PMCPA | Prescription Medicines Code of Practice Authority

# 2017 Annual Report

The aim of the 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 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 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.

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 26.

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.

# Contents

"I am pleased to contribute to the 2017 Annual Report of the Prescription Medicines Code of Practice Authority."

## Foreword

2017 has been another busy year for the PMCPA. In 2017 the PMCPA received 72 complaints, compared with 76 in 2016, and 54 in 2015. The number of individual allegations considered in 2017 was 404, similar to 2016, when there were 420.

There was a decrease in matters appealed in 2017 (18) over 2016 (33). Of the 18 matters appealed 44% were successfully appealed and 56% unsuccessfully appealed.

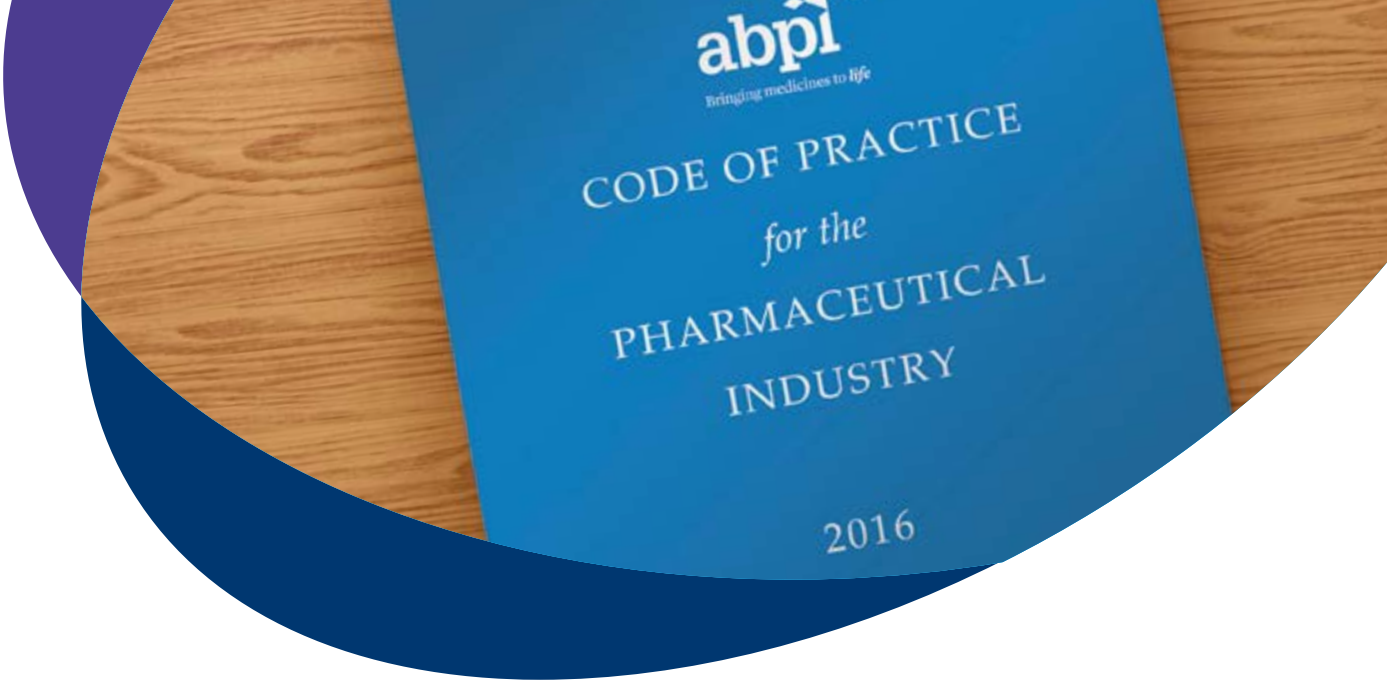
The proportion of the Code of Practice Panel rulings appealed in 2017 was 4% (18/404) compared to 8% (33/420) in 2016. The proportion of the Panel's rulings successfully appealed in 2017 was 2% (8/404) compared to 1% in 2016 (5/420); 2.5% (10/404) were unsuccessfully appealed in 2017, compared with 7% (28/420) in 2016.

The parties accepted without appeal 95.5% of the Panel's rulings, compared with 92% in 2016.

I make it clear, as is always 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 28 weeks in 2017, more than in 2016 (24.8 weeks).

Any increase in time taken to consider cases is reviewed and taken seriously. Some of the increase is due to the PMCPA being short staffed for most of 2017, due to reasons beyond its control. This will unfortunately delay the consideration of cases until a new member of staff starts work.




There was an increase to 16 in the number of cases ruled in breach of Clause 2 in 2017, compared with 13 in 2016. This is of concern as Clause 2 deals with serious matters. 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 2017 and reported one company to the ABPI Board in relation to a complaint received in 2017.

In a number of complaints received in 2017, the respondent companies failed to provide the PMCPA with complete and accurate information. This is very worrying. In almost all such cases the Appeal Board will publicly reprimand the company and often require an audit. The success of self regulation relies on the commitment of companies to providing full and accurate information.

One case in 2017 was particularly concerning as complete information did not become available until after the complainant's appeal was completed. This necessitated further action being taken by the Appeal Board.

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.

To conclude, I am extremely grateful to Heather Simmonds and all her staff for their commitment and hard work. In particular I would like to thank Jane Landles who, until 31 March 2017, was Secretary of the PMCPA. She was a key member of the Panel for 21 years. Her contribution and dedication will be sorely missed. Fortunately for us, she is continuing to provide support to the PMCPA as a consultant.

William Harbage QC.

**William Harbage QC**
Chairman
Code of Practice Appeal Board

# Director's report

The main focus of the PMCPA is, of course, the administration of the complaints procedure and this kept the PMCPA busier than ever in 2017.

Although the number of cases in 2017 decreased (73 cases from 72 complaints, compared to 100 cases from 76 complaints in 2016) the percentage of complaints from pharmaceutical companies was lower at 6% (4/72) in comparison with 14% in 2016 (11/76).

The percentage from health professionals also decreased slightly to 19% (14/72) in 2017 from 21% (16/76) in 2016. The number of complaints from health professionals in 2017 (14) was more than the number from pharmaceutical companies (both members and non-members of the ABPI) (4).

The usual pattern is that the PMCPA receives more complaints from health professionals than from companies.

Complaints nominally attributed to the Director decreased to 9 in 2017 (15 in 2016) with 6 being voluntary admissions by companies (13 in 2016). The fact that companies make admissions indicates the seriousness with which the industry takes the Code.

Some of the voluntary admissions again 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 European Federation of Pharmaceutical Industries and Associations (EFPIA) Code or other relevant codes. The PMCPA is working with EFPIA and others to discuss this issue.

The percentage of cases ruled in breach in 2017 at 56% (42/73) decreased slightly, compared with 57% (57/100) in 2016. If this is looked at on the basis of individual matters the percentages are different with 47% (188/404) ruled in breach in 2017 compared with 43% (182/420) in 2016.

The Panel continues to have a good record, with 98% (396/404) of its rulings being accepted by the parties, or upheld on appeal. The figure for 2016 was 99% (415/420).

The time taken to complete cases at Panel level increased to 14.3 weeks (from 10.4 in 2016). 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. The PMCPA was also short staffed for most of 2017.

This was a particularly demanding year and I would like to thank the staff of the PMCPA for all their unstinting support and hard work.

I would also like to wish Jane Landles, Secretary to the PMCPA until 31 March 2017, a very long and happy retirement. Many of you will know Jane and will have benefited from her expertise. Since joining the PMCPA in January 1996 she has made a significant contribution to the success of self regulation in the UK.

**Heather Simmonds**
Director, PMCPA

# Complaints

Seventy two complaints were received in 2017, compared with 76 in 2016. There were 54 complaints in 2015, 51 in 2014 and 80 complaints in 2013. There were 73 cases to be considered in 2017, compared with 100 in 2016 and 66 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 2017 at 56% (42/73) decreased slightly compared with, 57% (57/100) in 2016. The number of individual allegations (matters) considered in 2017 was 404, compared with 420 in 2016.

The number of individual allegations (matters) considered in 2017 was 404, compared with 420 in 2016. There was a decrease in matters appealed in 2017 (18) compared with 2016 (33). Of the 18 matters appealed in 2017, 44% were successful and 56% failed, compared with 33 matters appealed in 2016 , of which 15% succeeded and 85% failed.

**Time taken to deal with complaints**
There was an increase in the overall time taken to deal with complaints. The figure for 2017 was 15.2 weeks compared with 11.9 weeks in 2016. There was also an increase in the time to complete cases settled at Panel level, 14.3 weeks in 2017, compared to 10.4 weeks in 2016. Cases that went to appeal in 2017 took more time to complete (28 weeks) than in 2016 (24.8 weeks).

As mentioned elsewhere, the PMCPA was short staffed for nine months in 2017 which has 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 reaudits. 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**
Four formal reports were made by the Panel to the Code of Practice Appeal Board in relation to complaints received in 2017. This was one less than in 2016.

Two reports concerned voluntary admissions from two companies regarding failures to provide accurate prescribing information. Large numbers of materials with incomplete prescribing information had been used for a number of years. The Panel's rulings of breaches were not appealed.

The Appeal Board considered the two cases raised serious concerns about multiple failings . Both companies were reported to the ABPI Board, publicly reprimanded for a lamentable lack of concern for patient safety and wholly inadequate oversight and control. The Appeal Board required audits of each company in 2017 and reaudits in 2018 and 2019.

A third report concerned the conduct of senior employees and a lack of procedures for certification of material. The Panel decided the company should suspend use of the material, pending the final outcome of the case, and reported the company to the Appeal Board. The Appeal Board was concerned about the company's processes and Code knowledge, given the company's fundamental errors. The Appeal Board

## Complaints *continued*

publicly reprimanded the company and required the company to issue a corrective statement. It also decided that the PMCPA should audit and reaudit the company in 2018.

The fourth report concerned one of the companies under going audits and reaudits, when at a reaudit additional information came to light which had not been provided as part of that company's response to a separate complaint. That case had completed but nevertheless the Panel was very concerned about the failure to provide accurate information and reported the matter to the Appeal Board.

**Update on reports made on complaints received in 2015 and 2016**
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.

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 reaudits.

In reviewing the outcome of the October 2017 reaudits 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 reaudited in April 2018.

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

On receipt of the report of the April 2018 reaudits the Appeal Board decided both companies should be reaudited in 2019.

In June 2018 the ABPI Board decided it wanted to see the report of the 2019 reaudits 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.

# Complaints *continued*

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, and the details of the Appeal Board and ABPI Board actions are set out above.

**Complaints made in 2017**

Three reports were made to the ABPI Board by the Appeal Board in relation to complaints received in 2017 Two concerned a voluntary admission by 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. Reaudits 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 reaudit of the company in 2018 which had not previously been disclosed. The company failed to provide comprehensive, accurate information in the case. Given the circumstance the Appeal Board publicly reprimanded the company and reported it to the ABPI Board.

**Audits by the PMCPA**

There were 4 audits carried out by the PMCPA in relation to complaints received in 2017, the same as in 2016 but double the number in 2015.

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, twice in 2017 and once in 2018 and in 2019.

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. A further reaudit was carried out in 2017.

One complaint in 2016 concerning two cases resulted in audits of each company in 2016 and reaudits in 2017.

A voluntary admission in 2016 concerning two meetings resulting in a report to the Appeal Board resulted in an audit of the company in 2016 and reaudits in 2017 and 2018.

In all, an audit of one company and reaudits of eight were carried out in 2017.

## Complaints *continued*

**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, 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.

# 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 2017 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 2017 and companies are always encouraged to submit proposals for updates. Some work was started regarding updating existing guidance and this was continued in 2018.

**Training on the Code**

**Seminars**
Six seminars designed to explain the requirements of the Code were held by the PMCPA in central London in 2017. 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, 15 other in-house training sessions, speaking opportunities and talks took place during 2017.

**E Learning**
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. Ongoing feedback indicates that the vast majority of users would recommend it to others.

Although the PMCPA website was optimised to be accessible by mobile devices the module could not be, a review of the design of the training was undertaken to be introduced when the new website is in place in 2019.

**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

**PMCPA Compliance Network**
The popularity of this industry Network continued to grow. The meetings provide the opportunity for compliance staff working in pharmaceutical companies to talk directly with the PMCPA and other invited experts.

Attendance is limited to one staff member 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 were held every quarter, with about forty people at each. Topics covered in 2017 included detailed discussion of recently published cases, latest advice on Disclosure and guidance and updates on the MHRA, as well as international and European Codes.

One of the network members' roles is continuing to ensure that the Code and its operation remain fit for purpose, Compliance Network members continue to review the advice and guidance offered on specific topics, including Clause 3, meetings, patient support programmes and services linked to products. This work is detailed and the working groups taking part are meeting outside the Network to provide feedback and comment from colleagues in their companies, and therefore across the pharmaceutical industry.

The members of the Compliance Network are regularly consulted on the implementation of the Code and provide valuable feedback and advice.

**Disclosure Database updated, June 2017**
The ABPI published the second 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 each June and is publicly accessible (www.disclosureuk.org.uk).

**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.

Six advertisements (two were published in August and November 2017) featuring the activities of 12 companies were placed in the British Medical Journal, the Pharmaceutical Journal and the Nursing Standard. The advertisements were also published on the PMCPA website. One company was named three times and another was named twice.

# Communicating the Code *continued*

**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.

## 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. It operates only in relation to countries that do not have local arrangements, be that by self regulation or external regulation. In 2017 this group did not have any complaints to consider.

The IFPMA Ethics and Business Integrity Committee (eBIC) continued its work in 2017. 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.

Work on updating the IFPMA Code of Practice started in 2017. The next edition will come into operation on 1 January 2019.

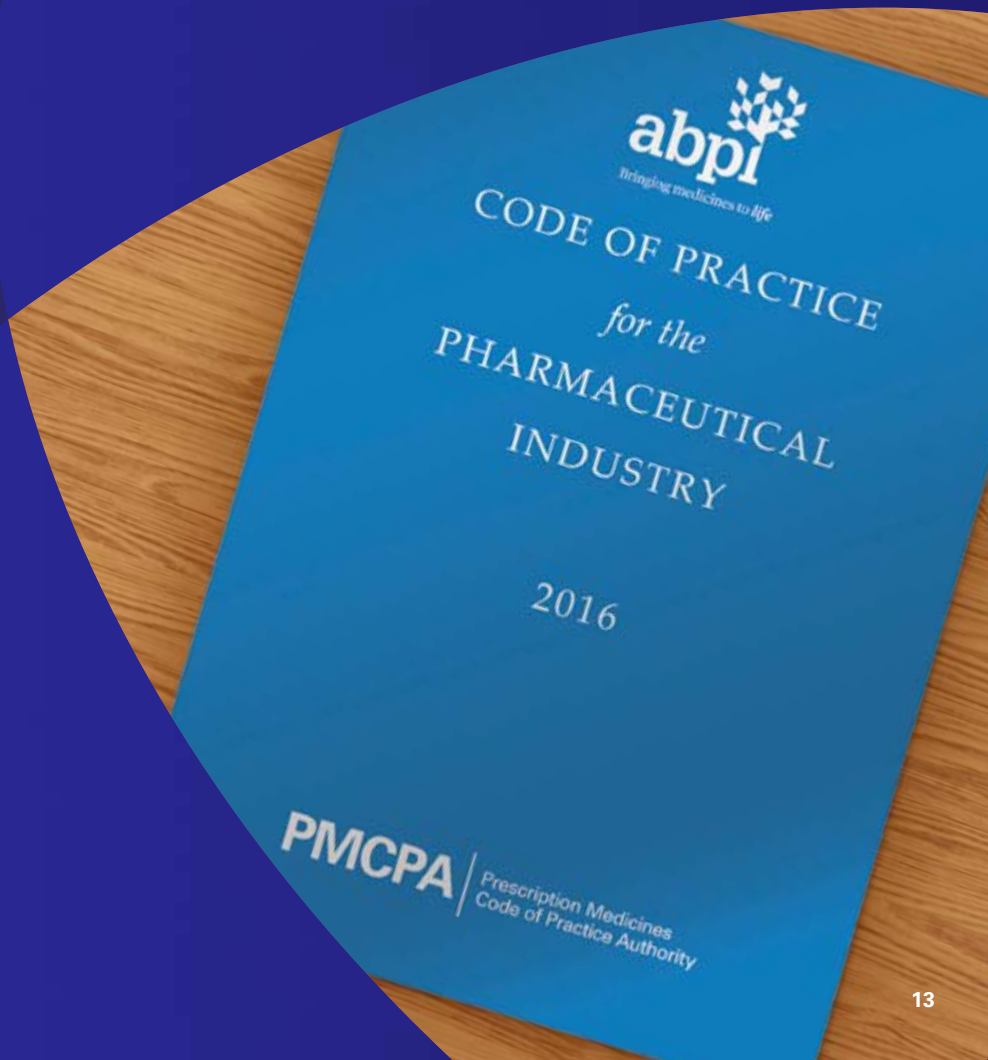
**European Federation of Pharmaceutical Industries and Associations**

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 finished in 2017.

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 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 57 times in 2017 (compared with 99 times in 2016). The vacancy at the PMCPA impacted on the number of meetings. The number of cases considered in 2017 was similar to 2016. 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. One company was required to suspend material in 2017. 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** was 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.

After 21 years at the PMCPA Jane retired on 31 March 2017.

**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 19 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 2017, the same as in 2016. It considered appeals in 5 cases (10 in 2016), and 18 matters (33 in 2016).

of Practice Authority (PMCPA)

# Membership and attendance during 2017

**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) (10/11)

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

Mr David Mills (Pharmacist) (3/3) until March 2017

Dr John Watkins (Hospital Consultant) (10/11)

Mr Andrew White (from an independent body that provides information on medicines) (9/11)

**Industry Members**

Dr Peter Barnes (Global Medical Affairs Lead, Janssen) (5/8) until October 2017

Dr Fenton Catterall (Compliance Officer, Shire Pharmaceuticals Limited, UK, Ireland, Nordics and Baltics, since November 2017. Previously Compliance Officer UK, Ireland and Canada, Biogen Idec Limited) (3/4) until February 2017

Dr Stephen McDonough (Vice President and Medical Director, GlaxoSmithKline UK Ltd) since March 2017 (6/9)

Mr Stuart Rose (Managing Director, Merz Pharma UK Ltd) (10/11)

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

Dr Mark Sampson (Chief Medical Officer, Shield Therapeutics Limited) since March 2017 (6/9)

Dr Mark Toms (Chief Scientific Officer UK, Novartis Pharmaceuticals UK Limited previously Executive Director, Medical Affairs, Merck Sharp & Dohme Limited) since March 2017 (5/9)

**Co-opted Members**

The Chairman can co-opt members for meetings of the Appeal Board so as to enable a quorum to be achieved.

During 2017, 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)

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 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 can be submitted to the PMCPA by
email: complaints@pmcpa.org.uk
phone: 0207 747 8880
write to: The Director, PMCPA, 7th Floor, Southside, 105 Victoria Street, London SW1E 6QT

## Complaints received by the PMCPA

| | 2017 | 2016 | 2015 |
|---|---|---|---|
| Complaints received | 72 | 76 | 54 |
| Not within the scope of the Code | - | - | - |
| Company declined to accept the PMCPA's jurisdiction before proceedings commenced | 8 | 5 | 5 |
| Inter-company dialogue successful | - | - | 1 |
| Complaints considered | 62 | 69 | 53 |
| Cases arising from these complaints | 73 | 100 | 66 |
| Individual matters considered | 404 | 420 | 198 |
| 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 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 these, seven cases did not proceed as the companies concerned declined to accept the PMCPA's jurisdiction before proceedings commenced.

## Outcomes of complaints considered

| | 2017 | 2016 | 2015 |
|---|---|---|---|
| Cases where a breach found | 42 | 57 | 35 |
| Cases where no breach found | 31 | 43 | 31 |
| Number of matters in these cases: | 404 | 420 | 198 |
| - in breach | 188 | 182 | 85 |
| - no breach | 216 | 238 | 113 |
| Cases where the Code of Practice Panel required suspension of materials | 1 | 1 | - |
| Corrective statements required | 2 | 3 | 5[2] |
| Public reprimands | 6 | 1 | 3[3] |
| Audits | 4 | 4 | 2 |
| Breaches of undertaking ruled | 2 | 2 | 1 |
| Breaches of Clause 2 ruled | 16 | 13 | 10 |
| Reports to the Code of Practice Appeal Board | 4 | 5 | 5[1] |
| Reports to the ABPI Board | 3 | 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** | **2017** | **2016** | **2015** |
|---|---|---|---|
| General practitioners | - | 1 | 2 |
| Hospital doctors | 5 | 2 | - |
| Other doctors | 1 | 4 | 1 |
| Pharmacists | 2 | 4 | 6 |
| Nurses | 1 | 2 | - |
| Managers | 3 | - | - |
| Clinical Commissioning Group | 1 | 2 | 1 |
| Other health professionals | 1 | 1 | - |
| | **14** | **16** | **10** |
| **Pharmaceutical companies** | | | |
| ABPI members | 2 | 7 | 11 |
| Non members | 2 | 4 | 1 |
| | **4** | **11** | **12** |
| **PMCPA Director** | | | |
| Alleged breach of undertaking | - | - | 2 |
| Arising from voluntary admissions | 6 | 13 | 4 |
| Arising from media criticism | 2 | 1 | 1 |
| Arising from published information | 1 | 1 | 1 |
| | **9** | **15** | **8** |
| **Others** | | | |
| Members of the public | 4 | 2 | - |
| Anonymous | 24[1] | 21[2] | 20[3] |
| Employees/ex employees | 5 | 4 | 2 |
| Anonymous employees | 1 | 4 | 2 |
| Anonymous ex employees | 1 | 3 | - |
| Pharmaceutical physician | 1 | - | - |
| Consultant to company | 9 | - | - |
| | **45** | **34** | **24** |
| **Total** | **72** | **76** | **54** |

[1] Seven of these were from anonymous health professionals

[2] Eight of these were from anonymous health professionals

[3] Six of these were from anonymous health professionals

# Appeals to the Code of Practice Appeal Board

| | 2017 | 2016 | 2015 |
|---|---|---|---|
| Total number of matters ruled upon by the Code of Practice Panel | 404 | 420 | 198 |
| Rulings accepted by the parties | 386 | 387 | 179 |
| Rulings successfully appealed | 8 | 5 | 6 |
| Rulings unsuccessfully appealed | 10 | 28 | 13 |
| Number of cases appealed | 5 | 10 | 8 |

| **Sources of appeals** | **2017** | **2016** | **2015** |
|---|---|---|---|
| Cases appealed by complainants | 2 | 4 | - |
| Cases appealed by respondents | 3 | 6 | 8 |

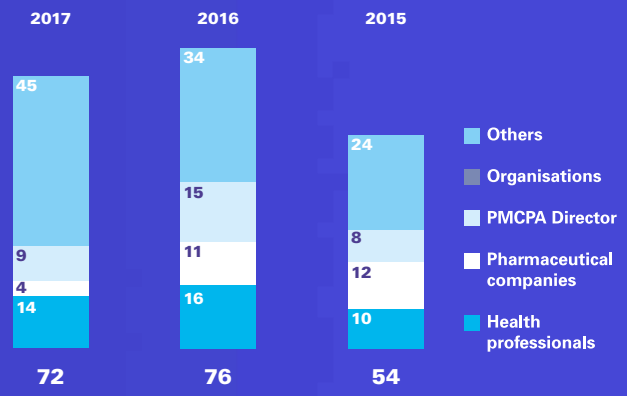
| **Appeals by complainants** | **2017** | **2016** | **2015** |
|---|---|---|---|
| Successful | - | 1 | - |
| Partly successful | 2 | 2 | - |
| Unsuccessful | - | 1 | - |
| | **2** | **4** | - |
| **Appeals by respondents** | | | |
| Successful | 1 | - | 3 |
| Partly successful | 1 | - | 3 |
| Unsuccessful | 1 | 6 | 2 |
| | **3** | **6** | **8** |
| **Rulings appealed by complainants** | | | |
| Successful | 3 | 5 | - |
| Unsuccessful | 6 | 9 | - |
| | **9** | **14** | - |
| **Rulings appealed by respondents** | | | |
| Successful | 5 | - | 6 |
| Unsuccessful | 4 | 19 | 13 |
| | **9** | **19** | **19** |

## 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.

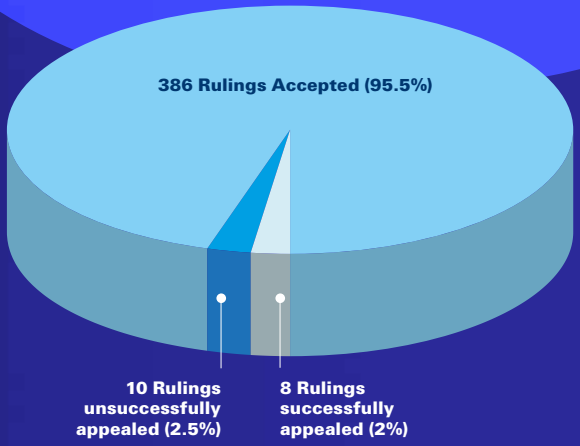
Complaints nominally made by the Director can also arise as a result of:

- 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 2017 the Code of Practice Panel made 404 rulings. Of these 386 (95.5%) were accepted by the complainants and the respondents. A further 10 (2.5%) were unsuccessfully appealed at the Appeal Board and the remaining 8 (2%) were successfully appealed.



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

| | 2017 | 2016 | 2015 |
|---|---|---|---|
| Cases settled at Code of Practice Panel level | 14.3 | 10.4 | 8.5 |
| Cases which were the subject of appeal | 28.0 | 24.8 | 19.2 |
| All cases | **15.2** | **11.9** | **9.8** |

## Scrutiny

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

In 2017 no advertisements were taken up as potentially being in breach of the Code.

## Companies ruled in breach of the Code (complaints received in 2017)

A Menarini Pharma UK SRL*
AbbVie
Astellas Pharma Europe Limited *
Astellas Pharmaceuticals UK Limited*
AstraZeneca UK Limited
Bayer plc*
Biogen
Celgene Limited
Chiesi Limited
Dr Falk Pharma UK Ltd
Janssen*
Johnson & Johnson
Martindale Pharma*
Novartis Pharmaceuticals UK Limited*
Novo Nordisk
Otsuka Pharmaceuticals UK
Pfizer Limited*
PharmaMar*
Pierre Fabre Limited*
Sanofi UK
Shire Pharmaceuticals Limited
Stirling Anglian
Sun Pharma
Sunovion Pharmaceuticals Europe Limited
Teva
Thame Laboratories*
Tor Generics Ltd*
UCB Pharma Limited*

*in breach of Clause 2

# Accounts 2017

The PMCPA has been self-financing from the beginning of 1996. In 2017 there was a planned surplus of £61,181 less tax of £12,336. The PMCPA cumulative reserves on 31 December 2017 were £521,272 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). Eighty per cent of the levy due was called up in 2017. 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 2017 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 2017 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.

# Accounts 2017 *continued*

| | 2017 | 2016 | 2015 |
|---|---|---|---|
| | £ | £ | |
| Levy | 605,134 | 346,583 | 290,533 |
| Administrative charges | 445,000 | 547,750 | 560,500 |
| Seminars & meetings | *163,266 | *195,113 | *174,466 |
| Company audits | 140,000 | 149,000 | 82,000 |
| Contributions to advertising costs | 44,000 | 52,000 | 19,000 |
| | 1,397,400 | 1,290,446 | 1,126,499 |
| **Expenditure** | **1,336,218** | **1,351,213** | **1,402,633** |

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 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**