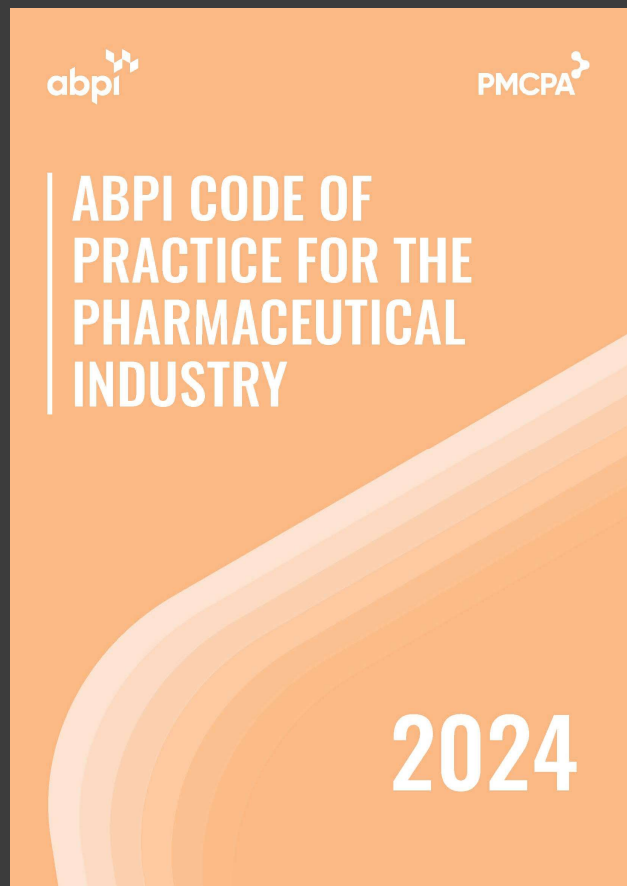


Prescription Medicines Code of Practice Authority Constitution and Procedure

2024 ABPI Code of Practice



PMCPA Constitution and Procedure



INTRODUCTION CLAUSES 1-10 CLAUSES 11-17 CLAUSES 18-22 CLAUSES 23-25 CLAUSES 26-27 CLAUSES 28-31 CONSTITUTION AND PROCEDURE

PRESCRIPTION MEDICINES CODE OF PRACTICE AUTHORITY CONSTITUTION AND PROCEDURE

INTRODUCTION TO THE PMCPA CONSTITUTION AND PROCEDURE	55
STRUCTURE AND RESPONSIBILITIES	
1 Prescription Medicines Code of Practice Authority	56
2 Code of Practice Panel – Constitution and Procedure	57
3 Code of Practice Appeal Board – Constitution	57
4 Code of Practice Appeal Board – Procedure	58
COMPLAINTS PROCEDURE	
5 Actions on Complaints	60
6 Abridged Complaints Procedure	61
7 Complaints arising from Medico-Legal Claims	62
8 Code of Practice Panel – Rules	62
9 Abridged Complaints Procedure – Rules and Sanctions	63
10 Code of Practice Panel – Reports to the Code of Practice Appeal Board	63
11 Action on Complaints about Safety from the Medicines and Healthcare products Regulatory Agency	63
12 Code of Practice Appeal Board – Rules and Sanctions	64
13 Reports to the Code of Practice Appeal Board	64
14 Code of Practice Appeal Board – Reports to the ABPI Board	65
15 Case Reports	65
GENERAL PROVISIONS	
16 Time Periods for Responding to Matters under the Code	67
17 Withdrawal of Complaints and Notices of Appeal	67
18 Code of Practice Levy and Charges	67
19 Sanctions	67
20 Provision of Advice and Assistance with Conciliation	68
21 Amendments to the Code of Practice and Constitution and Procedure	68
22 Annual Report	68

54 | INTRODUCTION

PMCPA CONSTITUTION AND PROCEDURE



Key changes— Structure and Responsibilities

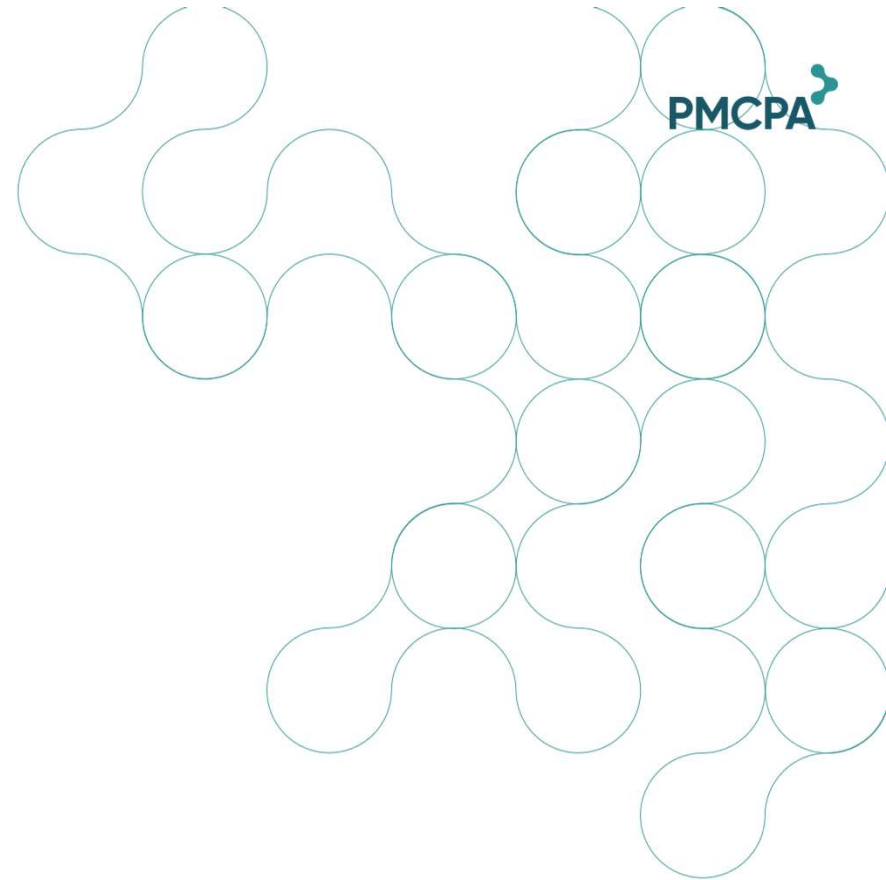


Paragraph 1: Prescription Medicines Code of Practice Authority

- Detail added about how senior leaders of the PMCPA are appointed

1.3 The Authority is appointed by and reports to the ABPI Board and includes the Chief Executive, Directors and Managers.

1.4 The appointments of the Chief Executive and Directors are made by representatives from the Authority, the Appeal Board and the ABPI Board, in consultation with the MHRA. These vacancies should be externally advertised.



Paragraph 1: Prescription Medicines Code of Practice Authority

- Detail added in relation to the Chief Executive’s reporting line, objective setting and how performance is measured

1.5 The Chief Executive reports to the Appeal Board for guidance on the interpretation of the Code.

The Appeal Board also has a supervisory role in relation to the operation of the complaints procedure. The Chief Executive must provide a regular status report to the Appeal Board on complaints submitted under the Code and details of the action taken on them.

If the Appeal Board has concerns about the operation of the complaints procedure, those concerns should be raised with the Chief Executive and, at the Appeal Board’s discretion, may be escalated to the President of the ABPI through the Chair of the Appeal Board.

The Chief Executive reports to the President of the ABPI* for administrative purposes.

The Chief Executive does not report to the President in relation to decisions and actions taken within the complaints procedure.

The President must consult the Chair of the Appeal Board before setting any aspect of the Chief Executive’s annual performance review which relates to the operation of the complaints procedure. Feedback from the Chair of the Appeal Board must be obtained to assist the President’s consideration of the Chief Executive’s performance.

*(or, where a conflict of interest is identified or the President is absent, the Vice President of the ABPI)

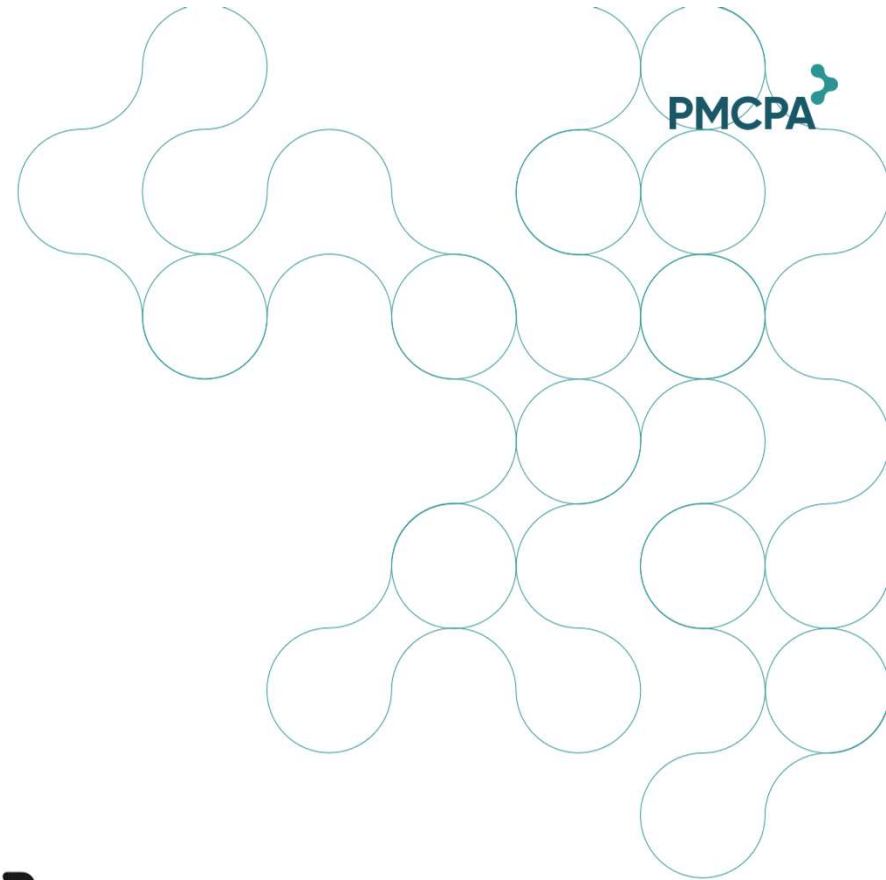
Paragraph 1: Prescription Medicines Code of Practice Authority

- Conflicts of interest provisions added

1.8 Members of the Authority must declare any conflicts of interest prior to appointment to the Authority, and before involvement in a case including acting as case preparation manager or adjudicating on a complaint.

Members of the Authority previously employed by a pharmaceutical company are restricted from involvement in a case as described above on a matter relating to their former employer for a minimum period of three years.

Co-optees must comply with the same conflicts of interest provisions.



Paragraph 1: Prescription Medicines Code of Practice Authority

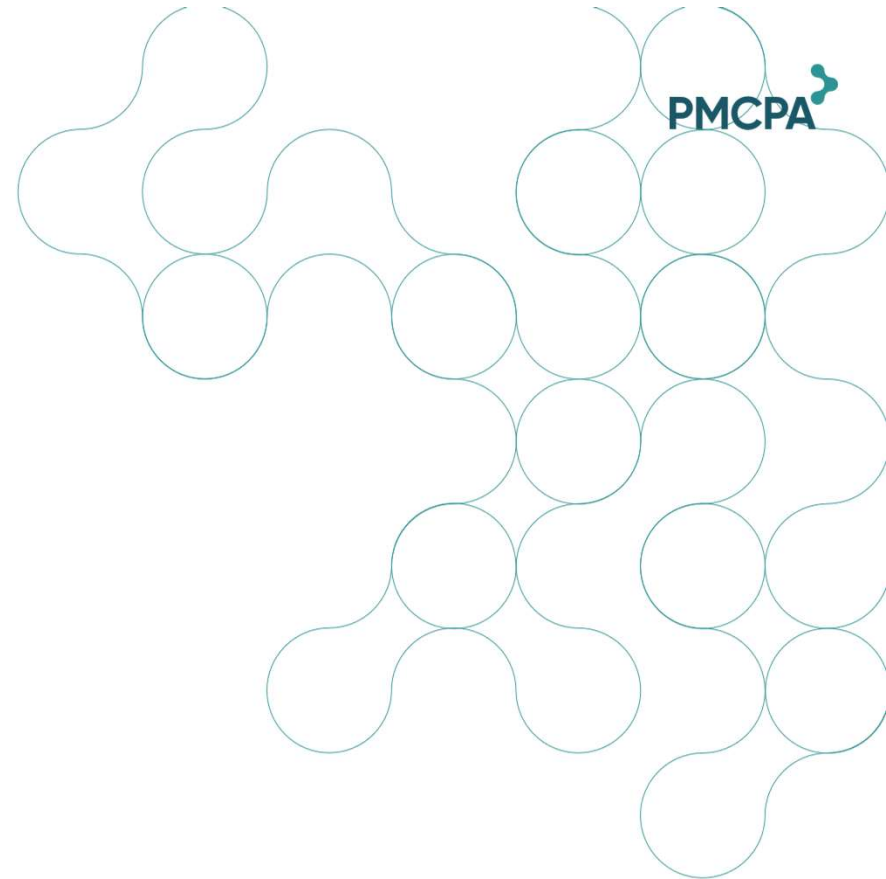
- Details about independent referees consolidated to avoid repetition

1.9 Matters are referred to independent referees in specific situations identified in this Constitution and Procedure.

Independent referees are identified by the Chief Executive and the Chair of the Appeal Board and may be, for example, a former independent member of the Appeal Board.

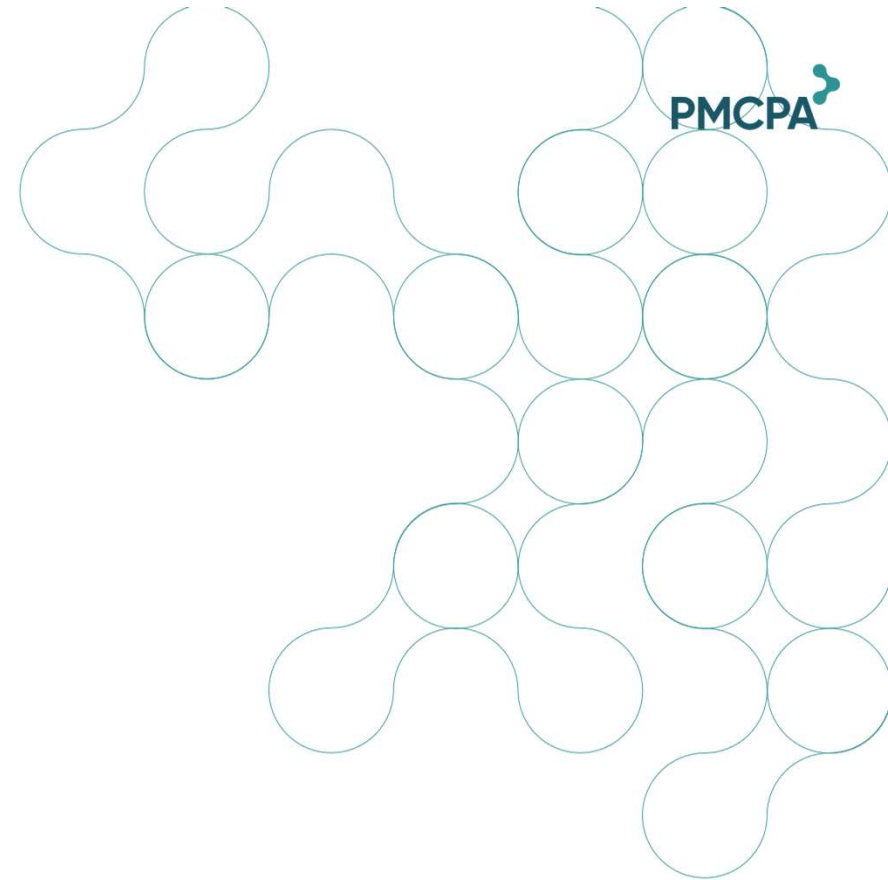
Independent referees must declare any conflicts of interest before involvement in a case.

The determinations of independent referees are final.



Paragraph 1: Prescription Medicines Code of Practice Authority

- Important new paragraphs:
 - 1.10** – Overriding Objective
 - 1.11** – Case Management Directions
 - 1.12** – Set Aside for Procedural Error



1.10: 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.

Dealing with cases fairly and justly includes:

- Dealing with each case in ways which are proportionate to the importance of the case and the complexity of the issues
- Avoiding unnecessary formality and adopting flexibility in the proceedings where appropriate
- Ensuring, so far as practicable, that the parties are able to participate fully in the proceedings
- Avoiding delay to the case in hand and other cases, so far as compatible with proper consideration of the issues

1.11: Case Management Directions

'Case management directions' are directions as to the manner in which proceedings will be conducted.

They may include, but are not limited to, directions about:

- (i) what material may go in front of the Panel or Appeal Board;
- (ii) what material may be redacted;
- (iii) whether a hearing is conducted remotely or in person; or
- (iv) providing dictation support to an individual who is unable to submit a complaint in writing.

Members of the Authority may give a case management direction at **any time prior to an appeal being heard**, including a direction amending, suspending, or setting aside an earlier direction.

The **Chair of the Appeal Board** may give a direction at any time in relation to **cases which have been appealed** to the Appeal Board, including a direction amending, suspending, or setting aside an earlier direction.

1.12: Set Aside for Procedural Error

A '**procedural error**' is where there has been an error in complying with the procedure set out in the Constitution for dealing with cases.

When a decision is set aside for procedural error, that decision will have no effect and **the case will proceed as if that decision had not been made**.

Before making a final decision to set a matter aside, the Chief Executive or Chair of the Appeal Board must give parties an opportunity to make written submissions. Directions setting aside a decision should be given in writing with an explanation of the procedural error.

Decisions to set aside will be referred to an independent referee at the request of any party.

The **Chief Executive** may give a direction at any time **before an appeal has been lodged**, setting aside a decision of the case preparation manager or Panel where there has been a procedural error. Where the Chief Executive is conflicted, such direction may be given by a Director.

The **Chair of the Appeal Board** may give a direction at any time **before an appeal has been heard**, setting aside a decision of the case preparation manager or Panel where there has been a procedural error.

The **Chair of the Appeal Board** may give a direction at any time setting aside a decision of the Appeal Board where there has been a procedural error.

Paragraph 2: Code of Practice Panel – Constitution and Procedure

- A new requirement that the names of members of the Authority and co-optees to the Panel must be published on the PMCPA website

<https://pmcpa.org.uk/about-us/how-the-pmcpa-works/the-code-of-practice-panel/>



The screenshot shows the PMCPA website page for 'The Code of Practice Panel'. The page includes a navigation menu with links for 'About us', 'Media', 'Publications', 'Training', 'Contact us', and a search bar. Below the navigation, there are links for 'Code', 'Guidance', 'Cases', and 'Complaint procedure'. The main content area is titled 'The Code of Practice Panel' and contains the following text:

The Code of Practice Panel consists of the Director, Deputy Director and Managers of the PMCPA.

The Panel considers all complaints made under the Code in the first instance with the benefit of independent medical and other such expert advice as appropriate. The Panel for each case is made up of at least two members of the Authority below, with another acting as the case preparation manager. The case preparation manager does not sit on the Panel for the consideration of that case.

Alex Fell is the Director of the PMCPA. Alex 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.

Alex joined the PMCPA in 2022.

Natalie Whittle is the Deputy Director of the PMCPA. Natalie has been a member of the Code of Practice Panel for several years. She is also a member of the IFPMA Code Complaint Adjudication Group. 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. Natalie joined the PMCPA in September 2018.

Keval Dabba is the Associate Director at the PMCPA. Keval is a registered pharmacist in the UK and has worked in community pharmacy, the NHS and in the pharmaceutical industry including being a final signatory, providing expert advice and training on the Code. His recent role at a pharmaceutical company involved leading the compliance and medical function. Keval joined the PMCPA in June 2021.

Maleeha Sultan is a Manager at the PMCPA. Maleeha is a UK-registered pharmacist and has worked in the NHS and community pharmacy and in the pharmaceutical industry including Medical Affairs, and later in Advertising & Promotion and Medical Governance and management of promotional review

Paragraph 3: Code of Practice Appeal Board – Constitution

3.1 Composition of the Appeal Board



This Photo by Unknown Author is licensed under CC BY-ND

Paragraph 3: Code of Practice Appeal Board – Constitution

The Appeal Board comprises:

- An independent, legally qualified Chair
 - 3x independent registered medical practitioners
 - One with recent experience as a GP
 - One with recent experience as a hospital consultant
 - 2x independent registered pharmacists
 - 1x independent registered senior nurse practitioner (minimum Band 7 or equivalent)
 - 1x independent member representing the interests of patients
 - 1x independent lay member
- 4x industry members being registered medical practitioners who are medical directors or senior executives of pharmaceutical companies
 - 4x industry members being directors or senior executives of pharmaceutical companies



Paragraph 3: Code of Practice Appeal Board – Constitution

3.1 Composition of the Appeal Board

3.2 Appointment terms

– Detail added in relation to Chair’s reappointment to introduce a limit on the number of times the Chair may be reappointed

The Chair of the Appeal Board is appointed for a term of 5 years which may be renewed once.

In exceptional circumstances, the ABPI Board may reappoint the Chair of the Appeal Board for a third term.

Members of the Appeal Board are appointed for a term of 3 years. Members may be reappointed but may serve for no more than two consecutive terms. In exceptional circumstances, the Chair may nominate a member who has served two terms for reappointment for a third term. A member of the Appeal Board who has served two or, following the Chair’s nomination, three consecutive terms of service is eligible for reappointment after a minimum interval of one year.



Paragraph 3: Code of Practice Appeal Board – Constitution

- 3.1** Composition of the Appeal Board
- 3.2** Appointment terms
- 3.3** The Appeal Board and its Chair are appointed by the ABPI Board. The Chair and other independent members are appointed following consultation with the MHRA
- 3.4** Vacancies for independent members, including the Chair, are advertised in appropriate journals and/or the national press
- 3.5** Industry members of the Appeal Board are proposed by their UK chief executive or equivalent. They are not representatives of their company when performing duties as a member of the Appeal Board.
- 3.6** The Chief Executive is responsible for providing appropriate administrative support to the Appeal Board, including the provision of case papers.



Paragraph 4: Code of Practice Appeal Board – Procedure

- Detail added in relation to the purpose of members of the Authority and others being present during Appeal Board meetings
- Detail added that meetings may be recorded

4.3 Members of the Authority may be present during Appeal Board meetings only at the invitation of the Chair.

For the Appeal Board’s consideration of an appeal or a report under Paragraph 13, members of the Authority may be present only at the invitation of the Chair and with the agreement of the party or parties involved in the appeal or report in question. The purpose of attendance is to understand as observers the work of the Appeal Board. A member of the Authority may provide clarification to the Chair of the Appeal Board during an Appeal Board meeting on a procedural matter relating to an appeal or report. Where they do, such assistance will be minuted.

On occasion, the Chair may invite others, such as the President of the ABPI, to attend an Appeal Board meeting as a guest. For the Appeal Board’s consideration of an appeal or a report under Paragraph 13, that guest may be present only with the agreement of the party or parties involved in the appeal or report in question. The purpose of attendance is to understand as an observer the work of the Appeal Board.

4.4 Appeal Board meetings may be recorded and kept in accordance with the PMCPA’s Privacy Policy for Complaints, published on the PMCPA website.

4.5 Records of decisions at prior Appeal Board meetings may be shared with Appeal Board members at the Chair’s discretion.



Key changes – Full Complaints Procedure



Paragraph 5: Action on Complaints

- Significant restructuring to improve flow and readability
- Details added in relation to complaints not proceeding

5.5 Where a decision is taken that a complaint will not be proceeded with in line with this Constitution and Procedure, the decision will be referred to an independent referee if any party so requests subject to the exception below.

Where a decision is taken that the matter should be dealt with by another UK authority (e.g. ASA, MHRA, GMC, GPhC), there is no right of referral to an independent referee. In such circumstances, the complainant will be provided with contact details for the relevant UK authority or, if the complainant is non-contactable, the complaint may be forwarded to the relevant UK authority.

Para.	Content	2021 Para.
5.1	Assignment of case preparation manager	5.1
5.2	Role of case preparation manager	5.1
5.3	Decision that a complaint should not proceed because: it is closely similar to a previous case	5.2
5.4	Decision that a complaint should not proceed because: it does not show that a company may have contravened the Code	5.2
5.5	Complaints not proceeding	5.2
5.6	Companies that don't accept the PMCPA's jurisdiction	5.2

Paragraph 5: Action on Complaints

- Significant restructuring to improve flow and readability
- Details added in relation to complaints not proceeding
- Provision added for the CPM to remove a clause raised by the complainant

5.8 If the complainant is not a pharmaceutical company, the case preparation manager may identify which clauses of the Code must be addressed by the respondent company.

If the complainant has cited a clause but, in the view of the case preparation manager, the complaint does not show that the company may have breached that clause, the clause will be removed from the complaint. The complainant will be informed, with written reasons given. For cases going through the full complaints procedure, if the complainant does not agree with the case preparation manager's decision to remove a clause, the clause will be included and provided to the company to provide a response.

Para.	Content	2021 Para.
5.7	Complaints proceeding: Case preparation manager requests response from company	5.2
5.8	Complaints proceeding: Identifying which clauses of the Code are to be addressed	5.2

Paragraph 5: Action on Complaints

- Significant restructuring to improve flow and readability
- Details added in relation to complaints not proceeding
- Provision added for the CPM to remove a clause raised by the complainant
- Text added regarding complainant actions

5.10 When a complaint is not from a pharmaceutical company, the Authority strongly encourages the complainant to be contactable to the Authority in order to fully participate in the complaints process. The Authority will not share the name or contact details of the complainant with other parties, including the respondent company. If it is considered necessary to share information which may identify the complainant with the respondent company, to enable the company to respond to the complaint, then it will only be shared with the prior permission of the complainant. Failure to give permission may result in the case preparation manager deciding that the case should not proceed under Paragraph 5.4.

Complainants are strongly encouraged, but not required, to initially attempt to resolve the complaint using the company's internal or external whistleblowing and/or dispute resolution procedures.

Para.	Content	2021 Para.
5.7	Complaints proceeding: Case preparation manager requests response from company	5.2
5.8	Complaints proceeding: Identifying which clauses of the Code are to be addressed	5.2
5.9	Complaints not from pharma companies: Asking complainant to declare any interests	5.2
5.10	Complaints not from pharma companies: Confidentiality	–

Paragraph 5: Action on Complaints

- Significant restructuring to improve flow and readability
- Details added in relation to complaints not proceeding
- Provision added for the CPM to remove a clause raised by the complainant
- Text added regarding complainant actions
- Increased time for a company to submit its response

5.12 Upon receipt of a complaint, the respondent company has **15 working days** in which to submit its response in writing. An extension of time to respond may be granted at the discretion of the case preparation manager.

Para.	Content	2021 Para.
5.7	Complaints proceeding: Case preparation manager requests response from company	5.2
5.8	Complaints proceeding: Identifying which clauses of the Code are to be addressed	5.2
5.9	Complaints not from pharma companies: Asking complainant to declare any interests	5.2
5.10	Complaints not from pharma companies: Confidentiality	–
5.11	Intercompany complaints	5.3
5.12	Timeline for responding to a complaint	5.4

Paragraph 5: Action on Complaints

- Significant restructuring to improve flow and readability
- Details added in relation to complaints not proceeding
- Provision added for the CPM to remove a clause raised by the complainant
- Text added regarding complainant actions
- Increased time for a company to submit its response
- Encouragement to submit voluntary admissions

5.14 Companies are encouraged to make voluntary admissions by advising the Authority where they consider that they may have breached the Code. The Chief Executive will treat the voluntary admission as a complaint. The case preparation manager may identify the clauses of the Code to be addressed and the company's response will be invited. When the response is received, the procedure under Paragraph 5.13 will be followed.

Para.	Content	2021 Para.
5.7	Complaints proceeding: Case preparation manager requests response from company	5.2
5.8	Complaints proceeding: Identifying which clauses of the Code are to be addressed	5.2
5.9	Complaints not from pharma companies: Asking complainant to declare any interests	5.2
5.10	Complaints not from pharma companies: Confidentiality	–
5.11	Intercompany complaints	5.3
5.12	Timeline for responding to a complaint	5.4
5.13	Case preparation manager's determination following receipt of company response	5.5
5.14	Voluntary admissions	5.6
5.15	Notification that the case has been referred to the Panel	5.7

Paragraphs 7, 8, 10–15

Paragraph 7: Complaints Arising from Media Criticism

- No material changes

Paragraph 8: Code of Practice Panel – Rulings

- Administrative charges associated with complaints must now be paid within **30 calendar days**, rather than 20 working days

Paragraph 10: Code of Practice Panel – Reports to the Code of Practice Appeal Board

- No material changes

Paragraph 11: Action on Complaints about Safety from the Medicines and Healthcare products Regulatory Agency

- No material changes

Paragraph 12: Code of Practice Appeal Board – Rulings and Sanctions

- New detail on sanctions

12.4 Where the Appeal Board rules that there is a breach of the Code, it may require an audit of the company's procedures in relation to the Code to be carried out by the Authority and, following that audit, decide whether to impose requirements on the company concerned to improve its procedures in relation to the Code. These could include a further audit, a specific scope audit, a requirement that the respondent company provides updates regarding implementation of the company's commitments to improve and/or a requirement that promotional material be submitted to the Authority for pre-vetting for a specified period ...

12.7 Where the Appeal Board rules that there is a breach of the Code, it may take other administrative steps as appropriate in line with the overriding objective, such as inviting a senior representative of a particular company to future meetings of the Appeal Board to report on progress, or requesting written confirmation that appropriate action has been taken.

Paragraphs 7, 8, 10–15

Paragraph 7: Complaints Arising from Media Criticism

- No material changes

Paragraph 8: Code of Practice Panel – Rulings

- Administrative charges associated with complaints must now be paid within **30 calendar days**, rather than 20 working days

Paragraph 10: Code of Practice Panel – Reports to the Code of Practice Appeal Board

- No material changes

Paragraph 11: Action on Complaints about Safety from the Medicines and Healthcare products Regulatory Agency

- No material changes

Paragraph 12: Code of Practice Appeal Board – Rulings and Sanctions

- New detail on sanctions
- New text that where there is an appeal and the Appeal Board rules no breach, it shall also determine (at the same meeting) whether additional sanctions are appropriate in relation to breach rulings accepted at the Panel level

12.8 Where the Appeal Board rules that there is no breach of the Code, it shall also determine whether additional sanctions as referred to in Paragraph 12 are appropriate in relation to breach rulings accepted at the Panel level.

Paragraphs 7, 8, 10–15

Paragraph 7: Complaints Arising from Media Criticism

- No material changes

Paragraph 8: Code of Practice Panel – Rulings

- Administrative charges associated with complaints must now be paid within **30 calendar days**, rather than 20 working days

Paragraph 10: Code of Practice Panel – Reports to the Code of Practice Appeal Board

- No material changes

Paragraph 11: Action on Complaints about Safety from the Medicines and Healthcare products Regulatory Agency

- No material changes

Paragraph 12: Code of Practice Appeal Board – Rulings and Sanctions

- New detail on sanctions
- New text that where there is an appeal and the Appeal Board rules no breach, it shall also determine (at the same meeting) whether additional sanctions are appropriate in relation to breach rulings accepted at the Panel level

Paragraph 13: Reports to the Code of Practice Appeal Board

- Clarification of sanctions, as above

Paragraph 14: Code of Practice Appeal Board – Reports to the ABPI Board

- Clarification of procedure
- Addition of text that the ABPI Board must ratify any recommendation made by the Appeal Board

Paragraph 15: Case Reports

- Procedure in relation to advertisements updated to reflect current practice
- Requested amendments to advertisements that cannot be agreed with the Chief Executive will be referred to the Chair of the Appeal Board for their decision, which is final

Paragraph 6:
Abridged Complaints Procedure

Paragraph 9:
Abridged Complaints Procedure – Rulings and Sanctions



Paragraph 6: Abridged Complaints Procedure

6.1 The case preparation manager may determine that the abridged complaints procedure will be followed in relation to a complaint or voluntary admission where:

(i) the allegations fall within the Authority's approved list for use of the abridged procedure (published on the PMCPA website)

and

(ii) it appears that the central facts will not be disputed

and

(iii) it is likely in the case preparation manager's view that there has been a breach of the Code.

The case preparation manager will notify the parties that the complaint is being handled through the abridged complaints procedure.

Abridged complaints procedure

Case type examples

- Isolated incidents of promotion of a Prescription only Medicine to the public (social media)
- Quality of digital materials (e.g. broken link to PI)
- Quality of company materials (e.g. use of word 'new' >12 months)
- Breaches of administrative Code requirements (e.g. delay in notifying PMCPA of updated signatories, incorrect certificate wording on materials)
- Governance over abbreviated advertisements (e.g. size requirements)
- Conduct of employees including representatives (e.g. lack of prior permission for promotional emails)
- Events/meetings (e.g. distributing pens from exhibition stands)
- Isolated incidences of errors with disclosure of ToV (e.g. a small number of missing or inaccurate disclosures)
- Failure to disclose ToV on time

PMCPA LIST FOR USE OF THE ABRIDGED COMPLAINTS PROCEDURE

Abridged Complaints Procedure Scope	2024 Code Example Clauses (non-exhaustive) and Guidance Notes
Isolated incidents of Promotion to the Public of a Prescription Only Medicine (e.g. small number of 'likes'/ 'shares' on social media, exposed mailings resulting in promotion to the public)	Clauses 15.4, 26.1, 26.2 Application of 26.1 and 26.2 is for minor social media breaches (e.g., individual or small number of likes/interactions on social media). Note: breaches in relation to incorrect or misleading safety information will unlikely be suitable for the abridged procedure
Quality of Digital Materials (e.g. isolated broken link to prescribing information, not made clear when leaving company website)	Clauses 5.8, 12.1 Note: breaches in relation to the content of prescribing information are unlikely to be suitable for the abridged complaints procedure. However, breaches in relation to isolated accessibility issues, such as a broken link, may be suitable for the abridged complaints procedure.

Paragraph 6: Abridged Complaints Procedure

- 6.2** Where a complaint comprises multiple allegations, the complaint will follow the full complaints procedure if any of the allegations do not fall within the scope of the abridged complaints procedure.



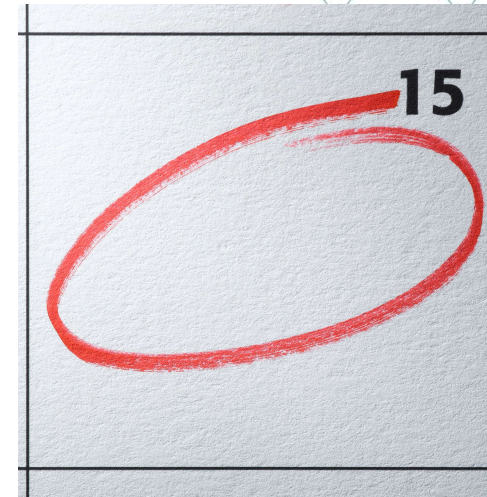
Paragraph 6: Abridged Complaints Procedure

- 6.3** If the complainant is not a pharmaceutical company, the case preparation manager may identify the clause(s) relevant to the allegation(s).
- 6.4** In the event that the case preparation manager does not agree that a clause cited by the complainant is relevant, the complainant will be informed with written reasons. If the complainant does not agree with the case preparation manager's decision to remove a clause they may request that the matter is referred to an independent referee.



Paragraph 6: Abridged Complaints Procedure

- 6.5** Upon receipt of a complaint, the respondent company has 15 working days in which to conduct its investigation and respond in writing. An extension of time to respond may be granted at the discretion of the case preparation manager.



Paragraph 6: Abridged Complaints Procedure

- 6.6** When the response from the respondent company is received, the case preparation manager must assess whether the response satisfies the following criteria:
- The respondent company **accepts the breach(es)** of the Code and provides 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
 - The respondent company confirms that, as a result of its investigation, it **has not identified a systemic compliance issue** in relation to the matter(s) alleged.

The undertaking must be signed by the managing director or chief executive or equivalent of the company or with their authority and must be accompanied by details of the actions taken by the company to implement the undertaking, including the date on which the material was finally used or appeared and/or the last date on which the activity took place.

- 6.7** If the case preparation manager assesses that the respondent company's response does not satisfy the criteria in Paragraph 6.6, the case will follow the full complaints procedure, including the requirement for the company to provide a complete response to the matter of complaint. The case preparation manager may identify additional clauses at this stage, where appropriate to do so.

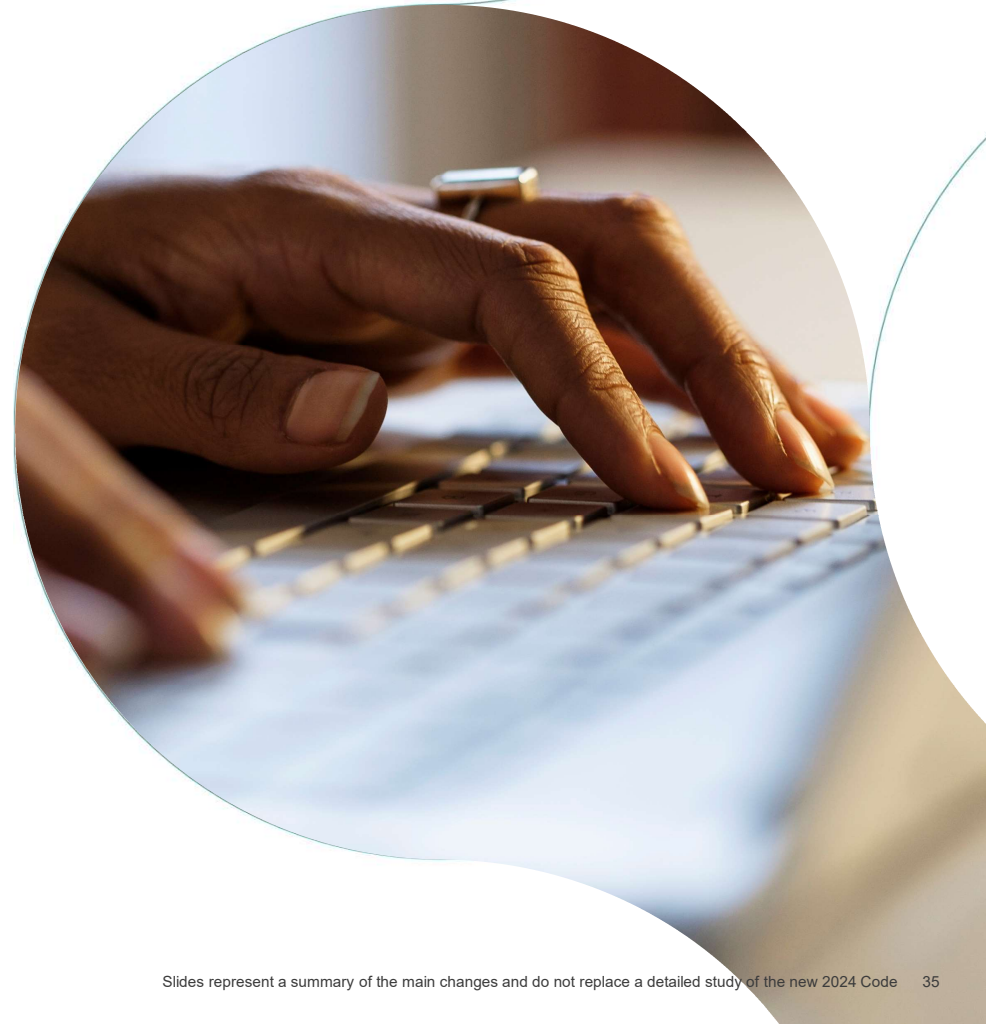
Paragraph 9: Abridged Complaints Procedure – Rulings and Sanctions

- 9.1** Where the case preparation manager has determined that the abridged complaints procedure will be followed, the case preparation manager will inform the complainant that the company has accepted a breach of the Code and provide details of the undertaking.



Paragraph 9: Abridged Complaints Procedure – Rulings and Sanctions

- 9.2** The case preparation manager will draft a case report for publication summarising the allegation, acceptance of the breach by the company and that the company has provided the required undertaking and assurances.



Paragraph 9: Abridged Complaints Procedure – Rulings and Sanctions

9.3 The Appeal Board receives reports on all complaints which have been considered under the abridged complaints procedure.

The Appeal Board cannot impose any additional sanctions on a complaint that has been handled through the abridged procedure.

However, in exceptional circumstances, such as patient safety concerns, the Appeal Board may request that the complaint is reassessed through the full complaints procedure.



Paragraph 9: Abridged Complaints Procedure – Rulings and Sanctions

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

Complainant:

No clauses have been ruled as 'no breach'

Respondent:

The company has accepted all breaches. If the company did not accept the breaches, the complaint would go through the full complaints procedure.



Paragraph 9: Abridged Complaints Procedure – Rulings and Sanctions

- 9.5** Administrative charges equal to one half of the cost of a complaint going through the full complaints procedure will be payable by the respondent company.



Illustration of abridged complaints procedure using a mocked up social media case

Complainant alleges that a Pillfix UK employee has shared a LinkedIn post made by the Pillfix Global corporate account, HQ in the US.

The complainant provides a screenshot of the post, which states that Pillfix's medicine Fixitall for the treatment of painful feet has received FDA approval and is first in class.

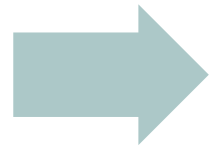
Fixitall already has a licence in the UK and is a POM

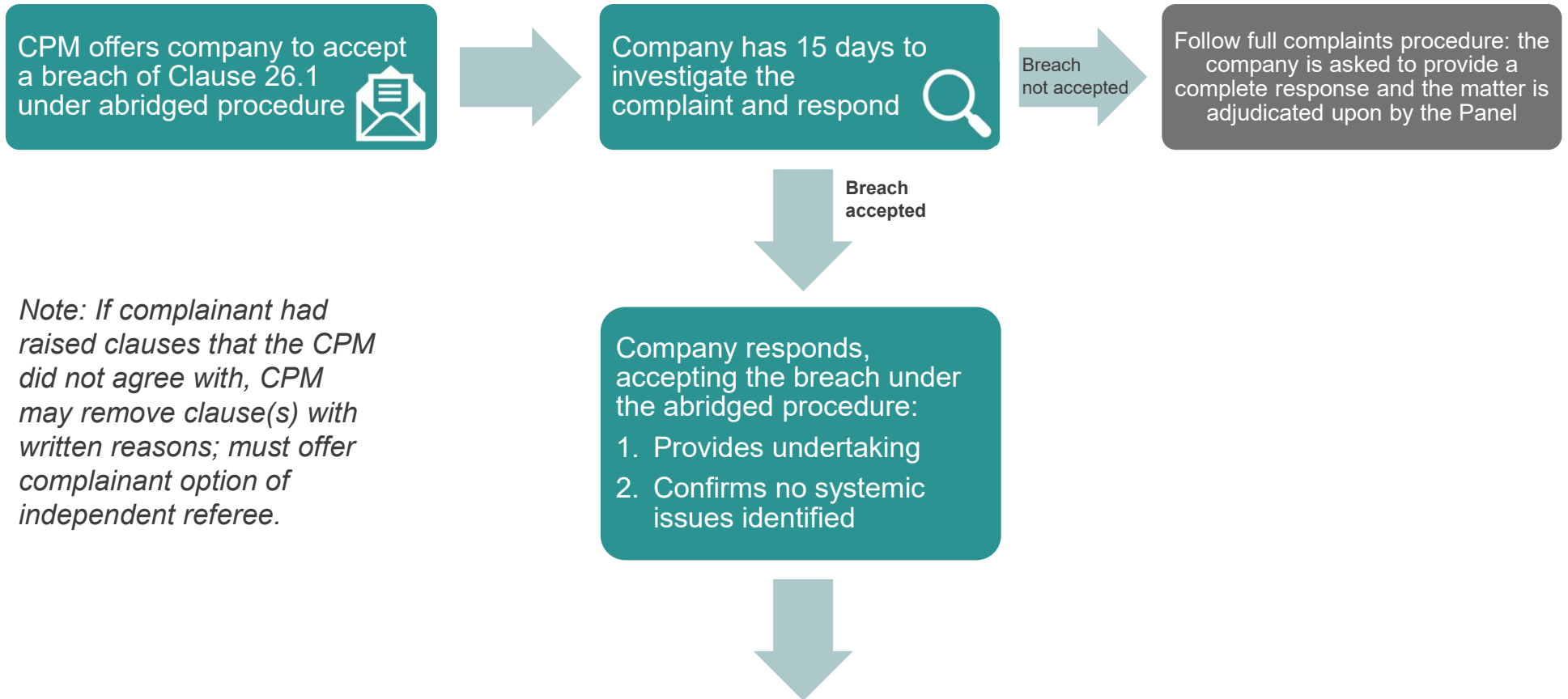
The complainant alleges that, by sharing the post, the UK employee has advertised a POM to the public.

The complainant does not cite any specific Code clauses.



Case Preparation Manager assesses the complaint and decides that it meets the criteria for the abridged complaints procedure





Note: If complainant had raised clauses that the CPM did not agree with, CPM may remove clause(s) with written reasons; must offer complainant option of independent referee.



FAQs on abridged complaints procedure
will be published PMCPA website





Key changes – General Provisions

Paragraphs 16–22

Paragraph 16: Time Periods for Responding to Matters under the Code

- No material changes

Paragraph 17: Withdrawal of Complaints and Notices of Appeal

- The consent of the respondent company is no longer required for a complainant to withdraw their complaint before the respondent company's response has been received by the Authority
- The consent of the respondent company is no longer required for a complainant to withdraw their appeal at any time

Paragraph 18: Code of Practice Levy and Charges

- New text added in relation to the abridged complaints procedure

Paragraph 19: Scrutiny

- Text added that members of the Authority may not adjudicate on a case relating to material/activity that they have reviewed as part of scrutiny
- Clarification that the Authority cannot approve any materials or activities

Paragraph 20: Provision of Advice and Assistance with Conciliation

- Addition of provision that complainants may seek the assistance of a conciliator

Paragraph 21: Amendments to the Code of Practice and Constitution and Procedure

- No material changes

Paragraph 22: Annual Report

- No material changes

Timelines and next steps

1 October 2024

New Constitution and Procedure comes into operation – including the abridged complaints procedure

Companies should:

- Familiarise themselves with the changes to the constitution and procedure.
- Encourage relevant staff to view these webinars outlining the changes
- Update relevant policies and procedures and train staff
- Ask if unsure on any of the changes





Prescription Medicines Code of
Practice Authority

The PMCPA is a division of the
ABPI which is a company limited
by guarantee registered in
England & Wales no 09826787.

Registered office 2nd Floor
Goldings House, Hay's Galleria, 2
Hay's Lane, London, SE1 2HB.

T | +44 (0)20 7747 8880
E | info@pmcpa.org.uk