PMCPA

Prescription Medicines
Code of Practice Authority

2019
Annual Report

Director's Introduction

The number of cases considered by the PMCPA in 2019 increased slightly (126 cases from 132 complaints) compared to 2018 (120 cases from 87 complaints)

The main focus of the PMCPA is, of course, the administration of the complaints procedure and both the increased number and complexity of cases occupied the Panel and Appeal Board throughout 2019.

Complaints

In 2019, the PMCPA received 132 complaints, compared with 87 in 2018. In 2017, there were 72 complaints with 76 in 2016 and 54 in 2015. In 2019, there were 36 complaints from one individual.

There were 126 cases to be considered in 2019, compared with 120 in 2018 and 73 in 2017. 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 number of individual allegations considered in 2019 was 597 a decrease from 694 in 2018 which was an increase from 404 in 2017.

The number of complaints from health professionals in 2019 (15) was more than the number from pharmaceutical companies (both members and non-members of the ABPI) (13). In addition, there were 51 complaints from anonymous health professionals.

The more complex cases considered by the Authority are generally inter-company complaints which often raise a number of issues. Thirteen complaints were nominally made by the Director, of which 11 arose from voluntary admissions by companies. One arose from published information and another from media criticism.

There were 11 complaints made by employees/ex-employees. One complaint was made by a consultant to a company and 9 complaints were from members of the public. There were 11 anonymous complaints in addition to the 51 from anonymous health professionals, five were from anonymous employees and three from anonymous ex employees.

The number of cases considered by the PMCPA in 2019 increased slightly (126 cases from 132 complaints) compared to 2018 (120 cases from 87 complaints)

The percentage of complaints from health professionals decreased to 11% (15/132 in 2019 compared to 18% (16/87) in 2018. The number of complaints from health professionals in 2019 (15) was more than from pharmaceutical companies (both members and non-members of the ABPI) (13). This follows the usual pattern, that the PMCPA receives more complaints from health professionals than from companies. The percentage of complaints from pharmaceutical companies was about the same in 2019 at 11% (15/132) and 2018 at 10% (9/87).

Complaints nominally attributed to the Director increased to 13 in 2019 (from 9 in 2018) with 11 being voluntary admissions by companies (7 in 2018). The fact that companies make admissions indicates the seriousness with which the industry takes the Code.

The percentage of cases ruled in breach in 2019 at 76% (96/126) is a substantial increase compared to 2018 at 50% (60/120). If this is looked at on the basis of individual matters, the percentages are different with 45% (271/597) in 2019 compared to 28% (196/694) in 2018.

Director's Introduction – continued

Panel

The Panel continues to have a good record, with 98% in both 2019 ((587/597) and 2018 (680/694) of its rulings being accepted by the parties, or upheld on appeal.

The time taken to complete cases at Panel level increased to 28.9 weeks (from 24.2 weeks in 2018). 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 increased number of complainants and their complexity impacted on the time to deal with them.

Appeals

There was a slight decrease in the number of matters appealed in 2019 (40) compared to 2018 (43) and 2017 (18). Of the matters appealed in 2019, 10 (1.7%) were successfully appealed and 20 (5%) unsuccessfully appeared in 2019 compared with 14 (2%) successfully appealed, and 29 (4.2%) unsuccessfully appealed in 2018. The proportion of the Code of Practice Panel rulings appealed in 2019 was 6.7% (40/597) compared to 6.2% (43/694) in 2018.

The proportion of the Panel's rulings successfully appealed in 2019 was 1.6% (10/597) slightly less than in 2018 which was 2% (14/694).

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 the consideration of a case which was the subject of appeal was 52.26 weeks in 2019 compared to 38.8 weeks in 2018. Any increase in time taken to consider cases is reviewed and taken seriously. Some of the increase is due to the volume of cases for the PMCPA to consider and that for some of the cases there were unavoidable delays in arranging appeal hearings, some due to conflicts of interest and the need for the Appeal Board to be quorate and others due to availability of pharmaceutical company staff.

There was an increase to 25 in the number of cases ruled in breach of Clause 2 in 2019 compared with 13 in 2018 and 16 in 2017. 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 3 companies to undergo 5 audits in relation to complaints received in 2019 but did not report any companies to the ABPI Board in relation to a complaint received in 2019. The PMCPA carried out 2 audits and 4 reaudits in 2019.
The average time taken to complete consideration of a case overall was 32.61 weeks in 2019 compared to 26.4 weeks in 2018.

As ever I am very grateful to the PMCPA team as well as the members and co-opted members of the Appeal Board for their hard work, support and contributions. They take their responsibilities extremely seriously.

Heather Simmonds
Director, PMCPA

The Code of Practice Panel

The Code of Practice Panel consists of three members of the Authority (the Director, Deputy Director and one of the Managers). The Panel met 63 times in 2019, compared with 59 times in 2018. The number of cases considered in 2019 was slightly more than 2018. 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 one of the Managers at the PMCPA (she was previously the Secretary). 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.

Natalie Hanna
is one of the Managers at the PMCPA (she was previously the Deputy Secretary). Natalie has a degree in medicine and joined the pharmaceutical industry in 2009, working in various pharmaceutical companies which included providing medical information, leading awareness of the ABPI Code and other relevant requirements, developing working practices, training and copy approval. Natalie joined the PMCPA in 2018.

The PMCPA Team

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.

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.

Lisa Matthews
is the Personal Assistant to the Deputy Director and Managers. 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 Head of Communications. Elly joined the PMCPA in 2015 and was previously at NHS London. 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 10 times in 2019, and 11 times in 2018. It considered appeals in 20 cases in 2019 (18 cases in 2018), and 40 matters in 2019 (43 matters in 2018).

Appeal Board membership and attendance 2019

Chairman

- Mr William Harbage QC

Independent Members

- Mrs Natasha Duke
  (Nurse Prescriber) (10/10)
- Dr Howard Freeman MBE
  (General Practitioner) (9/10)
- Mr Christopher Goard
  (Representing patients' interests) (10/10)
- Mrs Gillian Hawken
  (Lay member) (9/10)
- Dr Anne Hawkridge
  (General Practitioner) (7/9)
- Dr John Watkins
  (Hospital Consultant) (8/10)
- Mr Andrew White
  (from an independent body that provides information on medicines) (5/10)

Industry Members

- Dr Fenton Catterall
  (Compliance Officer, Shire Pharmaceuticals Limited, UK, Ireland, Nordics and Baltics) (8/10)
- Dr Karen Mullen
  (Vice President, Country Medical Director, UK and Ireland, GlaxoSmithKline UK Limited) (5/8) from March 2019
- Dr Rhiannon Rowsell
  (Retired, previously Promotional Affairs & Medical Excellence Director, AstraZeneca) (2/4) until March 2019
- Dr Rhiannon Rowsell (Retired, previously Promotional Affairs & Medical Excellence Director, AstraZeneca) (10/11)
- Dr Mark Sampson
  (Chief Medical Officer, Shield Therapeutics Limited) (2/4) until April 2019
- Dr Mark Toms
  (Chief Scientific Officer UK, Novartis Pharmaceuticals UK Limited (5/10)

Co-opted Members

The Chair can co-opt members for meetings of the Appeal Board so as to enable a quorum to be achieved. During 2019, the following were each co-opted for at least one meeting:

- Mr Toby Cousens (Commercial Strategy Director, Internal Medicines, Pfizer UK)
- Dr Anne Hawkridge, (Independent, General Practitioner)
- Mr David Hope (Sales and Marketing Director, Alliance Pharmaceutical Limited)
- Ms Caroline Horwood, (Strategic Medical Projects Officer, Sanofi UK Sanofi UK)
- Dr Sathish Kolli (Medical Director, Leo Pharma UK))
- Dr Marc Moodley, (Medical Director, Sanofi Genzyme UK and Ireland)
- Dr Karen Mullen, (Vice President, Country Medical Director, UK and Ireland, GlaxoSmithKline UK Limited)
- Dr Rhiannon Rowsell, (Retired industry member)
- Dr Paul Schofield (Medical Director Napp Pharmaceuticals Limited)
- Mr Stuart Rose (Managing Director, Merz Pharma UK Ltd)
- Mr John Russell, (VP Commercial, OUS, Immunocore Limited)
- Mrs Linda Stone, (Independent, Pharmacist)

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 and Managers 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). 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.

Complaints received by the PMCPA

	2019	2018	2017
Complaints received	**132**	87	72
Not within the scope of the Code	**6**	-	-
Company declined to accept the PMCPA's jurisdiction Before proceedings commenced	**11**	6	8
Complaints withdrawn	**3**	6	-
Inter-company dialogue successful Complaints considered	**112**	75	62
Cases arising from these complaints	**126**	120	73
Individual matters considered	**597**	694	404
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 2019, six led to 2 cases and one led to 10 cases of which two cases did not proceed as the companies concerned declined to accept the PMCPA's jurisdiction before proceedings commenced.

Of the complaints received in 2018, six each led to 2 cases; a seventh complaint led to 4 cases and an eighth complaint led 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.

Outcomes of cases considered	2019	2018	2017
Cases where a breach found	**96**	60	42
Cases where no breach found	**30**	60	31
Number of matters in these cases:	**597**	694	404
• in breach	**271**	196	188
• no breach	**326**	498	216
Cases where the Code of Practice Panel required suspension of materials	**0**	0	1
Corrective statements required	**0**	1	2
Public reprimands	**6**[1]	7[2]	6
Audits	**5**[4]	4[3]	4
Breaches of undertaking ruled	**6**	0	2
Breaches of Clause 2 ruled	**25**	13	16
Reports to the Code of Practice Appeal Board	**3**	3	4
Reports to the ABPI Board	**0**	0	3

1 two cases, two public reprimands
2 two cases, two public reprimands
3 three companies, four audits
4 three companies, five audits

Sources of complaints

	2019	2018	2107
Health Professionals			
General Practitioners	1	-	-
Hospital Doctors	2	5	5
Other Doctors	1	-	1
Pharmacists	5	6	2
Nurses	1	1	1
Managers	-	-	3
Clinical Commissioning Group	1	1	1
Other health professionals	4	3	1
	15	**16**	**14**
Pharmaceutical companies			
ABPI members	4	5	2
Non-members	9	4	2
	13	**9**	**4**
PMCPA Director			
Alleged breach of undertaking	-	-	-
Arising from voluntary admissions	11	7	6
Arising from media criticism	1	-	2
Arising from published information	1	1	1
	13	**8**	**9**
Others			
Members of the public	9	6	4
Anonymous	62[1]	36[2]	24[3]
Employees/ex-employees	11	7	5
Anonymous employees	5	3	1
Anonymous ex-employees	3	-	1
Pharmaceutical physician	-	1	1
Consultant to company	1	1	9
	91	**54**	**45**
Total	**132**	**87**	**72**

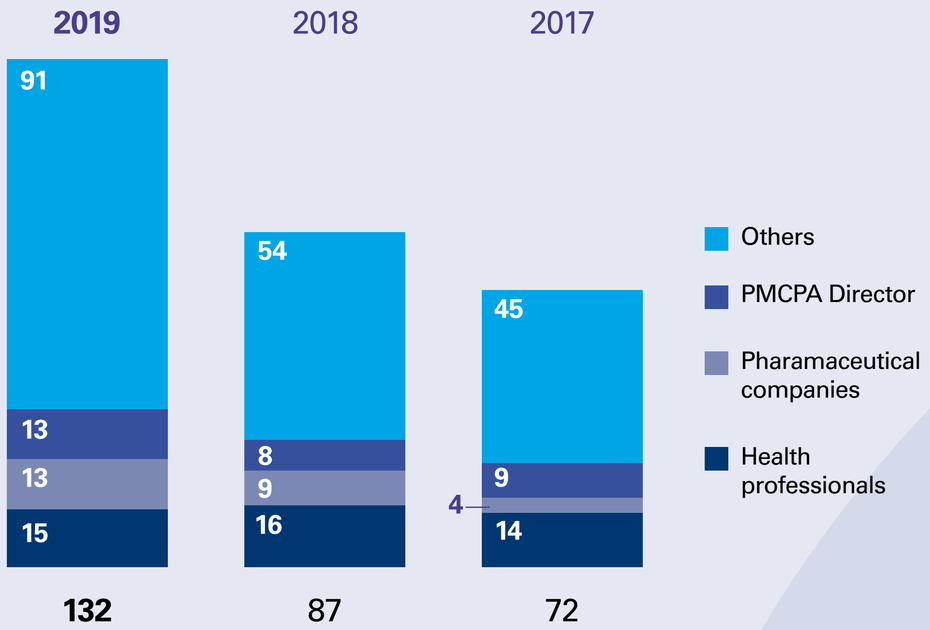
1 Fifty-one were from anonymous health professionals
2 Thirty were from anonymous health professionals
3 Seven were from anonymous health professionals

Appeals to the Code of Practice Appeal Board

	2019	2018	2017
Total number of matters ruled upon by the Code of Practice Panel	**597**	**694**	**404**
Rulings accepted by the parties	557	651	386
Rulings successfully appealed	10	14	8
Rulings unsuccessfully appealed	30	29	10
Number of cases appealed	20	18	5
Sources of appeals			
Cases appealed by complainants	12	2	2
Cases appealed by respondents	8	16	3
	20	**18**	**5**
Appeals by complainants			
Successful	2	-	-
Partly successful	1	-	2
Unsuccessful	9	2	-
	12	**2**	**2**
Appeals by respondents			
Successful	1	10	1
Partly successful	1	1	1
Unsuccessful	6	5	1
	8	**16**	**3**
Rulings appealed by complainants			
Successful	5	-	3
Unsuccessful	11	3	6
	16	**3**	**9**
Rulings appealed by respondents			
Successful	5	14	5
Unsuccessful	19	26	4
	24	**40**	**9**

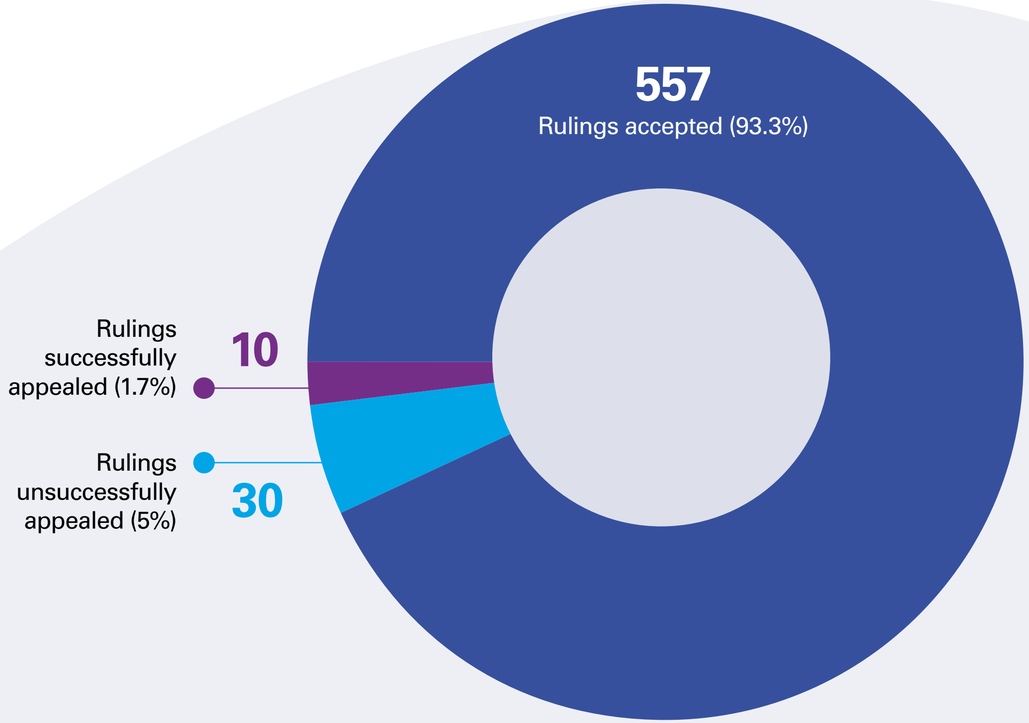
Complaints received 2019

Complaints nominally made by the Director can result from media criticism of pharmaceutical company activities covered by the Code. They 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 2019, the Code of Practice Panel made 597 rulings. Of these 557 (93.3%) were accepted by the complainants and respondents. A further 30 (5%) were unsuccessfully appealed at the Appeal Board and the remaining 10 (1.7%) were successfully appealed.



Average time taken to complete cases

(in weeks)

	2019	2018	2017
Cases settled at Code of Practice Panel level	**28.9**	24.2	14.3
Cases which were the subject of appeal	**52.26**	38.8	28.0
All cases	**32.61**	26.4	15.2

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 2019 no advertisements were taken up as potentially being in breach of the Code.

Companies ruled in breach of the Code

(complaints received in 2019)

Allergan*
Astellas
Almirall
Alexion
AstraZeneca
Bayer *
Bracco
Bristol-Myers Squibb*
Boehringer Ingelheim
Colonis Pharma*
Celgene
Daiichi-Sankyo*
Diurnal
Dr Falk Pharma
Ever Pharma
Endo Ventures
Ferring Pharmaceuticals
Gedeon Richter
Gilead*
GlaxoSmithKline
GW Pharmaceuticals
Grünenthal
Ipsen
Janssen*
Leo Pharma
Lilly
Merck Sharp & Dohme*
Merck Serono*
Merz
Mundibiopharma
Napp*
Novartis
Norgine
Novo Nordisk
Otsuka Europe*
Otsuka UK*
Orion Pharma
Pharmasure
Pfizer*
Sanofi
Strides Pharma
Teva*
UCB
Vifor Pharma*
ViiV Healthcare

*in breach of Clause 2

Accounts 2019

The PMCPA is required to be self-financing. In 2019 there was a surplus of £123,314 (£152, 926 minus £29, 612 tax). The PMCPA cumulative reserves on 31 December 2019 were £544,945 after tax.

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). The maximum levy (100%) was called up in 2019. 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 2019 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 2019 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.

	2019	2018	2017
	£	£	£
Levy	**821,401**	392,383	605,134
Administration charges	**560,000**	452,500	445,000
Seminars and meetings	**100,104**	193,416	163,266
Company Audits	**100,000**	120,000	140,000
Contributions to advertising costs	**24,000**	48,000	44,000
	1,605,504	1,206,300	1,397,400
Expenditure	**1,453,120**	1,328,659	1,336,218

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

PMCPA | Prescription Medicines Code of Practice Authority

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