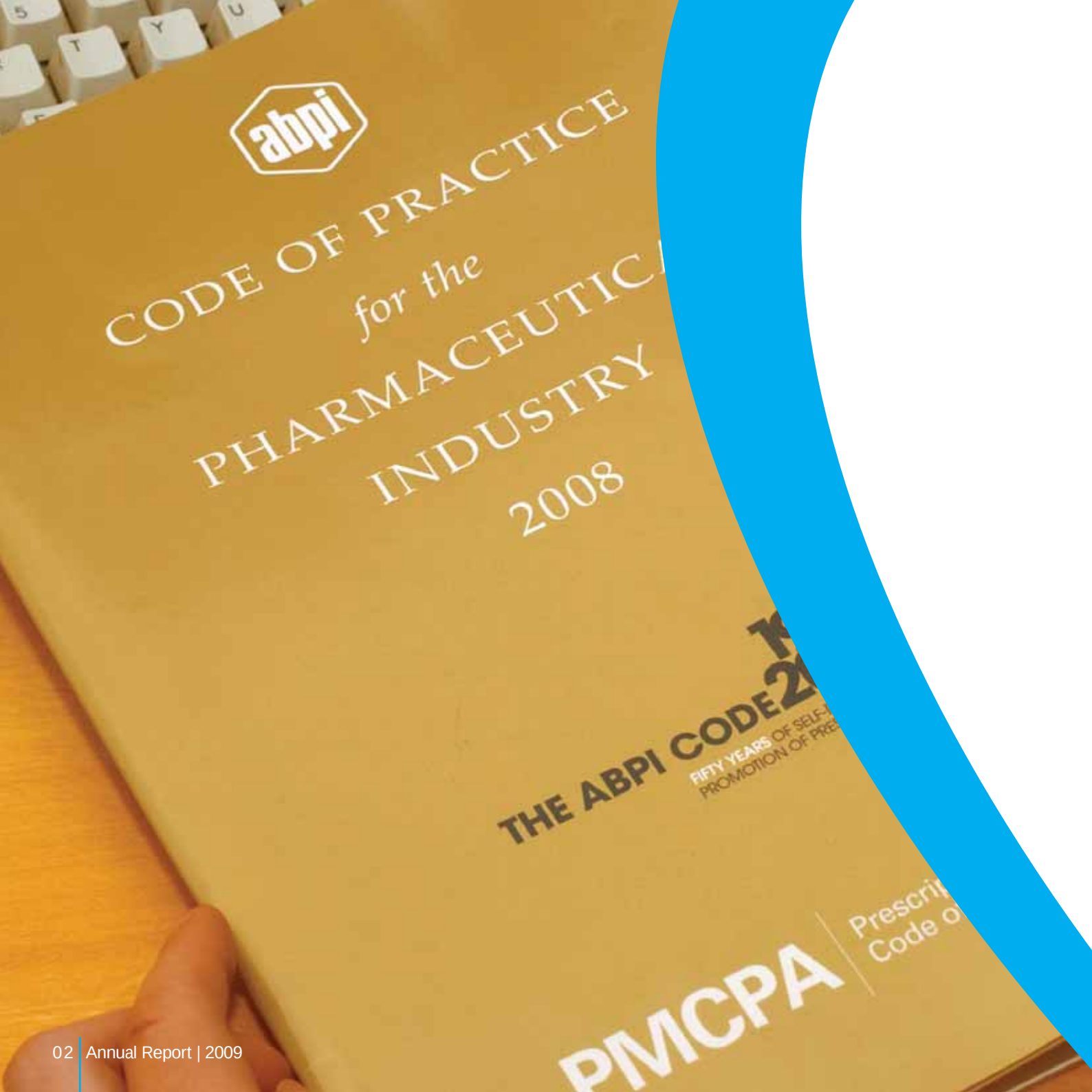
PMCPA | Prescription Medicines Code of Practice Authority

ANNUAL REPORT
2009

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


abpi
CODE OF PRACTICE
for the
PHARMACEUTICAL
INDUSTRY
2008
THE ABPI CODE
FIFTY YEARS OF SELF-
PROMOTION OF PRE
PMCPA
Prescri
Code o

Foreword

I am pleased to contribute to the 2009 Annual Report of the Prescription Medicines Code of Practice Authority.

The number of complaints to the PMCPA in 2009 was 92 – less than in 2008 when 112 complaints were received. The number of cases (85) was also less than those considered in 2008 (103). However there was a sharp increase in the number of individual allegations (matters) considered in 2009 (455) compared with 2008 (280). More matters were appealed in 2009 (67) than in 2008 (32). The number of matters successfully appealed in 2009 was 44 which was a significant increase on the 9 matters successfully appealed in 2008. Of the 67 matters appealed, 66% were successfully appealed and 34% were unsuccessfully appealed. The proportion of the Code of Practice Panel's rulings successfully appealed increased to 10% (44/455) in 2009 compared with 3% (9/280) in 2008. The parties accepted without appeal 85% of the Panel's rulings compared with 89% in 2008. 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 2009 (16.2 weeks) than in 2008 (17 weeks). Every effort is made to complete consideration of cases as quickly as possible and publish the outcomes. The publication of interim case reports – when the company has provided the requisite undertaking and assurance in relation to any breach rulings but is subject to additional sanctions, such as an audit, demonstrates the commitment to transparency as speedily as possible. There were some cases with a large number of allegations arising from inter-company complaints and these took a considerable amount of time for the Panel to consider prior to the consideration of any appeal. Clear, succinct inter-company complaints would help in reducing the time taken to complete cases. Although there was a very slight increase in time taken by the Panel to consider cases, some of these delays were due to the need to wait for further information from health professional complainants.

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 am grateful for their support and contributions.

William Harbage QC.

William Harbage QC
Chairman, Code of Practice Appeal Board

Director's Report

After the celebration of 50 years of the Code in 2008 it was thought that 2009 would be a quieter year. This was not so.

The main focus of the PMCPA is of course the administration of the complaints procedure. The percentage of complaints from pharmaceutical companies decreased, 26% (24 out of 92) in 2009 and 29% (33 out of 112) in 2008 whereas the percentage from health professionals increased, 43% (40 out of 92) in 2009 and 39% (44 out of 112) in 2008. The PMCPA usually receives more complaints from health professionals than from companies. This was still so in 2009.

Complaints nominally attributed to the Director increased (14 in 2009 compared to 6 in 2008). This was mostly due to an increase in the number of voluntary admissions (9 in 2009 compared with 4 in 2008) and allegations of breaches of undertaking (3 in 2009 compared with none in 2008).

A slightly larger percentage of complaints was ruled in breach in 2009 (73%) compared with 2008 (67%). However, if this is looked at on the basis of individual matters, 46% (209/455) were ruled in breach in 2009 compared to 52% (146/280) in 2008.

Details of the Panel's and Appeal Board's rulings are given elsewhere. The Panel has a good record with 90% (411/455) of its rulings in 2009 being accepted by the parties or upheld on appeal; the figure for 2009 is lower than that in 2008 which was 97% (271/280). The time taken to complete cases settled at Panel level increased slightly in 2009 to 7.6 weeks compared to 7.2 weeks in 2008. There was a significant increase in the number of matters considered by the Panel, 455 in 2009 compared with 280 in 2008. The Panel 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. This can sometimes cause delays outside the PMCPA's control.

"…The PMCPA aims to ensure that robust effective self regulation continues to support high quality patient care…"

In addition to dealing with the complaints much time was spent on training and providing informal guidance. These are useful services for those responsible for compliance with the Code.

Given the spotlight on self regulation in 2009, the PMCPA was pleased to see the continuation of strong endorsement from the MHRA for the role of self regulation in the control of medicines advertising. The PMCPA aims to ensure that robust effective self regulation continues to support high quality patient care.

I would like to thank the staff of the PMCPA for all their hard work throughout this year.

Heather Simmonds
Director, PMCPA

Complaints

Complaints in 2009

Ninety-two complaints were received in 2009 compared with one hundred and twelve complaints in 2008. There were 85 cases for the PMCPA to deal with. The number of individual allegations to be considered within these cases, at 455, was a significant increase on the corresponding figure for 2008 which was 280.

The largest number of complaints in 2009 came from health professionals.

Time to deal with complaints

There was an increase in the overall time taken to deal with complaints. The figure for 2009 was 9.1 weeks compared to 2008 at 8.6 weeks. There was a slight increase in the time taken to complete cases finalised at Panel level from 7.2 weeks in 2008 to 7.6 weeks in 2009. The majority of cases complete at the Panel level. The time taken to complete cases that went to appeal at 16.2 weeks was less in 2009 than in 2008 (17 weeks).

Reports to the Code of Practice Appeal Board from the Panel

Five formal reports were made by the Code of Practice Panel to the Code of Practice Appeal Board in relation to five complaints received in 2009.

One report concerned payments related to an audit. The Panel ruled breaches of the Code. The Panel reported the respondent company to the Appeal Board and required the company concerned to suspend the payments pending the final outcome of the case. The Appeal Board decided that the company be publicly reprimanded. It also required an audit and following that a second audit later in 2009.

The second report concerned promotion of a product prior to receipt of its marketing authorization. The Panel ruled breaches of the Code. The Panel reported the respondent company to the Appeal Board which decided to publicly reprimand the company. In addition the Appeal Board required an audit and following that a second audit to be carried out in 2010.

The third report concerned a breach of undertaking with regard to a new advertisement issued following a ruling of a breach of the Code. The Panel ruled breaches of the Code and reported the company to the Appeal Board. The Appeal Board required an audit to be carried out in 2010 following the company's review of its procedures.

The fourth report concerned a breach of undertaking in that the respondent company failed to withdraw material following a breach of the Code and also involved the provision of inaccurate information to the Panel. The Panel ruled breaches of the Code and reported the company to the Appeal Board. The Appeal Board noted that the company was already being audited as a result of another complaint (see second report above) and decided to require an audit in 2010 (this was the same audit as the re-audit in the second report above).

The fifth report concerned a survey which was alleged to be promotional. The Panel ruled breaches of the Code and reported the company to the Appeal Board. Some of the rulings of breaches were overturned by the Appeal Board upon appeal by the respondent company. The Appeal Board decided to take no further action in relation to the report from the Panel.

Report to the ABPI Board of Management from the Appeal Board

No reports were made to the ABPI Board of Management by the Code of Practice Appeal Board in relation to complaints received in 2009.

The report made in 2008 which resulted in a number of audits, including two in 2009, was concluded in early 2010.

Audits by the PMCPA

Four complaints received in 2009 resulted in an audit of the company's procedures. Two of these complaints concerned the same company. Of the four audits required, two were carried out in 2009 and both required reaudits, one of which was carried out in 2009 and the other in 2010. The remaining two audits were carried out in 2010. These audits were all required by the Code of Practice Appeal Board.

One reaudit carried out in 2009 was in relation to the same company and concerned complaints received in 2006 and 2008. This audit was required by both the Appeal Board and the ABPI Board of Management.

Two audits and two re-audits were carried out in 2009 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. In 2009 one company declined to agree to comply with the ABPI Code and the complainant was advised to contact the MHRA about the matter. Another company in responding to a complaint raised as a result of media criticism declined to agree to comply with the Code. The MHRA fully supports the Code. It encourages companies to comply with it and send senior managers to PMCPA training seminars.

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 2009 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

Six seminars designed to explain the requirements of the Code were held by the PMCPA in central London in 2009. These seminars are open to all. Places can be booked via the PMCPA website (www.pmcpa.org.uk). 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 35 training seminars or presentations on the Code were made for individual companies and other organisations, such as 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. Twelve such speaking engagements were undertaken in 2009.

International interest in the Code

The Director was asked by the Czech Republic trade association (AIPI) to present details about the ABPI Code to an audience of pharmaceutical company staff and government officials. The Spanish trade association (Farmaindustria) asked for some training on the ABPI Code.

The Russian trade association (AIPM) asked the Director to visit Moscow for a series of meetings. The arrangements in the UK were presented to a number of audiences including government officials, a member of the State Duma and the Russian equivalent to the MHRA. Presentations were also made to pharmaceutical company staff.

Communicating the Code

The campaign to inform health professionals and others about the Code continued in 2009 with efforts being made to ensure that a wider audience is aware of the Code and how it works.

Joint working with the NHS and other organisations

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

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 act as a sanction and highlight what constitutes a breach of the Code.

Three advertisements were placed in the BMJ, The Pharmaceutical Journal and the Nursing Standard as required by the 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 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.

Proposals to amend the Code and its operation

During 2009 work continued on proposals to amend the Constitution and Procedure for the PMCPA. Discussions were held with various groups including the ABPI Board of Management. Proposals were agreed in 2010 for implementation in 2011.

With regard to the Code itself work started on the regular review which happens every couple of years as well as possible amendments resulting from discussions as part of the ABPI Trust Imperative activities (see below). It is expected that a new Code will be before ABPI members for agreement in 2010 for implementation in 2011.

ABPI Trust Imperative

In 2009 the ABPI Trust Imperative started to discuss possible changes in pharmaceutical company behaviour to enhance the industry's reputation. The ABPI launched a consultation amongst its members and as a result of the consultation taskforces were established to make recommendations. The PMCPA contibuting to this work.

Royal College of Physicians Report

In 2009 a Royal College of Physicians Working Party published a report 'Innovating for Health – Patients, physicians, the pharmaceutical industry and the NHS'. The PMCPA submitted evidence to the Working Party as did the ABPI. The report urged the PMCPA to continue its Code awareness campaigns and to seek stronger collaborations with professional organisations. It also encouraged doctors to report violations of the Code to the PMCPA. The PMCPA is considering the report with regard to possible changes to the Code. The report has also been considered by the ABPI including those working on the ABPI Trust Imperative.

International and European Codes

International Federation of Pharmaceutical Manufacturers and Associations (IFPMA)

The Director of the PMCPA was reappointed as a member of an ad hoc group to adjudicate on complaints covered by the IFPMA Code complaints procedure. This operates only in relation to countries that do not have local arrangements, be that by self regulation or external regulation. In 2009 this group had no complaints to consider.

The IFPMA Code Compliance Network (CCN) continued its work in 2009. The CNN is an opertunity to share best practice and its members include national associations and member companies of the IFPMA. The Director of the PMCPA is a member of the CCN.

European Federation of Pharmaceutical Industries and Associations (EFPIA)

Following the implementation in 2008 of the 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 work continued on possible changes. The Director of the PMCPA is a member of the EFPIA steering group for the EFPIA Codes.

EU Directive

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

In 2009 the PMCPA responded to the Medicines and Healthcare products Regulatory Agency (MHRA) consultation on the proposed Directive. The PMCPA will continue to monitor progress of the proposed Directive. The quality of information provided to the public and not the source of that information should be the prime consideration.

The ABPI Code, 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.

ANNUAL REPORT
THE STATISTICS

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 79 times in 2009 (compared with 73 times in 2008). It 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 ruled in breach of the Code 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.

Members of the Appeal Board are appointed by the ABPI Board of Management for a fixed term which may be renewed. All independent members are appointed in consultation with the Medicines and Healthcare products Regulatory Agency. In addition the medical, pharmacist and nurse prescriber members are appointed in consultation with other relevant bodies.

The Appeal Board met 9 times in 2009 the same number as in 2008 and considered appeals in 15 cases in 2009 (the same as in 2008).

Membership and attendance during 2009

CHAIRMAN

Mr William Harbage QC (9/9)

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) (2/9)
Professor Richard Hobbs (University Academic/General Practitioner) (5/9)
Professor Peter Hutton (Hospital Consultant) (8/9)
Mrs Aileen Palanisamy (Nurse Prescriber) (6/9)
Mr Andrew Reid (Lay Member) (9/9)
Mrs Linda Stone OBE (Pharmacist) (6/9)
Dr Michael Wilson (General Practitioner) (9/9)

INDUSTRY MEMBERS

Dr Susan Bews (Previously Medical Director, Astellas Pharma Ltd) (8/9)
Dr Mike Geraint (Medical Director, Norgine Limited) (5/9)
Mr Stephen Miles (Respiratory Business Unit Director, Trinity-Chiesi Pharmaceuticals Ltd) (until April 2009) (2/2)
Ms Helen Roberts (UK & Ireland Legal Director, Novartis Pharmaceuticals UK Limited) (7/9)
Mr Stuart Rose (Managing Director, Merz Pharma UK Ltd) (from September 2009) (2/3)
Dr Rhiannon Rowsell (Director of Corporate Responsibility, AstraZeneca PLC) (until October 2009) (2/5)
Mr John Russell (Sales Director, Eli Lilly and Company Limited) (3/9)
Dr Mark Sampson (Senior Director, Medical Affairs - Europe, Gilead Sciences Europe Limited) (5/9)
Dr Gillian Shepherd (Director of Heath and Clinical Excellence, Merck Serono) (from July 2009) (3/5)
Mr Philip Watts (Customer Marketing Director, Pfizer Limited) (until March 2009) (1/2)

COOPTED MEMBERS

The Chairman can co-opt members for meetings of the Appeal Board so as to enable a quorum to be achieved. During 2009, 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 (Director of Health and Clinical Excellence, Merck Serono)
Mr Stuart Rose (Managing Director, Merz Pharma UK Ltd)
Dr Guy Yeoman (Medical and Regulatory Affairs Director, AstraZeneca UK Limited)

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/or other 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 ruled in breach of the Code 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 on its website at www.pmcpa.org.uk and in its quarterly Code of Practice Review. 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 received by the PMCPA

	2009	2008	2007
Complaints received	92	112	127
No prima facie case established*	-	7	13
Not within the scope of the Code	4	3	-
Covered by a previous case	-	-	1
Complaints withdrawn	3	-	-
Company declined to accept the PMCPA's jurisdiction before proceedings commenced	2	5 **	1
No prior inter-company negotiation	1	1	1
Complaints considered	82	96	111
Cases arising from these complaints	85	103	122
Individual matters considered	455	280	295

* 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

	2009	2008	2007
Cases where a breach found	62	69	74
Cases where no breach found	23	34	48
Number of matters in these cases:			
- in breach	209	146	143
- no breach	246	134	152
Cases where the Code of Practice Panel required suspension of materials	1	1	2
Breaches of undertaking ruled	7	-	4
Breaches of Clause 2 ruled	13	7	10
Reports to the Code of Practice Appeal Board	5	4 *	2
Reports to the ABPI Board of Management	-	1 *	-

*One report related to two similar complaints

Sources of complaints

	2009	2008	2007
Health professionals			
General practitioners	6	16	18
Hospital doctors	11	4	6
Other doctors	12	3	1
Pharmacists	2	14	17
Medical/pharmaceutical advisers	5	1	4
Nurses	1	4	2
Managers	3	2	9
	40	**44**	**57**
Pharmaceutical companies			
ABPI members	19	27	26
Non members	5	6	2
	24	**33**	**28**
PMCPA Director			
Arising from media criticism	2	2	7
Alleged breach of undertaking	3	-	1
Arising from voluntary admissions	9	4	5
	14	**6**	**13**
Organisations			
Medicines and Healthcare products Regulatory Agency	1	1	1
Myocardial Infarct National Audit Programme	-	-	1
Consumers International	-	1	-
Lifeblood the Thrombosis Charity	-	1	-
	1	**3**	**2**
Others			
Members of the public	2	6	6
Anonymous	6	15	15
Employees/ex employees	3	2	2
Anonymous employees	-	3	4
Anonymous ex employees	1	-	-
Consultant	1	-	-
	13	**26**	**27**
Total	**92**	**112**	**127**

Appeals to the Code of Practice Appeal Board

	2009	2008	2007
Total number of matters ruled upon by the Code of Practice Panel	455	280	295
Rulings accepted by complainants and respondents involved	388	248	243
Rulings successfully appealed	44	9	12
Rulings unsuccessfully appealed	23	23	40
Panel rulings declared a nullity	-	-	2 *
Number of cases appealed	15	15	25

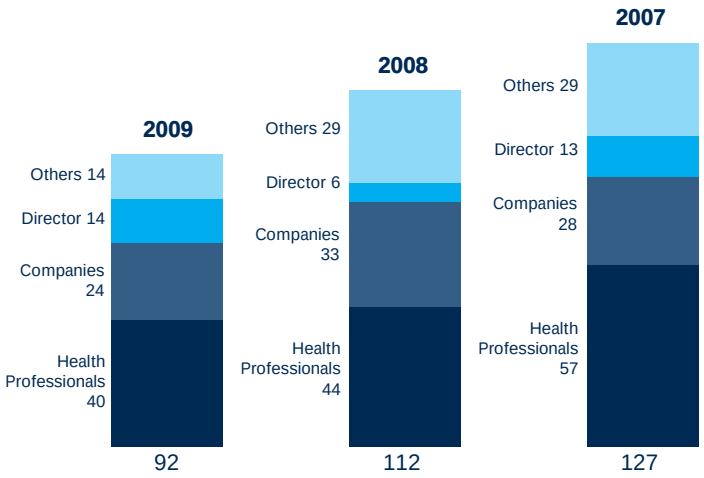
* In a case appealed by a respondent one Panel ruling was overturned. Two other Panel rulings were declared a nullity by the Appeal Board which decided that inter-company discussion had been successful and those aspects should not have proceeded. These are not included in the statistics.

Sources of appeals			
Cases appealed by complainants	6	3	4
Cases appealed by respondents	9	13	21

In one case in 2008 both the complainant and respondent appealed.

Appeals by complainants			
successful	3	-	-
partly successful	-	-	1
unsuccessful	3	3	3
	6	**3**	**4**
Appeals by respondents			
successful	3	2	6
partly successful	4	5	3
unsuccessful	2	6	12
	9	**13**	**21**
Rulings appealed by complainants			
successful	3	-	1
unsuccessful	6	3	7
	9	**3**	**8**
Rulings appealed by respondents			
successful	41	9	11
unsuccessful	17	20	33
	58	**29**	**44**

Complaints received

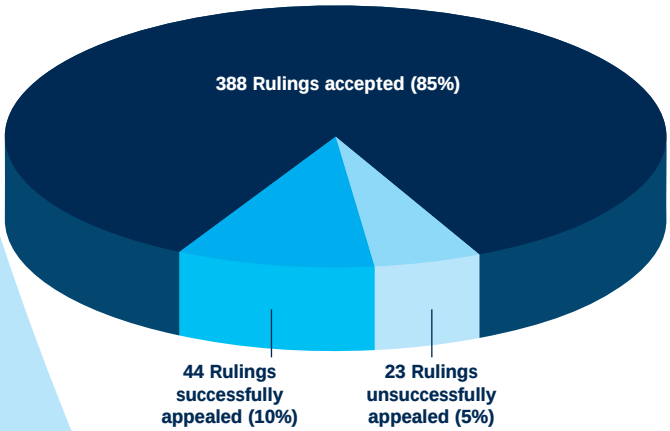


Complaints nominally made by the Director usually result from media criticism of the promotion of prescription medicines. Such criticism is always examined in relation to the Code.

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 2009 the Code of Practice Panel made 455 rulings. Of these, 388 (85 per cent) were accepted by the complainants and respondents involved. A further 23 (5 per cent) were the subject of unsuccessful appeals to the Code of Practice Appeal Board. The remaining 44 (10 per cent) were successfully appealed to the Appeal Board.

Average time taken to complete cases (in weeks)

	2009	2008	2007
Cases settled at Code of Practice Panel level	7.6	7.2	7.9
Cases which were the subject of appeal	16.2	17	18.6
All cases	9.1	8.6	10

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 2009 one advertisement was taken up as potentially being in breach of the Code. It was satisfactorily resolved with the company concerned.

Companies ruled in breach of the Code (complaints received in 2009)

* In breach of Clause 2

Alcon Laboratories (UK) Limited
Allergan Ltd
* Astellas Pharma Ltd
AstraZeneca UK Limited
* Boehringer Ingelheim Limited
Bracco UK Ltd
Cephalon UK Ltd
Chugai Pharma UK Ltd
CV Therapeutics Europe Limited
Daiichi Sankyo UK Ltd
* Eli Lilly and Company Limited
* Ferring Pharmaceuticals Ltd
GlaxoSmithKline UK Ltd
Janssen-Cilag Ltd
Leo Pharma
Lundbeck Ltd
MASTA Ltd
Merck Sharp & Dohme Limited
Merz Pharma UK Ltd
Napp Pharmaceuticals Limited
* Novartis Pharmaceuticals UK Limited
* Novo Nordisk Pharmaceuticals Limited
* Pfizer Limited
* Procter & Gamble Pharmaceuticals UK Limited
* ProStrakan Group plc
Reckitt Benckiser Healthcare (UK) Limited
Roche Products Limited
Sanofi-Aventis
Shire Pharmaceuticals Ltd
* Stiefel Laboratories Limited
* Solvay Healthcare Limited

Accounts 2009

The PMCPA has been self-financing from the beginning of 1996. In 2009 there was a surplus of £81,382 (£64,347 after tax). The PMCPA currently holds reserves of £351,341.

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. Fifty per cent of the levy due was called up in 2009. The costs of the PMCPA are 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 2009 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 2009 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.

	2009	2008	2007
	£	£	£
Levy	187,350	494,115	316,093
Administrative charges	588,000	405,938	535,650
Seminars/meetings	191,581	152,216	227,613
Company audits	31,168	10,000	24,000
Contributions to advertising costs	10,000	2,500	5,000
	£1,008,099	£1,064.768	£1,108,356
Expenditure	**£926,719**	**£1,060,452**	**£839,922**

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.
- 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 the Code.
- 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

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