

The logo for the Prescription Medicines Code of Practice Authority (PMCPA) features the acronym "PMCPA" in a bold, dark blue, sans-serif font. A thin vertical line is positioned to the right of the text, separating it from the full name.

**PMCPA**

Prescription Medicines  
Code of Practice Authority

The text "2014 Annual report" is displayed in a white, sans-serif font. The year "2014" is significantly larger than the words "Annual report", which are positioned directly below it. The text is set against a dark purple background with a large, overlapping light blue circular shape behind it.

**2014**  
**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 ABPI Code of Practice for the Pharmaceutical Industry.

The PMCPA is appointed by the ABPI Board of Management. It operates independently of the ABPI and has its own staff. The Director of the PMCPA reports to the Code of Practice Appeal Board on the operation of the complaints procedure. The Director reports to the President of the ABPI for administrative purposes. The PMCPA operates impartially between complainants and respondents, and between members of the ABPI and companies which are not members of the ABPI.

The Code has been regularly revised since its inception in 1958 and is drawn up in consultation with the British Medical Association, the Royal Pharmaceutical Society, the Royal College of Nursing, the Medicines and Healthcare Products Regulatory Agency of the Department of Health, the Competition and Markets Authority and the Serious Fraud Office.

Anyone is welcome to send suggestions for amendments to the Code.

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“I am pleased to contribute to the 2014 Annual Report of the Prescription Medicines Code of Practice Authority.”

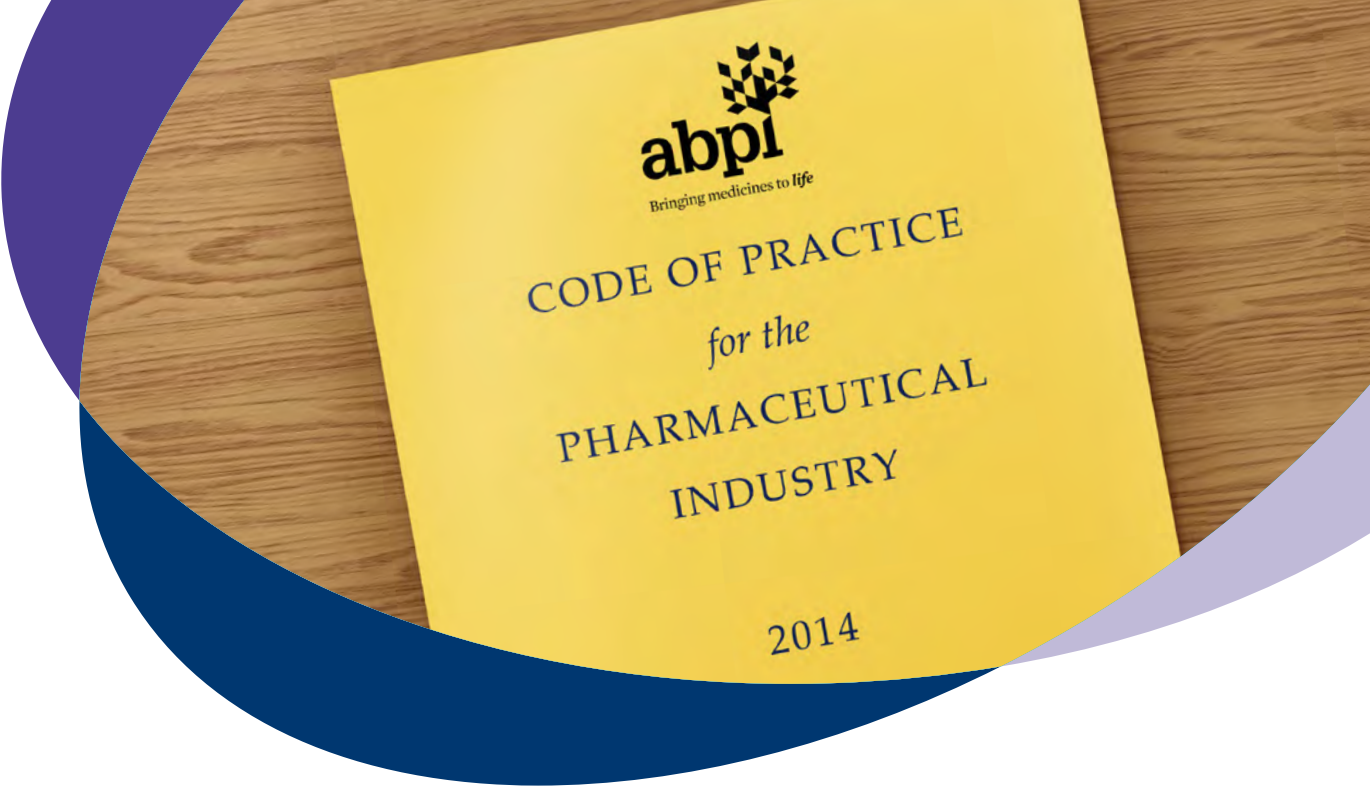
## Foreword

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The number of complaints to the PMCPA in 2014 was 51, fewer than in 2013 when 80 complaints were received. The number of cases (49) was much lower than considered in 2013 (105). The number of individual allegations (matters) considered in 2014 was 263 compared with 302 in 2013. More matters were appealed in 2014 (71) than in 2013 (38). Of the 71 matters appealed in 2014, 18% were successfully appealed and 82% were unsuccessfully appealed. The proportion of the Code of Practice Panel’s rulings appealed in 2014 was 27% (71/263) compared with 13%

(38/302) in 2013. The proportion of the Panel’s rulings successfully appealed in 2014, was 5% (13/263) compared with 3% (10/302) in 2013. 22% (58/263) were unsuccessfully appealed in 2014 compared with 9% (28/302) in 2013. The parties accepted without appeal 73% of the Panel’s rulings compared with 87% in 2013. 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 more in 2014 (23.3 weeks) than in 2013 (18.1 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. In 2014 two appeals were deferred by at least a month. One following a request from a complainant from outside the industry who wanted to attend. The second was deferred at the request of a respondent company.

The Appeal Board required two companies to undergo audits in relation to complaints received in 2014.

I would like to thank the members and co-opted members of the Appeal Board for their hard work. It is apparent to me from their contributions in meetings that 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.

Finally, two long serving independent members retired in 2014, Mrs Mary Baker MBE who represented the interests of patients and was appointed in 2001 and Mrs Linda Stone OBE

who was appointed in 1993 as the pharmacist member. I would like to thank them for their unstinting support and valuable 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 2014. The other main area of work related to amendments to the ABPI Code, as well as updates to the European Federation of Pharmaceutical Industries and Associations (EFPIA) Codes.

The percentage of complaints from pharmaceutical companies in 2014 at 16% (8/51) was less than the 19% (15/80) in 2013. The percentage from health professionals increased to 35% (18/51) compared with 20% (16/80) in 2013.

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 (7 in 2014 and 14 in 2013) were due to the number of companies making voluntary admissions (7 in 2014 and 11 in 2013). Unusually, there were no allegations of a breach of undertaking in 2014. There were 3 in 2013.

The percentage of cases ruled in breach in 2014 at 55% (27/49) was only slightly less than the 57% in 2013 (60/105). However, if this is looked at on the basis of individual matters, 59% (156/263) were ruled in breach in 2014 compared with 42% (126/302) in 2013.

The Panel continues to have a good record with 95% (250/263) of its rulings in 2014 being accepted by the parties or upheld on appeal; the figure for 2013 was 97% (292/302). The time taken to complete cases settled at Panel level in 2014 at 10 weeks was the same as 2013. 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 this was particularly difficult to obtain, thus lengthening the time taken to deal with them.

The number of complaints submitted anonymously increased slightly in 2014 (15/51, 29%) compared with 2013 (22/80, 28%). 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 2014, the second independent Chairman of the Code of Practice Committee and its replacement, the Code of Practice Appeal Board, Mr Philip Cox DSC QC died. Philip was Chairman when I first started working on the Code. He also had a long and successful career as a barrister. He was a wise and thoughtful Chairman, who was a staunch supporter of self regulation by the pharmaceutical industry.

On a happier note, there were some notable events in 2014. On 1 January the PMCPA celebrated its 21st birthday and by the end of the year the eight PMCPA staff had collectively worked for the Authority for over 100 years. I completed 30 years employment with the ABPI and PMCPA in October 2014 including 25 years working on the Code.

2014 was another busy year, particularly preparing changes to the Code. I would like to thank the staff of the PMCPA for all their hard work in 2014.

**Heather Simmonds**  
Director, PMCPA

# Complaints

## Complaints in 2014

Fifty-one complaints were received in 2014 compared with 80 in 2013. There were 49 cases for the PMCPA to deal with in 2014. Some complaints lead to more than one case as they involve more than one company. Some complaints do not proceed. The number of individual allegations to be considered within these cases, at 263, was slightly less than the corresponding figure for 2013 which was 302. However the number of matters per case rose in 2014 to 5 from 3 in 2013.

## Time to deal with complaints

There was a slight increase in the overall time taken to deal with complaints. The figure for 2014 was 11.7 weeks compared with 11.3 weeks in 2013. There was no change in the time taken to complete cases finalised at Panel level at 10 weeks in 2014 and 2013. The majority of cases complete at the Panel level. Cases that went to appeal in 2014 took longer to complete in 2014 (23.3 weeks) than in 2013 (18.1 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. Two appeals were deferred, each by at least a month following a request from one of the parties and with permission of the Chairman of the Appeal Board.

## Reports to the Code of Practice Appeal Board from the Panel

Three formal reports were made by the Code of Practice Panel to the Code of Practice Appeal Board in relation to complaints received in 2014.

One report concerned promotional material. The Panel required that the campaign be suspended pending the final outcome of the case. Both the complainant and the respondent appealed the Panel's rulings and both were unsuccessful. The Panel's rulings 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 the failure of a company to disclose interactions with patient organisations. The Panel ruled breaches of the Code. The Appeal Board was very concerned about

the breadth and scale of the failings and decided the company should be publicly reprimanded and undergo an audit in 2015.

Two cases concerning the same company resulted in one report to the Appeal Board. One case concerned advertising on a website. 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 amended the website but did not give the requisite undertaking and assurance. The Appeal Board noted that by failing to provide the requisite undertaking and assurance the company had failed to comply with the procedures set out in Paragraph 7 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.

## Complaints *continued*

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### **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 2014. No such reports have been made since 2008.

### **Audits by the PMCPA**

One report in 2013 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 and reaudit to be carried out in 2014.

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 same company in 2014 and a reaudit in 2014. Both these cases led to a reaudit in 2015.

A third matter in 2014, which arose from a voluntary admission from the same company of a formal report to the Appeal Board as referred to above, and resulted in an audit of the company in 2015.

One complaint in 2014 concerned materials used at a meeting. The Panel's rulings of breaches of the Code were appealed and all but one upheld. The Appeal Board was so concerned about the content of the material at issue, its potential effects and the impression given including a disregard for patient safety it decided to require the company to issue a corrective statement to attendees and recipients of pre-circulated material. The Appeal Board decided that the company should be audited and reaudited in 2015.

In all, four reaudits of two companies were carried out in 2014.

### **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. If the complainant is anonymous and non contactable then the PMCPA sends the complaint to the MHRA. The MHRA fully supports the Code and encourages companies to comply with it and to send senior managers to PMCPA training seminars.



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Two complaints made in 2013 about one company were ruled in breach by the Panel and the company was reported to the Appeal Board. The company appealed some of the Panel's rulings in each case. These were upheld by the Appeal Board. Once notified of the outcome of the appeals the company decided to leave the list of non member companies that agree to comply with the Code and accept the jurisdiction of the PMCPA. The matter was reported to the Appeal Board which in 2014 decided to remove the company from the list of non members which agree to comply with the Code and advise the MHRA and ABPI Board of Management of its decision.

Similarly, one of the complaints made in 2014 was ruled in breach of the Code and the company decided to leave the list of non member companies that agree 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 agree to comply with the Code and advise the MHRA and ABPI Board of Management of its decision. Further complaints about

these two companies were referred to the MHRA to deal with.

In 2015 the MHRA stated that the companies concerned informed the MHRA that they were both continuing to comply with the Code but had opted out of the complaints procedure. The MHRA was vetting all new advertising for one of the companies which had also been required to issue a corrective statement.

Full detail of all cases can be found at [pmcpa.org.uk/cases](http://pmcpa.org.uk/cases)



## 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 2014 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](http://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.

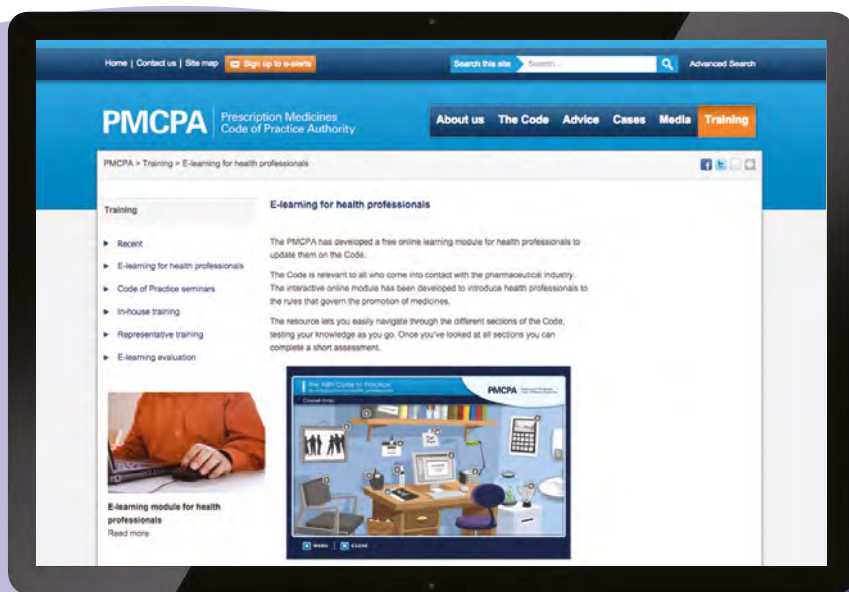
### Training on the Code

Five seminars designed to explain the requirements of the Code were held by the PMCPA in central London in 2014. These seminars are open to all and places can be booked via the PMCPA website ([www.pmcpa.org.uk](http://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, seventeen 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 Association (IFPMA) activities in particular its training workshops and stakeholder meetings. The Director spoke at three such events in 2014.

The PMCPA is regularly invited to lecture on training courses run by professional organisations and universities and to speak at conferences. Eight such speaking engagements were undertaken in 2014.



## Communicating the Code

The campaign to inform health professionals and others about the Code continued in 2014 with efforts being made to ensure that a wider audience is aware of the Code and how it works.

In 2014 a number of projects were initiated to help users navigate the Code and to explain the importance of self regulation to the industry and others.

### PMCPA Compliance Network

The PMCPA established the Compliance Network in 2011 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.

Meetings are held every quarter, with about twenty people at each. Topics covered in 2014 included updates on the APBI central platform for disclosure, international and European developments, the latest advice and guidance and changes to codes.

Attendees are limited to one per pharmaceutical company and the feedback from the 2014 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 have been ruled in breach of Clause 2 of the Code, were required to issue a corrective statement or were the subject of a public reprimand. These advertisements act as a sanction and highlight what constitutes a breach of the Code.

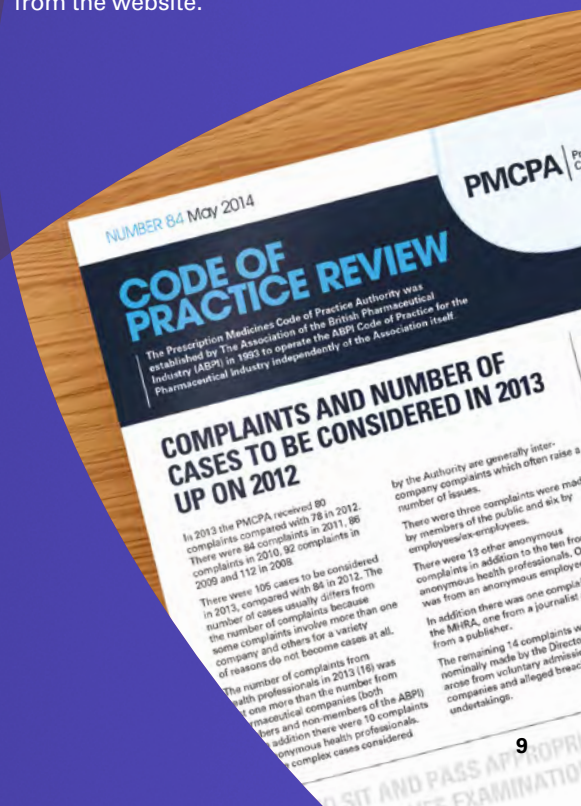
Four advertisements featuring the activities of nine companies were placed in the BMJ, The Pharmaceutical Journal and the Nursing Standard and also published on the PMCPA website.

### 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 ([www.pmcpa.org.uk](http://www.pmcpa.org.uk)) 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

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On 1 January 2014 a new Code came into operation with the usual transition period for newly introduced requirements such that during 1 January 2014 to 30 April 2014, no material or activity would be regarded as being in breach of the Code if it failed to comply with newly introduced requirements.

In November 2014 proposals to change the 2014 edition of the Code were agreed by ABPI members.

These proposals resulted mainly from work done by a group established by the ABPI Board of Management to review the Code. Additional changes were needed

to implement fully the 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 and updated in June 2014. The EFPIA General Assembly in June 2014 also agreed changes to the EFPIA Code on the Promotion of Prescription-Only Medicines to, and Interactions with, Healthcare Professionals. The Medicines and Healthcare Products Regulatory Agency (MHRA) consultation as part of the red tape challenge which led to changes in UK law as well as the regular update of the Code and its operation also led to amendments.

The proposals covered how the disclosures of certain transfers of value would be made ie on a central platform and work on this continued in 2014. The PMCPA will meet from its reserve some of the costs of developing the central platform. The running costs for the immediate future will be the responsibility of the ABPI.

Full details of the changes were published on the PMCPA website ([www.pmcpa.org.uk](http://www.pmcpa.org.uk)) and a presentation summarising the changes was also made available.

## International and European codes

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### **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 2014 this group did not have any complaints to consider.

The IFPMA Code Compliance Network (CCN) continued its work in 2014. 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. It also develops guidance and position papers.

In 2014 guidance was issued on sponsorship of events and meetings and competition law. A position paper was issued on disclosures of transfers of value. Members of the CCN, including the Director of the PMCPA, produced a paper, Ethical pharmaceutical promotion and communications worldwide: codes and regulations, which was peer reviewed and published in Philosophy, Ethics and Humanities in Medicine (Francer et al 2014).

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

### **European Federation of Pharmaceutical Industries and Associations**

The EFPIA Code on 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. It was updated in June 2014. Changes to the EFPIA Healthcare Professional Code were also agreed. These are reflected in the ABPI Code. The Director of the PMCPA is a member of various EFPIA groups in relation to the EFPIA Codes.

## EU and UK legal requirements

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Following publication of a case report for a 2013 case, the Medicines and Healthcare Product 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 which were included in the 2014 Code.

Two complaints about the same company made in 2013 resulted in the Appeal Board removing the company from the list of non members which had agreed to comply with the Code. The MHRA took further actions and required the company to issue a corrective statement and to submit its advertising for vetting prior to use.

## 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. One company was required to suspend material in 2014. 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 84 times in 2014 (compared with 90 times in 2013). 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 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 2013. Tannyth was on maternity leave for part of 2014.

## The PMCPA Team

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### **Anne Erwin**

is the Interim Deputy Secretary of the PMCPA and was appointed to cover Tannyth Cox's maternity leave from September 2014. Anne has worked in compliance for a pharmaceutical company and as a consultant for EFPIA, working on the transposition of EFPIA codes by national associations.



### **Peter Clift**

is Executive Officer at the PMCPA. He is responsible for the administration of the Code of Practice Appeal Board. Peter joined the PMCPA in May 2002 and was previously a biomedical scientist. Peter has a masters degree in biology and post graduate legal qualifications.



### **Nora Alexander**

is the Personal Assistant to the Director of the PMCPA, she has a background of working within the NHS and joined the PMCPA in 2007. Nora is the contact for the PMCPA seminars.



### **Lisa Matthews**

is PA to the Deputy Director and Secretary. She has been at the PMCPA for 16 years and is responsible for the day to day running of the office. Lisa is the contact for copies of the Code and the Review.



### **Vicky Bewer**

was Head of Communications at the PMCPA from 2009 to January 2015 when she left to take up another role. Vicky was responsible for all internal and external communication.



## The Code of Practice Appeal Board

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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 9 times in 2014 (11 times in 2013) and considered appeals in 6 cases (19 cases in 2013). The number of matters considered by the Appeal Board was more in 2014 (71) than in 2013 (38).



## Membership and attendance during 2014

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### Chairman

Mr William Harbage QC (9/9)

### Independent Members

Mrs Mary Baker MBE (Representing patients' interests) (1/1) until January 2014

Professor Stephen Chapman (From an independent body which provides information on medicines) (6/9)

Mrs Aileen Cherry (Nurse Prescriber) (9/9)

Dr Howard Freeman MBE (General Practitioner) (7/9)

Mr Christopher Goard (Representing patients' interests) (4/6) appointed May 2014

Mrs Gillian Hawken (Lay member) (9/9)

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

Mr David Mills (Pharmacist) (6/6) appointed May 2014

Mrs Linda Stone OBE (Pharmacist) (0/1) until January 2014

Dr John Watkins (Hospital Consultant) (4/6) appointed May 2014

### Industry Members

Dr Peter Barnes (Medical Director, Janssen) (4/9) appointed October 2013

Mr Stuart Rose (Managing Director, Merz Pharma UK Ltd) (5/8)

Dr Rhiannon Rowsell (Previously Promotional Affairs & Medical Excellence Director, AstraZeneca) (5/9)

Dr Pim Kon (Medical Director, GlaxoSmithKline UK Limited) (0/2) until February 2014

Dr Berkeley Phillips (Medical Director, Pfizer UK Limited) (4/9)

Dr Alan McDougall (Medical & Regulatory Affairs Director, Astellas Pharma Ltd) (2/6) appointed May 2014

Dr Fenton Catterall (Compliance Director, Merck Sharp & Dohme UK Ltd) (4/5) appointed May 2014

### Co-opted Members

The Chairman can co-opt members for meetings of the Appeal Board so as to enable a quorum to be achieved. During 2014, the following were each co-opted for at least one meeting:

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

Dr Satish Kolli (Medical Director, Leo Pharma UK)

Dr Jon Ryland (Medical Director, AbbVie Limited)

Dr Paul Schofield (Medical Director, Napp Pharmaceuticals Limited)

Dr Michael Wilson (General Practitioner)

## Statistics on complaints

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### 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. One company was asked to suspend promotional material in 2014.

In each case where a breach of the Code is ruled and accepted, 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 ([www.pmcpa.org.uk](http://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 in the Review.

Additional sanctions can also be imposed by the Appeal Board. 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. The companies at issue are required to contribute to the cost of such advertising.

## Complaints received by the PMCPA

	<b>2014</b>	<b>2013</b>	<b>2012</b>
Complaints received	51	80	78
Not within the scope of the Code	2	-	2
Insufficient information	-	1	-
Company declined to accept the PMCPA's jurisdiction before proceedings commenced	9	2	5
Inter-company dialogue successful	-	-	1
Complaints considered	40	76	67
Cases arising from these complaints	49	105	84
Individual matters considered	263	302	296

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 in 2013, one led to 26 cases 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 from that one complaint were taken up in 2014.

## Outcomes of complaints considered

	<b>2014</b>	<b>2013</b>	<b>2012</b>
Cases where a breach found	27	60	48
Cases where no breach found	22	45	36
Number of matters in these cases:	263	302	296
- in breach	156	126	154
- no breach	107	176	142
Cases where the Code of Practice Panel required suspension of materials	1	-	-
Breaches of undertaking ruled	-	3	5
Breaches of Clause 2 ruled	3	16	9
Reports to the Code of Practice Appeal Board	3	7*	2
Reports to the ABPI Board of Management	-	-	-

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

## Sources of complaints

	2014	2013	2012
<b>Health professionals</b>			
General practitioners	3	3	8
Hospital doctors	5	4	3
Other doctors	-	2	3
Pharmacists	6	5	6
Medical/pharmaceutical advisers	-	-	1
Nurses	1	-	-
Managers	3	2	-
	<b>18</b>	<b>16</b>	<b>21</b>
<b>Pharmaceutical companies</b>			
ABPI members	5	12	7
Non members	3	3	9
	<b>8</b>	<b>15</b>	<b>16</b>
<b>PMCPA Director</b>			
Alleged breach of undertaking	-	3	6
Arising from voluntary admissions	7	11	4
	<b>7</b>	<b>14</b>	<b>10</b>
<b>Organisations</b>			
Medicines and Healthcare Products Regulatory Agency	-	1	-
	<b>0</b>	<b>1</b>	<b>0</b>
<b>Others</b>			
Members of the public	1	4	5
Anonymous	13 <sup>1</sup>	21 <sup>2</sup>	19 <sup>3</sup>
Employees/ex employees	2	6	3
Anonymous employees	1	1	4
Anonymous ex employees	1	-	-
Journalist	-	1	-
Publisher	-	1	-
	<b>18</b>	<b>34</b>	<b>31</b>
<b>Total</b>	<b>51</b>	<b>80</b>	<b>78</b>

<sup>1</sup> Six of these were from anonymous health professionals

<sup>2</sup> Ten of these were from anonymous health professionals

<sup>3</sup> Eleven of these were from anonymous health professionals

## Appeals to the Code of Practice Appeal Board

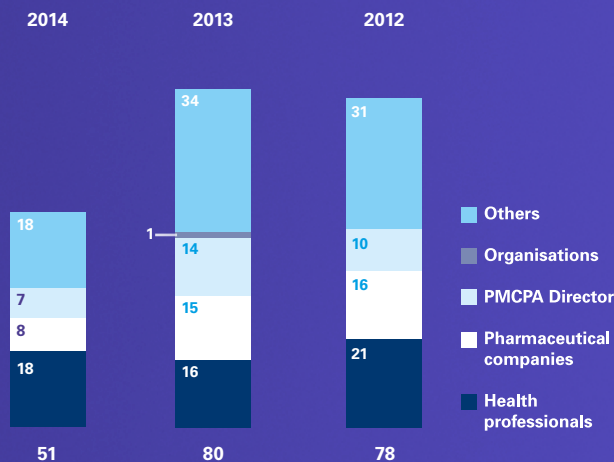
	<b>2014</b>	<b>2013</b>	<b>2012</b>
Total number of matters ruled upon by the Code of Practice Panel	263	302	296
Rulings accepted by the parties	192	264	253
Rulings successfully appealed	13	10	12
Rulings unsuccessfully appealed	58	28	31
Number of cases appealed	6	19	16
<b>Sources of appeals</b>	<b>2014</b>	<b>2013</b>	<b>2012</b>
Cases appealed by complainants	2	7	6
Cases appealed by respondents	5	12	11
<i>In one case in 2012 and 2014 both the complainant and the respondent appealed.</i>			
<b>Appeals by complainants</b>	<b>2014</b>	<b>2013</b>	<b>2012</b>
successful	-	1	2
partly successful	1	-	-
unsuccessful	1	6	4
	<b>2</b>	<b>7</b>	<b>6</b>
<b>Appeals by respondents</b>			
successful	-	5	3
partly successful	4	1	3
unsuccessful	1	6	5
	<b>5</b>	<b>12</b>	<b>11</b>
<b>Rulings appealed by complainants</b>			
successful	2	3	5
unsuccessful	3	14	8
	<b>5</b>	<b>17</b>	<b>13</b>
<b>Rulings appealed by respondents</b>			
successful	11	7	7
unsuccessful	55	14	23
	<b>66</b>	<b>21</b>	<b>30</b>

## 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.

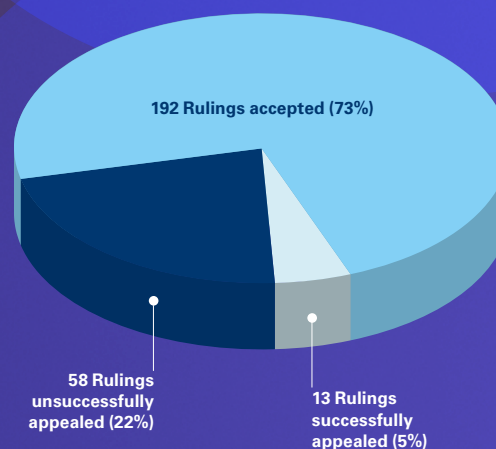
Complaints nominally made by the Director can also arise as a result of:

- 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
- voluntary admissions.



## Code of Practice Panel rulings

In 2014 the Code of Practice Panel made 263 rulings. Of these, 192 (73%) were accepted by the complainants and respondents involved. A further 58 (22%) were the subject of unsuccessful appeals to the Code of Practice Appeal Board. The remaining 13 (5%) were successfully appealed to the Appeal Board.



## Average time taken to complete cases (in weeks)

	2014	2013	2012
Cases settled at Code of Practice Panel level	10	10	9.9
Cases which were the subject of appeal	23.3	18.1	18.9
All cases	11.7	11.3	11.6

## Scrutiny

The PMCPA scrutinises a sample of all advertisements issued by pharmaceutical companies in accordance with the provisions of its Constitution and Procedure and takes up with the companies concerned any advertisements potentially in breach of the Code.

In 2014 no advertisements were taken up as potentially being in breach of the Code.

## Companies ruled in breach of the Code (complaints received in 2014)

\* In breach of Clause 2

Actelion Pharmaceuticals UK Ltd	Chiesi Ltd	Merck Sharp & Dohme Limited
Aegerion Pharmaceuticals Limited	Daiichi-Sankyo UK Ltd	Napp Pharmaceuticals Limited
Amdipharm UK Limited	Ferring Pharmaceuticals Ltd	Orion Pharma (UK) Ltd
Amgen Limited	Flynn Pharma Ltd	Pfizer Limited
Astellas Pharma Ltd	*Genzyme Therapeutics Limited	Pharmacosmos UK Ltd
Bayer Plc	GlaxoSmithKline UK Limited	Pierre Fabre Ltd
Boehringer Ingelheim Limited	Janssen	Roche Products Limited
	Meda Pharmaceuticals Ltd	*Sanofi
	*Merck Serono Limited	Tillotts Pharma



## Accounts 2014

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The PMCPA has been self-financing from the beginning of 1996. In 2014 there was a deficit of £79,139 before tax which meant some tax could be reclaimed (£20,211). The PMCPA cumulative reserves on 31 December 2014 are £753,618 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. All the levy due was called up in 2014. The costs of the PMCPA are mainly covered by administrative charges which are payable by companies 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 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 2014 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 2014 was £11,000 for member companies and £12,000 for non member companies.

Companies subject, as a sanction, to advertising in the medical, pharmaceutical or nursing press, are required to contribute to the cost of such advertising.

### **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 2014 continued

	<b>2014</b>	<b>2013</b>	<b>2012</b>
	<b>£</b>	<b>£</b>	<b>£</b>
Levy	658,292	480,205	393,174
Administrative charges	386,500	528,000	442,078
Seminars/meetings	186,669*	172,855	143,375
Company audits	70,000	14,000	38,000
Contributions to advertising costs	24,000	24,000	17,448
	<b>1,325,461</b>	<b>1,219,060</b>	<b>1,034,075</b>
<b>Expenditure</b>	<b>£1,404,600</b>	<b>£1,142,171</b>	<b>£1,247,555</b>

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

\* includes reimbursed expenses



## More information

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If you would like to find out more about the PMCPA or its work, please go to our website at [www.pmcpa.org.uk](http://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](mailto: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](mailto:complaints@pmcpa.org.uk)



**PMCPA** | Prescription Medicines  
Code of Practice Authority

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London, SW1E 6QT**

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**Fax: 020 7747 8881**

**[www.pmcpa.org.uk](http://www.pmcpa.org.uk)**