

## PMCPA strategy

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 prescribed medicines, including vaccines.

### We do this by

- Engaging and empowering companies by providing training and guidance on the ABPI Code of Practice for the Pharmaceutical Industry
- Ensuring high standards are upheld through a timely, robust, independent and transparent complaints system
- Using the benefit of self-regulation to ensure the ABPI Code and guidance react to changes in the environment and reflect latest industry practices

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## Chief Executive's introduction

**Alex Fell** 

Chief Executive



This report covers the PMCPA's activity and financial performance in the calendar year 2024 and includes analysis of all complaints received in 2023.

#### 2024 priorities:

The priorities for 2024 were the operation of the complaints procedure, including implementing measures to address the backlog of complaints, and the publication of the 2024 ABPI Code of Practice for the Pharmaceutical Industry.

With the launch of the 2024 ABPI Code in October 2024, the PMCPA implemented the first significant change to the PMCPA Constitution and Procedure and how self-regulation is delivered in the UK in many years. This included the addition of an overriding objective and an abridged complaints procedure which allow the PMCPA to, among other things, deal with each case in ways that are proportionate to the importance of the case and the complexity of the issues.

While the work on the new ABPI Code and some staff vacancies in Q1 and Q2 impacted on the number of case rulings published, Q3 and Q4 saw the number of rulings almost double as the impact of recruitment and process improvements started to be felt. I hope to see this increased momentum continue into 2025 as we continue to reduce the backlog of complaints.

Self-regulation remains a privilege and must continue to evolve to ensure that it regulates the pharmaceutical industry effectively.

"...Q3 and Q4 saw the number of rulings published almost double as the impact of recruitment and process improvements started to be felt....."

#### Complaints received in 2024:

This annual report provides greater transparency than in previous years on the full number of complaints received.

The PMCPA received 264 complaints in 2024.

#### Of these:

- 46% were referred to the Code of Practice Panel for adjudication
- 10% were not proceeded after receiving the pharmaceutical company's response
- 18% were not proceeded upon initial review
- 26% did not relate to a pharmaceutical company.

In 2024, 55 complaints were received from non-contactable complainants.

- Only 23 (42%) of the 55 complaints from non-contactable complainants were referred to the Code of Practice Panel for adjudication. The PMCPA strongly encourages complainants to be contactable to the PMCPA so that they can participate fully in the complaints procedure.
- Of the 148 complaints that were sent to a pharmaceutical company for response, 109 (74%) were from a contactable complainant. This is an increase on 2023, when the comparable reported figure was 100 (67%) of 149.

#### Cases ruled upon in 2024:

The majority of the 104 rulings issued in 2024 were for complaints received in 2023. The outcomes of these complaints are summarised in this report.

The outcomes of these cases remained broadly consistent with previous years, with approximately two-thirds of complaints ruled upon resulting in at least one breach ruling. The Panel continues to have a good record, with 97% of rulings either accepted by the parties or upheld on appeal.

#### New case management system:

The PMCPA implemented a new case management system in 2024 with all cases from 1 January 2023 onwards entered into the system. The new system allows for improved tracking of individual cases, case assignments and allocations. As more data is captured, it will enable improved reporting on trends. Introducing the new system means a change to the format of case numbers - with all complaints received being tracked through the system.

"97% of the Panel's rulings were either accepted by the parties or upheld on appeal."



## Chair of the Appeal Board's comments

#### **Kate Brunner KC**



#### Introduction:

This year has brought about much change at the PMCPA, but the central principles of this regulatory system remain the same, with a determinedly independent, thorough and fair approach at the heart of everything that the PMCPA and the Appeal Board do. I am proud of the work of the Appeal Board which has an important role in maintaining public confidence in this system.

#### Appeals:

My role as Chair includes guiding the Appeal Board in its deliberations to ensure that the Constitution and Procedure and ABPI Code are followed, and ensuring that proceedings are fair for all participants. The Board's membership is set out in our Constitution and Procedure. and Board members include senior clinicians, a GP, pharmacists, a representative of patients' interests, and pharmaceutical company senior executives. The Board is a collection of independent individuals who do not hesitate to challenge and debate, but who also listen with care to each other's views.

Some members of the Appeal Board reached the end of their terms in 2024, and they are thanked for their valuable contributions to our meetings over many years. We welcomed new members to the Appeal Board who have brought their unique perspectives to our meetings. My thanks to all of our Board members – both full time and co-opted - who work so hard to maintain the quality of our decisions.

"The Appeal Board is a collection of independent individuals who do not hesitate to challenge and debate, but who also listen with care to each other's views."

My thanks as well to the individuals and companies which have appeared in front of the Appeal Board this year. I recognise that it may be a daunting, and emotionally charged, process but the Appeal Board has been greatly assisted by the clear and courteous manner in which parties have presented their cases.

#### **Evolution of procedures:**

The Appeal Board also has a supervisory role and has been supporting the PMCPA's drive to modernise and streamline procedures.



We welcome the amendments to the Constitution and Procedure. One of the most significant changes is the introduction of an 'overriding objective', which is to deal with cases fairly and justly while protecting patient safety. This expressly requires the PMCPA and the Appeal Board to: (i) handle cases in a manner proportionate to the importance of the case and complexity of the issues; (ii) avoid "unnecessary formality" and adopt procedural flexibility where appropriate; (iii) ensure that parties fully participate in the proceedings; and (iv) avoid delays. An overriding objective is a tool used in many regulatory systems, and I am confident that it will be a useful framework for making procedural and discretionary decisions. It is important to note that the overriding objective does not just bind the PMCPA and the Appeal Board: under the Constitution and Procedure, all parties involved must assist in furthering the overriding objective, and I am sure that companies and individuals will bear these principles in mind when engaging with our system.

The need to avoid delay is particularly important when the PMCPA is addressing an accumulation of complaints built up over many years. I have been impressed by the dedication and hard work of the PMCPA team, and I am confident that the tide has been turned and case waiting time will decrease. The overriding objective and other procedural changes will assist the PMCPA and the Appeal Board to focus on faster resolution of cases where patient safety may be compromised.

"We welcome the amendments to the Constitution and Procedure. One of the most significant changes is the introduction of an 'overriding objective', which is to deal with cases fairly and justly while protecting patient safety."



# 2024 activity



# ABPI Code of Practice for the Pharmaceutical Industry 2024



### The updated ABPI Code of Practice came into effect on 1 October 2024.

In 2024, we were pleased to launch a new edition of the ABPI Code, containing changes which help to modernise and strengthen the Code. This was the culmination of 18 months of collaboration, involving numerous organisations and individuals.

#### Consultation on the changes:

Proposals to update the 2021 ABPI Code were developed by the PMCPA in collaboration with multiple stakeholders, including the MHRA, ABPI and member companies.

- A public consultation on proposals was undertaken for a 12-week period between December 2023 and February 2024.
- More than 3000 comments from over 100 individuals and organisations were received – including from pharmaceutical companies, healthcare professionals, patient organisations and patients.

The extensive engagement from a variety of stakeholders during the consultation process was welcomed and illustrated great interest and investment in the Code from different sectors.

#### Key changes made:

Given the volume and complexity of the comments received, the PMCPA, in agreement with the ABPI Board, decided to take a phased approach to updating the Code. The priorities for the 2024 update were Clause 12 and the PMCPA Constitution and Procedure.

Major updates were made to Clause 12, including the introduction of QR codes to access prescribing information on certain promotional materials. The rationale was to provide an option whereby scanning a QR code would always directly access the up-to-date version of the prescribing information.

Other changes to the 2024 ABPI Code included making gateway links from Disclosure UK to patient organisation and member of the public disclosure information on the pharmaceutical company's website a mandatory requirement, and mandating a written agreement when a company provides support to an individual health professional or other relevant decision maker to attend an event/meeting.



#### Launch of the 2024 ABPI Code:

The launch of the 2024 ABPI Code was supported by:

- resources on the PMCPA's website, including a summary of the changes made, Q&As, and downloadable slides outlining the key changes
- the launch of a new e-learning platform with three short webinars and a new e-learning module
- two 'Code in a Day' training events in London
- presentations at several external events.

The PMCPA received positive feedback from stakeholders on the 2024 ABPI Code update and the training resources that it made available.

#### **Next steps:**

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Feedback received in relation to social media. medical education and package deals will be looked at and addressed within quidance documents, Q&As or by a future Code update. The proposed changes to Clause 8 that were consulted upon but not progressed in the 2024 Code will be looked at in future years, following a broader review of certification and the role of the signatory.

"I would like to personally thank all those who engaged in the working groups and consultation process. I am also extremely grateful for the input from the MHRA and the unwavering support and commitment of the PMCPA team."

#### **Natalie Whittle**

Director -**Code Development** 



## **PMCPA** Constitution and Procedure

The updated PMCPA Constitution and Procedure came into effect on 1 October 2024.

The Constitution and Procedure defines how the self-regulation system operates and is administered by the PMCPA.

The updates included a new abridged procedure for complaints that meet certain criteria.

The abridged complaints procedure was introduced to allow the PMCPA the flexibility to continue to assess more serious complaints in full but deal with less serious complaints in a proportionate and resource-efficient manner.

The case preparation manager may determine that the abridged complaints procedure will be followed where:

- the allegations fall within the approved list for use of the abridged procedure, and
- it appears that the central facts will not be disputed, and
- it is likely, in the case preparation manager's view, that there has been a breach of the Code.

For a complaint to be handled through the abridged complaints procedure, the respondent company must:

- accept the breach(es) of the ABPI Code, and
- provide a written undertaking that the activity or use of the material in question and any similar material (if not already discontinued or no longer in use) will cease forthwith and that all possible steps will be taken to avoid a similar breach of the Code in the future, and
- confirm that, as a result of its investigation, it has not identified a systemic compliance issue in relation to the matter(s) alleged.

If the case does not satisfy these requirements, it will follow the full complaints procedure.

There is no right of appeal by either the complainant or the respondent company under the abridged procedure:

- the respondent company has accepted the breach(es) of the Code
- there are no 'no breach' rulings for the complainant to appeal.

New text was added to strengthen the operational independence of the PMCPA in line with the regulatory principle of transparency and the public law principles of procedural fairness and lack of bias.

The updates included the addition of an overriding objective:

"The overriding objective of the PMCPA Constitution and Procedure is to ensure that cases are dealt with fairly and justly while protecting patient safety. When making procedural and discretionary decisions, members of the Authority, the Appeal Board and any independent referee must act in a way they consider most likely to further the overriding objective.

All parties, including the complainant and respondent, must take all reasonable steps to assist the PMCPA and the Appeal Board to further the overriding objective."

The updated ABPI Code of Practice and PMCPA Constitution and Procedure will help ensure that the model of self-regulation in the UK remains robust. It will allow the PMCPA to handle all complaints in a proportionate manner and ultimately within a shorter timeframe.



## Other activity

The key priorities in 2024 were the operation of the complaints procedure and completion of cases, and the development of the new ABPI Code and PMCPA Constitution and Procedure. The following represents some of the other main activities that took place in 2024.

#### Operation of the complaints procedure

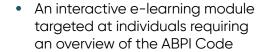
- Rulings issued for 104 cases
- 124 decisions to refer a case to the Panel
- 75 decisions to not proceed a case
- 1 audit of a pharmaceutical company

#### Launch of the 2024 **ABPI** Code



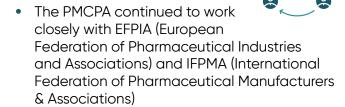
- Explanatory documentation to accompany the new ABPI Code
- Updates made to all associated Q&As and guidance documents
- New training and FAQs published
- Updated disclosure templates

#### Launch of the new PMCPA learning portal



• Three on-demand webinars explaining the changes in the 2024 ABPI Code

#### Collaboration with international bodies



- Alex Fell is Co-Chair of the EFPIA Code Committee
- Natalie Whittle is a member of the IFPMA Code Complaint Adjudication Group

#### Resourcing and team development



- Increased the number of members of the Code of Practice Panel from 6 in January 2024 to 9 in January 2025
- Ensured a broad range of relevant expertise in the team, with a good mix of experience from the pharmaceutical industry, the legal and regulatory sectors, healthcare, and others

#### Provision of advice and quidance on the ABPI Code



- 180 queries on the ABPI Code answered
- New guidance and Q&As published on Clause 12. Clause 10.4 and the Windsor Framework

#### **Process improvement**



- Implementation of a new case management system to improve efficiency and reporting
- Simplification of the case summary section of the case report to speed up the process of producing the reports while providing a quick-to-read summary of the case

#### **Compliance-focused events**

- Patient organisation event held in collaboration with ABPI in May 2024 - a continued priority to enable compliant interactions
- Compliance Network meeting held June 2024

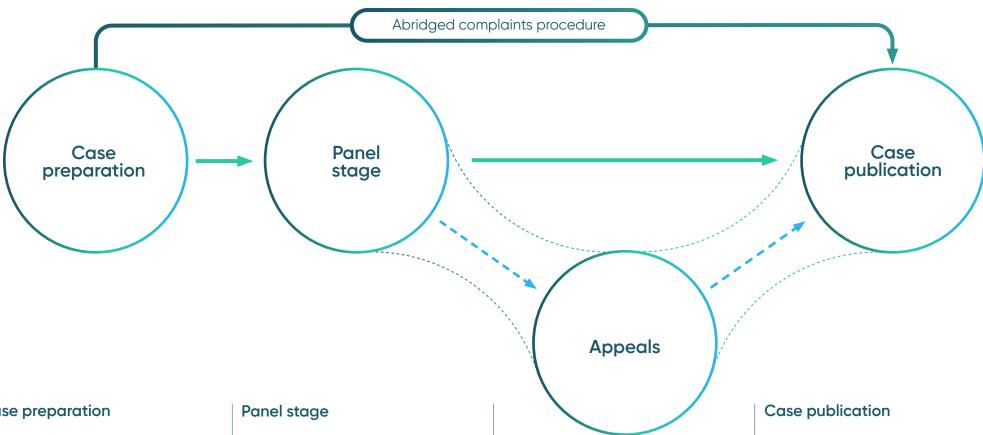
#### Relaunch of the 'Code in a Day' training events



- Two one-day in-person training seminars held in November 2024
- 153 attendees



# The complaints procedure



#### 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
- Complaints are considered by the Code of Practice Panel two members of the Panel form a quorum
- Complaints are judged on the evidence provided by both parties
- Rulings are made on the basis that a complainant has the burden of proving their complaint on the balance of probablities

#### **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
- As part of its supervisory role and for the purpose of considering whether any additional sanctions may be appropriate, the Appeal Board receives reports on all cases
- The PMCPA publishes reports of all completed cases on its website

For more detail about the complaints procedure, please see: www.pmcpa.org.uk/complaints-procedure



## The complaints procedure

#### **Complaints**

Complaints should be submitted to the PMCPA using the webform on the PMCPA website at pmcpa.org.uk/complaints-procedure/make-acomplaint/

When this is not possible, complaints can be submitted by email (complaints@pmcpa.org.uk), by phone (020 7747 8880) or in writing.

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

#### **Undertaking and assurance**

In each case where a breach of the Code is ruled, the company concerned must provide 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.

The company must also pay an administrative charge based on the number of matters ruled in breach of the Code.

#### **Breaches of Clause 2**

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.

#### Additional 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
- requiring the company to issue a corrective statement
- publication of a public reprimand
- other administrative steps, such as inviting a senior representative of the company to future meetings of the Appeal Board to report on progress, or requesting written confirmation that appropriate action has been taken
- reporting the company to the ABPI Board, who may suspend or expel the company from membership of the ABPI.

#### **Definitions:**

Case - Some complaints give rise to more than one case, as they may involve more than one company.

Matter - Each separate allegation that the Panel must consider is typically referred to as a matter. A matter may include multiple rulings.

Ruling - A 'ruling' refers to an individual ruling of a single clause of the ABPI Code.



## The PMCPA team

All members of the Code of Practice Panel can adjudicate on a case. Decisions are made by majority voting and two members of the Panel form a quorum.

More senior/experienced members of the team can also act as case preparation manager (CPM). The case preparation manager decides whether a case should proceed (through the full or abridged procedure) or not, and may identify the relevant clauses of the Code to be addressed in the company's response. The case preparation manager must not be a member of the Panel that subsequently considers that case.



**Alex Fell Chief Executive** 





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 Director - Code Development** 





Natalie's role of Director - Code Development is a newly created role, responsible for ensuring a fit-forpurpose ABPI Code now and into the future, supported by guidance. Natalie joined the PMCPA in September 2018 and is a highly experienced member of the Code of Practice Panel. She is also a member of the IFPMA Code Complaint Adjudication Group. She has a degree in Medicine and previously worked in the pharmaceutical industry in medical compliance and medical information roles at UK and European level.



**Owen Robinson** Director





Owen joined the PMCPA in September 2024. He is a solicitor with over 15 years post-qualification experience and is a healthcare, life sciences and public law specialist. He has worked in a range of senior roles at the heart of the UK Government, including the Cabinet Office and the Department of Health and Social Care. During his time in government, he operated for five years as a senior legal advisor to the MHRA and the NHS team. He left the government in February 2023 to join the global regulatory team at the law firm Hogan Lovells. He also sits as a part-time judge in the Employment Tribunals and in the Health, Education and Social Care Tribunals.



**Alicia White** Director





Alicia joined the PMCPA in October 2024. She qualified as a solicitor in 2012 and worked in private practice on behalf of a number of healthcare regulators before moving to the General Pharmaceutical Council (GPhC). For six years she held the role of Head of Professionals Regulation (Casework and Resolution) at the GPhC. During this time she grew and developed a large multidisciplinary team and had overall responsibility for progressing all fitness to practise investigations through to a final decision. In addition to the in-depth knowledge of the pharmacy sector, Alicia's recent experience includes leading on a number of improvement changes as part of a wider strategy to improve the timeliness of investigations while maintaining quality. This included the introduction of a fast track investigations process, resolving aged and complex cases, and streamlining processes.

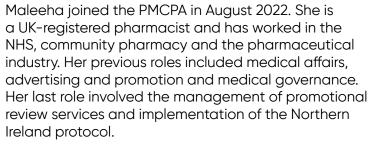




Maleeha Sultan **Senior Manager** 









**Helen Darracott** Senior 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.



**Holly Withers** Manager



Holly was appointed in 2024 and joined the PMCPA in January 2025. She has a degree in Biological Sciences (Neuroscience) and spent four years in a medical information consultancy firm before joining the pharmaceutical industry, where she worked in a number of medical affairs roles of increasing seniority. In her most recent role, she was a Senior Manager, Global Medical and Promotional Regulatory Affairs at a pharmaceutical company.



**Sharan Kaur** Manager



Sharan joined the PMCPA in August 2024. She is a Chartered Legal Executive and volunteers as a Magistrate for the East London Local Justice Area. Her previous experience includes roles such as Assessment Manager, Case Officer and Paralegal at the General Pharmaceutical Council. Prior to this, Sharan worked for Kingsley Napley solicitors and investigated Health and Care Professions Council cases on their behalf.







**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 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.



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**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.

#### Leavers and new starters during 2024

Name and position	Date
Reshma Thakkar Manager and member of the Panel	Joined July 2024 Left January 2025
Sharan Kaur Manager and member of the Panel	Joined August 2024
Owen Robinson Director and member of the Panel	Joined September 2024
Alicia White Director and member of the Panel	Joined October 2024
Keval Dabba Associate Director and member of the Panel	Joined June 2021 Left December 2024



## Co-optable members of the Code of Practice Panel in 2024

#### **Natalia Constantine**

Natalia was on the co-optable list from March 2024 to December 2024. Natalia is an independent regulatory and criminal barrister with a background in medical law and ethics.

#### **Charles Drinnan**

Charles is an independent regulatory, criminal and fraud barrister. Charles has experience in professional regulation within healthcare, medical law and ethics.

#### **Anne Erwin**

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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 updates to the ABPI Code.

#### **Etta Logan**

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

If necessary, the Chief Executive or a Director may co-opt an appropriate person to be a member of the Panel, from a list of persons approved for co-option. Co-optees must comply with the same conflicts of interest provisions as the other Panel members.

In 2024, the PMCPA explored a new cost-effective resourcing model with a Barristers Chamber to co-opt barristers with regulator experience to join the list of persons approved for co-option, with the primary goal of expediting the drafting of rulings. Natalia Constantine is no longer on the list for co-option to the Panel but is available to the PMCPA as an independent referee: Charles Drinnan remains on the co-optable list for 2025.



## The Code of Practice **Appeal Board**

#### Role

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 addition to its role in relation to appeals, the Appeal Board receives reports on all cases considered by the Panel and considers whether additional sanctions may be appropriate, and has a supervisory role in relation to the operation of the complaints procedure.

#### Meetings in 2024

The Appeal Board met nine times in 2024.

#### 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 members are appointed in consultation with their respective professional bodies. Independent members are paid, but industry members are not.

#### **Independent members**



















#### **Industry members**



















## Membership and Attendance

Chair	Role	
Ms Kate Brunner KC	Independent, legally qualified Chair	

Independent Members	Role	
Dr Richard Bortey	General Practitioner	
Dr Dominic Heaney	Hospital Consultant	
Ms Amina Hossain	Lay member	
Ms Aleksandra Houghton	Registered Pharmacist	
Ms Anna Pracz	Registered Pharmacist	
Professor Reecha Sofat	Registered Medical Practitioner	
Mr Bob Stevens	Representing the interests of patients	

Industry Members	Role
Dr Hubert Bland	VP & Country Medical Director, UK, GSK (previously Executive Medical Director UK&I, Bristol-Myers Squibb)
Dr Fenton Catterall	Head of Ethics & Compliance Commercial & Portfolio Strategy, Plasma Derived Therapies (PDT) BU, Takeda
Dr Frances Hall	Country Senior Medical Director UK&IE, Jazz Pharmaceuticals
Mr Alex Potlog	Senior Counsel, Global Legal Strategies & Policy, UK & Ireland, AbbVie Ltd
Dr Mark Toms (left the Appeal Board in 2024)	Vice President, Country Medical Director UK, Europe Medical Affairs, GSK

#### **Co-opted members**

The Chair can co-opt members for meetings of the Appeal Board to enable a quorum to be achieved. During 2024, 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	Role	Meetings
Dr Howard Freeman MBE	General Practitioner	2 meetings
Dr Christopher Goard	Representing the interests of patients	3 meetings
Dr Eddie Guzdar	Medical Director Oncology UK/Ireland and Medical Excellence Lead Northern Europe Hub, Eli Lilly and Company Limited	3 meetings
Dr Frances Hall	Country Senior Medical Director UK&IE, Jazz Pharmaceuticals	3 meetings as co-optee
Dr Marc Moodley	Oncology Medical Director, Daiichi Sankyo UK	4 meetings
Dr Edward Piper	Medical Director, AstraZeneca UK Limited	1 meeting
Mr Alex Potlog	Senior Counsel, Global Legal Strategies & Policy, UK & Ireland, AbbVie Ltd	3 meetings as co-optee



# Complaints received in 2024

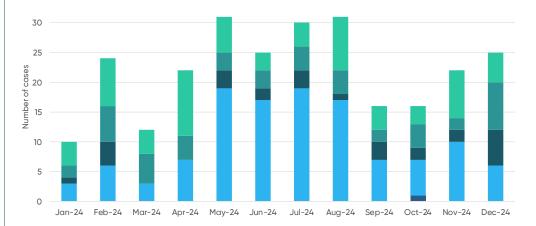
## Complaints received by the PMCPA

	Year complaint received		eceived
	2022	2023	2024
Cases referred to the Panel <sup>1</sup>	107	130	120
Cases completed under the abridged complaints procedure <sup>2</sup>	N/A	N/A	1
Not proceeded after receipt of company response <sup>3</sup>	18	14	27
	125	144	148
Not proceeded upon initial review <sup>4</sup> – pharmaceutical company	_	(5)	47
Not proceeded upon initial review <sup>4</sup> – not a pharmaceutical company	_	_	69
	-	-	116
TOTAL RECEIVED	-	-	264

- Some complaints give rise to more than one case because they involve more than one company.
- The abridged complaints procedure was brought in as part of the changes to the PMCPA's Constitution and Procedure with the publication of the 2024 ABPI Code of Practice in October 2024.
- When the respondent company's response is received, the case preparation manager must determine whether there is a prima facie case to answer under the Code. Other cases may not proceed at this point because the respondent company declines to accept the PMCPA's jurisdiction.
- In previous years, only a very small number of these complaints were captured in the annual report figures (e.g. the five in 2023).

#### Complaints received in 2024

- Not proceeded upon initial review no pharma company Not proceeded upon initial review - pharma company
- Not proceeded after company response
- Referred to the Panel
- Completed under the abridged complaints procedure



While the first quarter of 2024 saw relatively few complaints received, the numbers increased significantly from quarter two onwards and, in total, slightly more complaints were received in 2024 than in 2023.

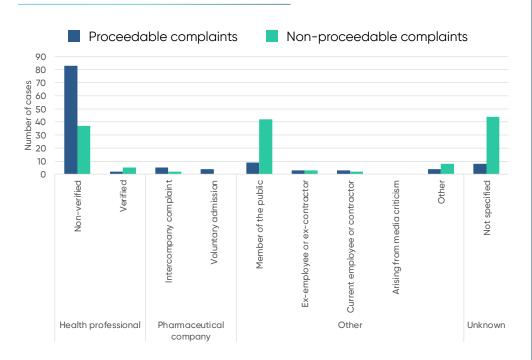
Fewer cases were referred to the Panel than in 2023, however, with more not proceeded after receipt of the response from the pharmaceutical company.

The implementation of a new case management system in 2024 allows full transparency and reporting of complaints received, including those that the case preparation manager decides will not proceed without inviting a response from a respondent company.

Complaints that do not proceed often relate to activities by clinics, pharmacies or influencers and are typically referred to the Advertising Standards Authority or the Medicines and Healthcare products Regulatory Agency. Others may be due to a lack of evidence that there may have been a breach of the Code, data privacy concerns, or concerns outside the scope of the ABPI Code.



## Sources of complaints received in 2024



Classification of complainants is based on how complainants define themselves.

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 did not confirm this.

"Other" complainants in 2024:

Proceedable – Academics; Campaign group; An industry (non-pharmaceutical company) employee complaining in personal capacity; An anonymous, non-contactable complainant who described themselves as a pharmaceutical company employee and declared no conflicts of interest

Non-proceedable – Medical writer; Patient organisation; First responder; MedComms agency employee; Consultant; Pharmaceutical company employee complaining in personal capacity

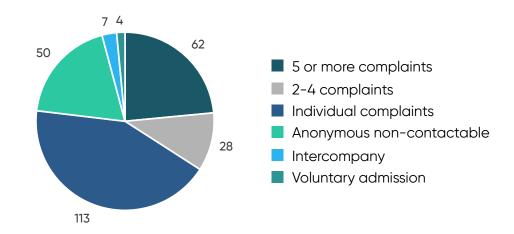
#### In 2024:

Seven people submitted five or more complaints each in 2024- a total of 62 complaints (23% of the total number of complaints received).

55 complaints had complainants who were non-contactable (21% of the total number of complaints received).

Of the 55 complaints with non-contactable complainants, 32 were not proceeded.

#### Cases received in 2024 - by category of complainant



Note: Five of the non-contactable complainants provided a name but no contact details. Some complainants were contactable at the case preparation stage but later became non-contactable - they are shown here as 'contactable'.



# Complaints that did not proceed

Following the implementation of a new case management system in 2024, the PMCPA is now able to report on all complaints received, including those that are not provided to a respondent company for a response.

#### Cases not relating to a pharmaceutical company

In 2024, the PMCPA received 69 complaints that were not related to a pharmaceutical company and so did not fall within the scope of the ABPI Code and the PMCPA's jurisdiction.

Typically, these complaints relate to promotion of a prescription medicine to the public by, for example, a pharmacy, clinic or online influencer.

Complainants are directed to the appropriate regulator, e.g. the Advertising Standards Agency (ASA) or the Medicines and Healthcare products Regulatory Agency (MHRA).

#### Cases relating to pharmaceutical companies but not proceeded

In 2024, 47 complaints were not proceeded by the case preparation manager before contacting the pharmaceutical company for a response. The most common reasons for this are:

- a lack of evidence that there may have been a breach of the ABPI Code
- data privacy concerns
- complaints outside the scope of the ABPI Code.

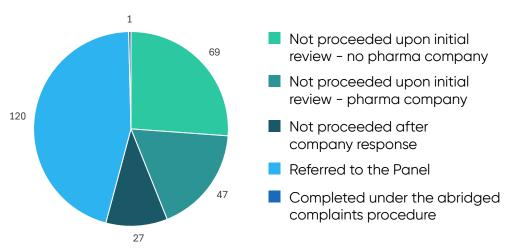
These decisions can be complex, with complainants entitled to challenge the case preparation manager's decision and request a review by an independent referee.

In 2024, a further 26 complaints were not proceeded following receipt of a response from the pharmaceutical company. Reasons why complaints may not proceed at this stage include:

- no UK nexus has been established
- there is insufficient evidence that the ABPI Code may have been breached or that the alleged activity occurred.

In some cases, a pharmaceutical company may decline to accept the PMCPA's jurisdiction, at which point the complaint is referred to the MHRA.

#### Complaints received in 2024



In 2024, the PMCPA made changes to the format and content of the 'Make a complaint' page of its website aimed at:

- reducing the number of non-proceedable complaints received
- · improving the quality of complaints and the evidence provided by complainants
- encouraging complainants to be contactable to the PMCPA.



## Sources of proceedable complaints

	Year complaint received	
	2023	2024
Health professionals <sup>1</sup>	68	85
Non-verified	62	83
Verified	6	2

Pharmaceutical companies	11	9
Intercompany complaint	2	5
Voluntary admission	9	4

Other	43	19
Member of the public	16	9
Ex-employee or ex-contractor	13	3
Current employee or contractor	10	3
Arising from media criticism	1	0
Other <sup>2</sup>	3	4

Unknown	8	8
Not specified	8	8

TOTAL PROCEEDABLE CASES	130	121
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Classification of complainants is based on how complainants define themselves.

- 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 did not confirm this.
- 2. "Other" complainants:
  - 2024 Academics; Campaign group; An industry (non-pharmaceutical company) employee complaining in personal capacity; An anonymous, non-contactable complainant who described themselves as a pharmaceutical company employee and declared no conflicts of interest
  - 2023 Two anonymous, non-contactable complainants who described themselves as pharmaceutical company employees and declared no conflicts of interest; "allied staff"



## Outcomes of proceeded cases

## Outcomes of proceeded cases

	Year complaint received			
	2021	2022	2023	2024
Number of cases	119	107	130	121
Cases where a breach found <sup>1</sup>	82 (69%)	79 (74%)	85 (65%)	36
Cases where no breach found <sup>1,2</sup>	37 (31%)	28 (26%)	45 (35%)	28
Cases not yet complete <sup>1</sup>	0	0	0	57

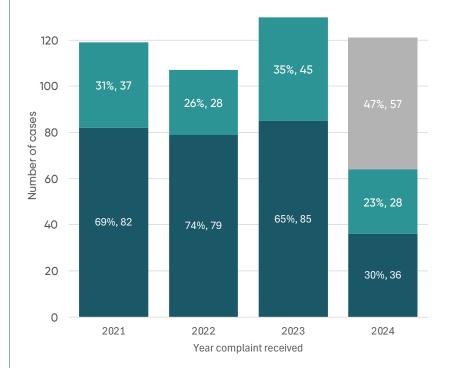
Number of matters ruled upon	910	577	598	328
Matters where at least one breach ruled <sup>1</sup>	278 (31%)	235 (41%)	252 (42%)	133 (41%)
Matters where no breach found <sup>1</sup>	632 (69%)	342 (59%)	346 (58%)	195 (59%)

Breaches of Clause 2 ruled <sup>1</sup>	23	16 cases 17 rulings	14 cases 16 rulings	11 cases 11 rulings
Reports from Panel to Appeal Board <sup>1</sup>	1	0	1	2

Sanctions <sup>1</sup>				
Suspension of materials required	0	0	0	0
Corrective statements required	0	0	0	0
Public reprimands	1	0	0	1
Audits	1	0	0	1
Other administrative steps	N/A	N/A	1	1
Reports to the ABPI Board	1	0	0	0
Number of cases where sanctions imposed	1	0	1	2

- 2024 data as at 1 July 2025
- Cases ruled outside the scope of the Code 2022; one case, 2023; two cases, 2024; one case

- Cases where no breaches found
- Cases where a breach found
  - Cases not yet considered



The outcomes of complaints received in 2023 remained broadly consistent with those received in previous years. Approximately two-thirds of complaints ruled upon result in at least one breach ruling. Approximately 40% of the matters ruled upon are found to be in breach.

The full data for complaints received in 2024 will be reported in future annual reports, as these cases progress through the complaints procedure.



# Appeals to the Code of Practice Appeal Board

	Year complaint received		
By number of cases	2021	2022	2023
Number of cases	119	107	130
Number of cases appealed	15 (13%)	9 (8%)	13 (10%)
Number of cases with successful or partly successful appeal	9 (8%)	7 (7%)	8 (6%)

Cases appealed by complainants	4	3	4
Successful	0	0	0
Partly successful	0	2	2
Unsuccessful	4	1	2

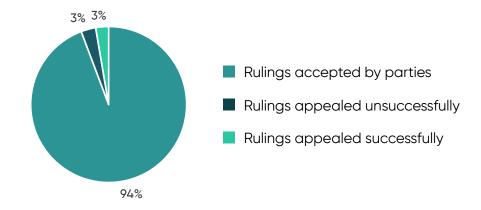
Cases appealed by respondents	11	6	9
Successful	3	1	6
Partly successful	6	4	0
Unsuccessful	2	1	3

<sup>\*</sup>Not all cases received in 2024 have been ruled upon by the Panel, so it is too soon to report this data.

The vast majority (90%) 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 rulings.

#### Rulings of complaints received in 2023

The Panel continues to have a good record, with 97% of rulings accepted or upheld on appeal (for complaints received in 2023).



	Year complaint received		eceived
By number of rulings	2021	2022	2023
Number of matters/rulings by the Panel <sup>1</sup>	910 matters	577 matters	786 rulings
Number of rulings appealed	66	45	45 (6%)
Number of rulings appealed successfully	20	16	21 (3%)

Rulings appealed by complainants	22	26	18
Successful	0	5	4
Unsuccessful	22	21	14

Rulings appealed by respondents	44	19	27
Successful	20	11	17
Unsuccessful	24	8	10

This data has previously been reported as the number of "matters" but will now be reported as the number of "rulings" to allow the percentage calculation below.



## Companies ruled in breach of the ABPI Code

Complaints received in 2023	
A Menarini Farmaceutical Internazionale SRL	Janssen-Cilag Limited
AbbVie Ltd	LEO Pharma Laboratories Ltd
Advanced Accelerator Applications	Merck Serono Limited
AGB-Pharma AB	Moderna Biotech UK Ltd *
ALK-Abelló Ltd	Novartis Pharmaceuticals UK Ltd *
AstraZeneca UK Limited *	Novo Nordisk Ltd *
BioMarin (UK) Limited	Otsuka Pharmaceutical Europe Ltd
Boehringer Ingelheim Limited	Otsuka Pharmaceuticals (UK) Ltd *
Celltrion Healthcare UK Limited	Pfizer Limited*
Consilient Health Ltd	Roche Products Ltd
CSL Vifor	Samsung Bioepis
Daiichi-Sankyo UK Ltd *	Sandoz Ltd
Eli Lilly and Company Limited	Stirling Anglian Pharmaceuticals Limited
Gilead Sciences Ltd	Takeda UK Limited
Grünenthal Ltd (UK)	Tetris Pharma UK Ltd
GSK UK Limited	UCB Pharma Ltd
Ipsen Limited	Valneva UK Ltd

<sup>\*</sup> in breach of Clause 2

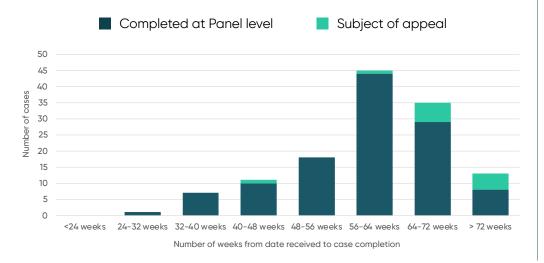


## Time taken for case completion

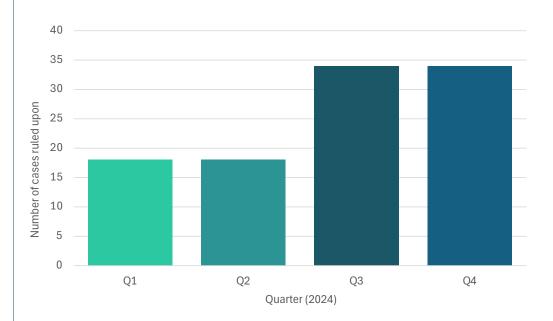
	Year complaint received					
	2021	2022	2023	2024		
Average number of weeks taken to complete cases						
All cases	38.4 (119 cases)	53.0 (107 cases)	60.4 (130 cases)	*		
Cases settled at Panel level	37.7 (104 cases)	51.7 (98 cases)	59.1 (117 cases)	*		
Cases that were the subject of appeal	43.3 (15 cases)	67.4 (9 cases)	72.0 (13 cases)	*		

<sup>\*</sup>Not all cases received in 2024 have been ruled upon by the Panel, so it is too soon to report this data.

#### Complaints received in 2023



#### Rulings issued in 2024



Implementing measures to address the backlog of complaints was one of the PMCPA's top priorities in 2024. The focus was on a combination of increasing the number of complaints processed and reducing the number of complaints taken up by the PMCPA. Four new Panel members were recruited in 2024.

While the average time taken to complete cases was higher for complaints received in 2023 than those received in previous years, the PMCPA is reassured that the number of cases ruled upon per quarter almost doubled: from 18 in Q1 and Q2 to 34 in Q3 and Q4. This does not include those complaints that were not proceeded.

With more changes agreed for 2025, including further recruitment, prioritisation based on patient safety, and 'batching' of similar cases, we expect this trend to continue.





### Accounts 2024

The PMCPA is required to be self-financing.

In 2024, there was a surplus of £26,323. The PMCPA cumulative reserves on 31 December 2024 were £401,759.

#### **Annual levy**

All ABPI member companies are required to pay an annual Code of Practice levy (in addition to their ABPI subscriptions) to fund the PMCPA.

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.

The levy income collected varies to ensure that the PMCPA covers its costs. In 2022 and 2023, 100% of the levy due was called up. In 2024, a levy of £5,250 out of the maximum of £6,000 was called up.

#### **Administrative charges**

Administrative charges are payable by pharmaceutical companies (both members and non-members of the ABPI) in relation to cases considered under the ABPI Code. The administrative charges are intended to contribute substantially to the costs of dealing with complaints. They are not fines.

Charges are only paid by pharmaceutical companies. Health professionals, members of the public and other individuals from outside the pharmaceutical industry do not pay any charges for making a complaint.

Charges are paid by companies ruled in breach of the Code and by those companies that make unsuccessful complaints. The administrative charges are based on the number of matters ruled upon in a case. Each case may comprise multiple matters, and each matter may consist of more than one clause breached.

Companies that are not members of the ABPI do not pay the levy and the administrative charges for them are consequently higher.

In 2024, the charge per matter where the decision of the Code of Practice Panel was accepted was £5,000 for member companies and £6,000 for non-member companies. Where the decision of the Panel was unsuccessfully appealed, the charge per matter in 2024 was £13,000 for member companies and £14,000 for non-member companies.

In addition, all companies ruled in breach of Clause 2 of the Code, or that are the subject of a public reprimand or are required to issue a corrective statement pay £4,000 towards the cost of advertising that fact in the medical, pharmaceutical and nursing press.



## Accounts 2024

#### Financial performance

In 2024, the PMCPA delivered a small surplus of £26,323.

Overall, income grew in line with expectations – with the new 'Code in a Day' training generating a positive return.

The surplus was achieved despite:

- vacancies within the Panel and time for new team members to get up to speed
- the resources required to launch the new 2024 ABPI Code
- the need to use a recruitment agency to identify suitable candidates for open positions.

The PMCPA recorded a bad debt provision of £20,000 against Sandoz for the non-payment of administrative charges. Such charges remain due and will need to be settled in full should Sandoz wish to rejoin the self-regulatory framework in the UK.

#### **Accounts detail**

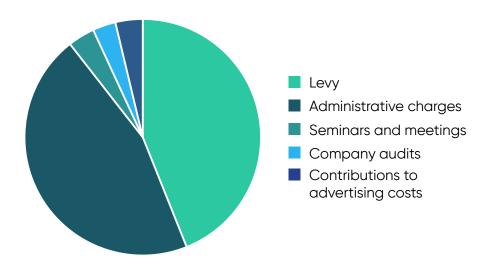
	2022	2023	2024
Levy	£854,000	£839,000	£1,114,313
Administration charges	£831,000	£874,000	£1,154,000
Seminars and meetings	£11,235	£3,000	£93,015
Company audits	£160,000	£60,000	£60,000
Contributions to advertising costs	£56,000	£68,000	£94,500
Total income	£1,912,235	£1,844,000	£2,515,827

Expenditure £1,951,707 £2,252,833 £2,489,504
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Annual surplus or deficit (after tax and expenditure)	-£39,472	-£408,833	£26,323	
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Expenditure includes salaries, fees, administration costs and the cost of office accommodation.

#### 2024 income







PMCPA Annual Report 2024