PMCPA

Prescription Medicines
Code of Practice Authority

2018
Annual Report

Introduction

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

The Prescription Medicines Code of Practice Authority (PMCPA) was established on 1 January 1993 by the ABPI to operate the ABPI Code of Practice for the Pharmaceutical Industry independently of the Association itself.

The PMCPA is appointed by the ABPI Board, 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 and 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 that are not members of the ABPI.

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.

Those with suggestions for amendments to the Code are welcome to contact the PMCPA. Anyone with concerns about pharmaceutical company activities should contact the PMCPA, see contact details on page 21.

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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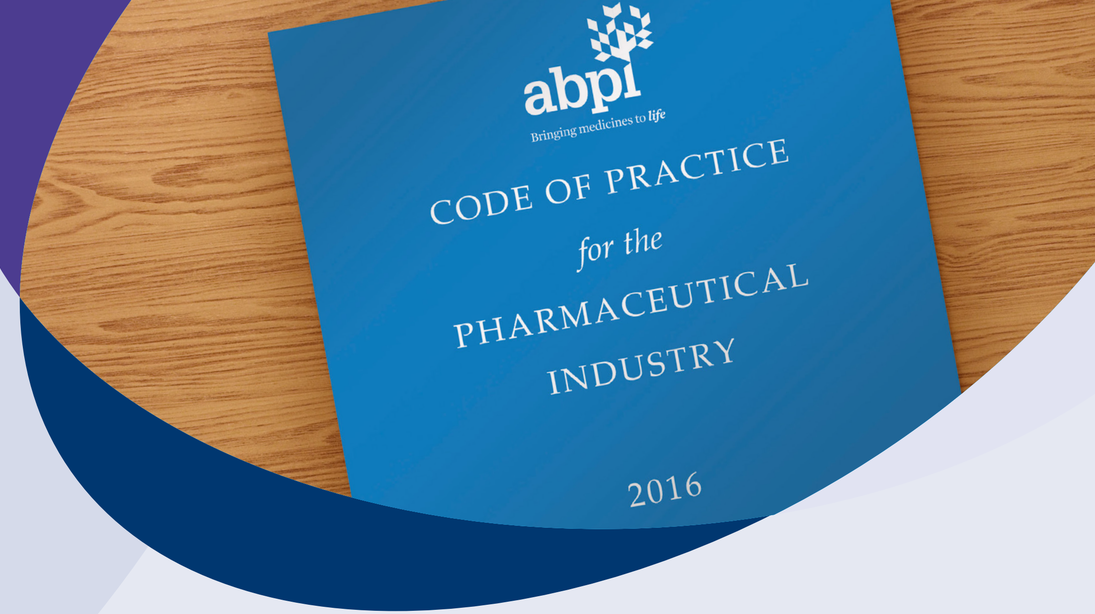
Foreword

"I am pleased to contribute to the 2018 Annual Report of the Prescription Medicines Code of Practice Authority in another challenging year"



2018 was another very busy year for the PMCPA which received 87 complaints, compared with 72 in 2017 and 76 complaints in 2016. The number of individual allegations considered in 2018 was 694, a substantial rise from 404 in 2017 and 420 in 2016.

There was an increase in matters appealed in 2018 (43) compared with 2017 (18) and 2016 (33). The Appeal Board considered appeals in 18 cases in 2018, an increase from 5 in 2017 and 10 in 2016.

The proportion of the Code of Practice Panel rulings appealed in 2018 was 6.2% (43/694), compared with 4% (18/404) in 2017. The proportion of the Panel's rulings successfully appealed in 2018 was 2% (14/694), as it was in 2017 2% (8/404). In 2018, 4% (29/694) of the Panel's rulings were unsuccessfully appealed with 2.5% (10/404) unsuccessfully appealed in 2017.

The parties accepted without appeal 93.8% of the Panel's rulings compared with 95.5% in 2017. It is always, and will remain, the case that 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 38.8 weeks in 2018, compared with 28 weeks in 2017. Any increase in time taken to consider cases is reviewed and taken seriously. The increase was due to a number of factors including the PMCPA being short staffed for most of 2018, until a new member of staff, Natalie Hanna, joined as Deputy Secretary in September 2018 and another was due to a backlog of cases which had grown because of an extraordinary amount of time being taken up with a small number of particularly complex cases.

There was a decrease to 13 in the number of cases ruled in breach of Clause 2 in 2018, compared with 16 in 2017, and 13 in 2016. Clause 2 deals with serious matters and is used when activities or materials have brought discredit upon or reduced confidence in the pharmaceutical industry. The Appeal Board required three companies to undergo 4 audits in relation to complaints received in 2018. No companies were reported to the ABPI Board in relation to a complaint received in 2018. Three were so reported in 2017. Further details are set out in this report.

It is of some concern that the number of anonymous complaints has again risen sharply this year. I am in no doubt that the PMCPA should accept complaints from anonymous sources. Some serious cases have come to light in the last few years as a result of anonymous complaints. However, complaints which are truly anonymous can cause difficulties in that a non-contactable complainant cannot be asked for further information - which might make the difference between his/her complaint satisfying the standard of proof or not - and cannot take part in an appeal if the Panel's ruling is adverse. It remains the case that the PMCPA encourages all complainants to identify themselves, if they are able to do so, and to take a full part in proceedings.

As ever I am very grateful to the members and co-opted members of the Appeal Board for their hard work, support and contributions. They take their responsibilities extremely seriously and devote a significant amount of time preparing for and attending meetings; they uphold that independence of thought which is the cornerstone of self-regulation and at the very heart of the arms' length relationship between the PMPCA and ABPI.

To conclude, I am extremely grateful to Heather Simmonds and all the PMCPA team for their unfailing commitment and hard work.

William Harbage QC.

William Harbage QC
Chairman
Code of Practice Appeal Board

Director's report

"Both the number and complexity of cases kept the PMCPA busier than ever in 2018"

The main focus of the PMCPA remains the administration of the complaints procedure and both the increased number and complexity of cases kept the PMCPA busier than ever in 2018.

The PMCPA administers the Code independently from the ABPI with the Director reporting to the Code of Practice Appeal Board in relation to guidance on the Code and the operation of the complaints procedure.

The number of cases considered by the PMCPA in 2018 increased (120 cases from 87 complaints) compared with 2017 (73 cases from 72 complaints). The percentage of complaints from pharmaceutical companies was higher at 10.3% (9/87) compared with 6% (4/72) in 2017.

The percentage from health professionals decreased slightly to 18% (16/87) in 2018 from 19% (14/72) in 2017. The number of complaints from health professionals in 2018 (16) was more than from pharmaceutical companies (both members and non-members of the ABPI) (9). This follows the usual pattern, that the PMCPA receives more complaints from health professionals than from companies.

Complaints nominally attributed to the Director decreased slightly to 8 in 2018 (9 in 2017) with 7 being voluntary admissions by companies (6 in 2017). The fact that companies make admissions indicates the seriousness with which the industry takes the Code. Full details are given on page 17.

The number of cases ruled in breach of the Code in 2018 at 50% (60/120) decreased compared with 58% (42/73) in 2017. If this is looked at on the basis of individual matters the percentages are different with 28% (196/694) ruled in breach in 2018 compared with 47% (188/404) ruled in breach in 2017.

In relation to a comparison of cases ruled not in breach of the Code in 2018 also at 50% (60/120) this was an increase compared with 2017 when 42% (31/73) were ruled not to be in breach of the Code.

The Panel continues to have a good record, with 98% (680/694) of matters it ruled on being accepted by the parties, or upheld on appeal. The percentage in 2017 was the same 98% (396/404).

The time taken to complete cases at Panel level increased to 24.2 weeks (from 14.3 weeks in 2017). The Panel is extremely conscious of the need to deal with cases as quickly and efficiently as possible. Some cases, however, required additional information before the Panel could make a ruling and in a few cases this was difficult to obtain, thus lengthening the time taken to deal with them. While we have recruited a new staff member, the PMCPA remained short staffed for 18 months in total which, inevitably, contributed substantially to the delays.

In addition to its work relating to cases, the PMCPA also worked on proposals to amend the 2016 ABPI Code of Practice and the PMCPA Constitution and Procedure in 2018 and a new Code was agreed to come into operation on 1 January 2019.

I would like to thank the staff of the PMCPA for their continued support and hard work in a challenging year.

I would like to welcome Natalie Hanna who joined the PMCPA as Deputy Secretary in September 2018.

Heather Simmonds
Director, PMCPA

Complaints

Eighty seven complaints were received in 2018, compared with seventy two complaints in 2017. There were 76 in 2016, 54 in 2015, 51 in 2014 and 80 complaints in 2013. They resulted in 120 cases to be considered in 2018, compared with 73 cases in 2017 and 100 in 2016.

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 2018 at 50% (60/120) decreased compared with 2017 at 58% (42/73).

The number of individual allegations (matters) considered in 2018 was 694, a marked increase from 404 in 2017. There was an increase in the number of matters appealed in 2018 (43), compared with 2017 (18). Of the 43 matters appealed in 2018, 14 (33%) were successful and 29 (67%) were not, compared with 18 matters appealed in 2017 of which 8 (44%) succeeded and 10 (56%) failed.

Time taken to deal with complaints

There was an increase in the overall time taken to deal with complaints. The average figure for 2018 was 26.4 weeks, compared with 15.2 weeks in 2017.

There was also an increase in the time to complete cases settled at Panel level, 24.2 weeks in 2018 compared with 14.3 weeks in 2017. Cases that went to appeal in 2018 took more time (38.8 weeks) to complete than in 2017 (28 weeks).

As mentioned elsewhere, the PMCPA was short staffed for most of 2018 (and most of 2017), which inevitably had an impact on the time taken to complete cases. This was outside its control. In addition to the impact of the reduced staff, there were a number of complex audits and re-audits. There was also a significant increase in the number of cases. Any increase in time taken to complete individual cases is a concern.

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

Three formal reports were made by the Code of Practice Panel to the Code of Practice Appeal Board in relation to two complaints received in 2018 (one of the complaints involved two companies). In 2017 four formal reports were made.

The two complaints were from employees. One concerned the process of the UK company and its UK based European Office for updating the summaries of product characteristics (SPCs) and prescribing information for a number of medicines. There were potential patient safety implications. The Panel's rulings of breaches were not appealed.

The Appeal Board was very concerned that in one complaint (two cases) an overall failure of governance in relation to the companies' processes in implementing SPC changes, updating prescribing information, updating and withdrawing promotional materials, and the update and submission to the MHRA of its risk minimisation materials in a timely manner had potential patient safety implications. It is crucial that health professionals and others can rely completely upon the industry for up-to-date and accurate information about its medicines. Both companies were publicly reprimanded and required to undergo audits in 2019.

The second complainant stated that one of the companies was not transparent in its response to the PMCPA in one of the cases also subject to a report. Relevant information which had not been disclosed was provided by the complainant who stated that there was no consistent clear communication around SPC changes. In the Panel's view, inadequacies in the process had been present since at least as far back as 2014 and had still not been fully corrected despite internal audits, concerns being raised internally and a complaint to the PMCPA. The Panel's rulings of breaches of the Code were not appealed.

Complaints – continued

The Appeal Board noted that it was only after the complaint was made to the PMCPA in 2018 that action was taken. This raised concerns about how seriously the company took the issue, its impact on patient safety and the company's culture. The Appeal Board was also concerned that the company had neither referred to nor provided the relevant information in its response to a previous case.

The Appeal Board was very concerned that an overall failure of governance in relation to the company's processes in implementing SPC changes, updating prescribing information and updating and withdrawing promotional materials in a timely manner had potential adverse patient safety implications. It was crucial that health professionals and others could rely completely upon the industry for up-to-date and accurate information about its medicines. The company was publicly reprimanded and required to undergo an audit in 2019.

Update on reports to the ABPI Board from the Code of Practice Appeal Board on complaints received in 2015, 2016 and 2017

In 2017 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, a 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 re-audits 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 re-audits 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 re-audited 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.
In June 2017 the ABPI Board gave serious consideration to expelling the company from membership of the ABPI but, noting the commitments from the company, its UK based European Office and Global, the ABPI Board decided to extend the suspension for another twelve months. This amounted to the maximum time (2 years) allowed under the ABPI Articles of Association. The ABPI Board reviewed the position in December 2017 and reviewed the reports of the October 2017 re-audits.

In reviewing the outcome of the October 2017 re-audits the Appeal Board noted that some progress had been made. The companies needed to take prompt action to implement the findings. There was still much work to do. The Appeal Board decided both companies should be re-audited in April 2018.

When reviewing the position in December 2017, including reports of the re-audits, the ABPI Board decided it wanted sight of the report of the April 2018 re-audits to review the position before the end of the suspension in June 2018.

On receipt of the report of the April 2018 re-audits the Appeal Board decided both companies should be re-audited in 2019.

In June 2018 the ABPI Board decided it wanted to see the report of the 2019 re-audits and be informed of major developments, including the outcome of an ongoing case. There was no need to consider expulsion and the suspension from membership of the ABPI ended on 24 June 2018.

The companies were re-audited in 2019.

There were a number of other reports made to the ABPI Board by the Appeal Board in relation to the same two companies as above. Three reports were made in 2017 to the ABPI Board by the Appeal Board in relation to complaints received in 2017.

Two concerned a voluntary admission by the two companies concerning the failure to provide accurate prescribing information for seven medicines. In addition, they acknowledged the deficiencies in their processes. The companies were audited, publicly reprimanded and a report was sent to the ABPI Board. One of the companies was suspended from membership of the ABPI. Re-audits of both companies were also carried out.

The third concerned a complaint by a health professional about one of the companies involved in the cases above. Breaches of the Code were ruled following an appeal by the complainant in 2018. Further information was identified at a re-audit of the company in 2018 which had not previously been disclosed. The company failed to provide comprehensive, accurate information in the case. Given the circumstances the Appeal Board publicly reprimanded the company and reported it to the ABPI Board with a recommendation that the company be expelled from membership of the ABPI. On reviewing the report and recommendation from the Appeal Board, the ABPI Board concluded that although the company had made mistakes it had taken action to address the issues arising from this case. The ABPI Board decided that taking everything into account no further action should be taken.

Audits by the PMCPA

There were 4 audits carried out by the PMCPA in relation to complaints received in 2018, the same as in 2017, and 2016.

One audit was in relation to a voluntary admission made in 2018 about a company's failure to disclose support to patient organisations as required by the Code and the provision of inaccurate information to the PMCPA in relation to an audit report. The Panel noted the sensitivities surrounding the pharmaceutical industry working with patient organisations; robust agreements setting out the arrangements, and certification of those agreements were important steps in ensuring that such interactions complied with the Code and in that regard they underpinned the self-regulatory compliance system. That projects and sponsorship

Complaints – continued

were able to go ahead without a certified agreement in place was unacceptable. Further, public disclosure of support was an important means of building and maintaining confidence in the industry. The Panel was also concerned that the information provided in response to the PMCPA's audit report was incorrect. These errors indicated that there was poor governance and control of materials. The Panel noted that self-regulation relied, among other things, upon the provision of complete and accurate information and that in 2017 the company had been criticised for not providing accurate information which led to it being audited. Breaches of the Code were ruled which were not appealed. The Appeal Board received the case report as set out in Paragraph 13.4 of the Constitution and Procedure.

The Appeal Board considered that the case raised serious issues including about the provision of incomplete and/or inaccurate information. The Appeal Board was of the view that consideration should be given to imposing further sanctions under Paragraph 11.1 of the Constitution and Procedure.

The Appeal Board decided that the company should be publicly reprimanded for providing inaccurate information to the PMCPA and audited. The audit was carried out in 2019.

Three other audits related to the cases reported to the Appeal Board by the Panel. These audits were carried out in 2019 and the Appeal Board required re-audits.

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 re-audited in 2016, twice in 2017 and once in 2018 and in 2019.

A voluntary admission in 2016 concerning two meetings resulted in a report to the Appeal Board which required an audit of the company in 2016 and re-audits in 2017 and 2018.

One complaint in 2017 concerning a disclaimer on a conference newsletter resulted in a report to the Appeal Board which required an audit of the company in 2018 and a re-audit in 2019.

In one complaint in 2017 the Appeal Board required an audit as the company had not provided accurate information. The audit was carried out in 2017 and a re-audit was required in 2018.

In all, an audit of one company and re-audits of 4 companies were carried out in 2018, compared with an audit of one company and re-audits of 8 companies in 2017.

ABPI members and non-members

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, then 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 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 not covered by the ABPI Code

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.

The most common of complaints received which were not covered by the Code concerned advertising of botulinum toxin products and other prescription only medicines (POMs) to the public by cosmetic clinics and other service providers. The complainants were advised to contact the MHRA or if the complainants were non contactable the complaints were sent to the MHRA.

Advice and Training

Informal advice on the Code

Many requests for informal guidance and advice on the operation of the Code were received in 2018 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 or email info@pmcpa.org.uk for informal advice on the Code.

Guidance

The PMCPA guidance continued to be accessed in 2018 and companies are always encouraged to submit proposals for updates. Work on updating existing guidance continued in 2018.

Seminars

Five seminars designed to explain the requirements of the Code were held by the PMCPA in central London in 2018. 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, other in-house training sessions, speaking opportunities and talks took place during 2018.

eLearning

The interactive eLearning module, designed initially for health professionals is also undertaken by individuals from across the pharmaceutical, consultancy and PR industries, giving practical examples of the operation of the Code. The module remained popular in 2018.

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' meeting.

Communicating the Code

Advertisements in the medical, pharmaceutical and nursing press

In accordance with the Constitution and Procedure, and timed to coincide with the publication of the 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), and/or 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 featuring the activities of 10 companies (11 cases a mixture of 2017 and 2018 cases) were placed in the BMJ, the Pharmaceutical Journal and the Nursing Standard in 2018 . The advertisements were also published on the PMCPA website.

Consultation on proposed changes to the 2016 edition of the Code

From 29 August to 10 October 2018 the PMCPA conducted a consultation with a wide variety of stakeholders and other regulators which culminated in agreed changes to the 2016 Code and the PMCPA Constitution and Procedure with the new edition of the Code coming into operation on 1 January 2019.

PMCPA Compliance Network

Meetings were held every quarter, with about sixty people at each. Topics covered in 2018 continued to focus on detailed discussion of recently published cases, latest advice on disclosure and guidance on a number of topics, together with other updates such as work to revise international and European Codes.

One of the network members' roles is to ensure that the Code and its operation remain fit for purpose and in that regard the Compliance Network helped during the consultation period on proposals to amend the 2016 Code. Members of the network also provided valuable feedback on the PMCPA activities and a number of individuals volunteered to assist the PMCPA with updating its website.

Disclosure Database updated, June 2018

The ABPI published the third year of data on the payment and or benefits in kind made to health professionals, other individuals and healthcare organisations in the UK by pharmaceutical companies. The database is updated annually in June and is publicly accessible (www.disclosureuk.org.uk).

Code of Practice Review

Detailed reports of all cases completed are published in the Code of Practice Review, which 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 regularly on the website (www. pmcpa.org.uk) and individuals can sign up to be alerted when a new case report, or other material is added to the site.

International and European codes

International Federation of Pharmaceutical Manufacturers and Associations (IFPMA)

The Director of the PMCPA is a member of an ad hoc group that adjudicates on complaints covered by the IFPMA Code complaints procedure. It operates only in relation to countries that do not have local arrangements, be that by self-regulation or external regulation. In 2018 this group did not have any complaints to consider.

The IFPMA Ethics and Business Integrity Committee (eBIC) continued its work in 2018. 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 to share best practice. It also develops guidance and position papers.

Work on updating the IFPMA Code of Practice continued during 2018, with a new version agreed coming into operation on 1 January 2019.

European Federation of Pharmaceutical Industries and Associations (EFPIA)

The Director of the PMCPA is a member of various EFPIA groups in relation to the EFPIA Codes and regularly attended these meetings. In 2018 work started on updating the EFPIA Codes with a new EFPIA Code being agreed in 2019 to come into operation in 2021.

UK legal requirements

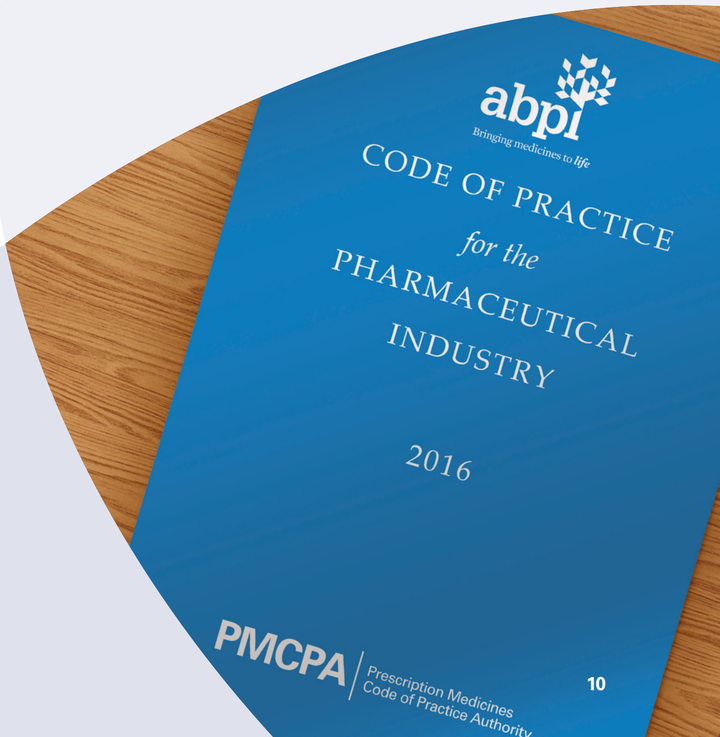
No corrective statements were required by the MHRA in 2018.

The number of complaints and scrutiny of cases in relation to prescription medicines which were upheld in 2018 was 3 (compared with 1 in 2017 and 6 in 2016). The MHRA noted that the number of upheld cases concerning prescription only medicines remained very low since the vast majority were dealt with under self-regulation.

During 2018 the MHRA started vetting all promotional material for one particular marketing authorisation holder following the renewal of its suspension from membership of the ABPI in 2017. The MHRA put the company on notice that, should it be expelled from the ABPI or be found in breach of the ABPI Code again, the MHRA would require all promotional material to be submitted for review before it could be issued. Following the PMCPA's decision to uphold a case concerning the company, the MHRA began vetting its material in December 2018.

The MHRA continued to monitor the advertising of a small number of companies which were not within the self-regulatory system. Such companies had informed the MHRA that they continued to adhere to the Code. The MHRA encouraged such companies to consider re-joining the self-regulatory system.

There were no cases in 2018 where material vetted by the MHRA was subsequently the subject of a complaint to the PMCPA



The Code of Practice Panel

The Code of Practice Panel consists of three of the Director, Deputy Director, Secretary and Deputy Secretary. The Panel met 59 times in 2018, compared with 57 times in 2017. The number of cases considered in 2018 was more than 2017. The Panel can meet at short notice when required and 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. 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.

Tannyth Cox
is the 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 and was promoted to Secretary in 2018.

Natalie Hanna
Natalie joined the PMCPA in September 2018 as the Deputy Secretary. She has a degree in medicine and joined the pharmaceutical industry in 2009, working in medical information. Her previous role was as a medical compliance manager where she was responsible for championing and leading awareness of the ABPI Code and other relevant requirements, developing working practices, training and support. She was also involved in copy approval.

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 20 years and is responsible for the day to day running of the office.

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 communication 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 up to eight other independent members. There are also up to 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 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 2018, and 11 times in 2017. It considered appeals in 18 cases (5 cases in 2017), and 43 matters (18 matters in 2017).

Appeal Board membership and attendance 2018

Chairman

- Mr William Harbage QC

Independent Members

- Mrs Natasha Duke (Nurse Prescriber) (11/11)
- Dr Howard Freeman MBE (General Practitioner) (10/11)
- Mr Christopher Goard (Representing patients' interests) (11/11)
- Mrs Gillian Hawken (Lay member) (11/11)
- Dr Anne Hawkridge (General Practitioner) (10/11)
- Dr John Watkins (Hospital Consultant) (10/11)
- Mr Andrew White (from an independent body that provides information on medicines) (9/11)

Industry Members

- Dr Fenton Catterall (Compliance Officer, Shire Pharmaceuticals Limited, UK, Ireland, Nordics and Baltics) (8/11)
- Dr Stephen McDonough (Vice President and Medical Director, GlaxoSmithKline UK Ltd) (3/4) until May 2018
- Mr Stuart Rose (Managing Director, Merz Pharma UK Ltd) (7/8) until September 2018
- Dr Rhiannon Rowsell (Retired, previously Promotional Affairs & Medical Excellence Director, AstraZeneca) (10/11)
- Dr Mark Sampson (Chief Medical Officer, Shield Therapeutics Limited) (7/11)
- Dr Mark Toms (Chief Scientific Officer UK, Novartis Pharmaceuticals UK Limited) (8/11)

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 2018, the following were each co-opted for at least one meeting:

- Dr Karen Mullen, (Vice President, Country Medical Director, UK and Ireland, GlaxoSmithKline UK Limited)
- Mr Stuart Rose (Managing Director, Merz Pharma UK Ltd)
- Dr Paul Schofield (Medical Director Napp Pharmaceuticals Limited)

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 activity or use of the material in question and any similar material will cease forthwith and that all possible steps will be 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 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
- a report to the ABPI Board; the ABPI Board may suspend or expel companies from membership of the ABPI. 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 can be submitted to the PMCPA by:
Email: complaints@pmcpa.org.uk,
Phone: 0207 747 8880

or write to:
The Director,
PMCPA,
7th Floor, Southside,
105 Victoria Street
London SW1E 6QT.

Statistics on Complaints

Complaints received	2018	2017	2016
Total complaints received	**87**	72	76
Not within the scope of the Code	**-**	-	-
Company declined to accept the PMCPA's jurisdiction before proceedings commenced	**6**	8	5
Complaints withdrawn	**6**	-	-
Complaints considered	**75**	62	69
Cases arising from these complaints	**120**	73	100
Individual matters considered	**694**	404	420
Allegations withdrawn before complaint	**-**	2	-

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 received in 2018, six each led to 2 cases; a seventh complaint led to 4 cases and an eighth complaint let to 37 cases, of which 1 case did not proceed as the company concerned declined to accept the PMCPA's jurisdiction before proceedings commenced.

Of the complaints considered in 2017 two each led to 2 cases and a third to 10 cases.

Of the complaints received in 2016, two each led to 5 cases; a third complaint led to 17 cases of which 7 cases did not proceed as the company concerned declined to accept the PMCPA's jurisdiction before proceedings commenced.

Outcomes of cases considered	2018	2017	2016
Cases where a breach found	**60**	42	57
Cases where no breach found	**60**	31	43
Number of matters in these cases:	**694**	404	420
• in breach	**196**	188	182
• no breach	**498**	216	238
Cases where the Code of Practice Panel required suspension of materials	**0**	1	1
Corrective statements required	**1**	2	3
Public reprimands	**7**[1]	6	1
Audits	**4**[2]	4	4
Breaches of undertaking ruled	**0**	2	2
Breaches of Clause 2 ruled	**13**	16	13
Reports to the Code of Practice Appeal Board	**3**	4	5
Reports to the ABPI Board	**0**	3	1

1 two cases, two public reprimands
2 three companies, four audits

Sources of complaints

	2018	2017	2016
Health Professionals			
General Practitioners	-	-	1
Hospital Doctors	5	5	2
Other Doctors	-	1	4
Pharmacists	6	2	4
Nurses	1	1	2
Managers	-	3	-
Clinical Commissioning Group	1	1	2
Other health professionals	3	1	1
	16	**14**	**16**
Pharmaceutical companies			
ABPI members	5	2	7
Non-members	4	2	4
	9	**4**	**11**
PMCPA Director			
Alleged breach of undertaking	-	-	-
Arising from voluntary admissions	7	6	13
Arising from media criticism	-	2	1
Arising from published information	1	1	1
	8	**9**	**15**
Others			
Members of the public	6	4	2
Anonymous	36[1]	24[2]	21[3]
Employees/ex employees	7	5	4
Anonymous employees	3	1	4
Anonymous ex employees	-	1	3
Pharmaceutical physician	1	1	-
Consultant to company	1	9	-
	54	**45**	**34**
Total	**87**	**72**	**76**

1 Thirty were from anonymous health professionals
2 Seven were from anonymous health professionals
3 Eight were from anonymous health professionals

Appeals to the Code of Practice Appeal Board

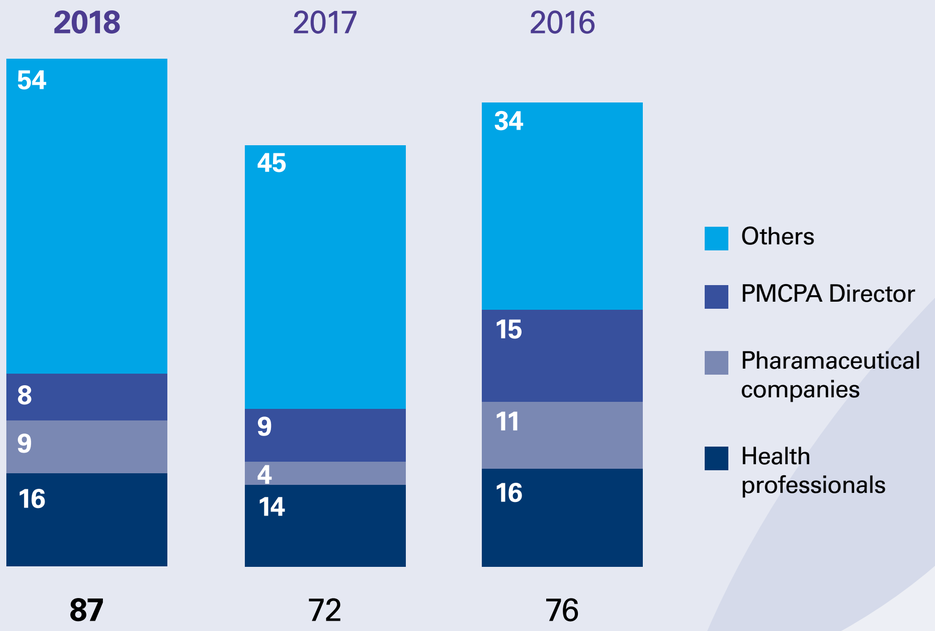
	2018	2017	2016
Total number of matters ruled upon by the Code of Practice Panel	**694**	**404**	**420**
Rulings accepted by the parties	651	386	387
Rulings successfully appealed	14	8	5
Rulings unsuccessfully appealed	29	10	28
Number of cases appealed	18	5	10
Sources of appeals			
Cases appealed by complainants	2	2	4
Cases appealed by respondents	16	3	6
Total	**18**	**5**	**10**
Appeals by complainants			
Successful	-	-	1
Partly successful	-	2	2
Unsuccessful	2	-	1
Total	**2**	**2**	**4**
Appeals by respondents			
Successful	10	1	-
Partly successful	1	1	-
Unsuccessful	5	1	6
Total	**16**	**3**	**6**
Rulings appealed by complainants			
Successful	-	3	5
Unsuccessful	3	6	9
Total	**3**	**9**	**14**
Rulings appealed by respondents			
Successful	14	5	-
Unsuccessful	26	4	19
Total	**40**	**9**	**19**

Complaints received 2018

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.

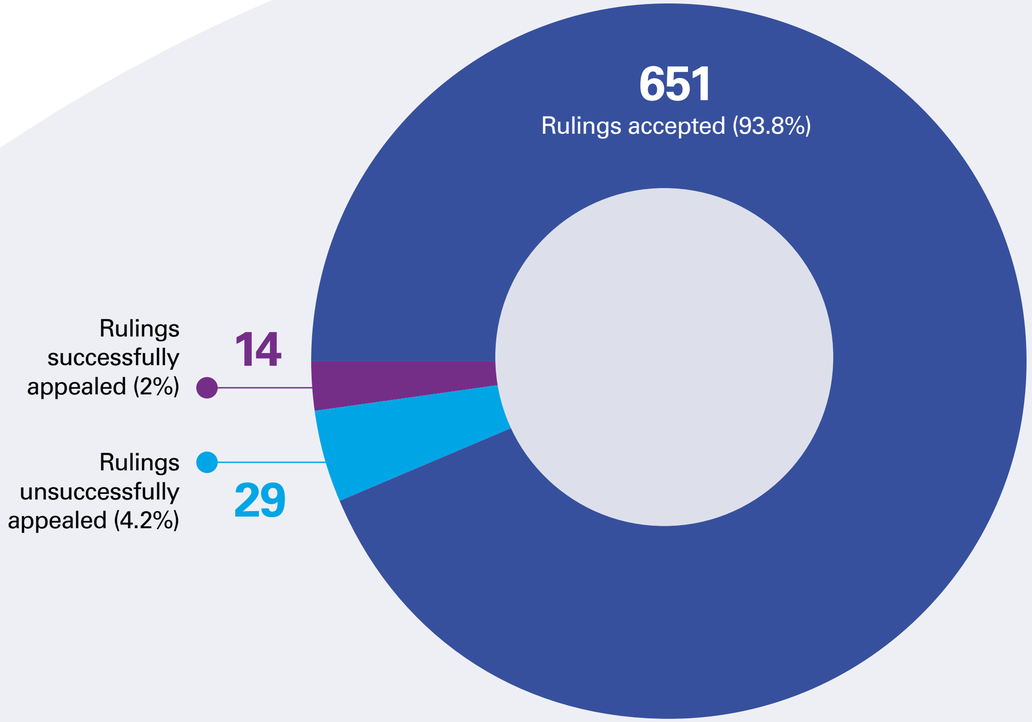
Complaints nominally made by the Director can also arise as a result of:

- 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 rulings

In 2018 the Code of Practice Panel made 694 rulings. Of these 651 (93.8%) were accepted by the complainants and respondents. A further 29 (4.2%) were unsuccessfully appealed at the Appeal Board and the remaining 14 (2%) were successfully appealed.



Average time taken to complete cases

(in weeks)

	2018	2017	2016
Cases settled at Code of Practice Panel level	**24.2**	14.3	10.4
Cases which were the subject of appeal	**38.8**	28.0	24.8
All cases	**26.4**	15.2	11.9

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 2018 no advertisements were taken up as potentially being in breach of the Code.

Companies ruled in breach of the Code

(complaints received in 2018)

A Menarini
AbbVie
Alexion
Allergan
Alliance Pharmaceuticals
Amgen
Astellas UK
AstraZeneca
Bayer*
Bristol-Myers Squibb
Celgene
Chiesi
Daiichi-Sankyo*
Dr Falk Pharma
Gilead Sciences Europe
GlaxoSmithKline
GW Pharmaceuticals*
Indivior*
Ipsen
Janssen
Lilly
Lundbeck
Merck Sharp & Dohme
Mitsubishi Tanabe Pharmaceutical Europe
Napp
Novartis
Novo Nordisk
Otsuka Europe*
Otsuka UK*
PharmaMar
Pharmasure*
Pierre Fabre*
Profile Pharma
Proveca*
Roche
Sanofi
Shield*
Sunovion*
Tesaro
UCB
ViiV Healthcare

*in breach of Clause 2

Annual accounts 2018

The PMCPA is required to be self-financing. In 2018 there was a planned deficit of £99,641 (£122,360 with reclaimed tax of £22,719). The PMCPA cumulative reserves on 31 December 2018 were £421,631. The planned deficit in 2018 was to reduce the PMCPA surplus.

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 2018. 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 2018 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 2018 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 pharmaceutical companies and others.

	2018	2017	2016
	£	£	£
Levy	**392,383**	605,134	346,583
Administrative charges	**452,500**	445,000	547,750
Seminars & meetings	***193,416**	*163,266	*195,113
Company audits	**120,000**	140,000	149,000
Contributions to advertising costs	**48,000**	44,000	52,000
Income	**1,206,300**	1,397,400	1,290,446
Expenditure	**1,328,659**	1,336,218	1,351,213

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
Twitter @PMCPAUK

The following publications are available to download from the PMCPA's website:

- The ABPI Code of Practice for the Pharmaceutical Industry;
- The 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. eAlerts 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

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