PMCPA

Prescription Medicines
Code of Practice Authority

2020
Annual Report

Director's Introduction

The number of cases considered by the PMCPA in 2020 was about the same as 2019 (127 cases from 148 complaints) compared to 2019 (126 cases from 132 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 2020.

Complaints

In 2020, the PMCPA received 148 complaints, compared with 132 in 2019. In 2018, there were 87 complaints with 72 in 2017 and 76 in 2016. In 2020, there were 55 complaints from one individual.

There were 127 cases to be considered in 2020, compared with 126 in 2019 and 120 in 2018. 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 2020 was 736, an increase from 597 in 2019 which was a decrease from 694 in 2018.

The number of complaints from health professionals in 2020 (13) was more than the number from pharmaceutical companies (both members and non-members of the ABPI) (5). In addition, there were 59 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. Ten complaints were nominally made by the Director, all of which arose from voluntary admissions by companies.

There were 9 complaints made by employees/ex-employees and 15 complaints were from members of the public. There were 31 anonymous complaints in addition to the 59 from anonymous health professionals, 2 from anonymous employees and 1 from anonymous ex employees.

The number of cases considered by the PMCPA in 2020 was about the same as 2019 (127 cases from 148 complaints) compared to 2019 (126 cases from 132 complaints)

The percentage of complaints from health professionals decreased to 9% (13/148) compared to 11% (15/132) in 2019. The number of complaints from health professionals in 2020 (13) was more than from pharmaceutical companies (both members and non-members of the ABPI) (5). 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 less in 2020 at 3.4% (5/148) compared with 2019 at 11% (15/132) and 2018 at 10% (9/87).

Complaints nominally attributed to the Director decreased to 10 in 2020 (from 13 in 2019) with 10 being voluntary admissions by companies (11 in 2019). The fact that companies make admissions indicates the seriousness with which the industry takes the Code.

The percentage of cases ruled in breach in 2020 at 66% (84/127) was a decrease compared to 2019 at 76% (96/126). If this is looked at on the basis of individual matters, the percentages are different with 33% (249/736) in 2020 compared with 45% (271/597) in 2019.

Director's Introduction – continued

Panel

The Panel continues to have a good record, with 96% of its rulings (707/736) being accepted by the parties or upheld on appeal compared with 98% in both 2019 (587/597) and 2018 (680/694).

The time taken to complete cases at Panel level decreased slightly to 27.7 weeks in 2020 (from 28.9 weeks in 2019). 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 complaints and their complexity impacted on the time to deal with them.

Appeals

There was a significant increase in the number of matters appealed in 2020 (78) compared with 2019 (40). Of the matters appealed in 2020, 29 (3.9%) were successfully appealed and 49 (6.7%) unsuccessfully compared with 2019, where 10 (1.7%) were successfully appealed and 20 (5%) unsuccessfully appealed. The proportion of the Code of Practice Panel rulings appealed in 2020 was 10.6% (78/736) compared with 6.7% (40/597) in 2019.

The proportion of the Panel's rulings successfully appealed in 2020 was 3.9% (29/736) more than in 2019 which was 1.6% (10/597).

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 39.4 weeks in 2020 compared with 52.26 weeks in 2019. It is reassuring to see a decrease in the time taken to consider cases however this is still higher than previously. Some of the increase over the last few years 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 30 in the number of cases ruled in breach of Clause 2 in 2020 compared with 25 in 2019 and 13 in 2018. 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 2 companies to undergo audits in relation to complaints received in 2020 but did not report any companies to the ABPI Board in relation to a complaint received in 2020. The PMCPA carried out 2 audits and 2 reaudits in 2020.

The average time taken to complete consideration of a case overall was 29.5 weeks in 2020 compared with 32.61 weeks in 2019.

During 2020, the PMCPA was involved in the preparation of an updated Code. This involved reviewing the Code in the light of changes to various other codes, in particular the EFPIA Code. The proposed ABPI Code was reordered to reflect the EFPIA Code and to group various topics in sections. A public consultation was carried out in 2020 and the PMCPA was heavily engaged in assessing and responding the comments received.

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 and had to adapt to working from home as a result of the pandemic.

I would like to thank the outgoing Chair, Mr William Harbage QC for his contribution to the Appeal Board, the PMCPA and more broadly the industry. He did not hesitate to champion the independence of the PMCPA and complaints system taking steps to ensure that the PMCPA operates without fear or favour to meet the expectations the public have that the pharmaceutical industry operates to the highest standards in its responsibilities to ensure the appropriate use of medicines and support the provision of high quality patient care. Mr Harbage finishes 15 years as Chair in 2020 we would like to wish him every success in the future.

Heather Simmonds
Director, PMCPA

Chairman's comments

The end of December 2020 brought to a close 15 years as Chairman of the Appeal Board. I arrived as someone who knew something of regulatory law and proceedings but nothing about the pharmaceutical industry. I left as someone full of admiration and respect for the industry as a whole and the people in it. The industry is served by people who are predominantly well intentioned, who understand the potential benefits to patients and put patients first.

As with all professions and industries, there have been lapses of judgment - one or two of them spectacular. Regulation is not there always to say 'No' to the industry; it is there to provide a clear framework which enables individual companies to go about their business with confidence in an ethical and fair manner. It is one of the necessary checks and balances in place to protect the interests of both patients and health care professionals and also, on occasion, to save the industry from itself.

The pharmaceutical industry is fortunate to maintain the privilege of self-regulation (as opposed to government imposed regulation). It should guard that privilege jealously. It has been fortunate to have had a very strong and committed team of individuals at the PMCPA for many years, ably led by the Director, Heather Simmonds. I pay tribute to her and all her staff all and thank them for all their hard work and dedication over my time in office. Their dedication has made my job as Chairman very much easier.

I must also pay tribute to all members of the Appeal Board over the last 15 years, both industry members and independent members. The former provide real insight into how the industry works 'on the ground'; the latter bring their various experiences and skill sets to the Appeal Board and give it huge credibility to the outside world. I have always been struck by the amount of time and care given by all members to the cases that arise. All have contributed hugely to regulation of the industry. It has been an absolute pleasure to have worked with so many good people.

Thank you all.

William Harbage QC

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 77 times in 2020, compared with 63 times in 2019. The number of cases considered in 2020 (127) was similar to 2019 (126). 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. 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 Whittle
is one of the Managers at the PMCPA. 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 and was on maternity leave in 2020.

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

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 12 times in 2020, and 10 times in 2019. It considered appeals in 20 cases in 2020 (20 cases in 2019), and 78 matters in 2020 (40 matters in 2019).

Membership and attendance during 2020

Chairman

- Mr William Harbage QC

Independent Members

- Mrs Natasha Duke
  (Nurse Prescriber) (12/12)
- Dr Howard Freeman MBE
  (General Practitioner) (11/12)
- Mr Christopher Goard
  (Representing patients' interests) (10/10)
- Mrs Gillian Hawken
  (Lay member) (9/12)
- Dr Anne Hawkridge
  (General Practitioner) (9/12)
- Dr John Watkins
  (Hospital Consultant) (8/12)
- Mr Andrew White
  (from an independent body that provides information on medicines) (9/12)

Industry Members

- Dr Fenton Catterall
  (Compliance Officer, Shire Pharmaceuticals Limited, UK, Ireland, Nordics and Baltics) (8/8)
- Mr Toby Cousens
  (Commercial Strategy Director, Internal Medicines, Pfizer UK) from June 2020 (6/7)
- Dr Karen Mullen
  (Vice President, Country Medical Director, UK and Ireland, GlaxoSmithKline UK Limited) (6/12)
- Dr Mark Moodley
  (Medical Director, Sanofi Genzyme UK and Ireland) from June 2020 (5/7)
- Dr Rhiannon Rowsell
  (Retired, previously Promotional Affairs and Medical Excellence Director, AstraZeneca) (6/7)
- Dr Mark Toms
  (Chief Scientific Officer UK, Novartis Pharmaceuticals UK Limited (5/9)

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 2020, the following were each co-opted for at least one meeting (some members of the Appeal Board whose terms completed in 2020 were coopted and then reappointed to the Appeal Board):

- Dr Fenton Catterall
  Head of Ethics and Compliance, Global Product & Launch Strategy (GPLS), Shire (Shire is now part of Takeda).
- Professor Steve Chapman
  Independent body involved in providing information on medicines
- Dr Mark Moodley
  Medical Director, Sanofi Genzyme UK and Ireland
- Mr Christopher Goard
  Representing patients' interests
- Mr David Hope
  Head of UK & ROI, Alliance Pharmaceutical Limited, Alliance Pharmaceutical Limited
- Dr Jasmin Hussein
  Franchise Head Immunology - Dermatology and Respiratory, Sanofi, UK & Ireland
- Ms Nazmin Pirmohamed
  Director, Compliance Officer for UK Ireland and Canada, Biogen Idec Ltd
- Dr Rhiannon Rowsell
  Retired industry member
- Mr Stuart Rose
  Managing Director, Merz Pharma UK Ltd
- Mr John Russell
  VP Commercial, OUS, Immunocore Limited
- Dr Mark Toms
  Chief Scientific Officer UK, Novartis Pharmaceuticals UK 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 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:
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

	2020	2019	2018
Complaints received	**148**	132	87
Not within the scope of the Code	**5**	6	-
Company declined to accept the PMCPA's jurisdiction Before proceedings commenced	**9**	11	6
Not proceeded (no prima facie case)	**6**		
Already covered by previous case	**1**		
Complaints withdrawn	**4**	3	6
Inter-company dialogue successful			-
No inter-company dialogue	**2**		
Complaints considered	**121**	112	75
Cases arising from these complaints	**127**	126	120
Individual matters considered	**736**	597	694
Allegations withdrawn before complaint		-	-

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 2020, five led to two cases and one led to four cases.

Of the complaints received in 2019, six led to two cases and one led to ten cases of which two cases did not proceed as the companies concerned declined to accept the PMCPA's jurisdiction before proceedings commenced.

Outcomes of cases considered	2020	2019	2018
Cases where a breach found	**84**	96	60
Cases where no breach found	**43**	30	60
Number of matters in these cases:	**736**	597	694
• in breach	**249**	271	196
• no breach	**487**	326	498
Cases where the Code of Practice Panel required suspension of materials	**0**	0	0
Corrective statements required	**0**	0	1
Public reprimands	**3**	6[1]	7[2]
Audits	**2**	5[4]	4[3]
Breaches of undertaking ruled	**3**	6	0
Breaches of Clause 2 ruled	**30**	25	13
Reports to the Code of Practice Appeal Board	**2**	3	3
Reports to the ABPI Board	**0**	0	0

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

	2020	2019	2018
Health Professionals			
General Practitioners	1	1	-
Hospital Doctors	-	2	5
Other Doctors	-	1	-
Pharmacists	1	5	6
Nurses	-	1	1
Clinical Commissioning Group	-	1	1
Other health professionals	11	4	3
	13	**15**	**16**
Pharmaceutical companies			
ABPI members	2	4	5
Non-members	3	9	4
	5	**13**	**9**
PMCPA Director			
Alleged breach of undertaking	-	-	-
Arising from voluntary admissions	10	11	7
Arising from media criticism	-	1	-
Arising from published information	-	1	1
	10	**13**	**8**
Others			
Members of the public	15	9	6
Anonymous	90[3]	62[1]	36[2]
Employees/ex-employees	9	11	7
Anonymous employees	2	5	3
Anonymous ex-employees	1	3	-
Pharmaceutical physician	2	-	1
Consultant to company	-	1	1
Organisation	1		
	120	**91**	**54**
Total	**148**	**132**	**87**

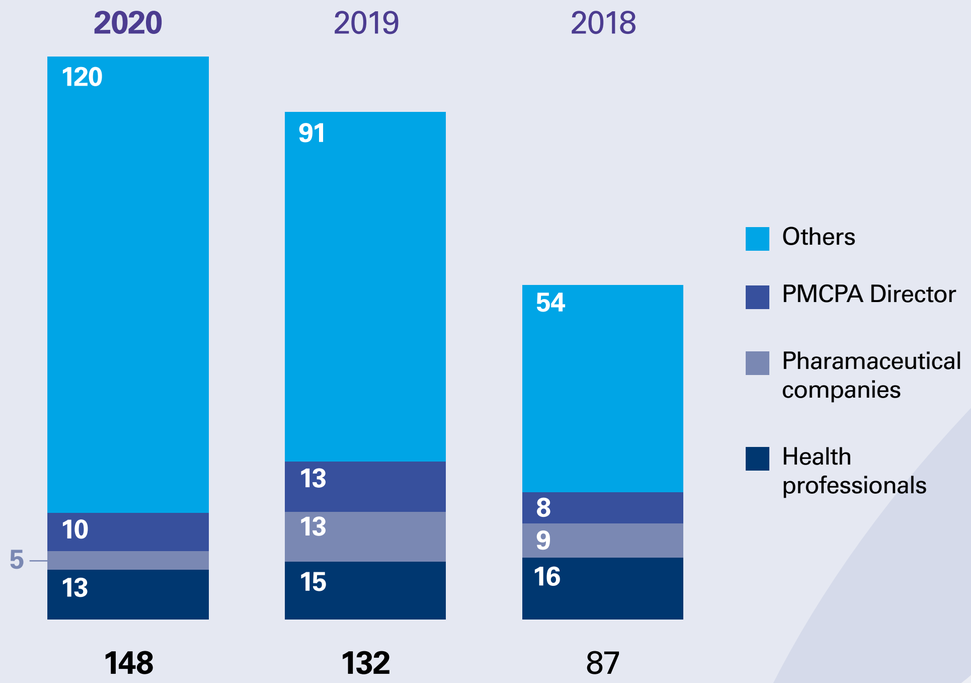
1 Fifty-one were from anonymous health professionals
2 Thirty were from anonymous health professionals
3 Fifty-nine were from anonymous health professionals

Appeals to the Code of Practice Appeal Board

	2020	2019	2018
Total number of matters ruled upon by the Code of Practice Panel	**736**	**597**	**694**
Rulings accepted by the parties	658	557	651
Rulings successfully appealed	29	10	14
Rulings unsuccessfully appealed	49	30	29
Number of cases appealed	20	20	18
Sources of appeals			
Cases appealed by complainants	8	12	2
Cases appealed by respondents	12	8	16
	20	**20**	**18**
Appeals by complainants			
Successful	0	2	-
Partly successful	2	1	-
Unsuccessful	6	9	2
	8	**12**	**2**
Appeals by respondents			
Successful	7	1	10
Partly successful	3	1	1
Unsuccessful	2	6	5
	12	**8**	**16**
Rulings appealed by complainants			
Successful	7	5	-
Unsuccessful	26	11	3
	33	**16**	**3**
Rulings appealed by respondents			
Successful	22	5	14
Unsuccessful	23	19	26
	45	**24**	**40**

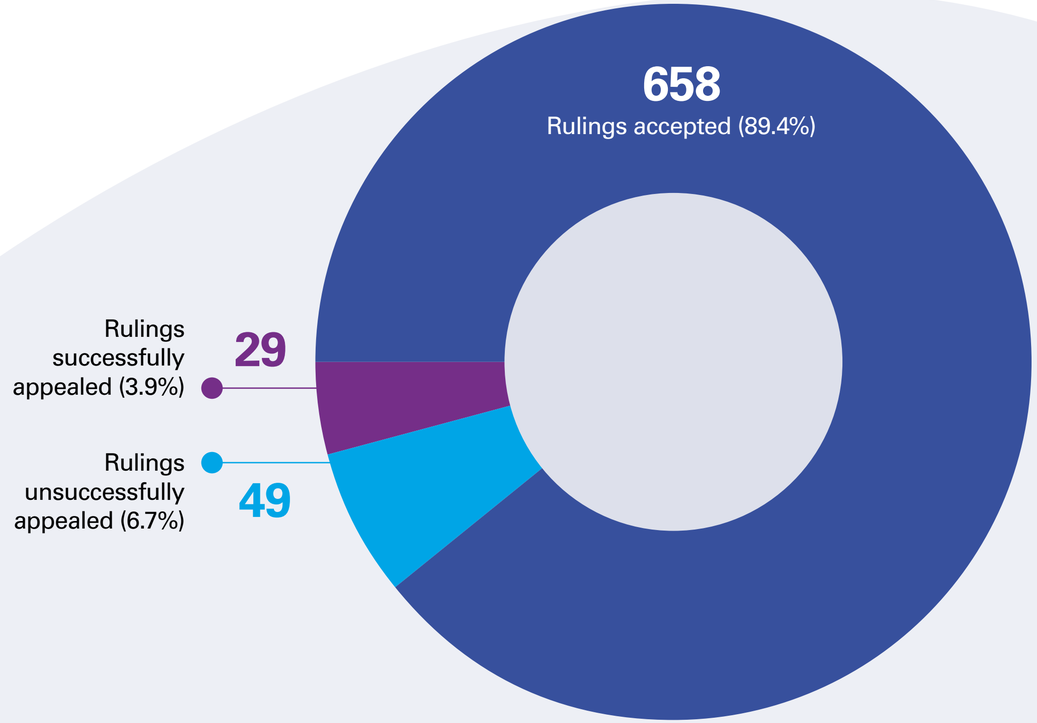
Complaints received 2020

Complaints nominally made by the Director can result from media criticism of pharmaceutical company activities covered by the Code. They can also arise as the 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 2020, the Code of Practice Panel made 736 rulings. Of these 658 (89.4%) were accepted by the complainants and respondents. A further 49 (6.7%) were unsuccessfully appealed at the Appeal Board and the remaining 29 (3.9%) were successfully appealed.



Average time taken to complete cases

(in weeks)

	2020	2019	2018
Cases settled at Code of Practice Panel level	**27.7**	28.9	24.2
Cases which were the subject of appeal	**39.4**	52.26	38.8
All cases	**29.5**	32.61	26.4

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 2020 no advertisements were taken up as potentially being in breach of the Code.

Companies ruled in breach of the Code

(complaints received in 2020)

Accord*
A.Menarini
Amgen
Allergan*
Alexion Pharma
Alimera
AstraZeneca*
Britannia*
Bristol-Myers Squibb
Boehringer Ingelheim*
Camurus*
Consilient*
Daiichi-Sankyo*
Ferring Pharmaceuticals
Gedeon Richter
GlaxoSmithKline*
Glenmark
Ipsen
IQ Pharma
Janssen*
Jazz Pharmaceuticals
Leo Pharma*
Merck Sharp & Dohme
Napp
Novartis*
Norgine*
Novo Nordisk*
Pharmasure*
Pfizer*
Rayner*
Reckitt Benckiser
Roche
Sanofi*
Sintetica Limited*
Sandoz
Shionogi Europe*
SOBI*
Stiefel
Strides Pharma*
Takeda
Teva
Vifor Pharma*
ViiV Healthcare

*in breach of Clause 2

Accounts 2020

The PMCPA is required to be self-financing. In 2020 there was a surplus of £56,155 (minus £11,471 tax). The PMCPA cumulative reserves on 31 December 2020 were £589,629 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). Sixty per cent of the levy due was called up in 2020. 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 2020 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 2020 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.

	2020	2019	2018
	£	£	£
Levy	**472,933**	821,401	392,383
Administration charges	**967,000**	560,000	452,500
Seminars and meetings	**-15,023**	100,104	193,416
Company Audits	**100,000**	100,000	120,000
Contributions to advertising costs	**120,500**	24,000	48,000
	1,645,410	1,605,504	1,206,300
Expenditure	**1,589,255**	1,453,120	1,328,659

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

* includes reimbursed costs

PMCPA | Prescription Medicines Code of Practice Authority

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