



PMCPA Policy

Pilot limitation period policy in relation to historical complaints

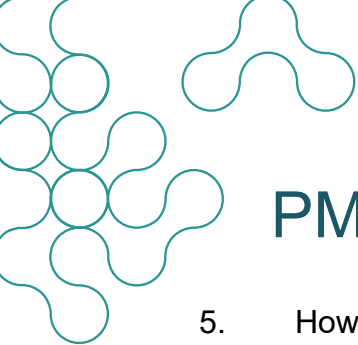
This policy was developed by the PMCPA in consultation with the MHRA (Medicines and Healthcare products Regulatory Agency).

Introduction

1. The PMCPA adopted this pilot limitation period policy, which came into force on 1 June 2025 and was due to expire on 30 June 2026. With approval from the Code of Practice Appeal Board, the PMCPA has decided to extend the policy until the outcome of a public consultation on proposed amendments to the PMCPA Constitution and Procedure (“**C&P**”). In the first 13 months of the pilot, only a small number of complaints were received that met the criteria for the pilot. The results of a public consultation are required before a decision is made on whether to adopt the policy permanently in the C&P and, if so, whether the policy should be amended in any way, based on the data and feedback gathered during the pilot and public consultation. This decision will be made following the public consultation later this year.
2. This policy does not amount to a formal amendment to the C&P. A PMCPA case preparation manager has existing discretion to determine that a case should not proceed under Paragraph 5 of the C&P. This is a temporary change to the PMCPA’s *application* of the C&P, having regard to the overriding objective in Paragraph 1.10 of the C&P. This policy has been prepared in consultation with the Code of Practice Appeal Board and the Medicines and Healthcare products Regulatory Agency.

Pilot limitation period

3. The PMCPA will not proceed with a complaint if it considers that the complaint has been received more than two years since:
 - a. the activity complained about took place, or
 - b. the material complained about was last used or appeared.
4. For complaints relating to social media, the limitation period will be six months, i.e. where the social media activity that is the subject of the complaint was dated more than six months before the date the PMCPA receives the complaint. This shorter six-month period has been chosen because social media posts have a more time-limited impact than other types of material.



PMCPA Policy

5. However, the two-year and six-month limitation periods are subject to an important exception: a complaint that would otherwise not be proceeded because of these limitation periods can still proceed if, in the case preparation manager's view, there are exceptional circumstances. Exceptional circumstances could be a reason which means that the application of the overriding objective points towards the case being proceeded with. An example is a complaint about an activity or material which may prejudice patient safety, or where the allegation may significantly reduce confidence in the pharmaceutical industry. The decision about what are exceptional circumstances is a matter of discretion for the case preparation manager applying this policy together with the C&P. The case preparation manager must attach greater weight to potential patient safety concerns that still exist at the time the complaint is made to the PMCPA.

Rationale for the policy

6. The PMCPA has decided to implement this policy because of:
- the high number of complaints that the PMCPA continues to receive each month,
 - 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, and
 - the importance of the overriding objective in Paragraph 1.10 of the C&P, as set out below:

"1.10 The overriding objective of this 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; and*



PMCPA Policy

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

Application of the policy

7. This policy applies to complaints received after 1 June 2025.
8. When the PMCPA's case preparation manager is considering a new complaint under Paragraph 5 of the C&P, they must apply this policy in relation to the material or activity complained about.
9. The case preparation manager will require evidence from the complainant that any social media activity complained about has been disseminated, or appeared in a social media newsfeed, within the last six months.
10. A case preparation manager's decision to not proceed with a complaint is subject to the right of the complainant to request a review of that decision by an independent referee (Paragraph 5.5 of the C&P).

Monitoring of the policy

11. If the case preparation manager decides that a complaint is within the scope of the ABPI Code, but that it should not proceed because of this limitation period policy, they must, nevertheless, send the complaint to the company involved. This is for the company's awareness and so it can take any appropriate action in the spirit of self-regulation.
12. The PMCPA will continue to provide the Appeal Board with details of all complaints received and details of the action taken upon them as required by Paragraph 13.1 of the C&P. This will enable the Appeal Board to provide oversight of the application of this policy. If the Appeal Board considers that the case preparation manager has made an error, e.g. by not proceeding an historical complaint where the Appeal Board considers there is a patient safety concern, the Appeal Board can request that the complaint should proceed.
13. The PMCPA will retain an internal record of complaints which are not proceeded where the case preparation manager has relied on this policy. The PMCPA will monitor the number of complaints and identify any patterns in relation to the activity and/or the company. The PMCPA will exercise its powers under Paragraph 19 of the C&P to undertake scrutiny if, in the view of the Chief Executive, this monitoring of non-proceeded cases warrants the use of such powers.