PMCPA | Prescription Medicines Code of Practice Authority

2012 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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Foreword

I am pleased to contribute to the 2012 Annual Report of the Prescription Medicines Code of Practice Authority.

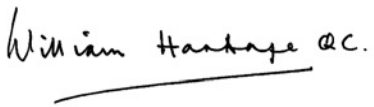
The number of complaints to the PMCPA in 2012 was 78, fewer than in 2011 when 84 complaints were received. The number of cases (84) was the same as considered in 2011. There was an increase in the number of individual allegations (matters) considered in 2012 (296) compared with 2011 (259). More matters were appealed in 2012 (43) than in 2011 (36). The number of matters successfully appealed in 2012 was 12 which was a decrease on the 21 matters successfully appealed in 2011. Of the 43 matters appealed in 2012, 28% were successfully appealed and 72% were unsuccessfully appealed. The proportion of the Code of Practice Panel's rulings successfully appealed decreased in 2012, 4% (12/296) compared with 8% (21/259) in 2011. 11% (31/296) were unsuccessfully appealed in 2012 compared with 6% (15/259) in 2011. The parties accepted without appeal 85% of the Panel's rulings compared with 86% in 2011. 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 longer in

2012 (18.9 weeks) than in 2011 (15 weeks). Every effort is made to complete consideration of cases as quickly as possible and publish the outcomes. The consideration of a number of appeals was deferred following a request from at least one of the parties. I consider requests for deferment carefully and generally agree only if the material at issue is no longer in use.

The Appeal Board required one company to undergo audits in relation to complaints received in 2012.

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. Two of the longest serving members of the Appeal Board retired in 2012. Both were members of the Code of Practice Committee prior to 1993 when the Authority and the Appeal Board were established. Dr Susan Bews was appointed in 1987 and has served continuously apart from a brief break. Dr Michael Wilson was appointed to the Code of Practice Committee in 1991 as an independent medical member. I would like to thank them for their unwavering support and outstanding contribution to the industry's self regulatory system.



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 this kept the PMCPA busy in 2012. The other main area of work related to amendments to the ABPI Code as well as to the EFPIA and IFPMA Codes. Uniquely for the PMCPA 2012 saw two versions of the ABPI Code in that the changes agreed in 2011 came into operation on 1 January 2012 and further changes agreed in April 2012 came into operation on 1 July 2012.

The percentage of complaints from pharmaceutical companies in 2012 at 20% (16/78) was lower than the 26% (22 out of 84) in 2011. The percentage from health professionals decreased at 27% (21/78) compared with 36% (30 out of 84) in 2011. The PMCPA usually receives more complaints from health professionals than from companies. Some of the anonymous complainants described themselves as health professionals but these are listed as anonymous complaints and not included in the figures above.

Complaints nominally attributed to the Director (10 in 2012 and 7 in 2011) were due to an increased number of allegations of breach of undertaking (6 in 2012 and 4 in 2011) and more companies making voluntary admissions (4 in 2012 and 1 in 2011).

A larger percentage of cases were ruled in breach in 2012, 57% (48/84) compared with 51% (43/84) in 2011. If this is looked at on the basis of individual matters, more were ruled in breach 52% (154/296) in 2012 compared with 36% (94/259) in 2011.

Details of the Panel's and Appeal Board's rulings are given elsewhere. The Panel has a good record with 96% (284/296) of its rulings in 2012 being accepted by the parties or upheld on appeal; the figure for 2011 was 92% (238/259). The time taken to complete cases settled at Panel level increased to 9.9 weeks in 2012 compared with 7 weeks in 2011. The Panel is extremely conscious of the need to deal with cases as quickly and efficiently as possible. Some cases however required additional information before the Panel could make a ruling. This can sometimes cause delays outside the PMCPA's control.

In 2012, changes to the UK law and an update to the IFPMA Code 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 June 2012 after the usual consultation and details appear below.

I would like to thank the staff of the PMCPA for all their hard work throughout this year. It was also a very productive year in every sense of the word as the same number of babies were born to staff at the PMCPA as there were editions of the Code.

Heather Simmonds
Director, PMCPA

Complaints in 2012

Seventy-eight complaints were received in 2012 compared with eighty-four in 2011. There were eighty-four cases for the PMCPA to deal with in 2012. Some complaints lead to more than one case as they involve more than one company. The number of individual allegations to be considered within these cases, at 296, was more than the corresponding figure for 2011 which was 259.

Time to deal with complaints
There was an increase in the overall time taken to deal with complaints. The figure for 2012 was 11.6 weeks compared with 8.8 weeks in 2011. There was an increase in the time taken to complete cases finalised at Panel level from 7 weeks in 2011 to 9.9 weeks in 2012. The majority of cases complete at the Panel level. Cases that went to appeal in 2012 took longer to complete in 2012 (18.9 weeks) than in 2011 (15 weeks).

Any increase in time taken to complete cases is a concern. Some of the delays were due to the need for additional information from the parties prior to the Code of Practice Panel making its ruling. A number of appeals were deferred following consideration by the Chairman of the Appeal Board of a request from one or even both parties.

Reports to the Code of Practice Appeal Board from the Panel
Two formal reports were made by the Code of Practice Panel to the Code of Practice Appeal Board in relation to complaints received in 2012.

Both reports concerned one company that had breached undertakings given in a previous case. 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.

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 2012. No such reports have been made since 2008.

Audits by the PMCPA
Two complaints received in 2012 about the same company, which were the subject of formal reports to the Appeal Board, resulted in audits of that company's procedures. The first audit was carried out in 2012 and two reaudits were carried out in 2013.

One complaint from 2011 about the same company as referred to above which was the subject of a formal report to the Appeal Board in 2011 resulted in an audit and reaudit in 2012. Two reaudits were to be carried out in 2013.

One complaint from 2010 led to an audit in 2010 and to two reaudits in 2011 with another reaudit 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.

Two complaints from 2011 about a company which were the subject of formal reports to the Appeal Board in 2011 resulted in audits of that company's procedures in November 2011 and two reaudits in 2012.

One complaint from 2011 which was the subject of a formal report to the Appeal Board in 2011 resulted in an audit of that company in 2012 and a reaudit later in the year. In addition

Complaints in 2012

certain documents had to be submitted for examination by the PMCPA.

In all, three audits and four reaudits were carried out in 2012.

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. The MHRA fully supports the Code and 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 2012 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 using the 'Advanced search' facility on 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 2012. These seminars are open to all and 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, 16 training seminars or presentations on the Code were given 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. Nineteen such speaking engagements were undertaken in 2012.

Communicating the Code

The campaign to inform health professionals and others about the Code continued in 2012 with efforts being made to ensure that a wider audience is aware of the Code and how it works.

Updated website

The focus of our communications in 2012 was to relaunch the PMCPA website which took place in August. An improved search facility, interactive Code and additional guidance were welcomed. Thanks to all those who user tested the site and provided detailed comments.

PMCPA Compliance Network

In 2011 the PMCPA identified that one way to try to help pharmaceutical companies understand and implement the requirements of the Code was to establish a PMCPA Compliance Network. The network is made up of those who have some responsibility for compliance within their companies. Current compliance issues in general are discussed and the learnings from recent cases are covered in detail.

Four meetings were held in 2012, with about twenty people at each and topics covered included updates on digital communications, the latest advice and guidance and changes to codes.

Attendees are limited to one per pharmaceutical company and the feedback from the 2012 meetings was very positive.

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 Reviews, 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 featuring the activities of eight companies 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 cases completed within the previous three months are published in the Code of Practice Review on a quarterly basis. The Review also carries comment on matters of current interest for the benefit of companies and others.

Case reports are published on a rolling basis on 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.

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. Details of these amendments were included in the 2011 Annual Report.

In June 2012 further proposals to amend the Code were agreed by members for implementation on 1 July 2012. These proposals to amend the Code arose as a result of the consolidation of UK medicines legislation by the Medicines and Healthcare products Regulatory Agency (MHRA) and the subsequent passing into law of new regulations (The Human Medicines Regulations 2012) in August. The ABPI and PMCPA both contributed to the MHRA's consolidation project.

The ABPI Code reflects and extends beyond UK law. The new regulations required minor amendments to the ABPI Code. These included changes to the definition of promotion, the requirements for price lists for unlicensed medicines and the requirements for prescribing information including for abbreviated advertisements. Minor changes were also needed following the new IFPMA Code of Practice which had to be implemented by 1 September. These included changes to the definitions of promotion and health professionals and to the requirements for working with patient organisations. The Code was also amended to prohibit starter packs.

The Second 2012 Edition of the Code came into operation on 1 July with the usual transition period for newly introduced requirements in that during the period 1 July 2012 to 31 October 2012 no promotional material or activity would be regarded as being in breach of the Code if it failed to comply with the newly introduced provisions.

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 and operates only in relation to countries that do not have local arrangements, be that by self regulation or external regulation. In 2012 this group considered one complaint.

The IFPMA Code Compliance Network (CCN) continued its work in 2012. 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 its members with an opportunity to share best practice. On 1 March 2012 the IFPMA announced changes to the IFPMA Code of Practice.

The CNN took the lead with proposing amendments to ensure that patients, governments and healthcare providers were confident that interactions were conducted to high ethical standards.

The name of the IFPMA Code was changed and it was expanded to include requirements for interactions with health professionals, medical organisations and patient organisations. High level guiding principles were included as well as requirements for training all employees.

Minor changes were made to the ABPI Code in July to include the new IFPMA requirements.

As part of the IFPMA outreach activities the Director of the PMCPA presented at a number of meetings including a training day on the IFPMA Code.

European Federation of Pharmaceutical Industries and Associations

EFPIA started work on a code to cover the disclosure of certain payments to health professionals and healthcare organisations. The EFPIA Board agreed a prefinal draft in December 2012. Consultation on implementation was undertaken with the code formally adopted by the EFPIA General Assembly in June 2013 to be implemented by national associations by 31 December 2013. The Director of the PMCPA is a member of various EFPIA groups in relation to 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 all prohibit 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. An update to the Directive was issued in 2011. The Directive did not progress any further in 2012.

The PMCPA will continue to monitor the position. The quality of information provided to the public and not the source of that information should be the prime consideration.

Medicines legislation
In 2012 the Medicines and Healthcare products Regulatory Agency (MHRA) completed work on reviewing and consolidating the UK medicines legislation. Much of The Medicines Act 1968 and a large number of statutory instruments were replaced by The Human Medicines Regulations 2012 which became law on 14 August 2012.

The new regulations meant that changes were needed to the Code and these were agreed in June 2012.

The Code of Practice Panel

The Code of Practice Panel consists of three 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. In serious cases the Panel may require a company ruled in breach of the Code to suspend the material or activity at issue pending the outcome of an appeal. No company has been required to suspend material or activity since 2009. The case preparation manager for a particular case, one of the Panel members, does not sit on the Panel for the consideration of that case.

The Panel met 83 times in 2012 (compared with 75 times in 2011). 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 was ultimately 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.

The Appeal Board has an independent legally qualified 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 (MHRA). In addition the medical, pharmacist and nurse prescriber members are appointed in consultation with their respective professional bodies. For the consideration of any case independent members must be in the majority.

The Appeal Board met 10 times in 2012 (10 times in 2011) and considered appeals in 16 cases in 2012 (19 cases in 2011).

Membership and attendance during 2012

Chairman
Mr William Harbage QC (10/10)

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

Professor Steve Chapman (From an independent body which provides information on medicines) (8/10)

Professor Richard Hobbs (University Academic/General Practitioner) (6/10)

Professor Peter Hutton
(Hospital Consultant) (8/10)

Mrs Aileen Cherry previously Palanisamy (Nurse Prescriber) (9/10)

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

Mrs Linda Stone OBE
(Pharmacist) (9/10)

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) (9/10)

Dr Alison O'Toole (Director of Oncology, Napp Pharmaceuticals Ltd) appointed June 2012 (5/5)

Ms Helen Roberts (UK & Ireland Legal Director, Novartis Pharmaceuticals UK Limited) (3/10)

Mr Stuart Rose (Managing Director, Merz Pharma UK Ltd) (5/9)

Dr Pim Kon (Medical Director, GlaxoSmithKline UK Limited) (3/10)

Dr Berkeley Phillips (Medical Director, Pfizer UK Limited) (6/10)

Ms Michelle Swift (Director of NHS & Regulatory Affairs, Takeda UK Ltd) appointed June 2012 (5/5)

Coopted Members
The Chairman can co-opt members for meetings of the Appeal Board so as to enable a quorum to be achieved. During 2012, the following were each co-opted for at least one meeting:

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

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

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 three 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.

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. No company has been asked to suspend material or activity since 2009.

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 confidential 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 the PMCPA can no longer accept responsibility for that company under the Code.

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

	2012	2011	2010
Complaints received	78	84	86
Not within the scope of the Code	2	7	2
Covered by a previous case	–	1	1
Complaints withdrawn	3	1	–
Company declined to accept the PMCPA's jurisdiction before proceedings commenced	5	4	2
Inter-company dialogue successful	1	1	3
Complaints considered	67	77	78
Cases arising from these complaints	84	84	78
Individual matters considered	296	259	241

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

	2012	2011	2010
Cases where a breach found	48	43	53
Cases where no breach found	36	41	25
Number of matters in these cases:			
- in breach	154	94	116
- no breach	142	165	125
Cases where the Code of Practice Panel required suspension of materials	–	–	–
Breaches of undertaking ruled	5	3	3
Breaches of Clause 2 ruled	9	8	12
Reports to the Code of Practice Appeal Board	2	5	2
Reports to the ABPI Board of Management	–	–	–

Sources of complaints

Health professionals	**2012**	**2011**	**2010**
General practitioners	8	16	5
Hospital doctors	3	3	5
Other doctors	3	-	5
Pharmacists	6	6	4
Medical/pharmaceutical advisers	1	-	2
Nurses	-	1	-
Managers	-	4	-
	21	**30**	**21**
Pharmaceutical companies			
ABPI members	7	13	11
Non members	9	9	12
	16	**22**	**23**
PMCPA Director			
Arising from media criticism	-	2	2
Alleged breach of undertaking	6	4	2
Arising from voluntary admissions	4	1	3
	10	**7**	**7**
Organisations			
Medicines and Healthcare products Regulatory Agency	–	–	1
Esprit	–	–	1
	0	**0**	**2**
Others			
Members of the public	5	3	4
Anonymous	19[1]	17[2]	18[3]
Employees/ex employees	3	–	6
Anonymous employees	4	1	2
Anonymous ex employees	–	1	2
Journalist	–	2	1
Publisher	–	1	–
	31	**25**	**33**
Total	**78**	**84**	**86**

[1] Eleven of these were from anonymous health professionals

[2] Six of these were from anonymous health professionals

[3] Four of these were from anonymous health professionals

Appeals to the Code of Practice Appeal Board

	2012	2011	2010
Total number of matters ruled upon by the Code of Practice Panel	296	259	241
Rulings accepted by the parties	253	223	197
Rulings successfully appealed	12	21	17
Rulings unsuccessfully appealed	31	15	27
Number of cases appealed	16	19	20

Sources of appeals	**2012**	**2011**	**2010**
Cases appealed by complainants	6	4	6
Cases appealed by respondents	11	16	14
In one case in 2011 and 2012 both the complainant and the respondent appealed.			

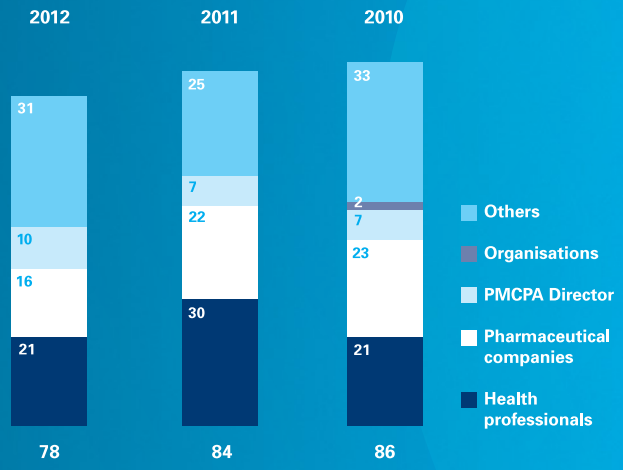
Appeals by complainants	**2012**	**2011**	**2010**
successful	2	–	2
partly successful	–	–	1
unsuccessful	4	4	3
	6	**4**	**6**
Appeals by respondents			
successful	3	10	3
partly successful	3	1	5
unsuccessful	5	5	6
	11	**16**	**14**
Rulings appealed by complainants			
successful	5	–	6
unsuccessful	8	5	9
	13	**5**	**15**
Rulings appealed by respondents			
successful	7	21	11
unsuccessful	23	10	18
	30	**31**	**29**

Complaints received

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

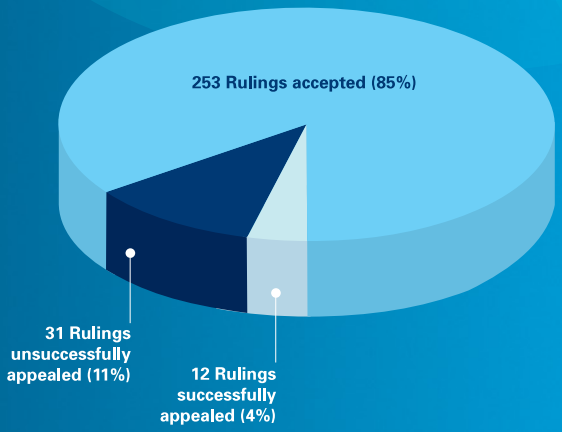
Complaints nominally made by the Director can also arise as a result of:

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



Code of Practice Panel rulings

In 2012 the Code of Practice Panel made 296 rulings. Of these, 253 (85%) were accepted by the complainants and respondents involved. A further 31 (11%) were the subject of unsuccessful appeals to the Code of Practice Appeal Board. The remaining 12 (4%) were successfully appealed to the Appeal Board.



Average time taken to complete cases (in weeks)

	2012	2011	2010
Cases settled at Code of Practice Panel level	9.9	7	8
Cases which were the subject of appeal	18.9	15	16.9
All cases	11.6	8.8	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 2012 no advertisements were taken up as potentially being in breach of the Code.

Companies ruled in breach of the Code (complaints received in 2012)

* In breach of Clause 2

Astellas Pharma Ltd
AstraZeneca UK Limited
*Allergan Ltd
*Bayer HealthCare
Baxter Healthcare Ltd
Boehringer Ingelheim Limited
*Daiichi Sankyo UK Ltd
*Eli Lilly and Company Limited
Eisai Limited
Ferring Pharmaceuticals Ltd
Flynn Pharma Limited
Genus Pharmaceuticals Ltd
GlaxoSmithKline UK Limited
Ipsen Limited
Janssen
Johnson & Johnson Limited
Meda Pharmaceuticals Ltd
Merck Serono Limited
*Merz Pharma UK Ltd
Napp Pharmaceuticals Limited
Novo Nordisk Limited
Orion Pharma (UK) Ltd
Pfizer Limited
ProStrakan Limited
Recordati Pharmaceuticals Ltd
Roche Products Limited
Sanofi
Sanofi Pasteur MSD
*Shire Pharmaceuticals Ltd
Takeda UK Ltd
*Vifor Pharma UK Limited

Accounts 2012

The PMCPA has been self-financing from the beginning of 1996.
In 2012 there was a planned loss of £213,480 before tax. The cost of office accommodation and support services in 2011 was paid in 2012.
It was decided that the PMCPA should use some of its reserves in 2012. The PMCPA currently holds reserves of £770,089 after tax.

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. Half of the levy due was called up in 2012. 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 2012 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 2012 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 2012

	2012	2011	2010
	£	£	£
Levy	393,174	558,023	349,500
Administrative charges	442,078	621,322	698,438
Seminars/meetings	143,375	110,109	184,748
Company audits	38,000	53,500	74,500
Contributions to advertising costs	17,448	24,000	25,000
	1,034,075	1,366,954	1,332,489
Expenditure	**£1,247,555**	**£891,928***	**£1,053,463**

Expenditure includes salaries, fees, administration costs and the cost of office accommodation.
The 2011 figure* does not include the cost of office accommodation. The payment for 2011 was made 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:

- 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
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Email: complaints@pmcpa.org.uk

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