Public consultation on proposed amendments to the PMCPA Constitution and Procedure

3 August 2026

Introduction

This public consultation is to seek views on the PMCPA's proposals to amend its Constitution and Procedure ("C&P").

These proposals have been developed from:

(a) A Working Group of ABPI members that met with us throughout 2025 to consider proposals for reform.
(b) Feedback we received from complainants and companies on their experience of our complaints regime.
(c) The PMCPA's experience of applying the 2024 edition of the C&P in practice.
(d) Input from the Code of Practice Appeal Board and the ABPI Board.
(e) Input from the MHRA.

The aim of these targeted amendments is to further modernise and strengthen the complaints process, to ensure a robust and effective system of self-regulation. The reforms we are putting forward for consultation seek to safeguard the transparency of the complaints process, ensuring all parties can participate fully, whilst always having regard to the overriding objective to ensure cases are dealt with fairly and justly while protecting patient safety.

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; and
- avoiding delay to the case in hand and other cases, so far as compatible with proper consideration of the issues.

The proposed amendments are grouped under the following themes:

1. Scope of the complaints procedure
2. Operation of the complaints procedure

The changes set out in this consultation document are proposals only.
All responses will be considered before deciding whether, and in what form, to take any of them forward.

3. Matters not related to the complaints procedure
4. Minor amendments/clarifications

References in the table below to "Paragraph" are to the paragraph number in the C&P. References to "the CPM" are to the case preparation manager. The list of proposed changes in the table below only contains extracts of those paragraphs where a change is proposed. Any C&P paragraphs not mentioned will remain unchanged.

The table of proposed changes includes four columns:

1. The first column refers to the proposal number.
2. The second column states the subject area and the relevant paragraph of the C&P.
3. The third column includes the new proposed wording in red text and the proposed wording to be removed is in red strikethrough text.
4. The fourth column explains the reason for the amendment.

An MS Forms accompanies this consultation which asks for comments on each of the proposed changes. There is also an open question for you to provide any comments or feedback on anything related to the C&P, whether included in this consultation or not.

We consider that there are three topics in this consultation that are the most significant and we have provided a more detailed explanation of the background, the rationale for change and deliberations that we have had with the Appeal Board, ABPI Board and our stakeholders.

1. An expanded abridged complaints procedure ("ACP")

We have spent time engaging with a Working Group of ABPI members, our Compliance Network and the Appeal Board to discuss how best to approach complaints which involve company personnel's personal use of social media.

One option that had been put forward was the idea of 'takedown'. This would have involved complaints about personal use of social media that may have contravened the Code being notified to the company and, if the company ensured that the post/interaction was 'taken down' within 48 hours, the PMCPA would not proceed with the complaint, regardless of its merits. The PMCPA would keep a register of such incidents and could raise a formal complaint, in the name of the PMCPA Chief Executive, if there were repeated incidents within a short period of time or any single serious incident.

Following feedback, we have decided not to pursue this takedown approach at this time for several reasons:

1. The number of social media related complaints received by the PMCPA is considerably lower than in previous years. In 2025, we received only 12 complaints (11% of the total) about activities on social media, compared to 30 complaints (23% of the total) in 2023. In the first half of 2026, we received five proceedable complaints related to social media. The need for a bespoke approach to social media has therefore receded.
2. Some social media related complaints have resulted in multiple breach rulings. Moving from a position of full Panel rulings on multiple clauses, to a position where the PMCPA effectively takes no publicly visible action could be seen as potentially weakening self-regulation and reducing the high standards expected of the industry.
3. Social media activity is most impactful within the first 48 hours. The ‘takedown’ approach may lead to more inappropriate activity on social media due to the diminished threat of a published case.
4. Many social media related complaints are breaches of the Code for which we believe there should be some form of sanction. We consider that ensuring most, if not all, social media complaints relating to company personnel’s personal use proceed through the ACP is the right approach between ruling multiple breaches on the one hand and taking no action at all on the other.
5. The PMCPA wants to be able to take a proportionate, streamlined approach to all types of cases where possible, not just those related to social media. Implementing a process which only applies to social media (i.e. a small proportion of our current caseload) does not future-proof the PMCPA complaints procedure.

Although we do not propose to adopt the takedown approach, for the reasons set out above, we have (at Question 26) invited views on it as part of our consultation questions.

Our proposed alternative approach is a change to the existing ACP such that the PMCPA will be given greater discretion to rely on the existing ability to remove irrelevant clauses. Currently the CPM can identify clauses “relevant” to the allegations (Paragraph 6.3). The complainant may also cite clauses. Currently, if the CPM disagrees with the clauses raised by the complainant, the complainant may request that the CPM’s decision is referred to an independent referee (Paragraph 6.4). We do not believe that the decision about relevant clauses is a matter sufficiently serious that it requires an independent referee to give an opinion on it.

The proposed amendment to the C&P will ensure that the decision on the relevance of clauses can be escalated to the Chief Executive of the PMCPA, rather than to an independent referee. We consider that the decision about *how* a complaint proceeds (i.e. which clauses are proceeded) is a matter for the PMCPA and does not need an external appeal route. The case will still proceed, and the CPM can only remove irrelevant clauses, not allegations that are in scope of the Code. In contrast, the decision to not proceed complaints at all would remain appealable to an independent referee.

In practice, what is 'relevant' will encompass what is proportionate based on the activity in question, taking into account the evidence provided by the complainant, and will potentially result in a smaller number of clauses proceeding.

We also propose to remove reference to the 'approved list for use of the abridged procedure' from the wording of Paragraph 6.1. The current approved list, which is not exhaustive, contains examples of what might be suitable for the ACP. The PMCPA will instead publish guidance which reflects the principles in that list and include the links to published completed abridged cases. With the exception of Clause 2, many clauses *may* be suitable for the ACP depending on the nature of the complaint provided that it appears the central facts will not be disputed. The Appeal Board will retain its oversight role as referred to in Paragraph 9.3.

We believe this change will allow more cases to proceed through the ACP and ensure the right balance of procedural fairness whilst dealing with complaints efficiently.

An additional change we intend to make is to allow the CPM to decide at any point before a case is referred to the Panel to apply the ACP. The current C&P is based on the CPM deciding whether to apply the ACP at the time of receiving the complaint. However, in practice, we've found that the company's response can often clarify whether the ACP is a viable option. This change was supported by the Code of Practice Appeal Board at its meeting in April 2025 and has already been used in practice in support of the overriding objective.

2. A limitation period for complaints

The PMCPA has piloted a limitation period policy since 1 June 2025 as an application of the overriding objective to ensure that cases are dealt with fairly and justly (Paragraph 1.10). We now intend to formalise it in the C&P.

The rationale for a limitation period is because of:

1. the risk that important contemporaneous complaints (particularly in relation to patient safety) will be delayed if PMCPA resources are allocated to ruling

on historical matters that may have limited, if any, ongoing importance to patients, the public or industry,

2. the importance of the overriding objective in Paragraph 1.10, and
3. the fact that many other regulators in the UK, and the equivalent self-regulatory bodies of the PMCPA in countries such as Spain and Germany, have limitation periods applicable to their complaints regimes.

The pilot limitation period policy has meant we have not been taking forward complaints about activities that took place, or materials that were last used, more than two years ago (or six months in the case of social media). We retained discretion throughout the pilot to take forward historical complaints in “exceptional circumstances” e.g. patient safety cases.

The rationale for the two-year period is that a complaint about an activity or material should reasonably be made to the PMCPA within two years of the activity taking place or the material having last been used. In relation to social media, we considered that this is a fast-paced medium in which posts/interactions tend to disappear from the newsfeed of users fairly quickly. We therefore considered six months to be a reasonable period in which someone should submit a complaint about social media content. In the case of inter-company dialogue (ICD), we would expect the ICD to have started within the applicable two-year/six-month time period, although it does not necessarily have to be escalated to the PMCPA within this period.

The pilot has been extended until the end of this C&P update process and we are keen to receive feedback about it as part of this public consultation.

It is not possible to know how many complaints may not have been submitted to us due to a potential complainant believing that the pilot policy would apply to their complaint. However, the pilot data that we do have so far is that we have used the policy to not proceed three complaints since June 2025. The decision to not proceed the complaint in one of these cases was appealed by a complainant, however, the independent referee upheld the CPM’s decision. In relation to all three complaints to which the pilot policy was applied, the Appeal Board received details of each complaint and the action taken, including the CPM’s rationale for not proceeding the complaint. This was part of the Appeal Board’s oversight role in relation to the application of the policy. If the Appeal Board had considered that the CPM had made an error, it could have requested that the complaint proceed.

One change we have made as a result of the pilot is that our proposed draft of the limitation period, for inclusion in the C&P, clarifies that the shorter period of six months that applies to social media complaints only applies to the company personnel’s *personal* accounts. This is to distinguish that type of social media activity from company-orchestrated social media activity e.g. via a company’s corporate account, or by its senior executives, who are communicating on behalf of the company and whose posts are more akin to an extension of the company's corporate social media account. Therefore such 'corporate posts' would be subject to the longer two-year period.

The Appeal Board will maintain its supervisory role in relation to the application of the limitation period through the existing Paragraph 1.5, which includes that 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. This approach has been applied throughout the pilot period.

We also intend to issue guidance and Q&A to further explain this policy. For example, this would cover the fact that engaging in ICD would 'stop the clock' such that any delays due to that process would not mean a complaint fell outside the limitation period.

3. Companies joining and leaving self-regulation

Currently, companies can leave self-regulation with no commitment to the PMCPA in relation to ongoing Code complaints. The transition from being part of the self-regulatory framework to statutory regulation does not allow a company to avoid scrutiny, but it may delay any regulatory action and oversight in relation to complaints.

In some cases, the PMCPA has been unable to recuperate any costs of Panel time spent on a case where a company has left self-regulation during the consideration of a complaint.

We propose that companies remain liable for Code breaches and related administrative charges for all complaints that were received while a company was within the PMCPA's jurisdiction. Setting out a company's liability within the C&P gives us the enforcement tools to ensure there is no regulatory delay in assessing potential breaches of the Code and/or UK law. In addition, the PMCPA can recuperate costs for any time spent adjudicating on complaints initiated before notice to leave self-regulation was received. It may also act as a deterrent for companies leaving self-regulation simply because they are unhappy with a decision of the Panel or Appeal Board. It is also in the interests of the complainant to ensure that their complaint is dealt with fairly in line with the overriding objective to resolve complaints and ensure company accountability.

We are also working to encourage more companies to accept the high standards of self-regulation and the PMCPA's jurisdiction. Before accepting the PMCPA's jurisdiction, companies are only subject to UK law. We acknowledge that for some companies, joining the self-regulatory framework is a step in improving compliance and it could be seen as unfair to retrospectively hold companies to the high standards of the Code during a period when they were not subject to those requirements. For that reason, where we receive a complaint which relates to an activity prior to a company accepting the PMCPA's jurisdiction, the complaint will only be assessed against those Code clauses which mirror UK law.

This is alongside other planned work to enhance support and guidance to new members (ABPI members and non-member companies that accept PMCPA jurisdiction) through tailored training and guidance.

Next steps

This public consultation is open for seven weeks: from 3 August 2026 until 21 September 2026.

Once we have reviewed and reflected on the results from the consultation and, subject to approval from the Appeal Board, ABPI Board and formal approval at an ABPI General Meeting, we intend to move to implementation of a new C&P in early 2027. The intention is that the new C&P will supersede the version within the 2024 Code and will be provided electronically only and published on our website. The 2024 Code will not be withdrawn. However, when the Code is next updated, the C&P will be entirely removed so that the ABPI Code and the C&P become two separate publications.

Proposed amendments to the wording of the Constitution and Procedure

PROPOSAL #	TOPIC	PROPOSED AMENDMENT WORDING	REASON FOR THE AMENDMENT
Scope of the complaints procedure			
1	Limitation period (Paragraph 5.4)	After Paragraph 5.4, insert the following new Paragraph: “**Limitation period** 5.4A If a complaint is received more than two years since: • the activity complained about took place, or • the material complained about was last used or appeared, the complaint will not proceed. For complaints about the personal social media activity of company personnel, the above limitation period is six months from the date of the social media activity. If, in the view of the case preparation manager, the complaint shows that a company may have contravened the Code, but the limitation period applies, the complaint will not proceed and the	See detailed explanation in the “A limitation period for complaints” section of the covering document above. For complaints not proceeding, the appeal route to an independent referee already described in Paragraph 5.5 would apply.

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		complainant will be so advised. The case preparation manager must send the complaint to the company for it to consider any corrective action but the company is not required to respond to the PMCPA. In exceptional circumstances, such as patient safety concerns, the case preparation manager may decide that the complaint should proceed."	
Operation of the complaints procedure			
2	Panel observation of Appeal Board proceedings (Paragraph 4.3)	Amend the first sentence of the second paragraph of Paragraph 4.3 as follows: "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~~."	Members of the Authority observe the Appeal Board from a separate room and are required to view the recording and transcript of the Appeal Board meeting to assist the Chair in the preparation of the minutes. The purpose of their attendance is to understand as observers the work of the Appeal Board. In addition, 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 as already explained in Paragraph 4.3.
3	Companies joining self-regulation (Paragraph 5.1)	After Paragraph 5.1, insert the following new Paragraph: "5.1A Companies that join self-regulation will only be held accountable	See detailed explanation in the "Companies joining and leaving self-regulation" section of the covering document above.

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		under the Code for activities that occurred prior to accepting the jurisdiction of the PMCPA where that activity is covered by UK law and where the Code clause mirrors the Human Medicines Regulations 2012.”	
4	Delay or amalgamation (Paragraph 5.2)	Amend the final sentence of Paragraph 5.2 as follows: “When a complaint is delayed or amalgamated, as above, the complainant may appeal against the delay or amalgamation to the Chief Executive whose decision is final ~~an independent referee~~.	A decision about delay or amalgamation relates to *how* a complaint proceeds. Engaging an independent referee may cause delays in progressing a complaint. The PMCPA believes that, when deciding on a procedural matter such as whether to amalgamate or delay a complaint, the Chief Executive should make this decision if the complainant disagrees. In contrast, we consider that decisions on whether a complaint should proceed at all (under Paragraph 5.5), should rightly remain referable to an independent referee.
5	Applicable clauses (Paragraph 5.8)	Amend the second paragraph of Paragraph 5.8 as follows: “If the complainant has cited a clause but, in the view of the case preparation manager, the complaint does not show	Some complainants cite clauses that are duplicate in nature (e.g. Clause 26.1 and Clause 3.2) or cite the same clause several times for the same material/activity (e.g. Clause 2), which may be unnecessary and/or disproportionate.

		that the company may have breached that clause, the clause will be removed from the complaint. If the case preparation manager considers that a complainant has cited a clause which is duplicative in nature, they may remove it. The complainant will be informed, with written reasons given. ~~For cases going through the full complaints procedure, i~~ 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 the Chief Executive to consider. The Chief Executive's decision is final. ~~the clause will be included and provided to the company to provide a response.~~"	This amendment allows the CPM to limit the number of duplicate clauses that are referred to the Panel and mirrors the escalation route proposed in Paragraph 6.
6	Abridged complaints procedure (Paragraph 6)	Amend Paragraph 6.1 as follows: "6.1 The case preparation manager may determine, at any point before a complaint is referred to the Panel, that the abridged complaints procedure will be followed in relation to a complaint or voluntary admission where, in the view of the case preparation manager: ~~(i) the allegations fall within the Authority's approved list for use of the~~	See detailed explanation in the "An expanded abridged complaints procedure" section of the covering document above.

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		~~abridged procedure (published on the PMCPA website) and~~ (i) it appears that the central facts will not be disputed, and (ii) it is likely ~~in the case preparation manager's view~~ that there has been a breach of the Code, but it is unlikely to be a breach of Clause 2. The case preparation manager will notify the parties that the complaint is being handled through the abridged complaints procedure."	
7	Abridged complaints procedure (Paragraph 6)	Amend the second sentence of Paragraph 6.4 as follows: "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~~ the Chief Executive to consider. The Chief Executive's decision is final."	See detailed explanation in the "An expanded abridged complaints procedure" section of the covering document above.
8	Companies that leave self-regulation (Paragraph 18)	After Paragraph 18.7 insert the following new paragraph: "18.8 A company that gives notice of its intention to leave self-regulation and the jurisdiction of the PMCPA, will remain liable for Code breaches, related	See detailed explanation in the "Companies joining and leaving self-regulation" section of the covering document above.

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		administrative charges and any other costs associated with sanctions, for any complaint the PMCPA receives before such notice was given. If the PMCPA receives a new complaint about a company that has given such notice, and the matter is covered by UK law: • the complainant will be advised to contact the Medicines and Healthcare products Regulatory Agency (if the complainant is contactable), or • the complaint will be forwarded to the Medicines and Healthcare products Regulatory Agency (if the complainant is non-contactable)."	
Matters not related to the complaints procedure			
9	Scrutiny (Paragraph 19.1)	Amend the first sentence of Paragraph 19.1 as follows: "The Authority may arrange for the scrutiny of samples of ~~advertisements, detail aids, leavepieces, other promotional items and meetings~~ materials and activities on a continuing	Part of the PMCPA's future strategic plan is being a more proactive regulator and scrutinising companies' materials/activities outside of the complaints procedure. This amendment will allow the PMCPA to future-proof how it approaches scrutiny by ensuring a broader range of materials and activities can be requested.

		basis in relation to the requirements of the Code.”	
Minor amendments/clarifications			
10	Conflicts (Paragraph 1.6)	Amend Paragraph 1.6 as follows: “A Director is authorised to act on behalf of the Chief Executive if the Chief Executive is absent or conflicted. A Manager is authorised to act on behalf of the Chief Executive if the Chief Executive and Directors are absent or conflicted.”	The additional wording will ensure that the PMCPA has the flexibility to assign responsibility between staff when there are conflicts; not just absences.
11	Updates required because of the unreasonable behaviour policy (Paragraph 1.11)	Amend the first paragraph of Paragraph 1.11 as follows: “‘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; (iv) setting out changes to the way the PMCPA communicates with parties as a result of their behaviour; or (~~i~~v) providing	The PMCPA’s ‘Managing persistent contact and unreasonable behaviour policy’ relies on existing Paragraphs 1.11 and 1.13. Although the examples (i) to (iv) in 1.11 are not exhaustive, adding this additional example about behaviour aligns with the policy.

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		dictation support to an individual who is unable to submit a complaint in writing.”	
12	Procedural error (Paragraph 1.12)	Amend the first paragraph of Paragraph 1.12 as follows: “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 an error in complying with the procedure set out in this Constitution for dealing with cases (a ‘procedural error’). For cases that are not appealed, the Chief Executive may give such a direction at any time before the case report is published.”	This amendment ensures that decisions can be set aside for procedural error in cases that are not appealed, as well as those that are.
13	Procedural error (Paragraph 1.12)	Amend the final paragraph of Paragraph 1.12 as follows: “Decisions related to set aside will be referred to an independent referee at the request of any party.”	Paragraph 1.12 is currently silent on whether there is any further right of appeal about a decision *not* to set aside a decision. This amendment clarifies that there is.
14	Procedural error (Paragraph 1.12)	After the final paragraph of Paragraph 1.12, insert the following new paragraph:	This amendment clarifies that, where there has been an exercise of discretion, that does not amount to a procedural error.

		"Decisions that are a matter of discretion are not procedural errors."	For example, a procedural error would cover situations where a complainant clearly alleges a "company has failed to maintain high standards" but the CPM does not raise Clause 5.1. In contrast, if the complainant does not use those words but just makes a complaint raising other clauses, it will be a matter of discretion for the CPM as to whether they raise Clause 5.1 or not. That decision could not be challenged as a procedural error.
15	Case preparation manager (Paragraph 5.2)	Amend the third bullet point of Paragraph 5.2 as follows: • "may delay processing a complaint if the facts are essentially similar to those before another UK regulator or external forum, such as an employment tribunal; this does not apply to matters before the Medicines and Healthcare products Regulatory Agency"	The amendment will ensure that the CPM has the option to delay a matter currently being investigated by another UK regulatory authority if the facts are essentially similar.
16	Abridged complaints procedure (Paragraph 9.5)	Amend Paragraph 9.5 as follows: "Administrative charges equal to one half of the cost of the~~a~~ complaint going through the full complaints procedure will be payable by the respondent company."	This is a typographical correction, to align with the wording in Paragraph 18.5.

17	Appeal process (Paragraph 12)	After Paragraph 12.8 insert the following new paragraph: "12.9 The determinations of the Appeal Board are final."	This clarifies that Appeal Board decisions are final.
18	Audit process (Paragraphs 12.4 and 13.4)	Amend the first sentence of Paragraph 12.4 as follows: "Where the Appeal Board rules that there is a breach of the Code, it may require an audit, or a specific scope 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." Amend the second bullet point of Paragraph 13.4 as follows: • "require an audit, or a specific scope audit, of the company's procedures in relation to the Code…"	Current wording of this paragraph could imply that a 'full audit' must be done first before a specific scope audit, but it is preferable if the Appeal Board has the flexibility to request a specific scope audit first, if it considers that appropriate.
19	Publishing an interim case report	Amend the final sentence of the first paragraph of Paragraph 15.6 as follows:	This amendment would allow the PMCPA to publish an interim case report in wider circumstances than just where there is an audit. This would include other reasons for a delay in publishing the final case report, such as

	(Paragraph 15.6)	"The Authority's website also carries interim case reports in respect of cases where publication of the final report is delayed ~~because either the Appeal Board or the ABPI Board has required an audit of the respondent company's procedures in relation to the Code~~ due to sanctions imposed by the Appeal Board or the ABPI Board."	where other ongoing sanctions from Paragraphs 12.7 and 13.4 have been imposed.
20	Sanctions – Advertisements (Paragraph 15.7)	Amend the first paragraph of Paragraph 15.7 as follows: "Following publication of the relevant case reports, the Authority will advertise in the [most relevant publications to be inserted post-consultation]~~medical, pharmaceutical and nursing press~~ brief details of cases in which companies were ruled in breach of Clause 2 of the Code, were required to issue a corrective statement or were the subject of a public reprimand. A press release ~~is also~~ will be issued to the media and other stakeholders. Such advertisements also appear on the Authority's website. The companies concerned must contribute to the cost of the press advertisements."	There is a need to modernise to the digital age in relation to where our Clause 2/public reprimand/corrective statement adverts are published e.g. the Pharmaceutical Journal no longer has a printed version and we also welcome views on whether publishing in the printed version of the BMJ and Nursing Standard is the best way to reach the target audience.

21	Clause 2 advertisements (Paragraph 15.7)	Amend the first sentence of the second paragraph of Paragraph 15.7 as follows: "~~A copy~~ The text of the advertisement must be sent to the respondent company prior to publication."	Update for logistical reasons to say that the company will be sent the final text of the advertisement rather than the final typeset version.