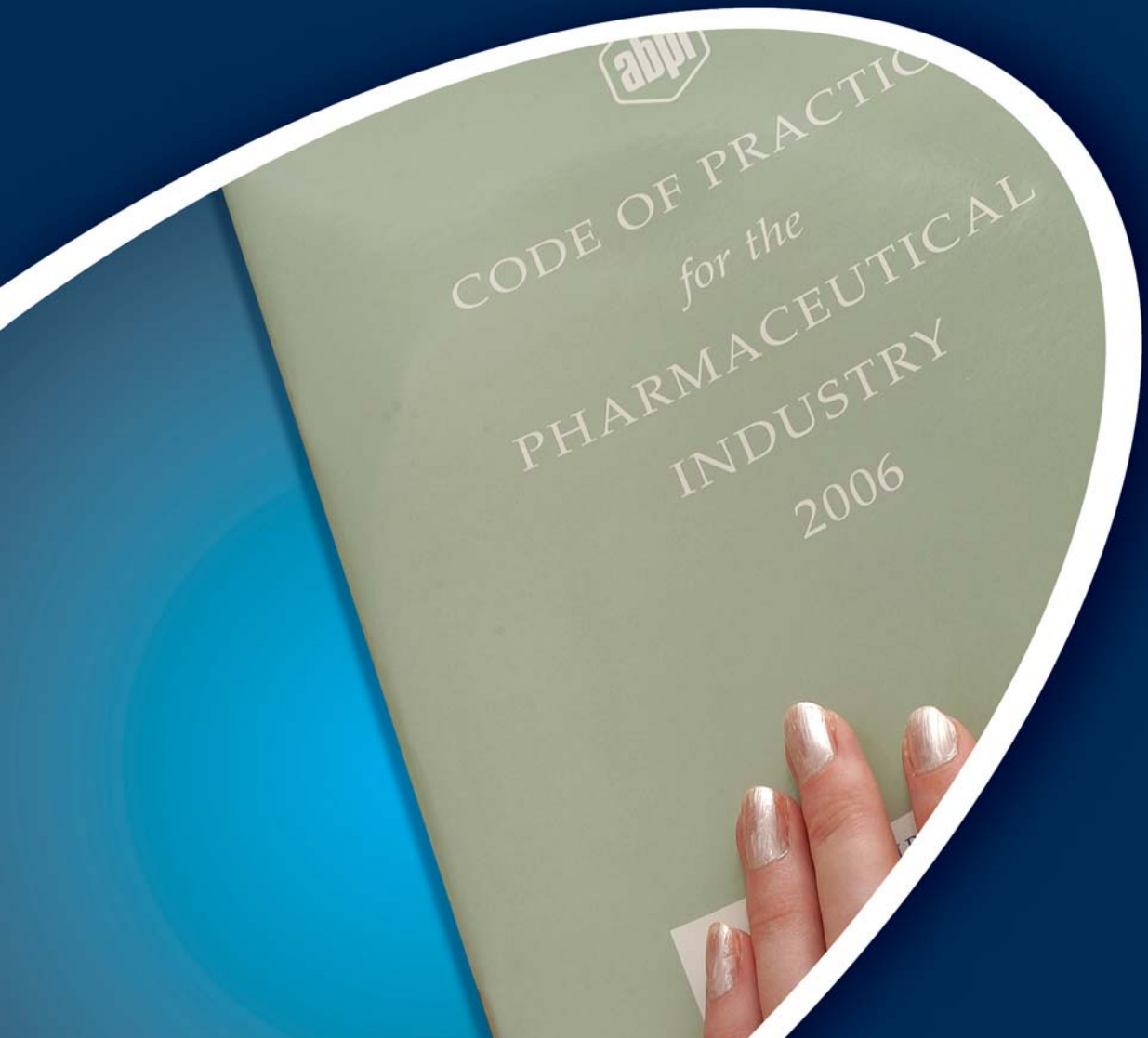
Annual Report | 2007

PMCPA | Prescription Medicines Code of Practice Authority



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 2007 of the Prescription Medicines Code of Practice Authority (PMCPA)."

Foreword

The number of complaints to the PMCPA in 2007 was 127 – slightly less than in 2006 when 134 complaints were received. Although the number of cases (122) was also slightly less than considered in 2006 (128), the number of individual allegations (matters) considered in 2007 at 295 was more than in 2006 (272). More matters were appealed in 2007 (52) than in 2006 (40). The number of matters successfully appealed in 2007 was 12 which was a decrease on the 15 matters successfully appealed in 2006. Of the 52 matters appealed, 23% were successfully appealed and 77% were unsuccessfully appealed. The proportion of the Code of Practice Panel's rulings successfully appealed decreased to 4% (12/295) in 2007 compared with 6% (15/272) in 2006. The parties accepted without appeal 82% of the Panel's rulings compared with 85% in 2006. In one case two Panel rulings were declared a nullity by the Appeal Board which decided that inter-company discussion as required under Paragraph 5.2 of the Constitution and Procedure had been successful and those aspects should not have proceeded. The Appeal Board has no hesitation in overturning the Panel's rulings where appropriate.

The average time taken to complete consideration of a case which was the subject of appeal was slightly less in 2007 (18.6 weeks) than in 2006 (19). 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 some companies were required to have follow-up audits. As a result of increased sanctions available to the Appeal Board from 1 January 2006 it was not necessary to report any company to the ABPI Board of Management. The only sanction available to the ABPI Board not available to the Appeal Board is suspension or expulsion from membership of the ABPI. In the case of a company that is not a member of the ABPI the ABPI Board could decide to remove that company from the list of non members which have agreed to comply with the Code and advise the Medicines and Healthcare products Regulatory Agency that responsibility for that company under the Code cannot continue to be accepted.

The Appeal Board considers each case entirely on its own merits. Members take their responsibilities extremely seriously and devote a significant amount of time to preparing for and attending meetings. The support of the co-opted members is particularly appreciated as they often step in at short notice. I thank them all for their contributions.

William Harbage QC.

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. Being a member of a working party which revised the European Federation of Pharmaceutical Industries and Associations' (EFPIA) Code of Practice on the Promotion of Medicines which led to two new EFPIA Codes took up some time. As did starting work on implementing the EFPIA Codes in a new ABPI Code which will come into effect in 2008.

The ABPI has had a Code for over 49 years and for the last 15 years it has been administered by the PMCPA which was established on 1 January 1993. The current Code of Practice Panel has worked together now for 10 years. The PMCPA has worked hard to ensure that its reputation, and thus that of the industry, is enhanced by the Code and the way it is administered. The Code is a very important factor in maintaining the confidence of external stakeholders, including the Medicines and Healthcare products Regulatory Agency (MHRA). The Code and its operation by the PMCPA is seen in many countries as a gold standard in self regulation. The PMCPA is very proud of its reputation, particularly in relation to external stakeholders.

The main focus of the PMCPA is of course the administration of the complaints procedure. The number of complaints from pharmaceutical companies increased (28 out of 127 in 2007 and 23 out of 134 in 2006), whereas the number from health professionals remained the same (57 in 2007 and 2006). The PMCPA usually receives more complaints from health professionals than from companies.

The 2006 Code requires information about inter-company dialogue at a senior level, or an indication that a request for such was refused, to be provided before an inter-company complaint can be accepted. Inter-company complaints are, however, an important feature of successful self regulation. It should be made very clear in inter-company complaints what has been settled and what has not.

It is interesting to note that there were more anonymous complaints in 2007 than in 2006 including more from employees. This may be due to increased awareness of the Code. Some of the anonymous complainants are contactable and fully involved in the complaints process but others are not. Like every complaint the ruling depends on the evidence provided. The position regarding anonymous complaints is kept under review and although such complaints are not ideal they often concern serious matters. The acceptance of anonymous complaints demonstrates the industry's commitment to effective self regulation.

Complaints nominally attributed to the Director decreased sharply (13 in 2007 compared to 27 in 2006).

A slightly larger percentage of complaints were ruled in breach in 2007 (61%) compared with 2006 (57%).

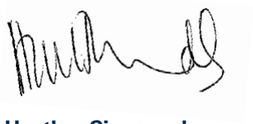
Details of the Panel's and Appeal Board's rulings are given elsewhere. The Panel has a good record with 96% (283/295) of its rulings in 2007 being accepted by the parties or upheld on appeal; the figure in 2006 was 94% (257/272). Since the Panel started work in 1993 this figure has ranged from 92% to 96% (mean 95%, mode 96%). The time taken to complete cases settled at Panel level decreased in 2007 to 7.9 weeks compared to 9.2 weeks in 2006.

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 work on raising the profile and awareness of the Code and its operation continued. The PMCPA was very pleased that the 2006 'It takes Two to Tango campaign' won another award – a real tribute to everyone who worked so hard to raise awareness about the Code. In 2007 the Code Awareness Day activities again concentrated on communicating with health professionals. The PMCPA receives many requests for informal guidance about the Code and the number from health professionals is increasing.

The implementation of the 2006 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 and without interference. I would like to thank the staff of the PMCPA for all their hard work throughout the year. The team has a difficult role which it carries out professionally. The PMCPA intends to continue to build on the successes of 2007, and the last fifteen years, by being seen to be fair, independent and totally without bias.



Heather Simmonds
Director, PMCPA

Complaints

One hundred and twenty seven complaints were received in 2007 compared with one hundred and thirty four in 2006. There were 122 cases for the PMCPA to deal with. The number of individual allegations to be considered within these cases, at 295, was more than the corresponding figure for 2006 which was 272.

The largest number of complaints in 2007 came from health professionals.

Time to deal with complaints
There was a slight decrease in the overall time taken to deal with complaints. The figure for 2007 was 10 weeks compared to 2006 at 10.9 weeks. There was a decrease in the time taken to complete cases finalised at Panel level from 9.2 weeks in 2006 to 7.9 weeks in 2007. The majority of cases complete at the Panel level. The time taken to complete cases that went to appeal at 18.6 weeks was slightly less in 2007 than the 19 weeks in 2006.

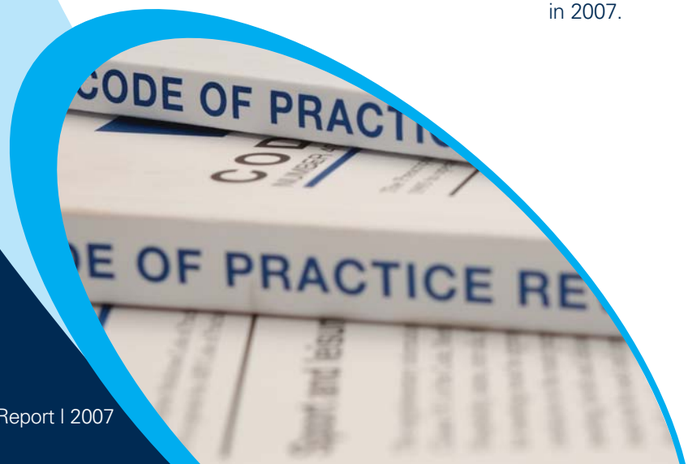
Reports to the Code of Practice Appeal Board
Two formal reports were made by the Code of Practice Panel to the Code of Practice Appeal Board in relation to complaints received in 2007.

One report concerned a paid for insert in a journal and prescribing guidelines. The Panel ruled breaches of the Code and required suspension of the prescribing guidelines pending the final outcome of the case. The journal insert was not in use. This was the first time the Panel had used this sanction which was introduced in 2006. The Panel reported the respondent company to the Appeal Board because it was concerned that it had not fully investigated the complaint when it had first replied to the complainant company and to the Panel. A full investigation had taken place following the Panel's request for additional information. The Appeal Board was extremely concerned and required an audit of the respondent company.

The second report concerned a referral aid for patients to give to their general practitioner. The Panel ruled breaches of the Code and required suspension of the material pending the final outcome of the case. The Panel considered the material undermined the patient/GP relationship. The Appeal Board upheld the Panel's rulings and required the company to take steps to recover the material.

Two reports made in 2006 were considered in 2007 in relation to the linking of medical and educational goods and services to the promotion of a medicine in internal documents. The Appeal Board required an audit of both companies and a re-audit of one of the companies.

Reports to the ABPI Board of Management
No reports were made by the Code of Practice Appeal Board to the ABPI Board of Management in relation to complaints made in 2007.



Audits by the PMCPA
One complaint received in 2007 resulted in an audit of the company's procedures. This audit was required by the Code of Practice Appeal Board. Four audits were carried out in relation to complaints received in 2006. All were required by the Appeal Board. In one case the company was required to undergo a re-audit later in 2007 and further audits in 2008. In another case a company was required to undergo a re-audit in 2008.

A total of four re-audits were carried out in 2007. Three in relation to complaints received in 2006 and one in relation to a complaint received in 2005. Three of these re-audits were required by the Appeal Board and the fourth re-audit was required by the ABPI Board of Management. The ABPI Board also required sight of the report of one of the other re-audits.

Nine audits and re-audits were carried out in 2007 in total.

ABPI members and non members
Compliance with the Code is obligatory for members of the ABPI and, in addition, more than sixty 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) directly. The MHRA fully supports the Code. It encourages companies to comply with it and send senior management to attend PMCPA training seminars.

Revisions to the 2006 Code 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 current 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. At the end of 2007, specific proposals were sent for comment to ABPI member companies and those non member companies that had agreed to comply with the Code. The process continued in 2008 with changes to be agreed at the ABPI Annual General Meeting on 30 April. The new ABPI Code will be operative from 1 July 2008 with a transition period until 31 October 2008.

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 2007 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.

A new section 'Latest advice on the Code' was added to 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. Nine such seminars were held in 2007 and demand for places was high. 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 twenty five presentations on the Code were held for individual companies and other organisations, including public relations companies and advertising agencies.

The PMCPA is regularly invited to lecture on training courses run by professional organisations and universities and to speak at conferences. Ten such speaking engagements were undertaken in 2007.

Communicating the Code

The campaign to inform health professionals and others about the Code continued in 2007 with efforts being made to ensure that a wider audience is aware of the Code and how it works.

Code Awareness Day

Code Awareness Day 2007 took place on 15 May. Fifty-four companies participated – four more than in 2006. On the day companies allocated time for sales representatives and others who have contact with external stakeholders to promote the Code to doctors, pharmacists, nurses and NHS management as part of their regular programme of calls.

Highlights from the day included:

- A targeted media campaign resulted in more than 20 features.
- An NHS Confederation Briefing on the ABPI Code was distributed to all NHS Confederation members.
- The NHS Alliance included 'The ABPI Code and You' leaflet in a mail shot to members.
- The Royal College of Nursing ran a banner on its website about Code Awareness Day throughout May. In addition, it devised a short quiz focusing on the relevance of the Code to nurses which was sent to 800 RCN staff on Code Awareness Day along with information about the day itself.
- Letters were sent to all members of the Health Select Committee and all MPs who signed the early day motion on Code Awareness Day 2006 informing them about activities in 2007.
- Many companies ran in-house events for staff.

Awards

The 2006 Code awareness campaign, 'It Takes Two to Tango', won the 2007 Communiqué award for Best Professional Campaign and the Judges' Special Recognition Award at the 2007 Pharmaceutical Marketing Effectiveness Awards (PMEA). It was also highly commended in the Innovation Award category at the PMEA awards. Code Awareness Day was part of this campaign.

The Communiqué judges said that this was a highly effective awareness-raising campaign that demonstrated the ethics and transparency of the industry and delivered outstanding results. The PMEA judges said it was a truly great campaign that handled a profoundly challenging topic with creativity and great thought. They also praised the use of stakeholder management to make this campaign happen as being phenomenal.

New PMCPA website

The PMCPA launched a redesigned, more user-friendly website in August 2007. Additional features on the site include an electronic alert system which gives instant access to the latest updates and advice on the Code and an online booking system for PMCPA training seminars on the Code.

Anyone can sign up to receive free PMCPA e-alerts at www.pmcpa.org.uk. Subscribers can choose to be alerted when new material such as advice on the Code, information about ongoing or completed cases, Code of Practice Reviews, public reprimands, corrective statements and news and events are added to the site. Subscribers manage their own subscription preferences online. By the end of 2007 more than 300 people had signed up for this service.

In addition, those looking for more in-depth training on the Code can now book online for PMCPA training seminars or arrange tailored in-house training with the PMCPA.

Advertisements in the medical and pharmaceutical 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 2007. 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 at www.pmcpa.org.uk and as individuals can now sign up to be alerted when a new Review is added to the site, less hard copies are being distributed. Case reports for 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 2007

Almost three quarters of doctors now aware of the ABPI Code

01/03/07

Almost three quarters of doctors (73%) are now aware of the Association of the British Pharmaceutical Industry's (ABPI) Code of Practice for the Pharmaceutical Industry compared to just over half (52%) last year. According to new research from the Prescription Medicines Code of Practice Authority (PMCPA), 89% of GPs and 56% of hospital doctors are now aware of the Code compared to just 65% of GPs and 40% of hospital doctors a year ago.

Industry aims to ensure that relations with the NHS remain ethical

09/5/07

More than 8,000 employees from more than 50 pharmaceutical companies across the UK will unite on Code Awareness Day – 15 May 2007 – to talk to doctors, nurses, pharmacists and other stakeholders about the Association of the British Pharmaceutical Industry (ABPI) Code of Practice for the Pharmaceutical Industry.

Code Awareness Campaign wins Communiqué award

13/07/07

The Code awareness campaign, 'It Takes Two to Tango', won the 2007 Communiqué award for Best Professional Campaign in July 2007. Four other campaigns were short listed in the category.

Improved access to advice and training on the ABPI Code

23/11/07

The pharmaceutical industry and others can now have instant access to the latest advice on the Association of the British Pharmaceutical Industry's (ABPI) Code of Practice for the Pharmaceutical Industry due to the launch of a new electronic alert system on the Prescription Medicines Code of Practice Authority's (PMCPA) website.

European and International Codes

European Federation of Pharmaceutical Industries and Associations

In 2007 the European Federation of Pharmaceutical Industries and Associations (EFPIA) Code of Practice on the Promotion of Medicines was updated leading to two new EFPIA Codes. These are the EFPIA Code 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. The Director of the PMCPA was a member of the EFPIA group that worked on the update. The EFPIA Codes have to be implemented by national associations by no later than 1 July 2008. Once the EFPIA Codes were agreed the PMCPA started to implement their requirements by amending the ABPI Code. The new ABPI Code is due to come into operation on 1 July 2008.

International Federation of Pharmaceutical Manufacturers and Associations

The International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) amended its Code of Pharmaceutical Marketing Practices in March 2006 to be implemented by 1 January 2007.

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 2007 there was no work for this group.

The IFPMA established a Code Compliance Network (CCN). Members included 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.

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 69 times in 2007 (compared with 63 times in 2006). 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 2007 (compared with 11 times in 2006) and considered appeals in 24 cases in 2007 (compared with 22 cases in 2006).

Membership and Attendance During 2007

Chairman

Mr William Harbage QC (9/9)

Industry Members

Mr Gary Bowler (Director of Sales, Servier Laboratories Ltd) (from February 2007) (3/9)

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

Dr Stuart Dollow (Vice President - Medical, GlaxoSmithKline UK Limited) (6/8)

Dr Mike Geraint (Medical Director, Norgine Limited) (from June 2007) (4/5)

Ms Helen Roberts (Legal Director and Company Secretary, Sanofi-Aventis) (5/8)

Dr Rhiannon Rowsell (Medical & Regulatory Affairs Director, AstraZeneca UK Limited) (6/9)

Mr John Russell (Sales Director, Eli Lilly and Company Limited) (2/9)

Dr Mark Sampson (Senior Director, Medical Affairs - Europe, Gilead Sciences Europe Limited) (6/9)

Mr Philip Watts (Customer Marketing Director, Pfizer Limited) (0/8)

Independent Members

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

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 (Member who is not a health professional) (5/9)

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

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

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 2007, the following were each co-opted for at least one meeting:

Dr Peter Bowen-Davies (Promotional Affairs Consultant, Pfizer Limited)

Dr David Farrow (Independent General Practitioner)

Dr Mike Geraint (Medical Director, Norgine Limited)

Dr Gillian Shepherd (Medical Director, Merck Serono)

Statistics on complaints

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 and details of those cases resolved but not yet published.

Additional sanctions can also be imposed. These can 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; and/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 and pharmaceutical 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

	2007	2006	2005
Complaints received	127	134	101
No *prima facie* case established	13	15	4
Covered by a previous case	1	-	1
Complaint withdrawn	-	1	1
Company declined to accept the PMCPA's jurisdiction before proceedings commenced	1	1	1
Insufficient information to proceed	-	-	1
No prior inter-company negotiation	1	-	-
Complaints considered	111	117	93
Cases arising from these complaints	122	128	107
Individual matters considered	295	272	275

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

	2007	2006	2005
Cases where a breach found	74	73	86
Cases where no breach found	48	55	21
Number of matters in these cases:			
- in breach	143	112	158
- no breach	152	160	117
Cases where the Code of Practice Panel required suspension of materials	2	-	-
Breaches of undertaking ruled	4	3	4
Breaches of Clause 2 ruled	10	11	17
Reports to the Code of Practice Appeal Board	2	6	3
Reports to the ABPI Board of Management	0	1	4

Sources of complaints

	2007	2006	2005
Health professionals			
General practitioners	18	22	20
Hospital doctors	6	2	6
Other doctors	1	5	2
Pharmacists	17	7	9
Pharmacy technicians	-	-	1
Medical/ pharmaceutical advisers	4	18	14
Nurses	2	1	-
Managers	9	2	-
	57	**57**	**52**
Pharmaceutical companies			
ABPI members	26	21	21
Non members	2	2	7
	28	**23**	**28**
PMCPA Director			
Arising from media criticism	7	13	2
Arising from other complaints	-	4	1
Alleged breach of undertaking	1	1	4
Arising from voluntary admissions	5	8	1
Arising from scrutiny	-	1	-
	13	**27**	**8**
Organisations			
Medicines and Healthcare products Regulatory Agency	1	2	-
Insulin Dependent Trust	-	-	1
Gays against Genocide	-	-	2
Myocardial Infarct National Audit Programme	1	-	-
Other organisations	-	2	-
	2	**4**	**3**
Others			
Members of the public	6	3	1
Anonymous	15	13	6
Employees	2	5	-
Anonymous employees	4	2	3
	27	**23**	**10**
Total	**127**	**134**	**101**

Appeals to the Code of Practice Appeal Board

	2007	2006	2005
Total number of matters ruled upon by the Code of Practice Panel	295	272	275
Rulings accepted by complainants and respondents involved	243	232	243
Number of cases appealed	25	22	17
Rulings successfully appealed	12	15	10
Rulings unsuccessfully appealed	40	25	22
Panel rulings declared a nullity	2*	-	-
Sources of appeals			
Cases appealed by complainants	4	5	4
Cases appealed by respondents	21	19	15

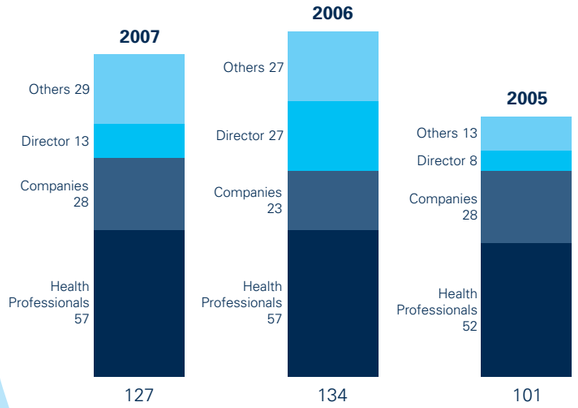
In two cases in 2006 and two cases in 2005, both the complainant and respondent appealed.

Appeals by complainants			
successful	0	1	-
partly successful	1	1	2
unsuccessful	3	3	2
	4	**5**	**4**
Appeals by respondents			
successful	6	7	3
partly successful	3	3	4
unsuccessful	12	9	8
	21	**19**	**15**
Rulings appealed by complainants			
successful	1	3	2
unsuccessful	7	10	4
	8	**13**	**6**
Rulings appealed by respondents			
successful	11	12	8
unsuccessful	33	15	18
	44	**27**	**26**

* 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

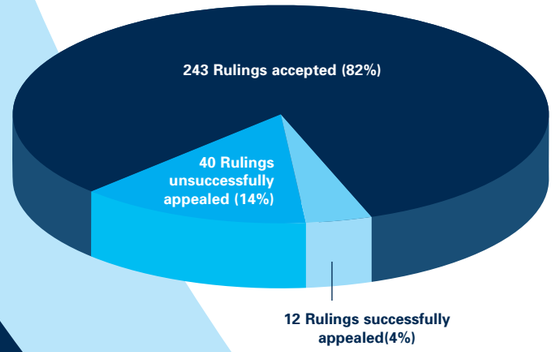


Complaints nominally made by the Director usually result from media criticism of the promotion of prescription medicines. Such criticism is always examined in relation to the Code.

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

- the routine scrutiny of advertisements;
- from the detection of other possible breaches when a complaint is being considered;
- 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 2007 the Code of Practice Panel made 295 rulings. Of these, 243 (82 per cent) were accepted by the complainants and respondents involved. A further 40 (14 per cent) were the subject of unsuccessful appeals to the Code of Practice Appeal Board. The remaining 12 (4 per cent) were successfully appealed to the Appeal Board.

Average time taken to complete cases (in weeks)

	2007	2006	2005
Cases settled at Code of Practice Panel level	7.9	9.2	8.4
Cases which were the subject of appeal	18.6	19	17.5
All cases	10	10.9	9.9

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 2007 four 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 2007)
* in breach of Clause 2 of the Code

Abbott Laboratories Ltd
Alk-Abelló Ltd
Altana Pharma Limited
* AstraZeneca UK Limited
Bayer plc Pharmaceutical Division
Bayer Schering Pharma
Beacon Pharmaceuticals Ltd
Biogen Idec Limited
Boehringer Ingelheim Limited
Bristol-Myers Squibb Pharmaceuticals Ltd
Elan Pharma International Ltd
* Eli Lilly and Company Limited
Galderma (UK) Limited
Genus Pharmaceuticals Ltd
Gilead Sciences Limited
GlaxoSmithKline UK Ltd
Grünenthal Ltd
Janssen-Cilag Ltd
Leo Pharma
Lundbeck Ltd
Merck Serono
Merck Sharp & Dohme Limited
Napp Pharmaceuticals Limited
Novartis Pharmaceuticals UK Limited
Novo Nordisk Limited
* 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
* Takeda UK Ltd
Teva UK Limited
* UCB Pharma Ltd

Companies ruled in breach of the Code (complaints received in 2006)
* in breach of Clause 2 of the Code

Altana Pharma Limited
Amgen Limited
* Apopharma Inc
Astellas Pharma
AstraZeneca UK Limited
* Bayer plc Pharmaceutical Division
Bristol-Myers Squibb Pharmaceuticals Ltd
* Daiichi-Sankyo UK Ltd
Eli Lilly and Company Limited
* GlaxoSmithKline UK Ltd
Ivax Pharmaceuticals UK Ltd
* Janssen-Cilag Ltd
Lundbeck Ltd
Merck Pharmaceuticals
* Merck Sharp & Dohme Limited
Novartis Pharmaceuticals UK Limited
Novartis Consumer Health
* Pfizer Limited
* Procter & Gamble Pharmaceuticals UK Limited
ProStrakan Group plc
Recordati Pharmaceuticals Ltd
Roche Products Limited
* Sanofi-Aventis
Schering Health Care Ltd
Serono Limited
* Servier Laboratories Limited
* Shire Pharmaceuticals Ltd
Swedish Orphan International (UK) Ltd

Accounts 2007

The PMCPA has been self-financing from the beginning of 1996. In 2007 there was a surplus of £118,434 (£83,084 after tax). The PMCPA currently holds reserves of £283,906.

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. It was agreed by the ABPI Board of Management that in 2007 the full levy would be called up and the surplus carried over to 2008 to defray the costs of marking the 50th anniversary of the Code and the publication of the 2008 Code.

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 2007 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 2007 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.

Income

	2007	2006	2005
	£	£	£
Levy	316,093	334,620	327,563
Administrative charges	535,650	341,825	395,250
Seminars/meetings	227,613	194,367	117,908
Company audits	24,000	48,000	32,000
Contributions to advertising costs	5,000	7,500	-
	£1,108,356	£926,312	£872,721
Expenditure	**£989,922**	**£897,741**	**£765,627**

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 our website at www.pmcpa.org.uk.

Alternatively you can contact the PMCPA at:

Prescription Medicines Code of Practice Authority (PMCPA)
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.
- Guidance Notes for Health Professionals: Understanding the ABPI Code of Practice for the Pharmaceutical Industry – a booklet that focuses on the most relevant parts of the Code for health professionals.
- A Quick Guide to the Code for patients and the public – a booklet setting out the most relevant parts of the Code for these audiences.
- The Code and You leaflet – which briefly introduces what the Code is.
- Information leaflets about the PMCPA and the Appeal Procedure.

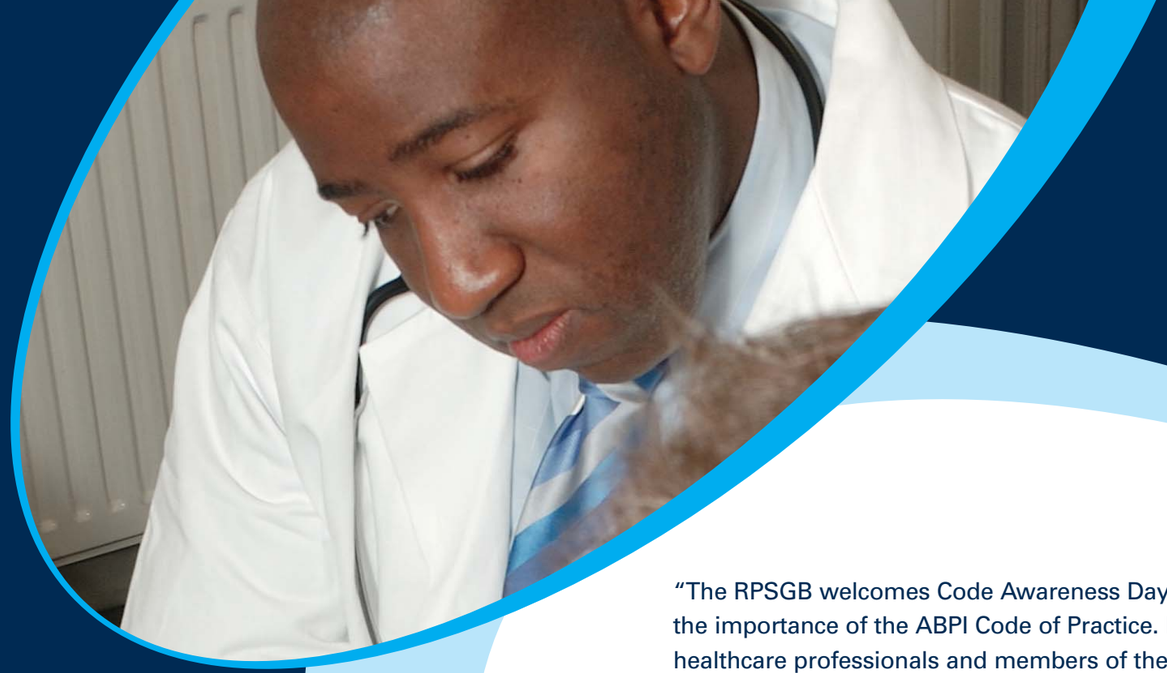
Reports of completed cases are available from the PMCPA's website which also carries brief details of ongoing cases and cases which have been completed but for which the case reports are not yet published.

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

Comments from stakeholders in support of Code Awareness activities in 2007



"Self-regulation of advertising and promotion has an important role to play alongside the statutory regulatory framework, and so we welcome this initiative to raise the profile of the ABPI Code of Practice. Given the recent changes to prescribing, it is particularly pleasing to see that doctors, pharmacists, and nurses are all being targeted with information about the Code."

Professor Kent Woods, Chief Executive of the Medicines and Healthcare products Regulatory Agency

"The ABPI Code illustrates the very high ethical standards which are expected of the industry in all of its dealings with patients, professionals, the Government, and other public bodies. It is continuously refined in the light of experience and developments in medicine, therapeutics, and advertising, and it enables the ABPI to inspire public confidence in such a large and powerful industry."

Dr Peter Fellows, Chairman of the Clinical and Prescribing subcommittee of the General Practitioners Committee at the British Medical Association (BMA)

"The General Medical Council welcomes the clarity the Code provides to doctors. It 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."

General Medical Council (GMC) President, **Sir Graeme Catto**

"The RPSGB welcomes Code Awareness Day and acknowledges the importance of the ABPI Code of Practice. It is important that healthcare professionals and members of the public are aware of the firm regulations and ethical standards governing the pharmaceutical industry, and we would encourage pharmacists to take this opportunity to learn more about the code."

Gerald Alexander, Vice-President of the Royal Pharmaceutical Society of Great Britain (RPSGB)

"The NHS Alliance fully supports Code Awareness Day. It is essential that the NHS and the pharmaceutical industry work closely together to ensure best care for patients and value for money. Awareness of the ABPI Code helps ensure that these relationships remain ethical and professional. The Alliance is distributing information about the code to its members in support of this initiative."

Michael Sobanja, Chief Executive of the NHS Alliance

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