PMCPA | Prescription Medicines Code of Practice Authority

2016
Annual report

The aim of the ABPI Code of Practice for the Pharmaceutical Industry is to ensure that the promotion of medicines to health professionals and other relevant decision makers is carried out within a robust framework, to support high quality patient care.

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 covers the promotion of medicines for prescribing to health professionals and other relevant decision makers and sets standards for interactions between the pharmaceutical industry and health professionals. The Code also sets standards relating to the provision of information about prescription only medicines to the public and patients and relationships with patient organisations. In summary the Code requires companies to ensure that their materials are appropriate, factual, fair and capable of substantiation and that all other activities are appropriate and reasonable. The Code does not cover the promotion of over the counter medicines to the public.

There are extensive UK and European legal requirements relating to the promotion of medicines and the Code not only reflects these requirements but extends beyond the relevant UK law. Although the Medicines and Healthcare products Regulatory Agency (MHRA) administers UK law on behalf of the Health Ministers, and could intervene should there be a clear case for protection, the requirements of the Code ensure that companies are able to meet stringent regulatory demands via an effective and transparent process of self-regulation.

The Code is regularly reviewed in consultation with the MHRA, the British Medical Association, the Royal Pharmaceutical Society, the Royal College of Nursing, the Competition and Markets Authority and The Serious Fraud Office.

Anyone with concerns about pharmaceutical company activities should contact the PMCPA. Those with suggestions for amendments to the Code are also welcome to contact the PMCPA see contact details on page 27.

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.

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"I am pleased to contribute to the 2016 Annual Report of the Prescription Medicines Code of Practice Authority."

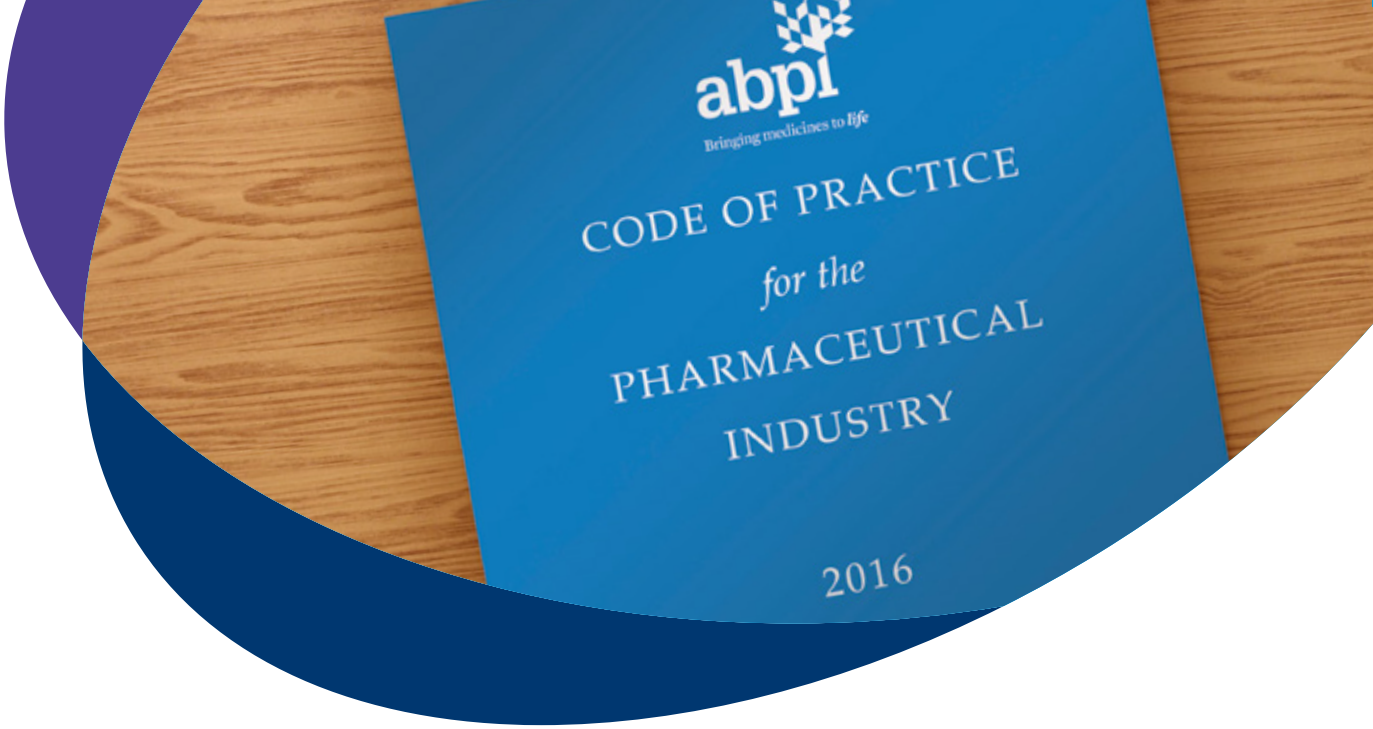
Foreword

2016 has been a very busy year. The number of complaints to the PMCPA in 2016 was 76, an increase from 2015 when 54 complaints were received. The number of cases (100) was significantly higher than those considered in either 2015 (66) or 2014 (49).

The number of individual allegations (matters) considered in 2016 was 420, compared with 198 in 2015. There was an increase in matters appealed in 2016 (33) over 2015 (19). Of the 33 matters appealed in 2016, 15% were successfully appealed and 85% failed.

The proportion of the Code of Practice Panel's rulings appealed in 2016 was 8% (33/420) compared with 10% (19/198) in 2015. The proportion of the Panel's rulings successfully appealed in 2016 was 1% (5/420) compared with 3% (6/198) in 2015. 7% (28/420) were unsuccessfully appealed in 2016, compared with 7% (13/198) in 2015. The parties accepted without appeal 92% of the Panel's rulings, compared with 90% in 2015. 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 24.8 weeks in 2016, more than in 2015 (19.2 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 2016 three appeals were deferred by two months as a result of procedural matters and a fourth was delayed by about a month following a request from the respondent company.



There was an increase in the number of rulings of a breach of Clause 2 in 2016 (13) compared with 2015 (10). This was of concern as Clause 2 deals with serious matters, but there was also a similar percentage increase in the number of complaints (76 in 2016 vs 54 in 2015). Companies need to ensure that they take great care when developing materials and planning activities.

The Appeal Board required four companies to undergo audits in relation to complaints received in 2016 and reported two companies to the ABPI Board of Management in relation to a complaint received in 2015. The ABPI Board suspended Astellas UK from membership of the ABPI in June 2016. This was extended in June 2017 for a further year, due to the outcome of the reaudits and following voluntary admissions from Astellas UK and Astellas Europe in 2016 and 2017. Astellas UK was the first company to be suspended from membership of the ABPI since 2008. The extension of the suspension in 2017 demonstrates the seriousness of the issues raised.

2016 was the first year that certain transfers of value were disclosed on the ABPI central platform, www.disclosureuk.org.uk. It was estimated that approximately 55% of individual health professionals agreed to have their names disclosed in relation to certain transfers of value made by the pharmaceutical industry in 2015. It is hoped that this figure will increase in future years. Under the Code, payments for clinical trials are disclosed in aggregate.

I am particularly grateful to the members and co-opted members of the Appeal Board for their unstinting hard work, support and contributions in such a busy year. They take their responsibilities extremely seriously and spend much time preparing for and attending meetings.

Aileen Cherry, nurse prescriber, appointed as an independent member in 2006 retired in 2014, however she continued as a regularly co-opted member until 2016. I would like to thank her for her 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 busier than ever in 2016.

Although the number of cases in 2016 increased, the percentage of complaints from pharmaceutical companies was lower at 14% (11/76), in comparison with 22% (12/54) in 2015.

The percentage from health professionals increased slightly to 21% (16/76) from 19% (10/54) in 2015. The usual pattern is that the PMCPA receives more complaints from health professionals than from companies.

Complaints nominally attributed to the Director nearly doubled (15 in 2016 vs 8 in 2015) mostly due to an increase in the number of companies making voluntary admissions (13 in 2016 vs 4 in 2015). The fact that companies make voluntary admissions indicates the seriousness with which the industry takes the Code.

Some of the voluntary admissions related to activities of companies located outside the UK but still in Europe (regional/European offices) which carry out activities with UK health professionals. It is of concern that these activities, when ruled in breach of the ABPI Code are also unlikely to meet the requirements of the EFPIA Code or other relevant codes. The PMCPA will work with EFPIA and others to discuss this issue.

The percentage of cases ruled in breach in 2016 at 57% (57/100) increased compared with 2015 at 53% (35/66). However, if this is looked at on the basis of individual matters, the percentages are similar for both years, at around 43% in breach in 2016 (182/420) and 2015 (85/198).

The Panel continues to have a good record with 99% (415/420) of its rulings in 2016 being accepted by the parties, or upheld on appeal; the figure for 2015 was 97% (192/198).

The time taken to complete cases settled at Panel level in 2016 was 10.4 weeks, an increase compared with 2015, at 8.5 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 increased number of complaints (76, compared with 54) leading to 100 cases in 2016, compared with 66 in 2015, brought significant additional workload as did the number of audits and reaudits undertaken in the year.

The number of complaints submitted anonymously decreased in 2016, at 36% (28/76) compared with 2015 at 41% (22/54). Given that the complaints system is designed to allow both parties to fully participate, it is regrettable that many of the anonymous complainants did not provide any contact details. Some of the more serious issues considered by the PMCPA in 2016 were raised anonymously.

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

Heather Simmonds
Director, PMCPA

Complaints

Complaints in 2016
Seventy six complaints were received in 2016, compared with 54 in 2015 and 51 in 2014. There were 100 cases for the PMCPA to consider in 2016, compared with 66 cases in 2015.

The number of cases usually differs from the number of complaints because some complaints involve more than one company and others, for a variety of reasons, do not become cases at all.

The percentage of cases ruled in breach in 2016 at 57% (57/100) increased compared with 2015 at 53% (35/66). However, if this is looked at on the basis of individual matters, 43% (182/420) were ruled in breach in 2016, compared with 43% (85/198) in 2015.

The number of individual allegations (matters) considered in 2016 was 420, compared with 198 in 2015. There was an increase in matters appealed in 2016 (33) over 2015 (19). Of the 33 matters appealed in 2016, 15% were successfully appealed and 85% failed.

Time taken to deal with complaints
There was an increase in the overall time taken to deal with complaints. The time taken to complete cases settled at Panel level in 2016 was 10.4 weeks, compared with 8.5 weeks in 2015. 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 increased number of complaints (76, compared with 54 in 2015) leading to 100 cases in 2016, compared with 66 in 2015 represented a significant increase in work.

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 Panel making its ruling. In 2016 three appeals were deferred by two months as a result of procedural matters and another was delayed by about a month following a request from the respondent company.

Reports to the Code of Practice Appeal Board from the Code of Practice Panel
Five formal reports were made by the Panel to the Code of Practice Appeal Board in relation to complaints received in 2016. This was the same as in 2015.

With regard to the reports from the Panel, the first two concerned two companies and a letter delivered to health professionals by representatives. The Panel's rulings of breaches of the Code were upheld on appeal. The Appeal Board required the companies to issue a corrective statement to those who had received the letter. In addition each company was audited in 2016 and required to be reaudited in 2017.

The third report concerned a voluntary admission relating to two promotional meetings. The Panel's rulings of breaches of the Code were not appealed. The Appeal Board was concerned about the company's supervision of its staff, and oversight of the meetings. It decided to audit the company in 2016 and required it to be reaudited once in 2017 and once in 2018.

Complaints *continued*

The fourth report concerned a voluntary admission regarding, *inter alia*, the company's oversight of patient support programmes. The Panel's rulings of breaches of the Code were not appealed. The Appeal Board was extremely concerned and decided to publicly reprimand the company, audit and reaudit it in 2017 and report the company to the ABPI Board.

The fifth report concerned a non member company which declined to pay the PMCPA administrative charge. There was no appeal of the Panel's rulings. The Appeal Board decided to give the company one final opportunity to pay, or be removed from the list of non members which have agreed to comply with the Code and accept the jurisdiction of the PMCPA. The company paid the charge.

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, and additional information which had come to light in February 2016. The Appeal Board had required two audits in 2015 and reaudits of each company in 2016. The ABPI Board considered the report in June 2016 and decided that the UK company should be suspended from membership of the ABPI for a period of up to 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 to the ABPI Board since 2008.

In November 2016 the Appeal Board decided that the companies should be reaudited in April 2017.

In December 2016 the ABPI Board considered that, although encouraged by improvements and progress at both companies, the suspension of the UK company from membership of the ABPI should continue and be reviewed in June 2017.

One report was made to the ABPI Board by the Code of Practice Appeal Board in relation to a voluntary admission received in 2016. The report concerned the company currently suspended from membership of the ABPI. In June 2017 the ABPI Board considered a number of matters and decided that the suspension should be extended for a further year, ie until June 2018. The ABPI Board wanted to see the reports of the October 2017 reaudits of both companies (required by the Appeal Board) so that it could review the position before the end of 2017.

Audits by the PMCPA

One complaint in 2014 concerned materials pre-circulated 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.

Complaints

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 be reaudited in 2016 and 2017.

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. The Appeal Board required a further reaudit to be carried out in 2017.

In all, audits of three companies and reaudits of four companies were carried out in 2016 (one company was reaudited twice).

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 was anonymous and non contactable then the PMCPA would send 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 against a non member company 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 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 its decision.

Another non member company that was ruled in breach of the Code in 2014 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.

In 2015, the MHRA stated that the two 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.

In 2016, one of the companies made a complaint about an ABPI member. The respondent company raised concerns about the situation when it appealed the Panel's rulings, submitting that such complaints should not be accepted. The Appeal Board considered, however, that there was nothing in the PMCPA Constitution and Procedure to preclude a complaint from a pharmaceutical company not on the list of non members which had agreed to comply with the Code and accept the jurisdiction of the PMCPA and that it was correct for the complaint to proceed.

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 2016 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 considered.

Advice is available via the PMCPA website and anyone can contact the PMCPA on 020 7747 8880 for informal advice on the Code.

Updated guidance on advisory boards
During 2015 the Medicines and Healthcare products Regulatory Agency (MHRA) 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 pre-vetting of advisory board meeting proposals that appeared to suggest that the resultant meeting would be promotional. The cases considered by the PMCPA, including one arising from an article in the lay media, raised similar concerns. The advice issued in 2015 by the PMCPA was augmented in April 2016 with a list of points to be considered.

Updated guidance on digital communications
The PMCPA guidance was reviewed and updated to include relevant 2016 Code requirements as was the series of frequently asked questions and answers.

Training on the Code

Seminars
Six seminars designed to explain the requirements of the Code were held by the PMCPA in central London in 2016. These regular 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 looks at particular scenarios and is highly valued by delegates. The PMCPA thanks all those who act as syndicate leaders. In addition, 28 other in-house training sessions, speaking opportunities and talks took place during 2016.

E Learning Module
The popular interactive E Learning module on the home page of the PMCPA website, designed primarily for health professionals, gives practical examples of the Code in action. Research showed that it is also used by pharmaceutical companies to improve employees' knowledge of the Code, and that the vast majority of users would recommend it to others. The module was updated in 2016 to reflect changes to the requirements for companies to disclose certain transfers of value to health professionals and others.

Speaking opportunities
The PMCPA is regularly invited to lecture on training courses run by professional organisations and universities and to speak at conferences. The PMCPA also presented at the Medicines and Healthcare products Regulatory Agency's 'Hot Topics' meetings.

Communicating the Code

Disclosure Database launched 30 June 2016
The ABPI published for the first time details of payments or benefits in kind made to doctors, nurses and pharmacists, as well as other health professionals and healthcare organisations in the UK on a publicly accessible database www.disclosureuk.org.uk. The publication of these data is a requirement of the Code and is part of a Europe-wide transparency initiative that has seen 33 countries make public these payments and benefits in kind in 2016.

The PMCPA met, from its reserve, the costs of developing the ABPI central platform for the disclosure of transfers of value. The running costs for the platform are paid by participating companies.

The PMCPA worked alongside the ABPI throughout the year to ensure that industry was prepared for disclosure (further details can be found in Clause 24 and below).

Guidance on the points that companies should consider when completing their methodological notes to accompany data were published on the PMCPA website. The Director contributed to the ABPI press conference to launch the 2016 data. 109 companies (54 ABPI member companies, 55 non member companies) disclosed transfers of value made to health professionals and healthcare organisations in 2015. The total of payments disclosed for 2015 was £340.3 million.

Approximately two thirds (£229.3 million, 67%) was research activity spend, primarily working with healthcare organisations on clinical trials. About one third (£111 million, 33%) was non-research activity spend, including Joint Working, contribution to the cost of events, donations and grants, fees for service, registration fees for events, and travel and accommodation.

The media coverage of the launch of Disclosure UK reflected the industry's aim to increase transparency and encourage health professionals to agree to the publication of their full details.

PMCPA Compliance Network
The PMCPA Compliance Network continues to be popular and to provide opportunities for compliance staff across the industry to talk directly with the PMCPA and other invited experts.

Attendees are limited to one per pharmaceutical company (employees of 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 2016 included overviews of recent cases, latest advice and guidance and updates on the ABPI, IFPMA and EFPIA codes. There were also presentations by ABPI staff on examinations and disclosure.

The Compliance Network regularly provides valuable feedback and advice.

Communicating the Code

Feedback shows that members of the Compliance Network particularly value being updated on recently published cases and having the chance to discuss and explore specific compliance issues, challenges and opportunities.

Discussion and debate is always lively and during 2016 members worked closely with the PMCPA to explore common questions and different approaches to compliance training, internal operating practices and points raised by specific cases. Attendees are invited to suggest agenda items.

As part of the ongoing work to ensure that the Code and its operation remain fit for purpose, Compliance Network members agreed a list of key topics to work on, these being: Clause 3, meetings, patient support programmes and services linked to products.

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 (bringing discredit upon, and reducing confidence in, the pharmaceutical industry), 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.

Five advertisements (two were published in August 2016) featuring the activities of 13 companies were placed in the British Medical Journal, the Pharmaceutical Journal and the Nursing Standard. The advertisements were also published on the PMCPA website (which provides alert emails to subscribers). Three companies were named twice.

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 website (www.pmcpa.org.uk) and individuals can sign up to be alerted when a new case report is added to the site.

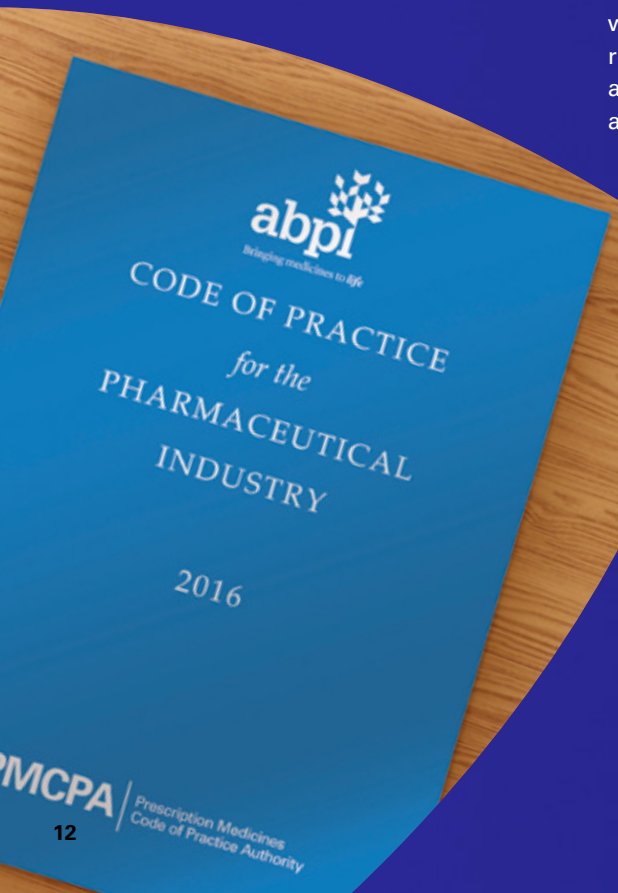
Proposals to amend the Code and its operation

On 1 January 2016 a new Code came into operation with the usual transition period for newly introduced requirements such that between 1 January 2016 and 30 April 2016, no material or activity would be regarded as being in breach of the Code if it failed to comply with newly introduced requirements.

In late 2015 proposals to change the 2015 edition of the Code were agreed by ABPI members. The changes resulted mainly from the move from aggregate disclosure of transfers of value from pharmaceutical companies to health professionals and other relevant decision makers to individual disclosure of named individuals on a publicly accessible website. Other changes included the withdrawal of the unaccredited ABPI representative's examination, action as a result of the ABPI Board Review and regular updating and tidying up.

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 next edition of the Code will be published in 2018.



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 2016 this group did not have any complaints to consider.

The IFPMA Code Compliance Network (CCN) continued its work in 2016, and changed its name to the Ethics and Business Integrity Committee (eBIC). Members include national associations and member companies of the IFPMA. The Director of the PMCPA is a member of eBIC, which 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 Director of the PMCPA is a member of various EFPIA groups in relation to the EFPIA Codes and regularly attended these meetings.

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 2016.

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 2016 a number of complainants with concerns about advertising by clinics offering cosmetic procedures were given the MHRA's details.

In 2016 the MHRA published three reports related to three PMCPA cases, two were 2015 cases and concerned one company and the third was a 2016 case. All cases involved health professionals attending meetings and were ruled in breach of the ABPI Code. In general the MHRA does not take action on cases already investigated by the PMCPA but in these three cases it decided that corrective action was required. In each case the MHRA considered that, even where health professionals had accepted in good faith a payment, or other benefit, that was subsequently found to breach the ABPI Code, this still potentially placed the health professionals in breach of legislation. The MHRA's policy position is that a corrective statement should be used to make the health professionals aware of what has happened and to correct any impression given that such payments by pharmaceutical companies were acceptable under the Code or UK law. The companies voluntarily agreed to issue a corrective statement to all UK health professionals who attended the meetings, informing them of the findings of the PMCPA case.

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 met 99 times in 2016 (compared with 77 times in 2015). It can meet at short notice when required. 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 2016. The case preparation manager for a particular case, one of the members of the Authority, does not sit on the Panel for the consideration of that case.

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 2013.

The PMCPA Team

Nora Alexander
is the Personal Assistant to the Director of the PMCPA. She joined the Authority in 2007 having previously worked for the NHS. Nora 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 2002 and was previously a biomedical scientist. Peter has a master's 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 18 years and is responsible for the day to day running of the office. Lisa is the contact for copies of the Code and Review.

Elly Button
is the PMCPA's Head of Communications. Elly joined the PMCPA in 2015 and was previously at NHS London. She has also had senior comms roles at the BBC, Shelter and the Audit Commission. Elly is responsible for the PMCPA website and the Compliance Network.

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 2016, one more than in 2015 and considered appeals in 10 cases (8 cases in 2015). The number of matters considered by the Appeal Board was 33 (19 in 2015).

Membership and attendance during 2016

Chairman

Mr William Harbage QC (11/11)

Independent Members

Mrs Natasha Duke (Nurse Prescriber, appointed Jan 2016) (9/10)

Dr Howard Freeman MBE (General Practitioner) (11/11)

Mr Christopher Goard (Representing patients' interests) (11/11)

Mrs Gillian Hawken (Lay member) (11/11)

Dr Anne Hawkridge (General Practitioner) (7/11)

Mr David Mills (Pharmacist) (11/11)

Dr John Watkins (Hospital Consultant) (11/11)

Mr Andrew White (from a body that provides information on medicines, appointed May 2016) (6/7)

Industry Members

Dr Peter Barnes (Global Medical Affairs Lead, Janssen) (9/10)

Dr Fenton Catterall Compliance Officer UK, Ireland and Canada, Biogen Idec Limited, previously Compliance Director, Merck Sharp & Dohme UK Ltd) (8/11)

Dr Alan McDougall (Medical & Regulatory Affairs Director, Astellas Pharma Ltd) until May 2016 (2/4)

Mr Stuart Rose (Managing Director, Merz Pharma UK Ltd) (9/11)

Dr Rhiannon Rowsell (Retired, previously Promotional Affairs & Medical Excellence Director, AstraZeneca) (10/11)

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 2016, 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)

Dr Sathish Kolli (Medical Director, Leo Pharma UK)

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

Dr Mark Sampson (Chief Medical Officer, Shield Therapeutics Limited)

Dr Mark Toms (Executive Director, Medical Affairs, Merck Sharp & Dohme 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 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.

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 which can be imposed by the Appeal Board 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

	2016	2015	2014
Complaints received	76	54	51
Not within the scope of the Code	-	-	2
Company declined to accept the PMCPA's jurisdiction before proceedings commenced	5	5	9
Inter-company dialogue successful	-	1	-
Complaints considered	69	53	40
Cases arising from these complaints	100	66	49
Individual matters considered	420	198	263

Some complaints involve a number of allegations, some 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 2016 two complaints each led to 5 cases; a third complaint led to 17 cases. Seven cases did not proceed as the companies concerned declined to accept the PMCPA's jurisdiction before proceedings commenced.

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

	2016	2015	2014
Cases where a breach found	57	35	27
Cases where no breach found	43	31	22
Number of matters in these cases:	420	198	263
- in breach	182	85	156
- no breach	238	113	107
Cases where the Code of Practice Panel required suspension of materials	1	-	1
Corrective statements required	3	5[2]	1
Public reprimands	1	3[3]	1
Audits	4	2	2
Breaches of undertaking ruled	2	1	-
Breaches of Clause 2 ruled	13	10	3
Reports to the Code of Practice Appeal Board	5	5[1]	3
Reports to the ABPI Board of Management	1	1	-

[1] Three of these reports concerned two companies and two cases
[2] Three of these concerned two cases and two companies
[3] One case, two public reprimands

Sources of complaints

Health professionals	**2016**	**2015**	**2014**
General practitioners	1	2	3
Hospital doctors	2	-	5
Other doctors	4	1	-
Pharmacists	4	6	6
Nurses	2	-	1
Managers	-	-	3
Clinical Commissioning Group	2	1	-
Other health professionals	1	-	-
	16	**10**	**18**
Pharmaceutical companies			
ABPI members	7	11	5
Non members	4	1	3
	11	**12**	**8**
PMCPA Director			
Alleged breach of undertaking	-	2	-
Arising from voluntary admissions	13	4	7
Arising from media criticism	1	1	-
Arising from published information	1	1	-
	15	**8**	**7**
Others			
Members of the public	2	-	1
Anonymous	21[1]	20[2]	13[3]
Employees/ex employees	4	2	-
Anonymous employees	4	2	1
Anonymous ex employees	3	-	1
	34	**24**	**18**
Total	**76**	**54**	**51**

[1] Eight of these were from anonymous health professionals

[2] Six of these were from anonymous health professionals

[3] Six of these were from anonymous health professionals

Appeals to the Code of Practice Appeal Board

	2016	2015	2014
Total number of matters ruled upon by the Code of Practice Panel	420	198	263
Rulings accepted by the parties	387	179	192
Rulings successfully appealed	5	6	13
Rulings unsuccessfully appealed	28	13	58
Number of cases appealed	10	8	6

Sources of appeals	**2016**	**2015**	**2014**
Cases appealed by complainants	4	-	2
Cases appealed by respondents	6	8	5

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

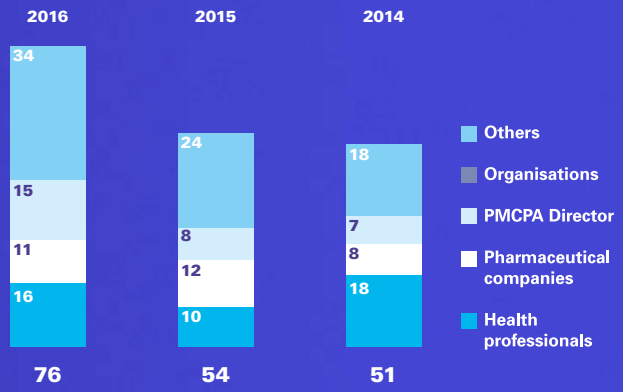
Appeals by complainants	**2016**	**2015**	**2014**
Successful	1	-	-
Partly successful	2	-	1
Unsuccessful	1	-	1
	4	**-**	**2**
Appeals by respondents			
Successful	-	3	-
Partly successful	-	3	4
Unsuccessful	6	2	1
	6	**8**	**5**
Rulings appealed by complainants			
Successful	5	-	2
Unsuccessful	9	-	3
	14	**-**	**5**
Rulings appealed by respondents			
Successful	-	6	11
Unsuccessful	19	13	55
	19	**19**	**66**

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.

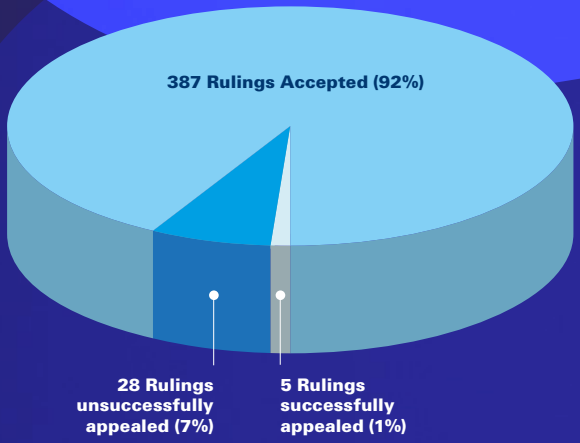
Complaints nominally made by the Director can also arise as a result of:

- 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 2016 the Code of Practice Panel made 420 rulings. Of these, 387 (92%) were accepted by the complainants and respondents involved. A further 28 (7%) were the subject of unsuccessful appeals to the Code of Practice Appeal Board. The remaining 5 (1%) were successfully appealed at the Appeal Board.



Average time taken to complete cases (in weeks)

	2016	2015	2014
Cases settled at Code of Practice Panel level	10.4	8.5	10
Cases which were the subject of appeal	24.8	19.2	23.3
All cases	**11.9**	**9.8**	**11.7**

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 2016 no advertisements were taken up as potentially being in breach of the Code.

Companies ruled in breach of the Code (complaints received in 2016)

* In breach of Clause 2

Actelion Pharmaceuticals UK
Amdipharm Mercury Company Limited
Astellas Pharma Europe Limited
* Astellas Pharmaceuticals UK Limited (ABPI membership suspended June 2016)
* AstraZeneca UK Limited
Bausch & Lomb
Bayer PLC
Baxter Healthcare
* Boehringer Ingelheim Limited
* Celgene Limited
Daiichi-Sankyo UK Limited
* Eli Lilly and Company Limited
Ferring Pharmaceuticals Ltd
GE Healthcare Limited
* Gedeon Richter (UK) Ltd
GlaxoSmithKline UK Limited
* Grunenthal
* Hospira UK Limited
Intrapharm Laboratories Limited
* Janssen
Lincoln Medical Ltd
Meda Pharmaceuticals Limited
Merck Sharp & Dohme Limited
Napp Pharmaceuticals Limited
Novartis Pharmaceuticals UK Ltd
Novo Nordisk Ltd
* Pierre Fabre Limited
Pfizer Limited
Recordati Pharmaceuticals Ltd
Roche Products Limited
Sanofi Genzyme
Sunovion Pharmaceuticals Europe Ltd
* Takeda Limited
UCB Pharma Ltd
* Vifor Pharma UK Limited

Accounts 2016

The PMCPA has been self-financing from the beginning of 1996. In 2016 there was a planned deficit of £60,767 before tax which meant some tax could be reclaimed (£15,655). The PMCPA cumulative reserves on 31 December 2016 are £472,427 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). Fifty per cent of the levy due was called up in 2016. 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 charge per matter in 2016 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 2016 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 2016 *continued*

	2016	2015	2014
	£	£	£
Levy	346,583	290,533	658,292
Administrative charges	547,750	560,500	386,500
Seminars & meetings	*195,113	*174,466	*186,659
Company audits	149,000	82,000	70,000
Contributions to advertising costs	52,000	19,000	24,000
	1,290,446	1,126,499	1,325,461
Expenditure	**1,351,213**	**1,402,633**	**1,404,600**

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
web: www.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).

Completed case reports 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. E Alerts can be requested on the home page and updated information will be sent to your inbox.

Complaints regarding potential breaches of the Code 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

Notes

Notes

PMCPA | Prescription Medicines Code of Practice Authority

7th Floor, Southside, 105 Victoria Street,
London, SW1E 6QT

Tel: 020 7747 8880
www.pmcpa.org.uk