PMCPA | Prescription Medicines Code of Practice Authority

ANNUAL REPORT 2010

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.

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Foreword

I am pleased to contribute to the 2010 Annual Report of the Prescription Medicines Code of Practice Authority.

The number of complaints to the PMCPA in 2010 was 86 – less than in 2009 when 92 complaints were received. The number of cases (78) was also less than those considered in 2009 (85). There was a sharp decrease in the number of individual allegations (matters) considered in 2010 (241) compared with 2009 (455) but the number in 2009 was usually high. Fewer matters were appealed in 2010 (44) than in 2009 (67). The number of matters successfully appealed in 2010 was 17 which was a significant decrease on the 44 matters successfully appealed in 2009. Of the 44 matters appealed in 2010, 39% were successfully appealed and 61% were unsuccessfully appealed. The proportion of the Code of Practice Panel's rulings successfully appealed decreased in 2010, 7% (17/241) compared with 10% (44/455) in 2009. 11% (27/241) were unsuccessfully appealed in 2010 compared with 5% (23/455) in 2009. The parties accepted without appeal 82% of the Panel's rulings compared with 85% in 2009. 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 more in 2010 (16.9 weeks) than in 2009 (16.2 weeks). Every effort is made to complete consideration of cases as quickly as possible and publish the outcomes. Some of the delay in completing cases was due to deferred appeals. I consider requests for deferment and generally agree only if the material at issue is no longer in use. 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.

The Appeal Board required two companies to undergo audits in relation to complaints received in 2010. One company was required to have a follow up audit and the other company two follow up audits.

I welcome the changes to the Code and to the Constitution and Procedure agreed in 2010. The increased emphasis on transparency is important when the pharmaceutical industry is often perceived as secretive. The publication of detailed case reports together with the advertising of certain breaches of the Code demonstrate the seriousness with which the pharmaceutical industry takes the responsibility of robust self regulation. The Code Awareness campaigns raise knowledge and I hope contribute to dispelling some of the myths about the pharmaceutical industry. It is very important to respond to the perceptions with information about the reality.

There were more anonymous complaints in 2010 than in 2009. This may be due to increasing awareness of the Code. Some of the anonymous complainants were contactable and fully involved in the complaints process. As with every complaint the outcome depends on the evidence provided. Although anonymous complaints are not ideal they often raise serious matters. The acceptance of anonymous complaints (and the receipt of voluntary admissions from companies) are I believe key factors in demonstrating the industry's commitment to robust self regulation.

Finally, I would like to thank the members and co-opted members of the Appeal Board for their support. They take their responsibilities extremely seriously and devote a significant amount of time to preparing for and attending meetings.

William Harbage QC.

William Harbage QC
Chairman, Code of Practice Appeal Board

Director's report

The main focus of the PMCPA is, of course, the administration of the complaints procedure and the PMCPA remained busy in 2010 dealing with complaints. The other main work related to the changes to the Code and to the Constitution and Procedure. These were agreed in 2010 after extensive consultation to come into operation in 2011 except for a limited number of changes which have longer transition periods.

The percentage of complaints from pharmaceutical companies in 2010 remained similar, 27% (23 out of 86) in 2010 and 26% (24 out of 92) in 2009 whereas the percentage from health professionals decreased, 24% (21 out of 86) in 2010 and 43% (40 out of 92) in 2009. The PMCPA usually receives more complaints from health professionals than from companies and so 2010 was an unusual year in that regard. Some of the anonymous complaints were said to be from health professionals but these are listed as anonymous complaints and not included in the figures above.

Complaints nominally attributed to the Director decreased (7 in 2010 compared with 14 in 2009). This was mostly due to a decrease in the number of voluntary admissions (3 in 2010 compared with 9 in 2009).

A slightly smaller percentage of complaints were ruled in breach in 2010, 68% (53/78) compared with 2009, 73% (62/85).

However, if this is looked at on the basis of individual matters, slightly more were ruled in breach in 2010, 48% (116/241) compared with 46% (209/455) in 2009.

Details of the Panel's and Appeal Board's rulings are given elsewhere. The Panel has a good record with 93% (224/241) of its rulings in 2010 being accepted by the parties or upheld on appeal; the figure for 2010 is higher than that in 2009 which was 90% (411/455). The time taken to complete cases settled at Panel level increased slightly in 2010 to 8 weeks compared with 7.6 weeks in 2009. 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.

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

Heather Simmonds
Director, PMCPA

Complaints

Complaints in 2010

Eighty-six complaints were received in 2010 compared with ninety-two in 2009. There were 78 cases for the PMCPA to deal with. The number of individual allegations to be considered within these cases, at 241, was a significant decrease on the corresponding figure for 2009 which was 455. The 2009 figure was unusually high – the 2008 figure was 280.

Time to deal with complaints

There was an increase in the overall time taken to deal with complaints. The figure for 2010 was 10 weeks compared with 2009 at 9.1 weeks. There was a slight increase in the time taken to complete cases finalised at Panel level from 7.6 weeks in 2009 to 8 weeks in 2010. The majority of cases complete at the Panel level. The time taken to complete cases that went to appeal at 16.9 weeks was slightly longer in 2010 than in 2009 (16.2 weeks).

Reports to the Appeal Board from the Panel

Two formal reports were made by the Panel to the Appeal Board in relation to two complaints received in 2010.

The first 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 two further audits to be carried out in 2011.

The second report concerned distribution of a document that had been commissioned and distributed by the company. It was described as being supported by an educational grant. The material showed a lack of understanding of the Code. The Panel ruled a breach of the Code and reported the company to the Appeal Board. The Appeal Board required an audit. Upon receipt of the audit report the Appeal Board was extremely concerned to learn that the material at issue had been more widely distributed than previously indicated by the company. It was vital that responses to the Authority were accurate and gave complete information. The Appeal Board publicly reprimanded the company and required a second audit to be carried out in 2011.

Report to the ABPI Board of Management from the Appeal Board

No reports were made to the ABPI Board of Management by the Appeal Board in relation to complaints received in 2010.

Audits by the PMCPA

The two complaints received in 2010 which were the subject of formal reports to the Appeal Board resulted in an audit of each company's procedures. Both were carried out in 2010 and both required reaudits to be carried out in 2011.

One of the cases required two audits in 2011. These audits were all required by the Code of Practice Appeal Board.

In all two audits and four re-audits were carried out in 2010.

ABPI members and non members

Compliance with the Code is obligatory for members of the ABPI and, in addition, over 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. Most 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 2010 one company declined to agree to comply with the ABPI Code and the complainant was advised to contact the MHRA about the matter. The MHRA fully supports the Code. It encourages companies to comply with it and to 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 2010 from various sources including pharmaceutical companies, health professionals, advertising agencies, 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 2010. 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, eighteen training seminars or presentations on the Code were made for individual companies and other organisations, such as public relations companies and advertising agencies.

The Director presented to the Australian trade association, Medicines Australia, about the ABPI Code and the changes agreed in 2010.

The PMCPA is regularly invited to lecture on training courses run by professional organisations and universities and to speak at conferences. Eleven such speaking engagements were undertaken in 2010.

In addition, four seminars were held for health professionals as part of Code Awareness 2010.

Communicating the Code

The campaign to inform health professionals and others about the Code continued in 2010 with efforts being made to ensure that a wider audience is aware of the Code and how it works.

Code Awareness

In 2010 the PMCPA ran a series of events aimed at engaging NHS employees in discussions about the Code and its impact on how the NHS and the pharmaceutical industry interact. The pilot roadshow was run in January 2010 with the NHS North West Medicines Management Network.

PMCPA staff presented at locations across the North West to a variety of NHS employees giving information about the Code and how the industry and the NHS working together benefits patient care. The pilot also looked at how information about the Code could be most effectively delivered to an NHS audience.

Blackpool, Preston, Bury and Manchester were selected to host events based on levels of interest from NHS staff and suitability of available venues. NHS staff with a focus on medicines management, doctors, pharmacists, nurse prescribers and other managers were invited. Over 70 NHS staff attended the events with hundreds more receiving emails about the ABPI Code and a link to the Quick Guide to the Code for Health Professionals.

Three seminars took place during the roadshow. The seminars included an introduction to the Code, interactive discussion activities, a presentation on joint working and finished with a question and answer session. Two were hosted and targeted within primary care trusts, whilst the other was run without the ownership of a specific trust. The PMCPA also presented in the continuing professional development (CPD) session at a nurse prescriber meeting.

During the seminars, the attendees' views and opinions were sought on what was learnt at the events and how useful it was to their roles and their experiences with pharmaceutical companies.

NHS employees who attended the roadshow said the main benefits were their increase in awareness and confidence to interact with the pharmaceutical industry and learning about the importance to NHS employees of knowing about the Code.

Feedback from the NHS North West Medicines Management Network was positive. The roadshow was well received and encouraged debate about how the NHS and the pharmaceutical industry can work together to deliver better outcomes for patients. With their knowledge of the Code the attendees said they were more confident to begin to work in partnership with pharmaceutical companies.

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.

Four 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 case report 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 2010 work continued on proposals to amend the Code and the Constitution and Procedure for the PMCPA. Discussions were held with various groups including the ABPI Board of Management. Proposals to amend the Code were agreed by ABPI members in November 2010 for implementation on 1 January 2011.

The proposals to amend the Code came from three sources. Firstly work led by the ABPI Trust Board, secondly suggestions from the PMCPA and thirdly the usual regular updating of the Code.

For the first time proposals were made available on the PMCPA website for public comment.

The 2011 Code came into effect on 1 January 2011 but with a transitional period before becoming fully operative on 1 May 2011 with longer transitional provisions for certain changes details of which are given in the supplementary information to the relevant clauses.

As well as the 2011 Code itself, details of the changes including a set of slides and a summary of responses to the consultation are available on the PMCPA website.

The agreed changes include increased transparency in that companies will be required to publish summary details and the results of non interventional studies with which a UK company has had any involvement. Monetary support and/or significant indirect/non financial support of patient organisations with a value of £250 or more per project will have to be publicly disclosed. Changes to employing health professionals and others as consultants were also agreed. This included publishing the total amount of fees paid for certain services starting with 2012 data. Companies will also have to publish the total amount spent, again starting with 2012 data, on sponsoring health professionals to attend meetings organised by third parties, the total number of recipients and the total number of attendances sponsored. There is no need to name individual health professionals.

The 2011 Code prohibits the provision of product branded promotional aids to health professionals. Patient support items are permitted provided they meet the requirements of the Code.

Proposals for amendment of the Constitution and Procedure for the Prescription Medicines Code of Practice Authority were agreed by ABPI members in April 2010.

The changes to the Constitution and Procedure included a requirement that independent members of the Appeal Board be in the majority for the consideration of any case. This change reflects the current position in practice. The changes also introduced the role of the case preparation manager with the responsibility of processing a complaint and where appropriate referring the papers to the Panel for consideration. This was to separate the preparation of the case from its adjudication.

The changes to the Constitution and Procedure came into operation on 1 January 2011, except for certain provisions which became operational in respect of complaints and voluntary admissions received on and after 1 January 2011.

International and European Codes

International Federation of Pharmaceutical Manufacturers and Associations (IFPMA)

The Director of the PMCPA is 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 2010 this group had no complaints to consider.

The IFPMA Code Compliance Network (CCN) continued its work in 2010. 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.

European Federation of Pharmaceutical Industries and Associations (EFPIA)

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

EFPIA Leadership Statement

In June 2010 EFPIA issued a leadership statement reinforcing industry commitment to self regulation and calling upon EFPIA to develop additional guidance around five topics to ensure that the industry continued to uphold the highest standards. These being:

1 The provision of information to the public
2 Medical sales representatives
3 Samples
4 Congresses and meetings
5 Relationships with patient organisations.

The leadership statement called for a review of the EFPIA Code on Relationships between the Pharmaceutical Industry and Patient Organisations. An updated EFPIA Code was agreed in June 2011.

Following discussion in 2010 EFPIA decided to propose amendments to the sample requirements in the EFPIA Code on the Promotion of Prescription Only Medicines to, and interactions with, Health Professionals. An updated EFPIA Code was agreed in June 2011.

Much of the additional guidance requested by the leadership statement is included in the 2011 ABPI Code. The ABPI Code has to reflect the EFPIA codes.

EU and UK legal requirements

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.

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.

In 2010 the Directive was discussed in the European Parliament and many amendments were suggested. These are being considered and an update to the Directive is expected in 2011.

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.

Medicines legislation

In 2010 the Medicines and Healthcare products Regulatory Agency (MHRA) continued work on reviewing and consolidating UK medicines legislation. The Medicines Act 1968 is supported by a number of statutory instruments and in the MHRA's view the current legal provisions are complex and fragmented. The project is intended to bring together the various provisions into a more ordered set and seek opportunities to improve and simplify the provisions. The plan is to have the new legislation in place in 2012.

The Bribery Act 2010

The Bribery Act received Royal Assent on 8 April 2010 and became UK law on 1 July 2011. It introduces a number of new offences in relation to offering, promising or giving a bribe in the private and public sectors and the offence of agreeing or receiving a bribe. It also introduces an offence of bribing a foreign public official and a corporate offence of failing to prevent bribery. The ABPI and PMCPA discussed the Code and other matters with the Serious Fraud Office (SFO). The SFO believes that the Code will help companies in relation to the requirements of the Bribery Act, particularly in relation to hospitality, gifts and inducements to prescribe. Discussions in 2010 included developing a memorandum of understanding between the ABPI, PMCPA and SFO. This was finalised and published in 2011 and is available on the PMCPA website.

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 59 times in 2010 (compared with 79 times in 2009). 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 11 times in 2010 (9 times in 2009) and considered appeals in 20 cases in 2010 (15 cases in 2009).

Membership and attendance during 2010

Chairman

Mr William Harbage QC (11/11)

Independent Members

Mrs Mary Baker MBE (Representing patients' interests) (10/11)

Professor Steve Chapman (Member from an independent body involved in providing information on medicines) (9/11)

Professor Richard Hobbs (University Academic/General Practitioner) (8/11)

Professor Peter Hutton (Hospital Consultant) (9/11)

Mrs Aileen Palanisamy (Nurse Prescriber) (6/11)

Mr Andrew Reid (Lay Member) (10/11)

Mrs Linda Stone OBE (Pharmacist) (10/11)

Dr Michael Wilson (General Practitioner) (11/11)

Industry Members

Dr Susan Bews (Previously Medical Director, Astellas Pharma Ltd) (10/11)

Dr Mike Geraint (Medical Director, Norgine Pharmaceuticals Ltd) (8/11)

Ms Helen Roberts (UK & Ireland Legal Director, Novartis Pharmaceuticals UK Limited) (8/11)

Mr Stuart Rose (Managing Director, Merz Pharma UK Ltd) (3/10)

Dr Mark Sampson (Senior Director, Medical Affairs - Europe, Gilead Sciences Europe Limited) (until May 2010) (3/5)

Dr Gillian Shepherd (Director of Health and Clinical Excellence, Merck Serono) (3/11)

Coopted Members

The Chairman can co-opt members for meetings of the Appeal Board so as to enable a quorum to be achieved. During 2010, the following were each co-opted for at least one meeting:

Dr Peter Barnes (Medical Director, Janssen-Cilag Limited)

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

Dr Alison O'Toole (Director of Oncology, Napp Pharmaceuticals Ltd)

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

Ms Michelle Swift (Director of NHS & Regulatory Affairs, Takeda UK Ltd)

Dr Guy Yeoman (Medical Director, AstraZeneca UK Limited)

Dr Pim Kon (Medical Director, GlaxoSmithKline UK Limited)

Dr Berkeley Phillips (Medical Director, Pfizer 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
- 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

	2010	2009	2008
Complaints received	86	92	112
No *prima facie* case established*	-	-	7
Not within the scope of the Code	2	4	3
Covered by a previous case	1	-	-
Complaints withdrawn	-	3	-
Company declined to accept the PMCPA's jurisdiction before proceedings commenced	2	2	5**
No prior inter-company dialogue	-	1	1
Inter-company dialogue successful	3	-	-
Complaints considered	78	82	96
Cases arising from these complaints	78	85	103
Individual matters considered	241	455	280

* 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

	2010	2009	2008
Cases where a breach found	53	62	69
Cases where no breach found	25	23	34
Number of matters in these cases:			
- in breach	116	209	146
- no breach	125	246	134
Cases where the Code of Practice Panel required suspension of materials	-	1	1
Breaches of undertaking ruled	3	7	-
Breaches of Clause 2 ruled	12	13	7
Reports to the Code of Practice Appeal Board	2	5	4*
Reports to the ABPI Board of Management	-	-	1*

*One report related to two similar complaints

Sources of complaints

	2010	2009	2008
Health professionals			
General practitioners	5	6	16
Hospital doctors	5	11	4
Other doctors	5	12	3
Pharmacists	4	2	14
Medical/pharmaceutical advisers	2	5	1
Nurses	-	1	4
Managers	-	3	2
	21	**40**	**44**
Pharmaceutical companies			
ABPI members	11	19	27
Non members	12	5	6
	23	**24**	**33**
PMCPA Director			
Arising from media criticism	2	2	2
Alleged breach of undertaking	2	3	-
Arising from voluntary admissions	3	9	4
	7	**14**	**6**
Organisations			
Medicines and Healthcare products Regulatory Agency	1	1	1
Consumers International	-	-	1
Lifeblood the Thrombosis Charity	-	-	1
Esprit	1	-	-
	2	**1**	**3**
Others			
Members of the public	4	2	6
Anonymous	18*	6	15
Employees/ex employees	6	3	2
Anonymous employees	2	-	3
Anonymous ex employees	2	1	-
Consultant	-	1	-
Journalist	1	-	-
	33	**13**	**26**
Total	**86**	**92**	**112**

*Four of these were from anonymous health professionals

Appeals to the Code of Practice Appeal Board

	2010	2009	2008
Total number of matters ruled upon by the Code of Practice Panel	241	455	280
Rulings accepted by complainants and respondents involved	197	388	248
Rulings successfully appealed	17	44	9
Rulings unsuccessfully appealed	27	23	23
Number of cases appealed	20	15	15

Sources of appeals

Cases appealed by complainants	6	6	3
Cases appealed by respondents	14	9	13

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

Appeals by complainants

successful	2	3	-
partly successful	1	-	-
unsuccessful	3	3	3
	6	**6**	**3**

Appeals by respondents

successful	3	3	2
partly successful	5	4	5
unsuccessful	6	2	6
	14	**9**	**13**

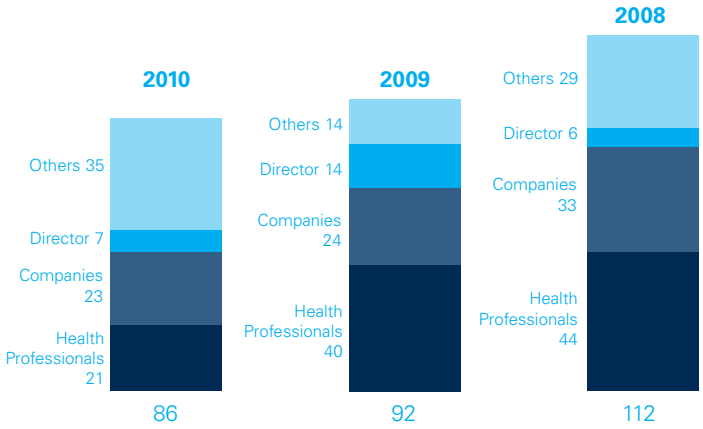
Rulings appealed by complainants

successful	6	3	-
unsuccessful	9	6	3
	15	**9**	**3**

Rulings appealed by respondents

successful	11	41	9
unsuccessful	18	17	20
	29	**58**	**29**

Complaints received

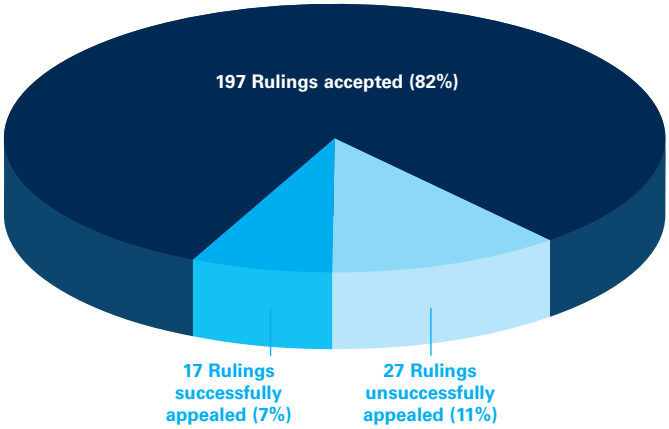


Complaints nominally made by the Director usually result from media criticism of the promotion of prescription medicines. Such criticism is always examined in relation to the Code.

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
- from voluntary admissions.

Code of Practice Panel rulings



In 2010 the Code of Practice Panel made 241 rulings. Of these, 197 (82 per cent) were accepted by the complainants and respondents involved. A further 27 (11 per cent) were the subject of unsuccessful appeals to the Code of Practice Appeal Board. The remaining 17 (7 per cent) were successfully appealed to the Appeal Board.

Average time taken to complete cases (in weeks)

	2010	2009	2008
Cases settled at Code of Practice Panel level	8	7.6	7.2
Cases which were the subject of appeal	16.9	16.2	17
All cases	10	9.1	8.6

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 2010 no advertisements were taken up as potentially being in breach of the Code.

Companies ruled in breach of the Code (complaints received in 2010)

* In breach of Clause 2

Alcon Laboratories (UK) Limited
* Allergan Ltd
AstraZeneca UK Limited
* Bayer Healthcare
* Bayer Schering Pharma
Boehringer Ingelheim Limited
* Cephalon UK Ltd
* Chiesi Limited
Dexcel Pharma Limited
* Eli Lilly and Company Limited
Ferring Pharmaceuticals Ltd
Flynn Pharma Ltd
Genus Pharmaceuticals Limited
GlaxoSmithKline UK Limited
* GlaxoSmithKline Consumer Healthcare
* Grünenthal Ltd
Johnson & Johnson Limited
Lincoln Medical Ltd
Merck Sharp & Dohme Limited
Movetis (UK) Limited
* Napp Pharmaceuticals Limited
Norgine Pharmaceuticals Limited
Novartis Pharmaceuticals UK Limited
Pfizer Limited
Pharmacosmos A/S
Sandoz Ltd
Sanofi-Aventis Ltd
Takeda UK Ltd

Accounts 2010

The PMCPA has been self-financing from the beginning of 1996. In 2010 there was a surplus of £279,026 (£250,694 after tax). The PMCPA currently holds reserves of £602,035.

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 2010. 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 2010 was £2,500 for member companies and £3,500 for non member companies where the decision of the Panel was accepted.

Where the decision of the Panel was unsuccessfully appealed, the charge per matter in 2010 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.

	2010	2009	2008
	£	£	£
Levy	349,500	187,350	494,115
Administrative charges	698,438	588,000	405,938
Seminars/meetings	184,748	191,581	152,216
Company audits	74,500	31,168	10,000
Contributions to advertising costs	25,000	10,000	2,500
	£1,332,489	£1,008.009	£1,064,768
Expenditure	**£1,053,463**	**£926,719**	**£1,060,452**

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

Contact 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)
7th Floor, Southside, 105 Victoria Street
London SW1E 6QT

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.
- 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 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
7th Floor, Southside
105 Victoria Street,
London, SW1E 6QT

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

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