



CHANGES TO THE PMCPA CONSTITUTION AND PROCEDURE

Updates to the PMCPA Constitution and Procedure

Background

In 2022, the ABPI and PMCPA commissioned an assessment to review and identify opportunities to improve the existing system of self-regulation as covered by the ABPI Code of Practice for the Pharmaceutical Industry and administered by the PMCPA. The review considered whether the current system

- (a) is fit for purpose now and in the future;
- (b) is seen as robust when compared with other self-regulatory models and stands up to external scrutiny, particularly in light of the potential implications for patient safety of non-compliant activities and materials;
- (c) has (and will continue to have) the confidence of stakeholders and in particular:
 - (i) the MHRA which agrees to the PMCPA adjudicating upon complaints involving companies that are ABPI members or have otherwise agreed to abide by the Code and accept the jurisdiction of the PMCPA; and
 - (ii) the pharmaceutical industry, in order to maintain high levels of industry engagement and compliance with the Code.

The review included consulting the MHRA, ABPI Board companies as well as the ABPI and PMCPA. The outcomes of the review were used as the basis for the updates to the Constitution and Procedure with the following priorities;

1. Further embedding the operational independence of the PMCPA into the structure of the ABPI/PMCPA model in line with the regulatory principle of transparency and the public law principles of procedural fairness and lack of bias.
2. Adopting a more proportionate approach to the resolution of certain complaints.
3. Making a number of other changes to the PMCPA Constitution and Procedure, governance arrangements and administration of the ABPI/PMCPA model to improve the robustness (including from a public law perspective) and efficiency of the complaints procedure.

The updated Constitution and Procedure was developed by the PMCPA with input from the ABPI Board and the Code of Practice Appeal Board ahead of public consultation from December 2023 to February 2024. The Constitution and Procedure was updated further following public consultation, taking into account the feedback received during consultation as well as further engagement with the ABPI Board and Appeal Board.

Summary of main changes to the Constitution and Procedure

When reviewing the updated Constitution and Procedure, the following should be borne in mind:

- Grammatical changes have been made across the document to improve readability.
- There have been changes to the ordering and flow of the document to make it easier to understand.
- Due to a change in job titles, all references to 'Director' of the PMCPA have been changed to 'Chief Executive'. The Deputy Director role will be re-categorised as a Director role and there will be more than one.

To aid navigation of the updated Constitution and Procedure, the following text **summarises the main changes** between the Constitution and Procedure in the 2021 and 2024 Codes, but is not an exhaustive list.

Not all differences to the version that was publicly consulted upon have been highlighted below. Please review in detail the full Constitution and Procedure in the new 2024 Code. This document does not replace a detailed study of the new 2024 Code.

Note that where changes made are covered by the administrative changes described above, they are not specifically mentioned. In addition, the paragraph numbers referred to below are those of the 2024 Constitution and Procedure.

STRUCTURE AND RESPONSIBILITIES

Paragraph 1: Prescription Medicines Code of Practice Authority

- Detail added regarding how senior leaders of the PMPCA (Chief Executive and Directors) are appointed. The text 'these vacancies should be externally advertised' was added following consultation feedback.
- Detail added regarding the Appeal Board's supervisory role in relation to the operation of the complaints procedure and how concerns are escalated.
- Detail added in relation to the Chief Executive's reporting line, objective setting and how performance is measured.
- New conflicts of interest provisions added in relation to how individuals involved in the complaints procedure declare conflicts of interest. This includes members of the Authority, co-optees, experts and independent referees.
- Clarified that the Chief Executive may consult the Chair of the Appeal Board or the Appeal Board upon any matter concerning the Code or its administration. The 2021 Code specified only the Appeal Board.
- Addition of a new 'overriding objective' of the Constitution and Procedure to ensure that cases are dealt with fairly and justly while protecting patient safety. This includes dealing with each case in ways which are proportionate to the importance of the case and the complexity of the issues.
- New provisions for 'case management directions', 'set aside for procedural error' and 'non-compliance' to ensure the complaints process is being administered fairly and justly and to clarify the procedure followed for different scenarios.

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 PMCPA website (added following consultation feedback).

Paragraph 3: Code of Practice Appeal Board – Constitution

- Changes in relation to the independent members of the Appeal Board to add a check of credentials and history as held on the relevant regulator website rather than consulting with trade associations/royal colleges as part of the reference checking procedure.
- Two changes to the membership of the Appeal Board. Firstly, an increase from one to two independent registered pharmacists rather than specifically requiring a member from an independent body involved in providing information on medicines (amended following consultation feedback). The second change is to amend the qualification requirements from an independent registered nurse prescriber to an independent registered senior nurse practitioner of minimum band 7 or equivalent.
- Detail added in relation to Chair's re-appointment to introduce a limit on the number of times the Chair may be re-appointed (this amendment was not in the version that went out to public consultation).
- Detail added in relation to how industry members of the Appeal Board are appointed and clarification that they are not representatives of their company when performing duties as a member of the Appeal Board (added following consultation feedback).

Paragraph 4: Code of Practice Appeal Board – Procedure

- Details added in relation to the purpose of members of the Authority and others being present during Appeal Board meetings, and that meetings may be recorded for the purpose of ensuring accurate minutes.

COMPLAINTS PROCEDURE

Paragraph 5: Actions on Complaints

- Significant restructuring to improve flow and readability.
- Details added in relation to complaints not proceeding.
- Provision added for the case preparation manager to remove a clause raised by the complainant if the complaint does not show that the company may have breached that clause with safeguards to allow the complainant to challenge that decision.
- Text added to strongly encourage complainants to 1) be contactable to the Authority and 2) attempt to resolve complaints using the company's own internal/external whistleblowing or dispute resolution procedures. Clarification that neither is mandatory.
- Added text that companies are encouraged to make voluntary admissions (this amendment was not in the version that went out to public consultation).
- Increased time for a respondent company to submit its response from ten to fifteen working days to allow sufficient time for companies to submit a complete response.

Paragraph 6: Abridged Complaints Procedure

- Introduction of a new abridged complaints procedure in relation to complaints and voluntary admissions. The new abridged procedure introduces an additional way for the Authority to assess certain complaints in an expedited way.
- Changes were made post consultation to remove reference to an approved 'clause' list and clarify that the procedure will be used where the allegations fall within the Authority's approved list for use of the abridged procedure and it appears the central facts will not be disputed. The list will be published on the PMCPA website.
- Further details about the undertaking to be provided by respondent companies (this detail was not in the version that went out to public consultation).

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 9 - Abridged Complaints Procedure – Rulings and Sanctions

- New paragraph detailing the abridged complaints procedure rulings and sanctions.
- Changes to incorporate consultation and Appeal Board feedback and clarify that, unlike for cases going through the full 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 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

- Clarification of Appeal Board sanctions to add a reference to a 'specific scope audit'; a requirement that the company provides updates regarding implementation of the company's commitment to improve; and inviting a senior company representative to a meeting to report on progress or to provide written confirmation that appropriate action has been taken.
- Addition of text that 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. This text has been added since public consultation following Appeal Board feedback that it should be made clear that this determination will happen at the same Appeal Board meeting and not at the following meeting when the case report is being reviewed by the Appeal Board.

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 in relation to procedure when Appeal Board reports a company to the ABPI Board.
- Addition of text that the ABPI Board must ratify any recommendation made by the Appeal Board (that the ABPI Board either expel or suspend a company from ABPI membership or remove it from the list of non members which agreed to comply with the Code) unless there was an error in formulating its recommendation or the recommendation is manifestly disproportionate.

Paragraph 15 - Case Reports

- Procedure in relation to Clause 2/public reprimand/press release/corrective statement advertisements have been updated to reflect current practice and to clarify that requested amendments to advertisements by companies that cannot be agreed with the Chief Executive will be referred to the Chair of the Appeal Board for their decision which is final.

GENERAL PROVISIONS

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

- No 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, or for a complainant to withdraw their appeal at any time (this amendment was not in the version that went out to public consultation).

Paragraph 18 - Code of Practice Levy and Charges

- New text added in relation to the abridged complaints procedure which states that administrative charges are equal to one half of the cost of the complaint going through the full 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 and 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 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.