

The logo for the Prescription Medicines Code of Practice Authority (PMCPA) is displayed in a bold, dark blue, sans-serif font. It is positioned in the upper right quadrant of the page, within a light blue circular graphic element. The background of the entire page is a vibrant blue with several large, overlapping circles in various shades of blue, creating a dynamic and modern aesthetic.

PMCPA

Prescription Medicines
Code of Practice Authority

2013
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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“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.”


Foreword

I am pleased to contribute to the 2013 Annual Report of the Prescription Medicines Code of Practice Authority.

The number of complaints to the PMCPA in 2013 was 80, slightly more than in 2012 when 78 complaints were received. The number of cases (105) was much higher than considered in 2012 (84). The number of individual allegations (matters) considered in 2013 (302) compared with 2012 (296). Fewer matters were appealed in 2013 (38) than in 2012 (43). Of the 38 matters appealed in 2013, 26% were successfully appealed and 74% were unsuccessfully appealed. The proportion of the Code

of Practice Panel’s rulings appealed in 2013 was around 13% (38/302) compared to around 15% (43/296) in 2012. The proportion of the Panel’s rulings successfully appealed in 2013, was 3% (10/302) compared with 4% (12/296) in 2012. 9% (28/302) were unsuccessfully appealed in 2013 compared with 11% (31/296) in 2012. The parties accepted without appeal 87% of the Panel’s rulings compared with 85% in 2012. The Appeal Board has no hesitation in overturning the Panel’s rulings where appropriate.

The average time taken to complete consideration of a case which was the subject of appeal was slightly less in



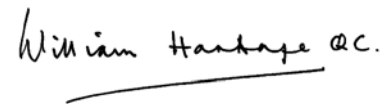
2013 (18.1 weeks) than in 2012 (18.9 weeks). Every effort is made to complete consideration of cases as quickly as possible and publish the outcomes. I consider requests for deferment of appeals carefully and generally agree only if the material at issue is no longer in use.

The Appeal Board required three companies to undergo audits in relation to complaints received in 2013.

It was unusual in 2013 that the number of cases far exceeded the number of complaints. One of the complaints in 2013 resulted in over 20 cases for the Panel to consider. Dealing with such a concentration of cases was a challenge for the Authority.

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. I am grateful for their support and contribution.



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 2013. The other main area of work related to amendments to the ABPI Code as well as to the European Federation of Pharmaceutical Industries and Associations (EFPIA) and International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) Codes. Uniquely in 2013 the PMCPA published an addendum to the Code rather than print a whole new edition. Changes agreed in April 2013 in relation to Clause 16 Training came into operation on 1 July 2013.

The percentage of complaints from pharmaceutical companies in 2013 at 19% (15/80) was similar to the 20% (16 out of 78) in 2012. The percentage from health professionals decreased 20% (16/80) compared with 27% (21 out of 78) in 2012. As usual, the PMCPA received 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 (14 in 2013 and 10 in 2012)

were due to an increased number of companies making voluntary admissions (11 in 2013 and 4 in 2012). There were half the number of allegations of a breach of undertaking in 2013 (3) compared with 2012 (6).

The same percentage of cases (57%) was ruled in breach in 2013, (60/105), compared with 2012 (48/84). However, if this is looked at on the basis of individual matters, 42% (126/302) were ruled in breach in 2013 compared with 52% (154/296) in 2012.

The Panel continues to have a good record with 97% (292/302) of its rulings in 2013 being accepted by the parties or upheld on appeal; the figure for 2012 was 96% (284/296). The time taken to complete cases settled at Panel level was 10 weeks in 2013 compared with 9.9 weeks in 2012. 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 and in a number of cases was particularly difficult to obtain, thus significantly lengthening the time taken to deal with them.

The number of complaints submitted anonymously increased in 2013. Given that the complaints system is designed

to allow both parties to fully participate, it is regrettable that many of the anonymous complainants were unable to do so because they did not provide any contact details.

In two appeals considered in 2013 no breach of the Code was ruled with the Appeal Board noting that if the information submitted for the appeal had been supplied to the Panel, its decision might have been different thus preventing an appeal.

2013 was the first year that companies were required under the Code to disclose certain payments to health professionals in aggregate. Additional disclosure on an individual named health professional basis will be required for certain payments in 2015 to be disclosed in 2016.

The PMCPA welcomed Tannyth Cox who was appointed as Deputy Secretary and joined in June 2013 to replace Ros Henley who left the PMCPA earlier in the year.

It has been a particularly busy year and I would like to thank the staff of the PMCPA for all their hard work in 2013.

Heather Simmonds
Director, PMCPA

Complaints in 2013

Eighty complaints were received in 2013 compared with 78 in 2012. There were 105 cases for the PMCPA to deal with in 2013. 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 302, was slightly more than the corresponding figure for 2012 which was 296.

Time to deal with complaints

There was a slight decrease in the overall time taken to deal with complaints. The figure for 2013 was 11.3 weeks compared with 11.6 weeks in 2012. There was a very slight increase in the time taken to complete cases finalised at Panel level from 9.9 weeks in 2012 to 10 weeks in 2013. The majority of cases complete at the Panel level. Cases that went to appeal in 2013 took slightly less time to complete in 2013 (18.1 weeks) than in 2012 (18.9 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. The increase in the number of cases to consider also played a part. A number of appeals were deferred following consideration by the Chairman of the Appeal Board.

Reports to the Code of Practice Appeal Board from the Panel

Seven formal reports were made by the Code of Practice Panel to the Code of Practice Appeal Board in relation to complaints received in 2013.

One report concerned a market research survey. The Panel ruled breaches of the Code and reported the company to the Appeal Board. The company appealed and was successful with regard to one of the Panel's rulings. The others were upheld by the Appeal Board. With regard to the report from the Panel, the Appeal Board considered that no further action was required.

One report concerned a breach of undertaking. The Panel ruled breaches of the Code and reported the company to the Appeal Board. The Appeal

Board was very concerned about the matter and decided the company should undergo an audit in 2014.

One report concerned the failure of a company to provide complete and accurate information to the Panel. The Appeal Board was concerned about the matter, this was the second time the company had failed to provide complete information. The Appeal Board considered this was completely unacceptable and publicly reprimanded the company. It also required an audit to be carried out in 2014.

Complaints in 2013 *continued*

Two cases concerning the same company resulted in four reports to the Appeal Board. Each case was reported twice. The Panel ruled breaches of the Code and considered that the difficulty in obtaining information and the lack of understanding about the Code should be reported to the Appeal Board. One case concerned emails regarding the company's involvement in an international meeting and another regarding offers to purchase. The other case concerned a meeting held in the UK.

The company appealed some of the Panel's rulings in each case and the Panel reported each case to the Appeal Board. The Appeal Board upheld the Panel's rulings and decided the company should undergo an audit and be publicly reprimanded in relation to each case. The company decided to leave the list of non member companies which had agreed to comply with the Code and accept the jurisdiction of the PMCPA. It did not give the undertakings relating to the appeals nor did it agree to undergo the audits. The Appeal Board noted that by failing to provide the requisite undertaking

and assurance and declining to audit the company had failed to comply with the procedures set out in Paragraph 10 of the Constitution and Procedure and thus the Appeal Board decided, in accordance with Paragraph 11.4, to remove it from the list of non member companies which had agreed to comply with the Code. Thus responsibility for the company under the Code could no longer be accepted. Consequently, the Appeal Board decided that the MHRA and ABPI Board of Management should be advised of its decision.

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 2013. No such reports have been made since 2008.

Audits by the PMCPA

Two reaudits of the same company were carried out in 2013 following two complaints received in 2012 which were the subject of formal reports to the Appeal Board in 2012. The first audit was carried out in 2012.

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 carried out in 2013.

One complaint from 2013 which was the subject of a formal report to the Appeal Board in relation to a breach of undertaking resulted in an audit of that company in 2014 and a reaudit later in 2014. Another complaint received in 2013 which was the subject of a formal report to the Appeal Board resulted in an audit of the company in 2014 and a reaudit in 2014.

Two complaints received in 2013 about the same company each of which was the subject of a formal report to the Appeal Board resulted in the Appeal Board requesting audits. These were not carried out as noted above and each were further reported to the Appeal Board.

In all, two reaudits were carried out in 2013.

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.

Two of the complaints made in 2013 were ruled in breach by the Panel and by the Appeal Board. Once notified of the outcome of the appeal the company decided to leave the list of non member companies that had agreed to comply with the Code and accept the jurisdiction of the PMCPA. The matter was reported to the Appeal Board which decided to remove the company from the list of non members which had agreed to comply with the Code and advise the MHRA and ABPI Board of Management of its decision.

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 2013 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 2013. 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, 22 training seminars or presentations on the Code were made for individual companies and other organisations including public relations companies and advertising agencies.

The PMCPA supports the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) activities in particular its training workshops and stakeholder meetings. The Director spoke at four such events in 2013.

Colleagues from the Norwegian trade association (LIF) visited the PMCPA and were given a presentation about the Code.

The Director spoke on behalf of the European Federation of Pharmaceutical Industries and Associations (EFPIA) about the EFPIA Code on Disclosure of Transfers of Value from Pharmaceutical Companies to Healthcare Professionals and Healthcare Organisations at a meeting of the European Forum on Advertising of Medicines (FOAM). FOAM is coordinated by the Medicines and Healthcare Products Regulatory Agency (MHRA) and is made up of those responsible for medicines regulation in each member state to exchange information.

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 2013.

Communicating the Code

The campaign to inform health professionals and others about the Code continued in 2013 with efforts being made to ensure that a wider audience is aware of the Code and how it works.

PMCPA Compliance Network

The PMCPA established the Compliance Network in 2011 as a way to try to help pharmaceutical companies understand and implement the requirements of the Code. 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 2013, 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 2013 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 completed in the previous

three months 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.

Communicating the Code *continued*

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 April 2013 proposals to change Clause 16 of the Second 2012 Edition of the Code were agreed by ABPI members. The changes, which relate to the representative examinations and the introduction of accredited examinations came into operation on 1 July 2013. A new edition of the Code was not printed and instead an addendum was made available.

In November 2013 further proposals to amend the Code were agreed by ABPI members for implementation on 1 January 2014. These proposals resulted mainly from the new EFPIA Code on Disclosure of Transfers of Value from Pharmaceutical Companies to Healthcare Professionals and Healthcare Organisations which was agreed at the EFPIA General Assembly in June 2013.

The changes to the ABPI Code related to the information to be collected by companies in 2015 for disclosure in 2016. The EFPIA General Assembly also agreed changes to the EFPIA Code on the Promotion of Prescription-Only Medicines to, and Interactions with, Healthcare Professionals. Other proposals to amend the ABPI Code and the PMCPA Constitution and Procedure were also included.

The proposal did not cover how the disclosure would be made ie on a central platform or company website. Subsequently the ABPI decided to develop a central database and this would be the subject of changes to the Code in 2014.

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 2013 this group considered one complaint.

The IFPMA Code Compliance Network (CCN) continued its work in 2013. 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.

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

European Federation of Pharmaceutical Industries and Associations

The EFPIA Code on the Disclosure of Transfers of Value from Pharmaceutical Companies to Healthcare Professionals and Healthcare Organisations was adopted by the EFPIA General Assembly in June 2013 to be implemented by national associations by 31 December 2013. Changes to the EFPIA Healthcare Professional Code were also agreed. The Director of the PMCPA is a member of various EFPIA groups in relation to the EFPIA Codes.

EU and UK legal requirements

Following publication of a case report the Medicines and Healthcare Products Regulatory Agency (MHRA) took further action resulting in the respondent company being required to issue a corrective statement. The MHRA brought the matter to the PMCPA's attention for discussion. The PMCPA proposed changes to the 2014 Code.

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 90 times in 2013 (compared with 83 times in 2012). 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.



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.



Tannyth Cox

is the Deputy Secretary of the PMCPA. Tannyth registered as a pharmacist in South Africa before coming to the UK to work in various pharmaceutical companies which included providing expert advice and training on the Code in addition to reviewing materials. Tannyth joined the PMCPA in June 2013 following the departure of Ros Henley in January 2013.



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 11 times in 2013 (10 times in 2012) and considered appeals in 19 cases in 2013 (16 cases in 2012).

Membership and attendance during 2013

Chairman

Mr William Harbage QC (11/11)

Independent Members

Mrs Mary Baker MBE (Representing patients' interests) (8/11)

Professor Steve Chapman (From an independent body which provides information on medicines) (7/11)

Dr Howard Freeman (General Practitioner) (7/9) appointed March 2013

Mrs Gillian Hawken (Lay Member) (9/10) appointed January 2013

Professor Richard Hobbs (University Academic/General Practitioner) (7/8) until October 2013

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

Mrs Aileen Cherry (Nurse Prescriber) (11/11)

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

Industry Members

Dr Peter Barnes (Medical Director, Janssen) (3/3) from October 2013

Ms Helen Roberts (Head of Legal Oncology Europe, Novartis Pharmaceuticals UK Limited) (5/10) until November 2013

Mr Stuart Rose (Managing Director, Merz Pharma UK Ltd) (5/11)

Dr Rhiannon Rowsell (Previously Promotional Affairs & Medical Excellence Director, AstraZeneca) (9/10)

Dr Pim Kon (Medical Director, GlaxoSmithKline UK Limited) (3/9)

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

Ms Michelle Swift (Director of NHS & Regulatory Affairs, Takeda UK Ltd) (3/4) until May 2013

Coopted Members

The Chairman can co-opt members for meetings of the Appeal Board so as to enable a quorum to be achieved. During 2013, the following were each co-opted for at least one meeting:

Dr Alan McDougall (Medical & Regulatory Affairs Director, Astellas Pharma Ltd)

Dr Fenton Catterall (Compliance Director, MSD UK Ltd)

Dr Peter Barnes (Medical Director, Janssen)

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

Dr Michael Wilson (General Practitioner)

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 completed in the previous three months where companies were ruled in breach of Clause 2 of the Code, were required to issue a corrective statement or were the subject of a public reprimand.

Complaints received by the PMCPA

| | 2013 | 2012 | 2011 |
|--|------|------|------|
| Complaints received | 80 | 78 | 84 |
| Not within the scope of the Code | – | 2 | 7 |
| Covered by a previous case | 1 | – | – |
| Complaints withdrawn | – | – | 1 |
| Company declined to accept the PMCPA's jurisdiction before proceedings commenced | 2 | 5 | 4 |
| Inter-company dialogue successful | – | 1 | 1 |
| Complaints considered | 76 | 67 | 77 |
| Cases arising from these complaints | 105 | 84 | 84 |
| Individual matters considered | 302 | 296 | 259 |

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'. Of the complaints considered, one led to 26 cases in 2013 and of these, one was covered by a previous case, one involved a different company and was taken up with that company and three cases did not proceed because the companies declined to accept the PMCPA's jurisdiction before proceedings commenced. A further six cases were taken up in 2014.

Outcomes of complaints considered

| | 2013 | 2012 | 2011 |
|---|------|------|------|
| Cases where a breach found | 60 | 48 | 43 |
| Cases where no breach found | 45 | 36 | 41 |
| Number of matters in these cases: | 302 | 296 | 259 |
| - in breach | 126 | 154 | 94 |
| - no breach | 176 | 142 | 165 |
| Cases where the Code of Practice Panel required suspension of materials | – | – | – |
| Breaches of undertaking ruled | 3 | 5 | 3 |
| Breaches of Clause 2 ruled | 16 | 9 | 8 |
| Reports to the Code of Practice Appeal Board | 7* | 2 | 5 |
| Reports to the ABPI Board of Management | – | – | – |

* Four of these reports concerned one company and two cases.

Sources of complaints

| | 2013 | 2012 | 2011 |
|--|-----------------|-----------------|-----------------|
| Health professionals | | | |
| General practitioners | 3 | 8 | 16 |
| Hospital doctors | 4 | 3 | 3 |
| Other doctors | 2 | 3 | – |
| Pharmacists | 5 | 6 | 6 |
| Medical/pharmaceutical advisers | – | 1 | – |
| Nurses | – | – | 1 |
| Managers | 2 | – | 4 |
| | 16 | 21 | 30 |
| Pharmaceutical companies | | | |
| ABPI members | 12 | 7 | 13 |
| Non members | 3 | 9 | 9 |
| | 15 | 16 | 22 |
| PMCPA Director | | | |
| Arising from media criticism | – | – | 2 |
| Alleged breach of undertaking | 3 | 6 | 4 |
| Arising from voluntary admissions | 11 | 4 | 1 |
| | 14 | 10 | 7 |
| Organisations | | | |
| Medicines and Healthcare Products Regulatory Agency | 1 | – | – |
| | 1 | 0 | 0 |
| Others | | | |
| Members of the public | 4 | 5 | 3 |
| Anonymous | 21 ¹ | 19 ² | 17 ³ |
| Employees/ex employees | 6 | 3 | – |
| Anonymous employees | 1 | 4 | 1 |
| Anonymous ex employees | – | – | 1 |
| Journalist | 1 | – | 2 |
| Publisher | 1 | – | 1 |
| | 34 | 31 | 25 |
| Total | 80 | 78 | 84 |

¹ Ten of these were from anonymous health professionals

² Eleven of these were from anonymous health professionals

³ Six of these were from anonymous health professionals

Appeals to the Code of Practice Appeal Board

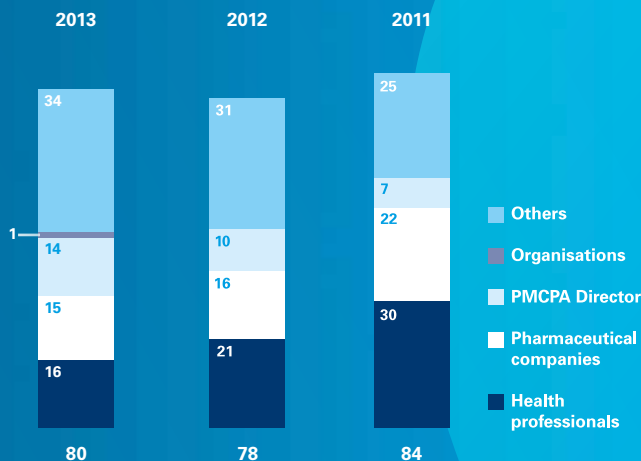
| | 2013 | 2012 | 2011 |
|---|-------------|-------------|-------------|
| Total number of matters ruled upon by the Code of Practice Panel | 302 | 296 | 259 |
| Rulings accepted by the parties | 264 | 253 | 223 |
| Rulings successfully appealed | 10 | 12 | 21 |
| Rulings unsuccessfully appealed | 28 | 31 | 15 |
| Number of cases appealed | 19 | 16 | 19 |
| Sources of appeals | 2013 | 2012 | 2011 |
| Cases appealed by complainants | 7 | 6 | 4 |
| Cases appealed by respondents | 12 | 11 | 16 |
| <i>In one case in 2011 and 2012 both the complainant and the respondent appealed.</i> | | | |
| Appeals by complainants | 2013 | 2012 | 2011 |
| successful | 1 | 2 | – |
| partly successful | 0 | – | – |
| unsuccessful | 6 | 4 | 4 |
| | 7 | 6 | 4 |
| Appeals by respondents | | | |
| successful | 5 | 3 | 10 |
| partly successful | 1 | 3 | 1 |
| unsuccessful | 6 | 5 | 5 |
| | 12 | 11 | 16 |
| Rulings appealed by complainants | | | |
| successful | 3 | 5 | – |
| unsuccessful | 14 | 8 | 5 |
| | 17 | 13 | 5 |
| Rulings appealed by respondents | | | |
| successful | 7 | 7 | 21 |
| unsuccessful | 14 | 23 | 10 |
| | 21 | 30 | 31 |

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.

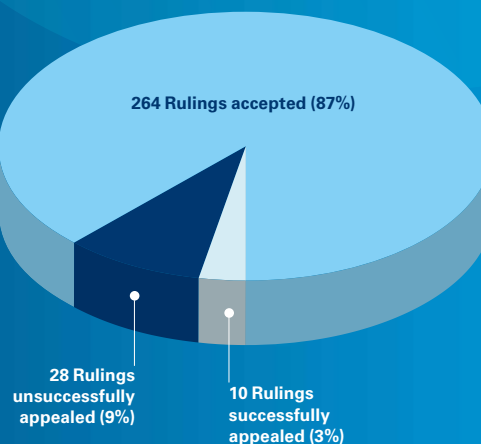
Complaints nominally made by the Director can also arise as a result of:

- 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 2013 the Code of Practice Panel made 302 rulings. Of these, 264 (87%) were accepted by the complainants and respondents involved. A further 28 (9%) were the subject of unsuccessful appeals to the Code of Practice Appeal Board. The remaining 10 (3%) were successfully appealed to the Appeal Board.



Average time taken to complete cases (in weeks)

| | 2013 | 2012 | 2011 |
|---|------|------|------|
| Cases settled at Code of Practice Panel level | 10 | 9.9 | 7 |
| Cases which were the subject of appeal | 18.1 | 18.9 | 15 |
| All cases | 11.3 | 11.6 | 8.8 |

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 2013 no advertisements were taken up as potentially being in breach of the Code.

Companies ruled in breach of the Code (complaints received in 2013)

* In breach of Clause 2

Abbott Healthcare Products Limited

AbbVie Ltd

Allergan Ltd

Amgen Limited

*Bayer Plc

Bristol-Myers Squibb Pharmaceuticals Limited

Chiesi Ltd

Ferring Pharmaceuticals (UK) Ltd

*Galderma (UK) Limited

*Gedeon Richter

*GlaxoSmithKline UK Limited

Grünenthal Ltd

*HRA Pharma UK

Leo Pharma

Eli Lilly and Company Limited

*Lundbeck Limited

*A Menarini Pharma

Merck Serono Limited

Merck Sharp & Dohme Limited

Napp Pharmaceuticals Limited

Norgine Pharmaceuticals Limited

Novartis Pharmaceuticals UK Ltd

Otsuka Pharmaceuticals (UK) Ltd

*Pharmaxis Pharmaceuticals Ltd

*Roche Products Limited

Rosemont Pharmaceuticals Ltd

*Servier Laboratories Ltd

*Sanofi

Sanofi Pasteur MSD

*Shire Pharmaceuticals Ltd

Tillotts Pharma

Takeda UK Ltd

Accounts 2013

The PMCPA has been self-financing from the beginning of 1996. In 2013 there was a surplus of £56,289 before tax. The PMCPA cumulative reserves on 31 December 2013 are £812,546 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. Seventy five percent of the levy due was called up in 2013. 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 2013 was £3,000 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 2013 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 2013 continued

| | 2013 | 2012 | 2011 |
|------------------------------------|-------------------|-------------------|------------------|
| | £ | £ | £ |
| Levy | 480,205 | 393,174 | 558,023 |
| Administrative charges | 528,000 | 442,078 | 621,322 |
| Seminars/meetings | 172,855 | 143,375 | 110,109 |
| Company audits | 14,000 | 38,000 | 53,500 |
| Contributions to advertising costs | 24,000 | 17,448 | 24,000 |
| | 1,219,060 | 1,034,075 | 1,366,954 |
| Expenditure | £1,142,171 | £1,247,555 | £891,928* |

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;
- Guidance (Digital, Clause 3 and Certification).

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 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



PMCPA | Prescription Medicines
Code of Practice Authority

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