PMCPA | Prescription Medicines Code of Practice Authority

2011
Annual report

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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"The average time taken to complete consideration of a case which was the subject of appeal was less in 2011 (15 weeks) than in 2010 (16.9 weeks)"

Foreword

I am pleased to contribute to the 2011 Annual Report of the Prescription Medicines Code of Practice Authority.

The number of complaints to the PMCPA in 2011 was 84, slightly fewer than in 2010 when 86 complaints were received. The number of cases (84) was more than those considered in 2010 (78). There was a little difference in the number of individual allegations (matters) considered in 2011 (259) compared with 2010 (241). Fewer matters were appealed in 2011 (36) than in 2010 (44).

The number of matters successfully appealed in 2011 was 21 which was an increase on the 17 matters successfully appealed in 2010. Of the 36 matters appealed in 2011, 58% were successfully appealed and 42% were unsuccessfully appealed.

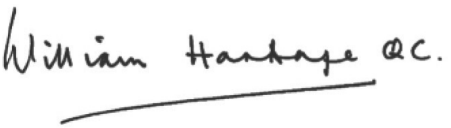
The proportion of the Code of Practice Panel's rulings successfully appealed increased in 2011, 8% (21/259) compared with 7% (17/241) in 2010. 6% (15/259) were unsuccessfully appealed in 2011 compared with 11% (27/241) in 2010.

The parties accepted without appeal 86% of the Panel's rulings compared with 82% in 2010. The Appeal Board has no hesitation in over-turning the Panel's rulings where appropriate. The average time taken to complete consideration of a case which was the subject of appeal was less in 2011 (15 weeks) than in 2010 (16.9 weeks).

Every effort is made to complete consideration of cases as quickly as possible and publish the outcomes. The Appeal Board required three companies to undergo audits in relation to complaints received in 2011.

The PMCPA is always keen to improve understanding of the Code and this year the launch of the e-module for health professionals, the compliance network and the discussion forum were welcomed by the Appeal Board. Details of these activities are given elsewhere but are examples of the PMCPA continuing to find new ways of interacting with its stakeholders.

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



William Harbage QC
Chairman
Code of Practice Appeal Board

Director's Report

The primary focus of the PMCPA is, of course, the administration of the complaints procedure and this kept the PMCPA busy in 2011. The other main work related to changes to the ABPI Code as well as to the EFPIA and IFPMA Codes. The changes to the ABPI Code were agreed in 2011 to come into operation in 2012.

The percentage of complaints from pharmaceutical companies in 2011 remained similar, 26% (22 out of 84) in 2011 and 27% (23 out of 86) in 2010 whereas the percentage from health professionals increased to 36% (30 out of 84) compared with 24% (21 out of 86) in 2010. The PMCPA usually receives more complaints from health professionals than from companies. 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 were the same (7 in 2011 and 2010).

A smaller percentage of complaints were ruled in breach in 2011, 51% (43/84) compared with 68% (53/78) in 2010. If this is looked at on the basis of individual matters, fewer were ruled in breach in 2011, 36% (94/259) compared with 48% (116/241) in 2010.

An additional member of the PMCPA was required as a consequence of the changes to the Constitution and Procedure which came into operation on 1 January 2011. We are delighted to welcome Ros Henley who was appointed as Deputy Secretary in June 2011. Etta Logan was appointed Deputy Director and Jane Landles as Secretary. Two members of the PMCPA work part-time, the others work full-time.

Details of the Panel's and Appeal Board's rulings are given elsewhere. The Panel has a good record with 92% (238/259) of its rulings in 2011 being accepted by the parties or upheld on appeal; the figure for 2010 was slightly higher at 93% (224/241). The time taken to complete cases settled at Panel level decreased in 2011 to 7 weeks compared with 8 weeks in 2010. 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.

In 2011, changes to the EFPIA Codes meant that the ABPI Code had to be amended; there was also a change to the PMCPA Constitution and Procedure. The amendments were agreed in November 2011 after the usual consultation and details appear below.

The PMCPA launched an e-learning module for health professionals as part of the 2011 Code Awareness Campaign. This was well received and more details are given below.

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

Heather Simmonds
Director, PMCPA

Complaints in 2011

Eighty-four complaints were received in 2011 compared with 86 in 2010. There were 84 cases for the PMCPA to deal with. The number of individual allegations to be considered within these cases, at 259, was slightly more than the corresponding figure for 2010 which was 241.

Time to deal with complaints
There was a decrease in the overall time taken to deal with complaints. The figure for 2011 was 8.8 weeks compared with 10 weeks in 2010. There was a slight decrease in the time taken to complete cases finalised at Panel level from 8 weeks in 2010 to 7 weeks in 2011. The majority of cases complete at the Panel level. Cases that went to appeal in 2011 were completed slightly more quickly (15 weeks) than in 2010 (16.9 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 2011.

The first report concerned material which the Panel considered clearly promotional whereas the company concerned had not. The Panel ruled breaches of the Code and on receiving the report the Appeal Board considered that serious errors had been made. The Appeal Board decided to require the company to recover the material and to undergo an audit. Following the first audit a reaudit was required in 2012.

The second report concerned the same company as the first report. The Panel ruled breaches of the Code and as the items at issue related to misleading claims about the safety profile of a medicine it reported the company to the Appeal Board. The Appeal Board was extremely concerned that the material had the potential to compromise patient safety and also that a second case raised very serious concerns about the expertise of the company signatories and the role of senior management. An audit was required and following that a reaudit in 2012.

The third report involved the activities of a medical liaison executive. The Panel ruled breaches of the Code in relation to promotion of a medicine for an unlicensed indication. There were potential issues of patient safety. The Panel reported the company to the Appeal Board. The company appealed and many of the breaches were overturned others were not. Given its rulings the Appeal Board decided to take no further action in relation to the Panel's report.

The fourth report concerned a company that had breached its undertaking in a previous case and had promoted an unlicensed indication. The Panel ruled breaches of the Code. Further the Panel had to ask the company for information on a number of occasions and the company had contradicted its initial response and its response to an earlier case. The Panel reported the company to the Appeal Board. The Appeal Board was very concerned about the number of requests made and the company's incomplete and misleading response. The Appeal Board decided the company should be publicly reprimanded and undergo an audit which would be carried out in 2012.

Complaints in 2011

The fifth report concerned a company that had twice breached its undertaking given in a previous case and had now done so again. The Panel ruled breaches of the Code and reported the company to the Appeal Board. The Appeal Board was very concerned about the company's behaviour and decided that the company should be publicly reprimanded and undergo an audit which would be carried out in 2012.

Reports 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 2011.

Audits by the PMCPA
Four complaints received in 2011, which were the subject of formal reports to the Appeal Board, resulted in an audit of three companies' procedures. One of these (which concerned two complaints about the same company) was carried out in 2011 and the other two audits were carried out in 2012.

One reaudit was carried out in relation to a complaint made in 2010 (the first audit had been carried out in 2010).

One complaint from 2010 led to an audit in 2010 and to two reaudits in 2011 with another reaudit carried out in 2012. During the third audit it became apparent that the company had not provided accurate information. Thus the Appeal Board decided that the company should be publicly reprimanded.

In all, one audit and three re-audits were carried out in 2011.

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. 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. 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 2011 from various sources including pharmaceutical companies, health professionals, public relations agencies and patients. A number of media enquiries were also received 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 contact the PMCPA for informal advice on the Code either by telephone (020 7747 8880) or via the website.

Training on the Code

Five seminars designed to explain the requirements of the Code were held by the PMCPA in central London in 2011. 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, 25 training seminars or presentations on the Code were made 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. Seven such speaking engagements were undertaken in 2011.

Communicating the Code

The campaign to inform health professionals and others about the Code continued in 2011 with efforts being made to ensure that a wider audience is aware of the Code and how it works.

Code Awareness
Code Awareness Week 2011 took place in early April. During Code Awareness Week, employees from pharmaceutical companies talked to doctors, nurses, pharmacists and other stakeholders about how the industry works to the high standards required by the Code and about the latest changes to the Code. Events were held in England, Scotland, Wales and Northern Ireland and attended by representatives from charities, NHS organisations, pharmaceutical companies, agencies, royal colleges and medical regulators.

To help health professionals understand the requirements of the Code the PMCPA launched an e-learning module on its website and an updated Quick Guide to the Code for Health Professionals. The interactive e-learning module sets out how the pharmaceutical industry can promote medicines to health professionals; key points from the Code covered include the content of advertisements and arrangements for meetings. The module has been certified as meeting the guidelines for continuing professional development. Feedback has been positive and between April and December 2011 over 3,000 people accessed the module.

Digital communication
In early April the PMCPA published informal guidance on digital communication to help increase understanding on how the pharmaceutical industry can use this media. The guidance set out the requirements of the Code which were most relevant to digital communication and answered some frequently asked questions about the topic. The Medicines and Healthcare products Regulatory Agency (MHRA) welcomed the PMCPA's informal guidance.

PMCPA Discussion Forum and Compliance Network
During autumn 2011 the PMCPA conducted an internal review of its engagement activities with industry and identified a number of ways to try to help with the understanding and implementation of the requirements of the Code.

In order to enhance communication with pharmaceutical companies, the Authority established the PMCPA Discussion Forum and the PMCPA Compliance Network.

The PMCPA Discussion Forum was established to facilitate discussion on a regular basis between the PMCPA and those in companies who work with and interpret the ABPI Code. The forum provides an opportunity for attendees from a variety of roles such as sales, marketing, medical, medical information and compliance to come together.

The first meeting was held in September 2011 and included updates on digital communications, the latest advice and guidance and changes to codes.

Attendees at the first discussion forum were from a variety of pharmaceutical companies and the feedback was very positive.

The PMCPA Compliance Network was established for compliance specialists within pharmaceutical companies. The first meeting was held in November 2011 and was welcomed by attendees who appreciated the opportunity to discuss cases in detail with the Panel. The agenda for the compliance network focuses on compliance issues and includes detailed discussion and learnings from recent cases.

Advertisements in the medical, pharmaceutical and nursing press
In accordance with the Constitution and Procedure, and timed to coincide with the publication of the quarterly Code of Practice Review, 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 were 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. Copies are available on request. The Review is also 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

In November 2011 proposals to amend the Code and the Constitution and Procedure for the PMCPA were agreed by ABPI members for implementation on 1 January 2012.

The proposals to amend the Code arose from changes to the 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 and the EFPIA Code of Practice on Relationships between the Pharmaceutical Industry and Patient Organisations. The changes were to the requirements for samples and payments to patient organisations.

The changes to the Constitution and Procedure were to give the ABPI Board of Management discretion in relation to the need for formal approval at an ABPI General meeting if a proposal to amend the ABPI Code arises solely from the ABPI's obligation to comply with the EFPIA codes. ABPI member companies must nonetheless be consulted in relation to the proposed texts of the changes.

The changes came into operation on 1 January 2012.

International and European Codes

International Federation of Pharmaceutical Manufacturers and Associations

The Director of the PMCPA is a member of an ad hoc group that adjudicates 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 2011 this group had no complaints to consider.

The IFPMA Code Compliance Network (CCN) continued its work in 2011. Members include national associations and member companies of the IFPMA. The Director of the PMCPA is a member of the CCN. The CCN meets twice a year and provides members with an opportunity to share best practice. In October 2011 the CCN met in London and presentations included one from the IFPMA President and one from the Medicines and Healthcare products Regulatory Agency. An update was also given on the UK Bribery Act.

European Federation of Pharmaceutical Industries and Associations

Following the implementation in 2011 of the European Federation of Pharmaceutical Industries and Associations (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, work continued on possible changes. The Director of the PMCPA is a member of the EFPIA steering group for 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 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. In the UK 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 requirements more restrictive than the current position.

In 2010 the Directive was discussed in the European Parliament and many amendments were suggested. An update to the Directive was issued 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 2011 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 PMCPA responded to the MHRA consultation. The MHRA plans to have the new legislation in place in 2012.

The Bribery Act 2010

The Bribery Act became UK law on 1 July 2011. 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. The memorandum of understanding between the ABPI, PMCPA and SFO 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, Deputy Director, Secretary and Deputy Secretary of the PMCPA. The Panel considers all complaints made under the Code with the benefit of independent medical and/or other expert advice as appropriate. The case preparation manager for a particular case, who is one of the above, does not sit on the Panel for consideration of that case.

The Panel met 75 times in 2011 (compared with 59 times in 2010). 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 Deputy Director of the PMCPA. Etta chairs the Code of Practice Panel in the Director's absence including when the Director is the case preparation manager.

Etta is a solicitor and joined the PMCPA as Secretary in 1997 from private practice in London where she specialised in medical negligence and professional indemnity litigation. Etta was appointed Deputy Director in 2011.

Jane Landles is the 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 becoming a nominated signatory. She joined the PMCPA as Deputy Secretary in 1996 and was appointed Secretary in 2011.

Ros Henley is the Deputy Secretary of the PMCPA. Ros has a biology degree and a legal qualification and spent 15 years in the pharmaceutical industry including as a nominated signatory. She joined the PMCPA in June 2011.

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 eight 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. For the consideration of any case independent members must be in the majority.

The Appeal Board met 10 times in 2011 (9 times in 2010) and considered appeals in 19 cases in 2011 (20 cases in 2010).

Membership and Attendance During 2011

Chairman
Mr William Harbage QC (10/10)

Independent Members
Mrs Mary Baker MBE (Representing patients' interests) (9/10)

Professor Steve Chapman (Member from an independent body involved in providing information on medicines) (8/10)

Professor Richard Hobbs (University Academic/General Practitioner) (3/10)

Professor Peter Hutton (Hospital Consultant) (9/10)

Mrs Aileen Palanisamy (Nurse Prescriber) (10/10)

Mr Andrew Reid (Lay Member) (9/10)

Mrs Linda Stone OBE (Pharmacist) (8/10)

Dr Michael Wilson (General Practitioner) (10/10)

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

Dr Mike Geraint (Medical Director, Norgine Limited) (7/10)

Ms Helen Roberts (UK & Ireland Legal Director, Novartis Pharmaceuticals UK Limited) (5/10)

Mr Stuart Rose (Managing Director, Merz Pharma UK Ltd) (4/10)

Dr Gillian Shepherd (Director of Heath and Clinical Excellence, Merck Serono) (1/7) until September 2011

Dr Pim Kon (Medical Director, GlaxoSmithKline UK Limited) appointed February 2011 (2/8)

Dr Berkeley Phillips (Medical Director, Pfizer UK Limited) appointed February 2011 (4/7)

Coopted Members
The Chairman can co-opt members for meetings of the Appeal Board so as to enable a quorum to be achieved. During 2011, 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)

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, Deputy Director, Secretary and Deputy Secretary of the PMCPA, with the benefit of independent medical and/or other expert advice as appropriate. The case preparation manager, for a particular case, who is one of the above, does not sit on the Panel for consideration of that case.

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

	2011	2010	2009
Complaints received	84	86	92
Not within the scope of the Code	7	2	4
Covered by a previous case	1	1	–
Complaints withdrawn	1	–	3
Company declined to accept the PMCPA's jurisdiction before proceedings commenced	4	2	2
No prior inter-company dialogue	–	–	1
Inter-company dialogue successful	1	3	–
Complaints considered	77	78	82
Cases arising from these complaints	84	78	85
Individual matters considered	259	241	455

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

	2011	2010	2009
Cases where a breach found	43	53	62
Cases where no breach found	41	25	23
Number of matters in these cases:			
- in breach	94	116	209
- no breach	165	125	246
Cases where the Code of Practice Panel required suspension of materials	–	–	1
Breaches of undertaking ruled	3	3	7
Breaches of Clause 2 ruled	8	12	13
Reports to the Code of Practice Appeal Board	5	2	5
Reports to the ABPI Board of Management	–	–	–

Sources of complaints

Health professionals	**2011**	**2010**	**2009**
General practitioners	16	5	6
Hospital doctors	3	5	11
Other doctors	–	5	12
Pharmacists	6	4	2
Medical/pharmaceutical advisers	–	2	5
Nurses	1	–	1
Managers	4	–	3
	30	**21**	**40**
Pharmaceutical companies			
ABPI members	13	11	19
Non members	9	12	5
	22	**23**	**24**
PMCPA Director			
Arising from media criticism	2	2	2
Alleged breach of undertaking	4	2	3
Arising from voluntary admissions	1	3	9
	7	**7**	**14**
Organisations			
Medicines and Healthcare products Regulatory Agency	–	1	1
Esprit	–	1	–
	0	**2**	**1**
Others			
Members of the public	3	4	2
Anonymous	17[Δ]	18*	6
Employees/ex employees	–	6	3
Anonymous employees	1	2	–
Anonymous ex employees	1	2	1
Consultant	–	–	1
Journalist	2	1	–
Publisher	1	–	–
	25	**33**	**13**
Total	**84**	**86**	**92**

[Δ] Six of these were from anonymous health professionals

* Four of these were from anonymous health professionals

Appeals to the Code of Practice Appeal Board

	2011	2010	2009
Total number of matters ruled upon by the Code of Practice Panel	259	241	455
Rulings accepted by complainants and respondents involved	223	197	388
Rulings successfully appealed	21	17	44
Rulings unsuccessfully appealed	15	27	23
Number of cases appealed	19	20	15

Sources of appeals	**2011**	**2010**	**2009**
Cases appealed by complainants	4	6	6
Cases appealed by respondents	16	14	9

In one case in 2011 both the complainant and the respondent appealed.

Appeals by complainants	**2011**	**2010**	**2009**
successful	0	2	3
partly successful	0	1	0
unsuccessful	4	3	3
	4	**6**	**6**

Appeals by respondents			
successful	10	3	3
partly successful	1	5	4
unsuccessful	5	6	2
	16	**14**	**9**

Rulings appealed by complainants			
successful	0	6	3
unsuccessful	5	9	6
	5	**15**	**9**

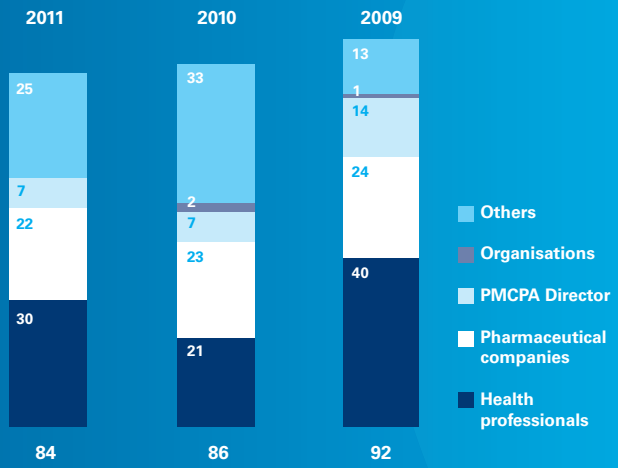
Rulings appealed by respondents			
successful	21	11	41
unsuccessful	10	18	17
	31	**29**	**58**

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.

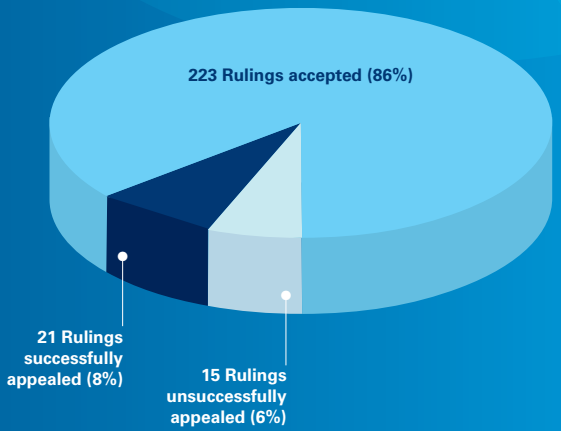
Complaints nominally made by the Director can also arise as a result of:

- 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 2011 the Code of Practice Panel made 259 rulings. Of these, 223 (86 per cent) were accepted by the complainants and respondents involved. A further 15 (6 per cent) were the subject of unsuccessful appeals to the Code of Practice Appeal Board. The remaining 21 (8 per cent) were successfully appealed to the Appeal Board.



Average time taken to complete cases (in weeks)

	2011	2010	2009
Cases settled at Code of Practice Panel level	7	8	7.6
Cases which were the subject of appeal	15	16.9	16.2
All cases	8.8	10	9.1

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 2011 no advertisements were taken up as potentially being in breach of the Code.

Companies ruled in breach of the Code (complaints received in 2011)

* In breach of Clause 2

Astellas Pharma Ltd
Abbott Laboratories Limited
Alk-Abelló Ltd
Alcon Laboratories (UK) Limited
* Allergan Limited
* Bayer Healthcare
Baxter Healthcare Ltd
Biogen Idec Limited
* Boehringer Ingelheim Limited
* Chiesi Limited
Cephalon (UK) Limited
Eli Lilly and Company Limited
GlaxoSmithKline Consumer Healthcare
Grünenthal Ltd
Janssen
Johnson & Johnson Limited
Leo Pharma Limited
Lundbeck Limited
Novo Nordisk Ltd
Pfizer Limited
Sandoz Ltd
Sanofi Aventis
Servier Laboratories Ltd
Shire Pharmaceuticals Limited
Teva Pharmaceuticals Ltd
* Vifor Pharma UK Limited

Accounts 2011

The PMCPA has been self-financing since 1996. In 2011 there was a surplus after tax of £524,248. Accommodation and support costs for 2011 will be paid to the ABPI in 2012. The PMCPA currently holds reserves of £1,126,283.

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 £3,500 to £28,000 depending on the size of the company. 90 per cent of the levy due was called up in 2011. 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 2011 was £3,500 for member companies and £4,000 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 2011 was £11,000 for member companies and £12,000 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.

Accounts 2011

	2011	2010	2009
	£	£	£
Levy	558,023	349,500	187,350
Administrative charges	621,322	698,438	588,000
Seminars/meetings	110,109	184,748	191,581
Company audits	53,500	74,500	31,168
Contributions to advertising costs	24,000	25,000	10,000
	1,366,954	£1,332,489	£1,008,009
Expenditure	**£891,928**	**£1,053,463**	**£926,719**

Expenditure includes salaries, fees, administration costs, office accommodation and support costs. Accommodation and support costs for 2011 will be paid to the ABPI in 2012.

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)
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
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