PMCPA | Prescription Medicines Code of Practice Authority

2015
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 a division of the ABPI which is a company limited by guarantee registered in England and Wales, No 09826787. Registered office: 7th Floor, Southside, 105 Victoria Street, London, SW1E 6QT.

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 to the PMCPA suggestions for amendments to the Code.

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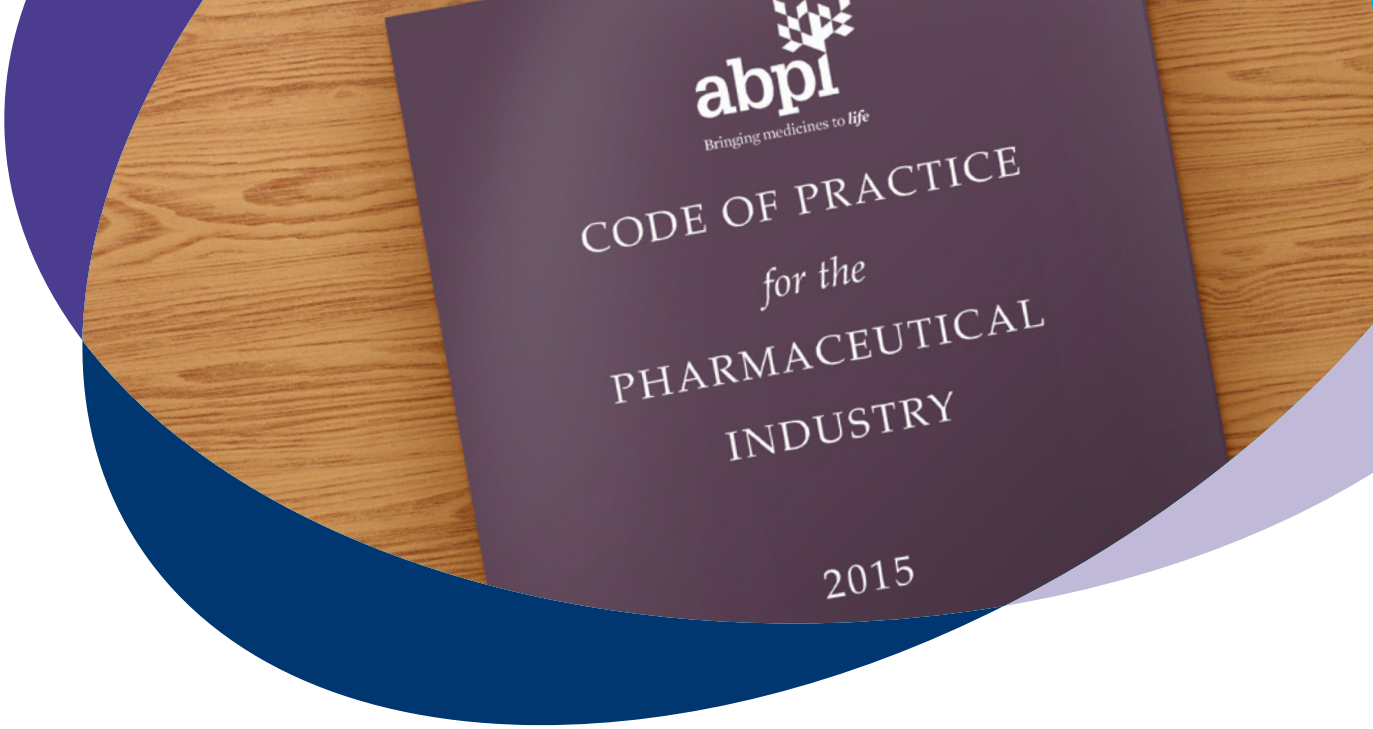
Foreword

I am pleased to contribute to the 2015 Annual Report of the Prescription Medicines Code of Practice Authority.

The number of complaints to the PMCPA in 2015 was 54, similar to that in 2014 when 51 complaints were received. The number of cases (66) was much higher than considered in 2014 (49). The number of individual allegations (matters) considered in 2015 was 198, compared with 263 in 2014. Fewer matters were appealed in 2015 (19) than in 2014 (71).

Of the 19 matters appealed in 2015, 32% were successfully appealed and 68% were unsuccessfully appealed. The proportion of the Code of Practice Panel's rulings appealed in 2015 was 10% (19/198) compared with 27% (71/263) in 2014. The proportion of the Panel's rulings successfully appealed in 2015, was 3% (6/198) compared with 5% (13/263) in 2014. 7% (13/198) were unsuccessfully appealed in 2015 compared with 22% (58/263) in 2014. The parties accepted without appeal 90% of the Panel's rulings, compared with 73% in 2014. 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 less in 2015 (19.2 weeks) than in 2014 (23.3 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 2015 two appeals were deferred by about a month as a result of requests from respondent companies.

There was an increase in the number of rulings of a breach of Clause 2 in 2015 (10) compared to 2014 (3). This was of concern as similar numbers of complaints were received (54 in 2015 and 51 in 2014). Companies need to ensure that they take great care when developing materials and planning activities.

The Appeal Board required two companies to undergo audits in relation to complaints received in 2015. The Appeal Board reported two companies to the ABPI Board of Management in relation to the conduct of senior employees.

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 spend much time preparing for and attending meetings. I am grateful for their support and contribution.

Two long serving independent members retired in 2015, Dr Peter Hutton (hospital consultant) and Professor Stephen Chapman (independent member from a body that provides information on medicines), both were appointed in 2006. I would like to thank them for their support and valuable contribution to the industry's self regulatory system.

William Harbage QC.

William Harbage QC
Chairman
Code of Practice Appeal Board

Director's report

The main focus of the PMCPA is, of course, the administration of the complaints procedure and this kept the PMCPA busy in 2015.

The other main area of work related to amendments to the ABPI Code as well as work with the European Federation of Pharmaceutical Industries and Associations (EFPIA) Codes.

The percentage of complaints from pharmaceutical companies in 2015 at 22% (12/54) was more than the 16% (8/51) in 2014. The percentage from health professionals decreased to 19% (10/54) compared with 35% (18/51) in 2014. The usual pattern is that the PMCPA 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 (8 in 2015 and 7 in 2014) were mostly due to the number of companies making voluntary admissions (4 in 2015 and 7 in 2014). In addition two arose from media or public criticism in 2015 (none in 2014) and there were two allegations of a breach of undertaking in 2015 (none in 2014).

The percentage of cases ruled in breach in 2015 at 53% (35/66) was only slightly less than the 55% in 2014 (27/49). However, if this is looked at on the basis of individual matters, 43% (85/198) were ruled in breach in 2015, compared with 59% (156/263) in 2014.

The Panel continues to have a good record with 97% (192/198) of its rulings in 2015 being accepted by the parties, or upheld on appeal; the figure for 2014 was 95% (250/263). The time taken to complete cases settled at Panel level in 2015 at 8.5 weeks was less than in 2014, 10 weeks. The Panel is extremely conscious of the need to deal with cases as quickly and efficiently as possible. Many cases however required additional information before the Panel could make a ruling and in a few cases this was difficult to obtain thus lengthening the time taken to deal with them.

The number of complaints submitted anonymously increased in 2015 at 41% (22/54) compared with 29% in 2014 (15/51). 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.

However, some of the more serious issues considered by the PMCPA have been raised anonymously.

In 2015 the PMCPA updated its guidance about advisory boards as there were a number of complaints about such meetings ruled in breach of the Code. All the PMCPA guidance can be found on the website.

This was yet another productive year and I would like to thank the staff of the PMCPA for all their hard work.

Heather Simmonds
Director, PMCPA

Complaints

Complaints in 2015
Fifty-four complaints were received in 2015, compared with 51 in 2014. There were 66 cases for the PMCPA to deal with in 2015, some complaints lead to more than one case as they involve more than one company. Some complaints did not proceed. The number of individual allegations to be considered within these cases, at 198, was fewer than the corresponding figure for 2014 which was 263.

Time taken to deal with complaints
There was a decrease in the overall time taken to deal with complaints. The figure for 2015 was 9.8 weeks compared with 11.7 weeks in 2014. There was also a decrease in the time taken to complete cases finalised at Panel level at 8.5 weeks in 2015 compared with 10 weeks in 2014. The majority of cases complete at the Panel level. Cases that went to appeal in 2015 took less time to complete in 2015 (19.2 weeks) than in 2014 (23.3 weeks).

Any increase in time taken to complete individual cases is a concern. This is sometimes 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 a month following a request from the respondent companies and with permission of the Chairman of the Appeal Board.

Reports to the Code of Practice Appeal Board from the Panel
Five formal reports were made by the Code of Practice Panel to the Code of Practice Appeal Board in relation to complaints received in 2015. This was an increase on 2014 (3).

The first report concerned an advisory board meeting. The Panel's rulings of breaches of the Code were not appealed. With regard to the report from the Panel, the Appeal Board considered that the company should be required to issue a corrective statement.

The second report concerned the failure of a UK company and its UK based European office to provide accurate information and the dismissive nature of a very senior executive when speaking to employees about the Panel's rulings in a previous case.

The Panel ruled breaches of the Code. The Panel's rulings regarding the dismissive nature of a senior employee were upheld by the Appeal Board following an appeal from the company. In relation to the report, the Appeal Board was very concerned about the breadth and scale of the failings and decided the companies should be publicly reprimanded, send an updated corrective statement and undergo audits in 2015. Reaudits were to be carried out in 2016. Following the 2015 audits the companies provided more information which led to the Panel reconvening and reporting the companies again to the Appeal Board as a number of senior employees in the European company had not provided complete and accurate information. There was an institutional failure with respect to compliance and staff had lied.

The Appeal Board decided to publicly reprimand the companies again, require another corrective statement and report the companies to the ABPI Board (see below).

The fourth report concerned an advisory board meeting. The Panel

Complaints *continued*

ruled breaches of the Code and reported the company to the Appeal Board. The Appeal Board decided that the company should be required to issue a corrective statement and undergo an audit which took place in 2016. The Appeal Board decided the company should be reaudited in 2016.

Finally, a company that failed to provide accurate information was reported to the Appeal Board. The Appeal Board decided that the company should be publicly reprimanded and required to issue a corrective statement.

Reports to the ABPI Board from the Appeal Board

One report was made to the ABPI Board by the Code of Practice Appeal Board in relation to complaints received in 2015. The report concerned two companies, the UK company and its UK based European office. The ABPI Board considered the report in June 2016 and decided that the UK company should be suspended from membership of the ABPI for 12 months. The ABPI Board wanted to see the reports of the September 2016 reaudits of both companies so that it could review the position including the length of the suspension, before the end of 2016. This was the first such report since 2008.

Audits by the PMCPA

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 and a reaudit of that company in 2014. Another complaint received in 2013 about the same company was the subject of a formal report to the Appeal Board, which resulted in an audit and reaudit of the company in 2014. Both these cases led to a reaudit in 2015. A third matter in 2014, which arose from a voluntary admission was the subject of a formal report to the Appeal Board, resulted in an audit of the company in 2015.

One complaint in 2014 concerned materials precirculated and 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 and audited for a third time in 2015. This third audit was postponed to 2016 due to major restructuring and reorganisation of the company concerned.

One complaint in 2015 concerning an advisory board which was the subject of two formal reports to the Appeal Board resulted in an audit of two companies, the UK company and its UK based European office. The audits were carried out in 2015 and the Appeal Board required that both companies should be reaudited in 2016.

One complaint in 2015 concerning an advisory board was reported to the Appeal Board which required an audit and this was carried out in 2016. A reaudit was also carried out in 2016.

In all, audits of three companies and reaudits of two companies were carried out in 2015. Four companies were involved.

Complaints

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 pharmaceutical 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 staff, including senior managers, to PMCPA training seminars.

Complaints *continued*

Two 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 concerned 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 in 2014 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.

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 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 its decision. Further complaints about these two companies were referred to the MHRA to deal with.

In 2015 the MHRA stated that the two companies which had left the list of non member companies had 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. The vetting of advertising continued in 2016.

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 2015 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 2015. 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, twenty-three training seminars or presentations on the Code were made for individual companies and other organisations, including public relations companies and advertising agencies.

The PMCPA is regularly invited to lecture at training courses run by professional organisations and universities and to speak at conferences. Ten such speaking engagements were undertaken in 2015. The PMCPA also presented at the Medicines and Healthcare products Regulatory Agency 'Hot Topics' meetings.

Communicating the Code

A strategy to improve the PMCPA website was agreed at the beginning of the year. The aim was to ensure that all web based interaction and communication with PMCPA stakeholders and audiences be quicker, easier and more effective. This meant investing time and resource in reviewing and updating the website and as a result pmcpa.org.uk is optimised for use on mobile phones and tablets.

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. Attendees are limited to one per pharmaceutical company (either an ABPI member or a non member company that has agreed to comply with the Code and accept the jurisdiction of the PMCPA). Meetings are held every quarter, with about forty-five people at each. Topics covered in 2015 included updates on the amendments to the Code, the work on disclosure of transfers of value, latest advice and guidance and updates on the IFPMA and EFPIA codes. There were presentations from a variety of guest speakers, including the ABPI and MHRA.

The Compliance Network continues to be popular. Feedback regularly shows that members particularly value being updated on recently published cases and having the opportunity to discuss and explore specific compliance issues, challenges and opportunities. During 2015 Network members worked closely with the PMCPA to explore common questions and different approaches to compliance training. As a result the Code in Context slide set, designed to be adapted for in-house use and to give staff an opportunity to debate the ownership and necessity of the Code in day-to-day work, was provided to members of the Compliance Network.

New members are welcome and attendees are invited to suggest agenda items.

Updated guidance on advisory boards

A number of 2015 cases about advisory boards were ruled in breach of the Code. The PMCPA updated its informal guidance and this was circulated to pharmaceutical companies as an attachment to a letter from the President of the ABPI requesting that companies took action and a letter from the Director of the PMCPA. The PMCPA Director recommended that the advice was widely circulated to all relevant staff including UK, regional and global colleagues to ensure that the arrangements for advisory boards were appropriate.

Communicating the Code

Although it is acceptable to arrange advisory boards and pay health professionals and others for genuine advice, advisory boards must not be promotional. Health professionals and others must not be paid to attend promotional meetings.

The Medicines and Healthcare products Regulatory Agency (MHRA) had raised concerns about advisory boards with the PMCPA including in its response to the consultation on changes to the Code. The MHRA had seen examples during its vetting of advisory board meeting proposals that appeared to be promotional. The cases considered by the PMCPA, including one arising from an article in the media, raised similar concerns.

The updated advice was augmented early in 2016 by the publication of a list of points to be considered.

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.

Three advertisements featuring the activities of four companies were placed in the British Medical Journal, 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. It is available on the PMCPA website.

Case reports are published on a rolling basis on the PMCPA's website (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

On 1 January 2015 a new Code came into operation with the usual transition period for newly introduced requirements such that between 1 January 2015 to 30 April 2015, 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 2015 proposals to change the 2015 edition of the Code were agreed by ABPI members.

The proposals resulted mainly from work done by a group established by the ABPI Board to review the Code.

The proposed changes to the 2014 Code and the PMCPA Constitution and Procedure were consulted upon twice in 2015. Proposals were sent to ABPI member companies, non member companies that had agreed to comply with the Code and those organisations cited in the PMCPA Constitution and Procedure as well as being available on the PMCPA website.

The changes related to the move from aggregated disclosure of certain transfers of value to individual named health professional and other relevant decision maker disclosure and the implementation of the EFPIA Code on Disclosure of Transfers of Value from Pharmaceutical Companies to Healthcare Professionals and Healthcare Organisations (EFPIA Disclosure Code). Other proposals reflected the outcome of the ABPI Board review of the Code, views of the ABPI Board, the change to the accredited ABPI examination for representatives as well as the usual minor amendments.

One of the main changes was to certification of materials and activities. Following some discussion the ABPI Board decided that the proposal for one signatory (rather than two) should remain. This was in line with EFPIA requirements and the ABPI Board was confident that there were sufficient controls to ensure that the quality of material and activities was maintained. Companies could, of course, keep two signatories if they so wished.

Proposals were agreed at the ABPI Half Yearly General Meeting on 11 November and at a special meeting of the ABPI on 1 December 2015. The new Code and PMCPA Constitution and Procedure came into operation on Friday 1 January 2016.

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

The PMCPA has met, from its reserve, the costs of developing the ABPI central platform for the disclosure of transfers of value. The running costs for the immediate future would be the responsibility of the ABPI.

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 2015 this group did not have any complaints to consider.

The IFPMA Code Compliance Network (CCN) continued its work in 2015. Members are from 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.

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. Under the EFPIA Disclosure Code, the first publication of data (covering 2015 transfers of value) was due by 30 June 2016.

The Director of the PMCPA is a member of various EFPIA groups in relation to the EFPIA Codes.

UK legal requirements

In 2014 the Appeal Board removed two companies from the list of non members which had agreed to comply with the Code and accept the jurisdiction of the PMCPA. The MHRA was informed and it took further action. The MHRA required one of the companies to issue a corrective statement and to submit its advertising for vetting prior to use. The vetting continued in 2015.

If a complaint is received by the PMCPA about matters not covered by the Code then the complainant is so informed and given details of where to send their complaint. For example in 2015 a number of complainants with concerns about advertising by clinics offering Botulinum toxin and other procedures were given the MHRA's details.

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 was required to suspend material in 2015. 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 77 times in 2015 (compared with 84 times in 2014). 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. She 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.

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. Tannyth was on maternity leave for part of 2015 returning to the office in September.

The PMCPA Team

Anne Erwin
was the Interim Deputy Secretary of the PMCPA appointed to cover Tannyth's maternity leave which ended in September 2015. Anne worked in compliance for a pharmaceutical company as well as for EFPIA regarding the transposition of EFPIA Codes by national associations.

Nora Alexander
is the Personal Assistant to the Director of the PMCPA. She joined the PMCPA in 2007 and is responsible for the PMCPA seminars.

Peter Clift
is the 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.

Lisa Matthews
is the Personal Assistant to the Deputy Director and Secretary. She has been at the PMCPA for 17 years and is responsible for the day to day running of the office. She is the contact for copies of the Code and Review.

Elly Button
is Head of Communications. Elly joined the PMCPA in January 2015 and was previously at NHS London. She has also had senior comms roles at the BBC, Shelter and the Audit Commission.

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 2015 (9 times in 2014) and considered appeals in 8 cases (6 cases in 2014). The number of matters considered by the Appeal Board was 19 in 2015, much fewer than in 2014 (71).

Membership and attendance during 2015

Chairman

Mr William Harbage QC (10/10)

Independent Members

Professor Stephen Chapman (From an independent body which provides information on medicines) (5/5) until July 2015

Dr Howard Freeman MBE (General Practitioner) (9/10)

Mr Christopher Goard (Representing patients' interests) (10/10)

Mrs Gillian Hawken (Lay member) (10/10)

Professor Peter Hutton (Hospital Consultant) (4/5) until July 2015

Mr David Mills (Pharmacist) (10/10)

Dr John Watkins (Hospital Consultant) (9/10)

Industry Members

Dr Peter Barnes (Medical Director, Janssen) (6/10)

Mr Stuart Rose (Managing Director, Merz Pharma UK Ltd) (5/10)

Dr Rhiannon Rowsell (Retired, previously Promotional Affairs & Medical Excellence Director, AstraZeneca) (8/10)

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

Dr Alan McDougall (Medical & Regulatory Affairs Director, Astellas Pharma Ltd) (7/9)

Dr Fenton Catterall (from May 2015 Compliance Officer UK, Ireland and Canada, Biogen Idec Limited, previously Compliance Director, Merck Sharp & Dohme UK Ltd) (8/9)

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 2015, the following were each co-opted for at least one meeting:

Professor Stephen Chapman (from an independent body which provides information on medicines)

Mrs Aileen Cherry (Nurse Prescriber)

Mr David Hope (Sales and Marketing Director – Secondary Care, Alliance Pharmaceuticals Limited)

Professor Peter Hutton (Hospital Consultant)

Dr Satish Kolli (Medical Director, Leo Pharma UK)

Dr Pim Kon (Vice President, Medical Governance, GlaxoSmithKline UK Ltd)

Dr Stephen McDonough (Vice President and Medical Director, GlaxoSmithKline UK Ltd)

Dr Jon Ryland (Medical Director, AbbVie Limited)

Dr Paul Schofield (Medical Director, Napp Pharmaceuticals Limited)

Statistics on complaints

The complaints procedure
Complaints are ruled upon in the first instance by the Code of Practice Panel which is made up of 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.

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) 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

	2015	2014	2013
Complaints received	54	51	80
Not within the scope of the Code	-	2	-
Insufficient information	-	-	1
Company declined to accept the PMCPA's jurisdiction before proceedings commenced	5	9	2
Inter-company dialogue successful	1	-	-
Complaints considered	53	40	76
Cases arising from these complaints	66	49	105
Individual matters considered	198	263	302

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. Of the complaints received in 2015, one led to 15 cases and, of these, one was covered by another case and 5 did not proceed because the companies concerned declined to accept the PMCPA's jurisdiction before proceedings commenced.

Outcomes of complaints considered

	2015	2014	2013
Cases where a breach found	35	27	60
Cases where no breach found	31	22	45
Number of matters in these cases:	198	263	302
- in breach	85	156	126
- no breach	113	107	176
Cases where the Code of Practice Panel required suspension of materials	-	1	-
Corrective statements required	5[3]	1	-
Public reprimands	3[4]	1	3
Audits	2	2	2
Breaches of undertaking ruled	1	-	3
Breaches of Clause 2 ruled	10	3	16
Reports to the Code of Practice Appeal Board	5[2]	3	7[1]
Reports to the ABPI Board of Management	1	-	-

[1] Four of these reports concerned one company and two cases.
[2] Three of these reports concerned two companies and two cases
[3] Three of these concerned two cases and two companies
[4] One case, two public reprimands

Sources of complaints

Health professionals	**2015**	**2014**	**2013**
General practitioners	2	3	3
Hospital doctors	-	5	4
Other doctors	1	-	2
Pharmacists	6	6	5
Nurses	-	1	-
Managers	-	3	2
Clinical Commissioning Group	1	-	-
	10	**18**	**16**
Pharmaceutical companies			
ABPI members	11	5	12
Non members	1	3	3
	12	**8**	**15**
PMCPA Director			
Alleged breach of undertaking	2	-	3
Arising from voluntary admissions	4	7	11
Arising from media criticism	1	-	-
Arising from published information	1	-	-
	8	**7**	**14**
Organisations			
Medicines and Healthcare products Regulatory Agency	-	-	1
	0	**0**	**1**
Others			
Members of the public	-	1	4
Anonymous	20[1]	13[2]	21[3]
Employees/ex employees	2	2	6
Anonymous employees	2	1	1
Anonymous ex employees	-	1	-
Journalist	-	-	1
Publisher	-	-	1
	24	**18**	**34**
Total	**54**	**51**	**80**

[1] Six of these were from anonymous health professionals

[2] Six of these were from anonymous health professionals

[3] Ten of these were from anonymous health professionals

Appeals to the Code of Practice Appeal Board

	2015	2014	2013
Total number of matters ruled upon by the Code of Practice Panel	198	263	302
Rulings accepted by the parties	179	192	264
Rulings successfully appealed	6	13	10
Rulings unsuccessfully appealed	13	58	28
Number of cases appealed	8	6	19

Sources of appeals	**2015**	**2014**	**2013**
Cases appealed by complainants	-	2	7
Cases appealed by respondents	8	5	12

In one case in 2014 both the complainant and the respondent appealed.

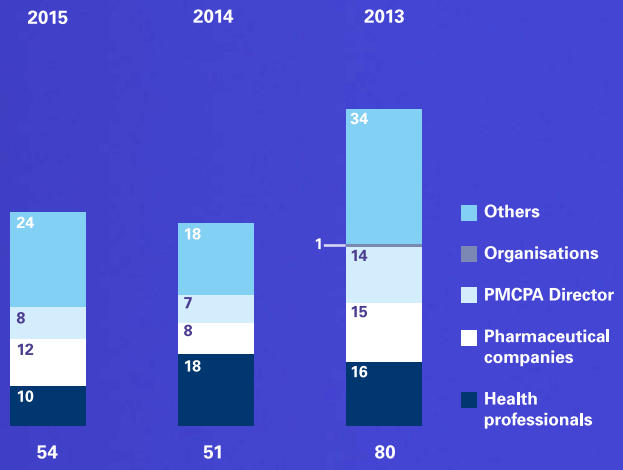
Appeals by complainants	**2015**	**2014**	**2013**
successful	-	-	1
partly successful	-	1	-
unsuccessful	-	1	6
	-	**2**	**7**
Appeals by respondents			
successful	3	-	5
partly successful	3	4	1
unsuccessful	2	1	6
	8	**5**	**12**
Rulings appealed by complainants			
successful	-	2	3
unsuccessful	-	3	14
	-	**5**	**17**
Rulings appealed by respondents			
successful	6	11	7
unsuccessful	13	55	14
	19	**66**	**21**

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.

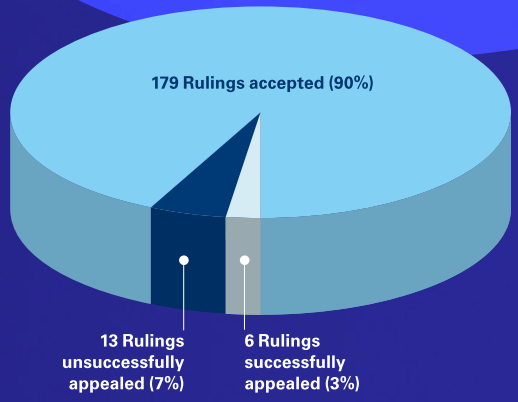
Complaints nominally made by the Director can also arise as a result of:

- 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 2015 the Code of Practice Panel made 198 rulings. Of these, 179 (90%) were accepted by the complainants and respondents involved. A further 13 (7%) were the subject of unsuccessful appeals to the Code of Practice Appeal Board. The remaining 6 (3%) were successfully appealed to the Appeal Board



Average time taken to complete cases (in weeks)

	2015	2014	2013
Cases settled at Code of Practice Panel level	8.5	10	10
Cases which were the subject of appeal	19.2	23.3	18.1
All cases	**9.8**	**11.7**	**11.3**

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 2015 no advertisements were taken up as potentially being in breach of the Code.

Companies ruled in breach of the Code (complaints received in 2015)

* In breach of Clause 2

A Menarini Pharma UK SRL
Actavis UK Ltd
Amgen Limited
Amicus Therapeutics UK Ltd
*Astellas Pharma Europe Limited
*Astellas UK Limited
AstraZeneca UK Limited
*Bausch & Lomb UK Limited
Bayer Plc
Boehringer Ingelheim Limited
Chugai Pharma UK Ltd
Daiichi-Sankyo UK Ltd
GlaxoSmithKline UK Limited
*Guerbet Laboratories Ltd
Ipsen Limited
Janssen
*Merck Serono Limited
Mylan EDP/BGP Products Ltd
*Napp Pharmaceuticals Limited
Novartis Pharmaceuticals UK Ltd
*Otsuka Pharmaceuticals UK Ltd
Pierre Fabre Ltd
Piramal Healthcare UK Ltd
Shire Pharmaceuticals Limited
*Stirling Anglian Pharmaceuticals Ltd
Teva UK Limited
ViiV Healthcare UK Ltd

Accounts 2015

The PMCPA has been self-financing from the beginning of 1996. In 2015 there was a planned deficit of £276,134 before tax which meant some tax could be reclaimed (£40,055). The PMCPA cumulative reserves on 31 December 2015 are £517,539 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 £4,000 to £32,000 depending on the size of the company, but companies with only one vote were subdivided depending on their ABPI subscription (which relates to company size). Forty per cent of the levy due was called up in 2015. The costs of the PMCPA are mainly covered by administrative charges which are payable by companies actually involved in cases. The Levy income collected varies to ensure that the PMCPA covers its costs.

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 Levy income collected varies to ensure that the PMCPA covers its costs.

The charge per matter in 2015 was £3,500 for member companies and £4,500 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 2015 was £12,000 for member companies and £13,000 for non member companies.

Companies subject to advertising in the medical, pharmaceutical or nursing press, are required to contribute to the cost of such advertising (£4,000).

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 2015 *continued*

	2015	2014	2013
	£	£	£
Levy	290,533	658,292	480,205
Administrative charges	560,500	386,500	528,000
Seminars/meetings	174,466	186,659*	172,855
Company audits	82,000	70,000	14,000
Contributions to advertising costs	19,000	24,000	24,000
	1,126,499	1,325,461	1,219,060
Expenditure	**1,402,633**	**1,404,600**	**1,142,171**

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

* includes reimbursed costs

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
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
- The leaflet about the Authority – which briefly introduces the Code
- Information leaflets about the PMCPA and the Appeal Procedure
- Guidance (including on Digital, Clause 3, Certification and Advisory Boards).

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
Email: complaints@pmcpa.org.uk

PMCPA | Prescription Medicines Code of Practice Authority

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