

## PMCPA LIST FOR USE OF THE ABRIDGED COMPLAINTS PROCEDURE

Paragraph 6.1 of the 2024 Constitution and Procedure includes that 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 (this document, 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 PMCPA list for use of the abridged complaints procedure is provided in the table below and includes the types of allegations for which the abridged complaints procedure might be applied, with non-exhaustive clause examples. The list is designed to be read in conjunction with the 2024 ABPI Code.

Post implementation, the list and use of the abridged complaints procedure will be subject to regular review and oversight from the Appeal Board.

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.
Quality of Company Materials  (e.g. use of 'new' beyond 12 months to describe a medicine, incorrectly coloured black triangle, failure to include clear references to published studies, failure to include the date on which the promotional material was created or last revised.)	Clauses 5.6, 6.5, 12.3,12.5, 12.6, 12.7, 14.2, 15.3  Note: Breaches in relation to the prominence of a statement may be suitable for the abridged procedure. A lack of statement altogether may be deemed unsuitable for the abridged procedure, depending on the particulars of the case.  With regard to the black triangle, depending on the incorrect colour, it may or may not be deemed suitable for the abridged procedure. For example, a dark grey that is not quite black may be deemed suitable for the abridged procedure but a colour that may cause confusion to the reader e.g. orange, may be unsuitable for the abridged procedure.
Breaches of Administrative Code Requirements (e.g. delay in notifying PMCPA of nominated signatories, incorrect certificate wording)	Clauses 8.4, 8.5  Note: breaches in relation to certificate wording may be considered suitable for the abridged procedure. Material that had gone past its two year certification date may pose a safety issue and therefore would unlikely be suitable for the
Governance over Abbreviated Advertisements (e.g. failure to meet size limitations, non- compliant distribution)	and therefore would unlikely be suitable for the abridged procedure.  Clauses 13.2, 13.3, 13.7, 13.9  See note above regarding the black triangle
Conduct of Company Employees, Including Representatives (e.g. failure to respect a health professional's request to be removed from a mailing list,	Clauses 5.2, 9.4, 15.5, 16.4  Note: Inclusion of new Clause 5.2 (all company personnel must maintain a high standard of

failure to meet the representative examination timelines)	ethical conduct in the discharge of their duties and comply with all relevant requirements of the Code) may be linked to other breaches within the abridged complaints procedure.
Events/Meetings Organised or Sponsored by Companies (e.g. distributing pens from exhibition stands, failure to include a sufficiently prominent declaration of sponsorship on material relating to an event/meeting)	Clauses 10.5, 10.6, 10.7, 10.10  See note above about prominence of statement versus a lack of statement.
Isolated Incidences of Errors with Disclosure of Transfers of Value	Clauses 28.1, 28.6, 29.1, 30.1
(e.g. a small number of missing or inaccurate disclosures by a company or a missing methodological note. For guidance, a small number would be less than 10 payments in need of correcting with total value of <£50k)	
Failure to Disclose Transfers of Value on Time, Publish for the Required Period or have a Disclosure UK gateway link.	Clauses 29.1, 30.1, 31.1, 31.2