCRIPTION MEDICINES
PMCPA
Prescription Medicines
Code of Practice

Accounts 2008

The PMCPA has been self-financing from the beginning of 1996. In 2008 there was a surplus of £4,319 (£3,088 after tax). The PMCPA currently holds reserves of £286,994.

From 1993 until 1995, the PMCPA was subsidised by the ABPI as its income was insufficient to meet expenses. This subsidy was repaid to the ABPI in 2003.

Annual 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 PMCPA.

The levy is £3,000 to £24,000 depending on the size of the company. Seventy five per cent of the levy due was called up in 2008. The costs of the PMCPA are, however, mainly covered by administrative charges which are payable by companies actually involved in cases.

Administrative charges

Administrative charges are payable by companies (both members and non members of the ABPI) in relation to complaints made under the Code. Companies which are not members of the ABPI do not pay the levy, so the administrative charges for them are consequently higher. No charges whatsoever are payable by complainants from outside the industry.

Charges are paid either by the company found to be in breach of the Code or, where there is no breach of the Code, by the company which made the unfounded allegations. The charges are assessed per matter ruled upon and a number of matters may arise in a particular case.

The charge per matter in 2008 was £2,500 for member companies and £3,500 for non member companies where the decision of the Code of Practice Panel was accepted.

Where the decision of the Panel was unsuccessfully appealed, the charge per matter in 2008 was £10,000 for member companies and £11,000 for non member companies.

Seminars

Additional income is generated by the PMCPA training seminars on the Code. These seminars, designed to explain the requirements of the Code, are held by the PMCPA on a regular basis in London or in-house for companies and others.

	2008	2007	2006
	£	£	£
Levy	494,115	316,093	334,620
Administrative charges	405,938	535,650	341,825
Seminars/meetings	152,216	227,613	194,367
Company audits	10,000	24,000	48,000
Contributions to advertising costs	2,500	5,000	7,500
	£1,064.768	£1,108,356	£926,312
Expenditure	**£1,060,452**	**£839,922**	**£897,741**

Expenditure includes salaries, fees, administration costs and the cost of office accommodation.

More information

If you would like to find out more about the PMCPA or its work, please go to its website at www.pmcpa.org.uk.

Alternatively you can contact the PMCPA at:

Prescription Medicines Code
of Practice Authority
12 Whitehall
London SW1A 2DY

Tel: 020 7747 8880
Fax: 020 7747 8881
Email: info@pmcpa.org.uk

The following publications are available to download from the PMCPA's website or from the PMCPA upon request:

- The ABPI Code of Practice for the Pharmaceutical Industry.
- The quarterly Code of Practice Review – which comments on current issues and reports the outcome of complaints made under the Code.
- The ABPI Code and Healthcare Professionals – a leaflet which focuses on the controls on the promotion of prescription medicines.
- Quick Guide to the Code for Health Professionals.
- Quick Guide to the Code for the Public.
- Quick Guide to the Code for Patient Organisations.
- The ABPI Code and You leaflet – which briefly introduces what the Code is.
- Information leaflets about the PMCPA and the Appeal Procedure.

Reports of completed cases are available from the PMCPA's website which also carries brief details of ongoing cases or, if resolved, cases for which the case report is not yet published.

Complaints about the promotion of medicines should be submitted to:

The Director
Prescription Medicines Code
of Practice Authority
12 Whitehall
London SW1A 2DY

Tel: 020 7747 8880
Fax: 020 7747 8881
Email: complaints@pmcpa.org.uk

Testimonials about the Code in its 50th anniversary year

"Self-regulation, supported more recently by the statutory role of the MHRA, has promoted high standards in medicines advertising over the last 50 years and the ABPI Code continues to develop to meet the challenges of increasing expectations. We welcome the steps industry is taking to promote wider awareness of the Code among health professionals."
Professor Kent Woods, Chief Executive, Medicines and Healthcare products Regulatory Agency

"We are pleased to see the continued evolution and strengthening of the ABPI Code of Practice as it reaches its first half century. There has never been a greater need for everyone involved in healthcare to be able to demonstrate their adherence to high standards of ethical conduct in their professional relationships. We are pleased to work with the ABPI to ensure the Code continues to reflect and develop those high standards as medicine and therapeutics advance."
Dr Bill Beeby, Chairman, Clinical and Prescribing Subcommittee of the General Practitioners' Committee at the British Medical Association

"The RCN warmly welcomes this year's Code Awareness Week and hopes it continues to improve transparency of the ethical standards required of the pharmaceutical industry when interacting with nurses. The RCN is delighted to contribute to this important work and gladly endorses any efforts that will help enhance patient safety as well as the appropriate use and effectiveness of medicines. It is vital that the NHS and the pharmaceutical industry work in partnership to ensure that there are high standards of safety for patients in every part of the health service. The RCN also wishes the Code all the best in this, its 50th anniversary year."
Dr Peter Carter, Chief Executive & General Secretary, Royal College of Nursing

"The ABPI's Code provides clarity to doctors as to what is expected of them in their relationships with industry. The Code compliments our own guidance and taken together, gives doctors and pharmaceutical representatives greater assurance of the ethical principles upon which a good working relationship should be founded. We welcome the Code's 50th anniversary and encourage all doctors to refresh their memory of its principles."
Sir Graeme Catto, President, General Medical Council

"Pharmacists are the experts in medicines and patients and the public turn to them for advice, knowledge and experience they can trust. Pharmacists need to know they can have faith in the pharmaceutical industry - that the medicines they dispense have come from an industry which maintains the highest standards. The Code reassures all healthcare professionals that they can have faith in the industry and that there is open communication."
Steve Churton, President, Royal Pharmaceutical Society of Great Britain

"The NHS Alliance fully supports Code Awareness Week in the fiftieth anniversary year of the ABPI Code. It is essential that the NHS and the pharmaceutical industry work closely together to ensure best care for patients and value for money. Increased awareness of the ABPI Code will help to ensure that these relationships remain ethical and professional."
Michael Sobanja, Chief Executive, NHS Alliance

PMCPA | Prescription Medicines Code of Practice Authority

Prescription Medicines Code of Practice Authority
12 Whitehall London SW1A 2DY
Tel: 020 7747 8880
Fax: 020 7747 8881

www.pmcpa.org.uk