PMCPA Annual Report

2022 & 2023

PMCPA

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PMCPA

The PMCPA is the self-regulatory body for the pharmaceutical industry in the UK. By embedding high ethical standards and holding companies accountable for compliance, we provide confidence to patients and the public who rely on medicines and vaccines.

We do this by

Engaging and empowering companies by providing training and guidance on the ABPI Code of Practice

Ensuring high standards are upheld through a timely, robust, independent and transparent complaints system

Using the benefit of self-regulation to ensure the Code and guidance react to changes in the environment and reflect latest industry practices.

Introduction

Alex Fell

Director of the PMCPA & a member of the Panel

Director's introduction

This report provides detailed analysis of all complaints received in the calendar year 2022. It also reports on the financials and activities of the PMCPA in 2022 and 2023.

The PMCPA is taking a new approach to the annual reporting cycle to improve timeliness and regularity of reporting. Rather than waiting until all cases received in a calendar year have been completed before publishing the annual report, in future, the PMCPA will publish a report in the first quarter of each year. The report will cover the cases received in the previous calendar year and a summary of the PMCPA's activities and financial performance. For the purposes of comparability with prior years, the PMCPA will continue to analyse the outcomes of cases based on the cases received during a calendar year. This will be included in the next annual report published following the completion of all cases received in a particular year.

It is both a privilege and a responsibility to take on the leadership of the PMCPA. Successful self-regulation of the pharmaceutical industry in the UK depends on many factors, including the confidence of the public, the support of statutory regulators and an understanding that self-regulation is a privilege which must continually evolve to remain fit for purpose.

While transitioning into the role in 2022, I appreciated the support and advice from all the PMCPA team, as well as from the outgoing Director, Heather Simmonds, and Deputy Director, Etta Logan, both of whom fundamentally shaped self-regulation in the UK.

The PMCPA is now going through a significant organisational transformation to respond to the increased volume of complaints over the last seven years and the resultant increased case processing times, as well as adapting to a change in leadership and the departure of some experienced team members.

While I recognise the importance of dealing with complaints quickly, the issues raised are often highly complex and it is critical that the high quality of casework is preserved. The Code of Practice Panel has a public duty to ensure that each case is considered carefully and with due diligence and rigour. Each allegation must be considered appropriately, and most complaints include multiple allegations.

Delivering the changes needed to meet the evolving demands of industry regulation will take time but we are committed to doing so to create a sustainable organisation that is fit for the future.

The following measures are among those being taken immediately to increase the volume of complaints the PMCPA can process while additional measures are implemented.

Prioritisation: Cases that may have an impact on patient safety are prioritised above other cases that present a lower risk such as where a company in their response has accepted a breach of the Code and changed their practices, or those cases relating to administrative breaches.

Funding: An increase in administrative charges and the annual levy paid by ABPI members was agreed at the Annual General Meeting of the ABPI in December 2023, with the new charges effective from 1 January 2024. This first increase since 2014 will help the PMCPA invest to deliver on our priorities.

Process improvement: The PMCPA started a process improvement programme to enhance efficiency of the complaints procedure. This included implementing simplified case report summaries, reducing the volume of correspondence in cases and selecting a new case management system.

Resourcing: The PMCPA started to invest in additional headcount (both permanent and experienced contractors) in 2023, before the increased funding became available. This was funded using part of the operating surplus built up in prior years. Due to the specialist nature of the work at the PMCPA, the team is being increased in a phased way so that new Panel members can receive the training and support needed to be effective.

Changes to the complaints procedure: Proposals for a new abridged complaints procedure were included as part of a broader public consultation on the ABPI Code and PMCPA Constitution and Procedure which launched in December 2023, with the updated Code expected to be published in 2024.

A strength of the UK self-regulatory system is that complaints are accepted from all sources and acted upon in a fair and robust manner. With the increased volume of complaints, particularly since 2020, the PMCPA needs additional ways of processing them. The proposed abridged complaints procedure will allow the PMCPA the flexibility to continue to assess more serious complaints in full and with the full range of potential sanctions available but to deal with less serious cases in a proportionate and resource-efficient manner.

"The PMCPA is now going through a significant organisational transformation to respond to the increased volume of complaints..."

Commentary on complaints received in 2022

The following comments relate to cases received in 2022, the majority of which were assessed in 2023. This data is directly comparable with the 2021 annual report.

Rulings

The Panel continues to have a good record, with 97% (561/577) of its rulings for complaints received in 2022 being accepted by the parties or upheld on appeals, compared with 98% of its rulings (892/910) in 2021 and 96% in 2020 (707/736).

At least one breach of the Code was found in 74% (79/107) of the 2022 cases, compared to 69% (82/119) of 2021 cases and 66% (84/127)

of 2020 cases. There were 17 cases ruled in breach of Clause 2, which is a sign of particular censure / seriousness, compared to 30 in 2021 and 23 in 2020.

When analysing case outcomes, we consider the number of matters and the number of rulings. Each separate allegation that the Panel must consider is typically referred to as a matter and this may include multiple rulings on different clauses of the Code. Each clause appealed is ruled upon separately by the Appeal Board.

For the cases received in 2022, we also saw an increase in the proportion of individual matters found in breach of the Code. This was 41% (235/577) in 2022, compared to 31% (278/910) in 2021 and 34% (249/736) in 2020.

Case completion time

The time taken to complete cases at Panel level increased to 51 weeks, on average, for cases received in 2022 compared to 38 weeks in 2021. This is predominantly a consequence of the continued high volumes of complaints received and the significant resource consumed by conducting nine company audits in 2022. In several cases, additional information was required before the Panel could make a ruling. The Panel is extremely conscious of the need to deal with cases as quickly and efficiently as possible.

The average time taken to complete the consideration of a case which was the subject of appeal rose to 62 weeks for cases received in 2022 compared with 43 weeks in 2021. Some of the increase is due to the increased volume of cases for the PMCPA to consider and that for some of the cases there were unavoidable delays in arranging appeal hearings. There were significant delays in completing one of the nine cases appealed, while issues around confidentiality and enclosures could be settled between the parties. This particular case comprised 18 of the 45 rulings for cases received in 2022. A further case was deferred due to addressing conflicts of interest and the need for the Appeal Board to be quorate. An appeal is only deferred with the agreement of the Chair.

Appeals

There were fewer rulings appealed in the cases received in 2022 (45 rulings) than those from 2021 (66 rulings) and 2020 (78 rulings). This represented a similar proportion of the total rulings compared to 2021 cases: 7.8% (45/577) for 2022 cases compared to 7.3% (66/910) for 2021 cases.

Of the 577 rulings in the cases received in 2022, 2.8% (16) were successfully appealed and 5.0% (29) were unsuccessfully appealed.

It is always, and will remain, the case that the Appeal Board operates entirely independently of the PMCPA and has no hesitation in overturning the Panel's rulings where appropriate.

Audits

The PMCPA conducted nine company audits in 2022. Eight of these were re-audits requested by the Appeal Board. There was one company audit requested by the ABPI Board. In 2023, the PMCPA conducted three company audits, two of these were re-audits requested by the Appeal Board and one company re-audit was requested by the ABPI Board.

The Appeal Board may require an audit of the company's procedures in relation to the Code to be carried out by the PMCPA and, following that audit, decide whether to impose additional requirements on the company concerned to improve its procedures in relation to the Code. Audits form a critical part of self-regulation in the UK and are an effective method of supporting a company to bring its compliance programme to the expected standard.

In 2022, the ABPI Board requested an audit of a company's procedures in relation to the Code to assist in deciding whether to suspend or expel an ABPI Member company. The ABPI Board requested an audit in 2023 to assess progress to improve compliance for a company suspended from membership.

Kate Brunner KC

Chair of the Appeal Board

Chair's introduction

The work of the Appeal Board is crucial to the effectiveness and integrity of this regulatory system. The vast majority of cases are resolved at Panel level, but any complainant or respondent can appeal to the Appeal Board if they are dissatisfied with the Panel's findings.

The proportion of cases appealed to the Appeal Board has remained relatively consistent in recent years at around 7–10% of total cases. In 2022 there were nine cases appealed to the Appeal Board, although that low number belies the complexity of the work. Within those nine cases there were 45 separate rulings. Each of those rulings required separate consideration by the Appeal Board, and it was not unusual for the Appeal Board to overturn an appeal on some rulings but not others within the same case. About a third of rulings which were appealed were overturned by the Appeal Board. Those figures chime with my impression from leading the Appeal Board and working closely with PMCPA: this is a regulatory system which is working well and is respected by participants, with most rulings accepted by parties at the Panel stage. For those who do not accept findings, there is open access to a fully independent appeal route that operates at arm's length from the rest of the PMCPA.

Hearing appeals

I chair the Appeal Board as a legally qualified independent member. Members of the Appeal Board include doctors, pharmacists, a representative of patients' interests, and pharmaceutical company senior executives. The different backgrounds and expertise of Appeal Board members is a significant strength of the Appeal Board. Decisions are informed by medical and clinical expertise so that the Appeal Board understands when risks to patient safety are created. Decisions are informed by the patient perspective so that the Appeal Board bears in mind how patients may interpret material. Decisions are informed by the industry perspective so that the Appeal Board understands how compliance systems operate. All of these viewpoints and more feed into rounded decisions on the wide range of topics which reach the Appeal Board.

Some members of the Appeal Board reached the end of their terms in 2022 and 2023. We welcomed many new members to the Appeal Board who bring fresh views to our meetings. I thank them all for their contributions and insights.

Amongst all this change, the central tenets of the Appeal Board have remained stable: it is an independent body which is committed to fair and robust decision making. At each Appeal Board meeting there is careful analysis of the Code and its application to the particular facts of the cases in front of us, and there is often rigorous discussion and debate.

One aspect of procedural fairness is full participation of complainants and respondents, and the Appeal Board is keen to ensure that all parties can take part in proceedings. Where necessary, the Appeal Board adjusts its procedures to support complainants with particular needs. Complainants are not required to participate in Appeal Board proceedings but I encourage them to do so: we are often assisted by hearing directly from individuals about their complaints.

"...this is a regulatory system which is working well and is respected by participants, with most rulings accepted by parties at the Panel stage."

Other work

The Appeal Board has functions beyond hearing appeals. At each meeting, the Appeal Board reviews all cases completed at Panel level and considers whether further sanctions are appropriate. Where the Appeal Board requires a company to be audited, the Appeal Board reviews the audit report conducted by the PMCPA along with the company's response to it and determines what further steps should be taken.

As well as dealing with individual cases, the Appeal Board has a supervisory role in relation to the operation of the complaints procedure. The Appeal Board was acutely aware of the increasing length of time which it took to conclude cases in 2022. At each Appeal Board meeting we review the numbers of cases going through the system and receive updates on measures which PMCPA is taking to reduce delay. It is plain that the PMCPA team has been working extremely hard to seek to reduce the backlog of cases waiting to be considered by the Panel.

Under Alex Fell's leadership, various measures have been put in place to seek to reduce the time taken complete. The approach of PMCPA in 2022 and 2023 to modernise the organisation, improve resourcing and structure, and streamline processes is welcomed and supported by the Appeal Board. It is recognised that it will take some time to see the effects of those significant changes.

Looking forward

I am grateful to the ABPI Presidents in 2022 and 2023 and all members of the PMCPA for their unwavering commitment to preserve the independence of the Appeal Board. Independence does not, of course, mean an absence of communication, and the strong working relationships between me as Chair, the President of the ABPI and the Director of the PMCPA strengthen this regulatory system. It is a system that I have a great respect for, and which I expect to go from strength to strength in the years ahead.

The complaints procedure

PMCPA

Case preparation

- Upon receipt of a complaint, the case preparation manager is responsible for processing the matter and determines whether the case should go before the Panel.
- The case preparation manager for a particular case does not sit on the Panel for the consideration of that case.

Panel stage

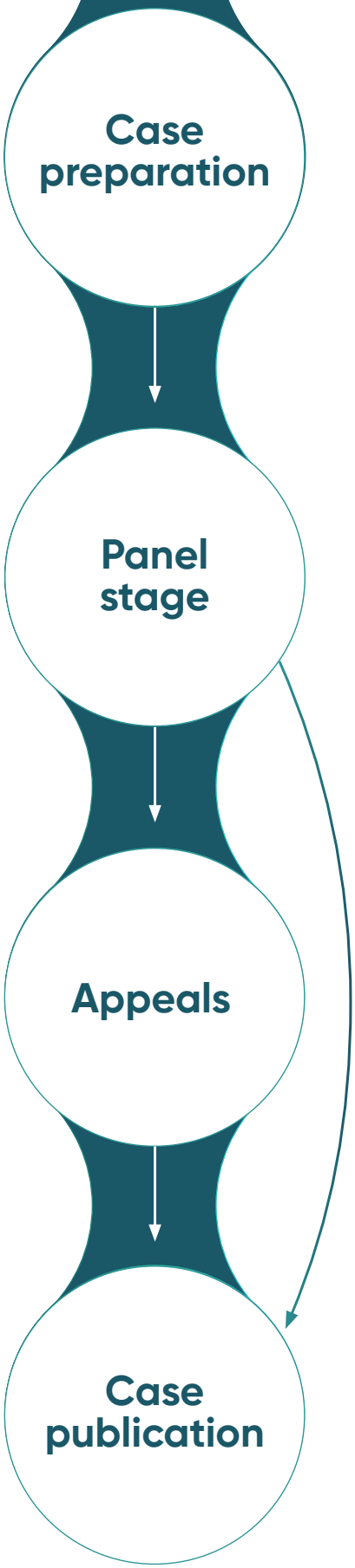
- Complaints are considered by the Code of Practice Panel which is made up of at least two members.
- Complaints considered by the Code of Practice Panel are judged on the evidence provided by both parties

Appeals

- The complainant may appeal the Panel's rulings of no breach of the Code.
- The respondent company may appeal the Panel's breach rulings.
- In these cases, the matter is referred to the Code of Practice Appeal Board.

Case publication

- For the purpose of considering whether any additional sanctions may be appropriate, the Appeal Board receives reports on all cases considered by the Panel.
- The PMCPA publishes reports of all completed cases on its website.



Complaints

Complaints can be submitted to the PMCPA:

- using the web form on the PMCPA website at www.pmcpa.org.uk
- by email to complaints@pmcpa.org.uk
- by phone (020 7747 8880)
- by writing to The Director, PMCPA, 2nd Floor Goldings House, Hay's Galleria, 2 Hay's Lane, London SE1 2HB.

Complaints taken up in the Director's name can result from media criticism of pharmaceutical company activities, scrutiny of advertisements, and from alleged breaches of undertaking.

Undertakings and assurances

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.

Sanctions

Additional sanctions that can be imposed by the Appeal Board include:

- an audit by the PMCPA of a company's procedures in relation to the Code.
- 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
- a report to the ABPI Board, who 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.

When companies are ruled in breach of Clause 2 of the Code, the PMCPA advertises brief details of the case in the medical, pharmaceutical and nursing press. The companies at issue are required to contribute to the cost of such advertising.

The PMCPA team
Panel members

Alex Fell
Director

Alex joined the PMCPA in June 2022. He has held ethics and compliance leadership roles in the UK, USA, and Singapore for a large global pharmaceutical company as well as an international ethics and compliance leadership role in a small biotechnology company. Alex started in the pharmaceutical industry in a global internal audit role with a specific focus on Code compliance.

Natalie Whittle
Acting Deputy Director

Natalie joined the PMCPA in September 2018. She has been a member of the Code of Practice Panel for several years. She previously worked in the pharmaceutical industry in Medical Compliance and Medical Information roles at UK and regional level. She has a degree in Medicine.

Keval Dabba
Associate Director

Keval joined the PMCPA in June 2021. He is a registered pharmacist in the UK and has worked in community pharmacy, the NHS and the pharmaceutical industry. His last role at a pharmaceutical company involved leading the compliance and medical function.

Maleeha Sultan

Manager

Maleeha joined the PMCPA in August 2022. She is a UK-registered pharmacist and has worked in the NHS, community pharmacy and the pharmaceutical industry. Her previous roles included medical affairs, advertising and promotion and medical governance. Her last role involved the management of promotional review services and implementation of the Northern Ireland protocol.

Helen Darracott

Manager

Helen joined the PMCPA in February 2023. She is a Fellow of the Royal Pharmaceutical Society, with degrees in pharmacy and law. She has worked in regulatory, policy, legal, compliance and ethics roles for health professional regulatory bodies, industry representative organisations and pharmaceutical companies.

Emily Boys

Manager

Emily joined the PMCPA in November 2023. She was previously head of project delivery at an independent medical publisher, working in partnership with pharmaceutical companies to deliver a range of projects. She has a broad range of experience in science/data communication and a PhD in Genetics/Plant Pathology.

Co-opted Code of Practice Panel members

Anne Erwin

Anne has extensive compliance experience and started working with the PMCPA in 2014 as a Panel member covering a 12 month maternity leave. Over the past ten years Anne has worked closely with the PMCPA on multiple projects, including the re-writing of the 2021 ABPI Code.

Etta Logan

Having spent 25 years supporting and providing legal advice to the PMCPA, Etta left her role in 2022 and now works as a consultant to the PMCPA in addition to holding senior positions outside the pharmaceutical industry.

The PMCPA
Back office team

Peter Clift
Operations and Governance Manager

Peter joined the PMCPA in May 2002. He was previously a biomedical scientist and has a master's degree in biology and postgraduate legal qualifications.

Peter is responsible for the administration of the Code of Practice Appeal Board, the PMCPA's data privacy programme and for the development of the PMCPA website and digital communications.

Nora Alexander
PA to the Director

Nora joined the PMCPA in 2007 having previously worked for the NHS. Her role primarily involves supporting with the intake of complaints along with supporting the Panel with sending out outcome letters.

Lisa Matthews
Senior Case Coordinator

Lisa joined the PMCPA in 1999. Her responsibilities include performing a key role in the intake and assessment of complaints, along with supporting the Panel with sending out outcome letters. Lisa also supports key department projects.

The PMCPA
Leavers and new starters

Name and position	Date joined - left
2022	
Alex Fell – Director, PMCPA	June 2022 - Present
Maleeha Sultan – Manager, PMCPA	August 2022 - Present
Etta Logan – Deputy Director, PMCPA	September 1997 - November 2022
Heather Simmonds – Director, PMCPA	1989 - December 2022
2023	
Ciara O'Brien – Manager (Contractor), PMCPA	February 2023 - May 2023
Helen Darracott – Manager, PMCPA	February 2023 - Present
Rachael Orme-Smith – Deputy Director, PMCPA	February 2023 - December 2023
Emily Boys – Manager, PMCPA	November 2023 - Present
Tannyth Cox – Deputy Director, PMCPA	June 2013 - December 2023

The Code of Practice Appeal Board

Role

A complainant whose complaint has been rejected or respondent company ruled to be in breach of the Code may appeal the Panel's ruling to the Code of Practice Appeal Board.

In addition to its role in relation to appeals, the Appeal Board receives reports on all cases considered by the Panel and has a supervisory role in relation to the operation of the complaints procedure.

Composition

The Appeal Board comprises an independent legally qualified Chair, up to eight other independent members, and up to eight senior executives from pharmaceutical companies.

For the consideration of any case, independent members must be in the majority.

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). The medical, pharmacist and nurse prescriber members are appointed in consultation with their respective professional bodies. Independent members are paid, but industry members are not.

Meetings

The Appeal Board met 11 times in 2022 and seven times in 2023.

Membership and Attendance

Chair	2022	2023
Ms Kate Brunner KC	✓	✓

Independent Members	2022	2023
Dr Richard Bortey - General Practitioner		✓
Dr Judith Dawson - General Practitioner		✓
Dr Natasha Duke – Nurse Prescriber*	✓	
Dr Howard Freeman MBE – General Practitioner*	✓	
Mr Christopher Goard – Representing Patients' Interests*	✓	✓
Mrs Gillian Hawken – Lay Member	✓	
Dr Anne Hawkridge - General Practitioner	✓	
Dr Dominic Heaney - Hospital Consultant		✓
Miss Amina Hossain – Lay Member	✓	✓
Ms Aleksandra Houghton – From an independent body that provides information on medicines		✓
Ms Anna Pracz - Pharmacist	✓	✓
Professor Reecha Sofat - Registered Medical Practitioner		✓
Dr John Watkins - Hospital Consultant*	✓	✓
Mr Andrew White – From an independent body that provides information on medicines	✓	

* Also co-opted in one of the years

Industry Members	2022	2023
Dr Hubert Bland - Executive Medical Director UK&I, Bristol-Myers Squibb Pharmaceuticals*		✓
Dr Fenton Catterall – Head of Ethics and Compliance, Global Product & Launch Strategy (GPLS) at Shire, now part of Takeda*	✓	
Mr Toby Cousens - Hospital Business Unit Country Lead, Pfizer UK	✓	✓
Dr Marc Moodley - Medical Director, Sanofi Genzyme UK and Ireland	✓	✓
Dr Karen Mullen – Vice President, Country Medical Director UK and Ireland, GSK*	✓	
Dr R Rowsell – Retired	✓	✓
Dr Mark Toms – Global Head, Evidence Excellence, Novartis Pharmaceuticals Global Medical Affairs	✓	✓

* Also co-opted in one of the years

Co-opted members

The Chair can co-opt members for meetings of the Appeal Board to enable a quorum to be achieved. For Appeal Boards held in 2022 or 2023, the following were each co-opted for at least one meeting (some members of the Appeal Board whose terms completed in a prior year were co-opted and then reappointed to the Appeal Board):

Co-opted Members	2022	2023
Dr Hubert Bland - Executive Medical Director UK&I, Bristol-Myers Squibb Pharmaceuticals	✓	
Dr Frances Hall - Country Senior Medical Director UK&IE, Jazz Pharmaceuticals	✓	✓
Mr Alex Potlog - Legal Director, UK & Ireland, AbbVie	✓	✓
Mr Andrew White – From an independent body that provides information on medicines		✓

Our data

2020 - 2023

by the PMCPA

PMCPA

Complaints received by the PMCPA

The table below shows complaints that have been received by the PMCPA from 2020 - 2023. Whilst there has been a rise in the number of complaints received in 2023, the amount that have not proceeded has remained in line with that of 2022. The total number of cases considered in 2023 cannot be provided at this time as not all cases received have been considered at the point of this reports publication.

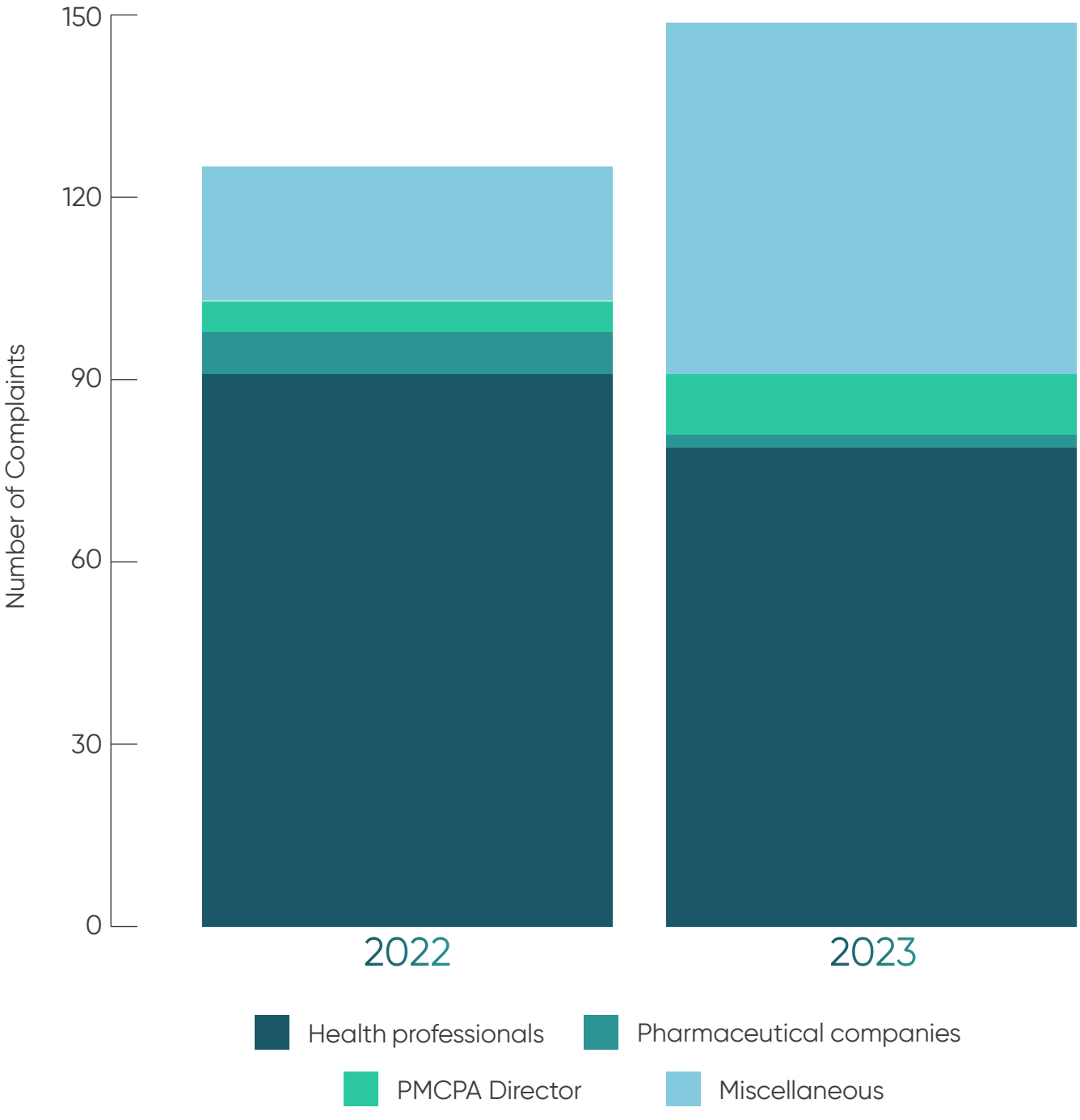
	Year complaint received			
Complaints received by the PMCPA	**2020**	**2021**	**2022**	**2023**
Complaints received	148	143	125	149
Not proceeded [1]	25	25	18	18
Cases considered [2] (as at 31st December [3])	127	119	107	

[1] Includes complaints that are not within the scope of the Code; complaints where the company was not a member of the ABPI and declined to accept the PMCPA's jurisdiction; withdrawn complaints; and no prima facie cases.

[2] Some complaints give rise to more than one case as they involve more than one company.

[3] Not all cases received in 2023 have been considered.

Sources of complaints received



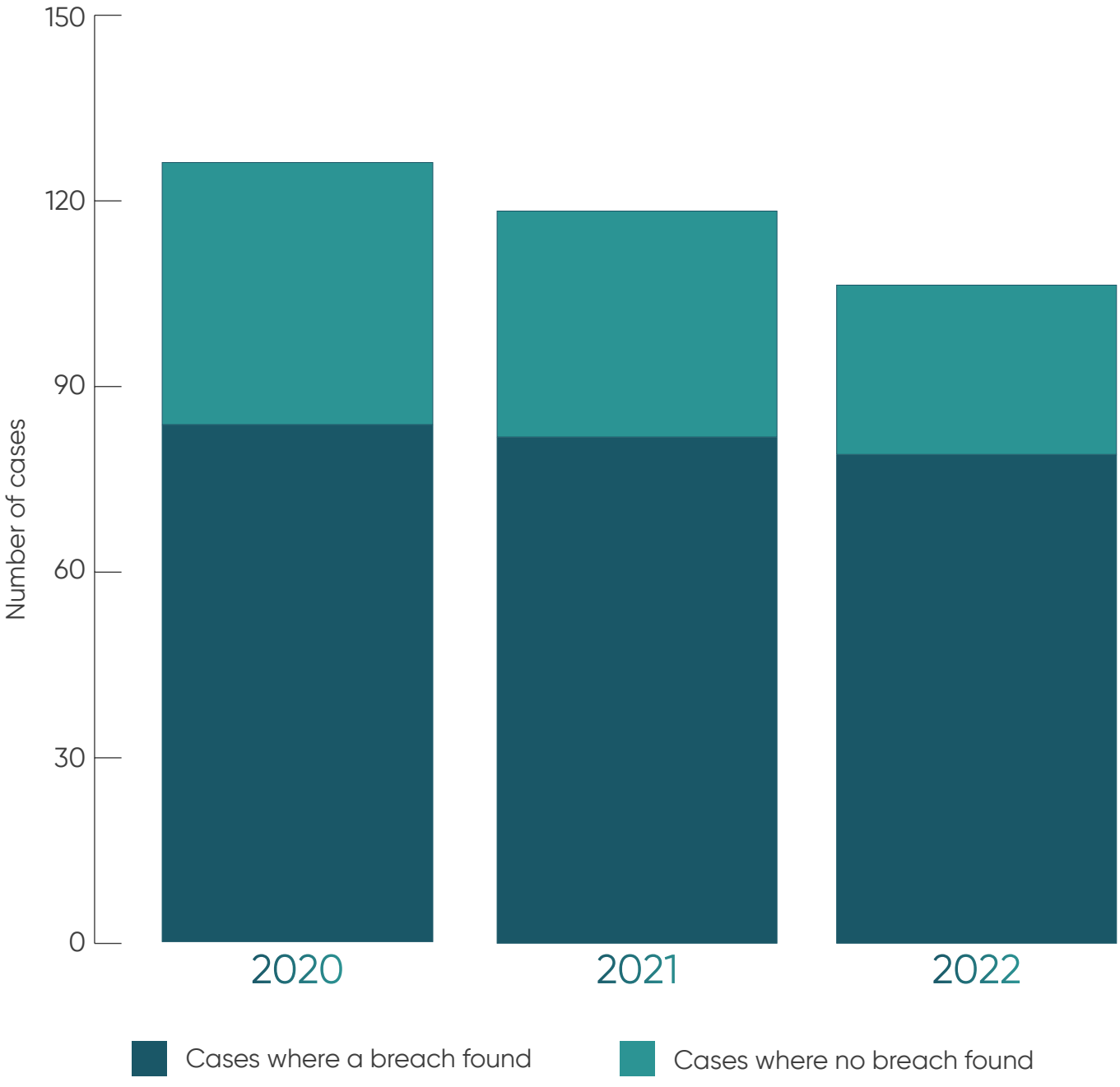
For 2022 and 2023, the PMCPA has updated its categorisation of complainants to improve transparency. Classification is based on how complainants define themselves.

	Year complaint received	
Sources of complaints received	**2022**	**2023**
Health professionals [1]	91	79
Non-verified	84	72
Verified	7	7
Pharmaceutical companies	7	2
ABPI members	5	1
Non-members	2	1
PMCPA Director	5	10
Arising from media criticism	0	1
Arising from voluntary admissions	5	9
Miscellaneous	22	58
Employees/ex-employees	7	27
Members of the public	8	20
Other [2]	1	2
Unknown/not specified	6	9

[1] Verified health professionals are those who the PMCPA was able to confirm to be a health professional (e.g. NHS email address). Non-verified health professionals are those who described themselves as a health professional but the PMCPA was unable to confirm this.

[2] Agency employee; unspecified pharmaceutical company employee; "allied staff"

Outcomes of cases considered



The table below shows the outcomes of each complaint from 2020 through to 2022.

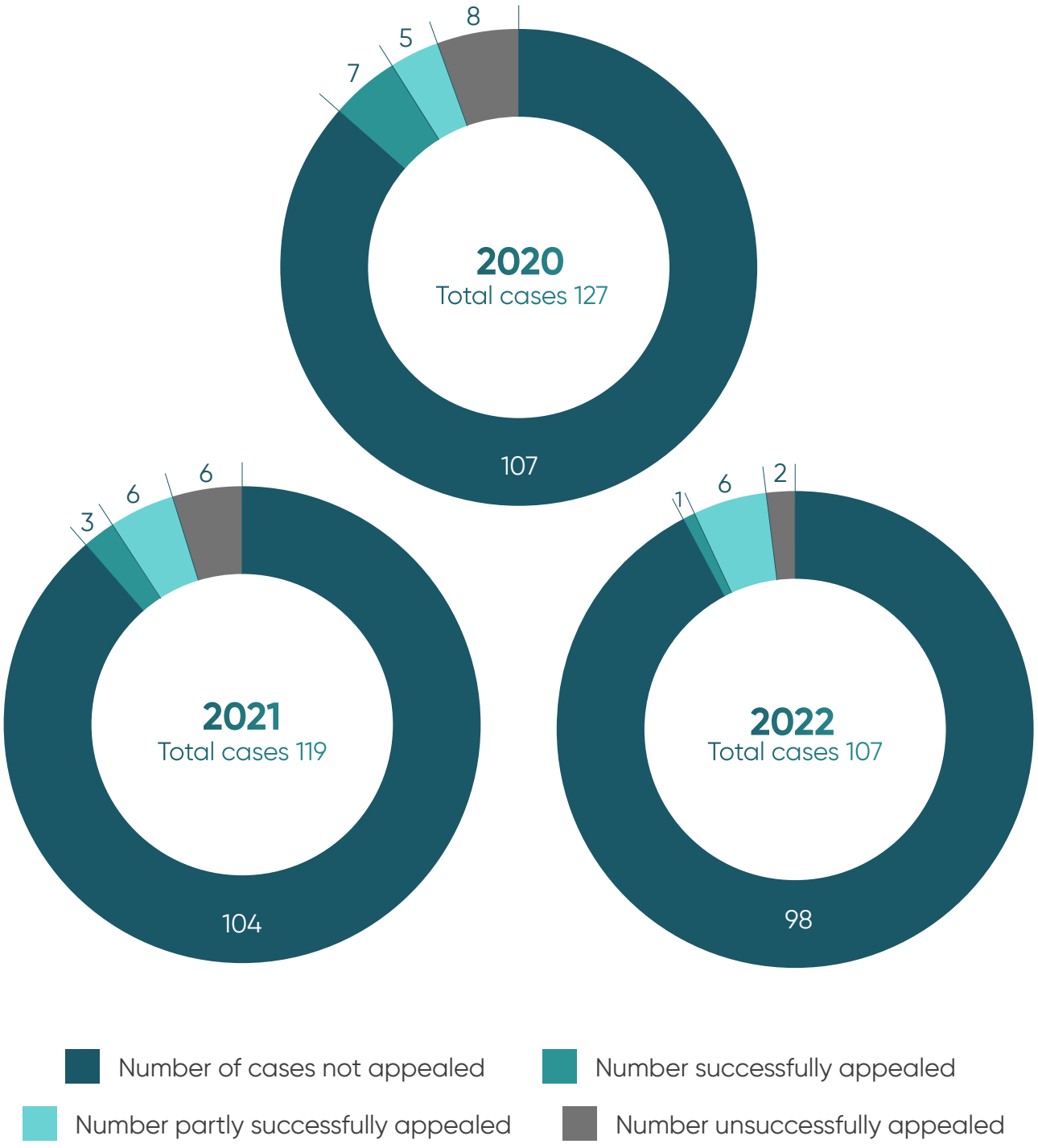
	Year complaint received		
Outcomes of cases received	**2020**	**2021**	**2022**
Number of cases	127	119	107
Cases where a breach found	84	82	79
Cases where no breach found	43	37	28 [1]
Outcomes	736	910	577
Matters where a breach found	249	278	235
Matters where no breach found	487	632	342
Breaches of undertaking ruled	3	6	1
Breaches of Clause 2 ruled	30	23	17
Additional sanctions	7	4	0
Reports from Panel to the Appeal Board	2	1	-
Suspension of materials required	-	-	-
Corrective statements required	-	-	-
Public reprimands	3	1	-
Audits	2	1	-
Reports from Appeal Board to the ABPI Board	-	1	-

[1] Including one no breach case ruled outside the scope of the Code

The data shown in the table below gives an indication of the average time required, in weeks, to complete a case in 2020 through to 2022.

	Year complaint received		
Average number of weeks taken to complete cases	**2020**	**2021**	**2022**
Cases settled at Panel level	27.7	37.7	51.7
Cases that were the subject of appeal	39.4	43.3	67.4
All cases	29.5	38.4	53.0

Appeals to the Code of Practice Appeal Board



The data below shows the number of appeals made by complainants and respondents in 2020, 2021 and 2022. Both the number of appeals received and the number of cases appealed successfully has decreased year on year.

	Year complaint received		
Appeals on cases	**2020**	**2021**	**2022**
Number of cases	127	119	107
Number of cases appealed	20 (16%)	15 (13%)	9 (8%)
Cases appealed by complainants	8	4	3
Successful	0	0	0
Partly successful	2	0	2
Unsuccessful	6	4	1
Cases appealed by respondents	12	11	6
Successful	7	3	1
Partly successful	3	6	4
Unsuccessful	2	2	1

	Year complaint received		
Appeals on matters ruled upon	**2020**	**2021**	**2022**
Number of matters ruled upon by the Panel	736	910	577
Number of rulings appealed	78	66	45
Number of rulings appealed successfully	29	20	16
Rulings appealed by complainants	33	22	26
Successful	7	0	5
Unsuccessful	26	22	21
Rulings appealed by respondents	45	44	19
Successful	22	20	11
Unsuccessful	23	24	8

Companies ruled in breach of the Code

Complaints received in 2022	
AbbVie*	Galapagos
Accord	Gilead
Aimmune	GSK
Allergan	Janssen
Amgen	Leo
Astellas	Merck Sharp & Dohme
AstraZeneca*	Novartis*
Bayer	Novo Nordisk*
BMS	Pacira BioSciences
Boehringer Ingelheim	Pfizer
Britannia	Proveca
Chiesi	Roche*
Croma Pharma*	Sandoz
CSL Vifor	Small Pharma
Daiichi Sankyo*	Sobi
Dr Falk	Strides Pharma
Eli Lilly	Teva*
Ethypharm	Tillotts
Ferring	UCB

* in breach of Clause 2

Other activity

2022 - 2023

PMCPA

Introduction

2022 was a transitional year for the PMCPA as Heather Simmonds retired after working with the PMCPA for 30 years since its inception in 1993 and as the Director for 25 years. The new Director worked closely with Heather to ensure a smooth transition.

The following represents some of the main activities conducted by the PMCPA in 2022 and 2023 other than operating the complaints procedure which is described above.

Social media guidance

In January 2023, the PMCPA published social media guidance in response to increasing activity in this area.

This guidance was developed by the PMCPA following a project involving various stakeholders including the MHRA, the ABPI and pharmaceutical company representatives, which identified the areas where pharmaceutical companies required further guidance. The guidance built on the extensive work the PMCPA had already done on this topic and outlines the PMCPA's views based on case precedent. It also reflects the relevant UK legal requirements as well as the codes of practice and guidance and advice from the European Federation of Pharmaceutical Industries and Associations (EFPIA), the International Federation of Pharmaceutical Manufacturers & Associations (IFPMA), and the MHRA.

Updates to the 2021 ABPI Code

During 2023, the ABPI and PMCPA initiated a public consultation on proposals to update the 2021 ABPI Code. The changes proposed to the ABPI Code include the modernisation of certain clauses and strengthening Code requirements in other areas. There were also proposed changes to the Constitution and Procedure, including an abridged complaints procedure. The updated Code is expected to be implemented in 2024.

ABPI/PMCPA governance review of self-regulation

During 2022, the ABPI and PMCPA commissioned an independent review of self-regulation of the pharmaceutical industry. The purpose of this work was to review and identify any opportunities to improve the existing system of self-regulation covered by the ABPI Code and administered by the PMCPA. The outcomes of this work were included in the proposed revisions to the PMCPA Constitution and Procedure that were published as part of a public consultation in December 2023.

Audits

The PMCPA conducted nine company audits in 2022 and three in 2023.. Audits form a critical part of self-regulation in the UK and are an effective method of supporting a company to bring their compliance programme to the expected standard.

PMCPA audits focus on company culture, the compliance framework (using the Guidelines on Company Procedures in relation to the Code of Practice) and adherence to the ABPI Code.

Good practices and common issues identified during the audits conducted in 2022 were shared externally in 2023 to help pharmaceutical companies strengthen their compliance programmes.

Code queries

The PMCPA continues to answer queries to assist companies in the interpretation of the Code. In 2022 and 2023 (combined), the PMCPA answered over 375 queries. Queries are analysed to identify trends which might lead to FAQs or guidance documents.

Contactable complainants

During 2023, the PMCPA enhanced the visibility of privacy policies and communicated the benefits of complainants being contactable, even if they remain anonymous.

Complainants who are not contactable by the PMCPA are unable to participate fully in the complaints procedure. For example, they cannot be informed about the Panel's determination and so cannot appeal rulings of no breach of the Code, and they cannot be provided with case reports prior to publication for their review.

In 2023, 100/149 (67%) of complaints were from contactable complainants. This metric will continue to be tracked to measure progress over time.

Case management

During 2023, a new case management system was selected with the objective of improving efficiency and reporting on cases and outcomes. The system will be implemented in the first half of 2024.

Accounts

2022 - 2023

PMCPA

Accounts overview 2022 - 2023

The PMCPA is required to be self-financing. In 2022, there was a deficit of £39,472 and in 2023, a deficit of £408,833. The PMCPA cumulative reserves on 31 December 2023 were £375,436.

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 annual levy in 2022 and 2023 ranged from £4,000 to £32,000, depending on the size of the company.

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. One hundred per cent of the levy due was called up in 2022 and 2023.

In December 2023, it was agreed at the Annual General Meeting of the ABPI that from 1 January 2024 the levy would increase by 50% from £4,000 per vote to £6,000 with the largest companies paying an annual levy of up to £48,000.

Administrative charges

Administrative charges are payable by companies (both members and non-members of the ABPI) in relation to breaches of the Code Companies that are not members of the ABPI do not pay the levy, so the administrative charges for them are consequently higher.

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. No charges whatsoever are payable by complainants from outside the industry. When calculating the number of administrative charges for cases, the number of matters is used to calculate the charge. Each case may comprise multiple matters, and each matter may consist of more than one clause breached.

The charge per matter in 2022 and 2023 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 2022 and 2023 was £12,000 for member companies and £13,000 for non-member companies.

In December 2023, it was agreed at the Annual General Meeting of the ABPI that from 1 January 2024 the administrative charges would increase to £5,000 for member companies and £6,000 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 would increase to £13,000 for member companies and £14,000 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).

Financial performance

In 2023, a deficit was expected as the PMCPA started to invest in additional resources to work on complaints. Despite an increase in the number of complaints assessed in 2023 compared to 2022, the administrative income was lower. This was mainly due to a smaller number of unsuccessful appeals, which attract the higher administrative charges. In 2023, compared to the administrative charges for accepted rulings at Panel level, an additional income of £38,000 was generated due to unsuccessful respondent company appeals. This compares to income from unsuccessful appeals of £255,000 in 2022 (equal to 29% of total 2022 administrative charges income).

Account details 2023

	2021	2022	2023
Income			
Levy	£799,083	£854,000	£839,000
Administration charges	£933,250	£831,000	£874,000
Seminars and meetings	£3,083	£11,235	£3,000
Company audits	£120,000	£160,000	£60,000
Contributions to advertising costs	£95,500	£56,000	£68,000
Total income	**£1,950,916**	**£1,912,235**	**£1,844,000**
Expenditure	**£1,656,837**	**£1,951,707**	**£2,252,833**
Annual surplus/deficit*	**£294,079**	**- £39,472**	**- £408,833**

* After tax and expenditure

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

PMCPA