MEMORANDUM OF UNDERSTANDING

BETWEEN

(1) THE ASSOCIATION OF THE BRITISH PHARMACEUTICAL INDUSTRY
(2) THE PRESCRIPTION MEDICINES CODE OF PRACTICE AUTHORITY
(3) THE HEALTH RESEARCH AUTHORITY

Purpose

1. The purpose of this Memorandum of Understanding ("**MOU**") is to set out the regulatory responsibility between the Prescription Medicines Code of Practice Authority ("**PMCPA**") and the Health Research Authority ("**HRA**") in relation to the regulation of UK participant-facing clinical trial recruitment materials.

2. Participant-facing clinical trial recruitment materials are materials aimed at individuals who may participate as a subject in a clinical trial. Examples of such materials include:

    a. posters and flyers
    b. advertisements on social media, websites, radio or television,
    c. participant information sheets, and
    d. informed consent documents.

3. These types of material are referred to collectively as clinical trial recruitment materials (**"CTRM"**) in this MOU.

The Parties

4. This MOU is between the three parties listed below, who are referred to collectively in this MOU as "**the Parties**".

(1) The Association of the British Pharmaceutical Industry

5. The Association of the British Pharmaceutical Industry ("**ABPI**") is the trade association for the UK pharmaceutical industry. The PMCPA is a division of the ABPI and therefore it is appropriate for the ABPI to also be a party to this MOU.

(2) The Prescription Medicines Code of Practice Authority

6. The PMCPA is the self-regulatory body which administers the ABPI Code of Practice for the Pharmaceutical Industry ("**the Code**"). The Code reflects and extends beyond the relevant UK law.

7. The PMCPA is an operationally independent regulator within the ABPI. The PMCPA administers the complaints procedure under which the materials and activities of pharmaceutical companies are considered in relation to the requirements of the Code.

8. Complaints about pharmaceutical companies that are members of the ABPI, or non-members that have formally agreed to abide by the Code and accept the jurisdiction of the PMCPA, may be within the scope of the PMCPA's complaints procedure. Complaints about other pharmaceutical companies will be referred to the Medicines and Healthcare products Regulatory Agency (**MHRA**) if the matter being complained about is covered by UK law.

9. In its complaints procedure role, the PMCPA is not an investigatory body. The PMCPA:

    a. assesses the complaints it receives,

    b. invites a response to the complaint from the relevant pharmaceutical company if it appears there may have been a breach of the Code, and

    c. refers the complaint to the Code of Practice Panel (if there is a case to answer), and the Panel will issue a ruling on whether the complaint amounts to a breach of the Code.

10. When making any procedural or discretionary decision (including decisions applying this MOU), the PMCPA must act in a way most likely to further the 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. Dealing with cases fairly and justly includes:

    a. dealing with each case in ways which are proportionate to the importance of the case and the complexity of the issues;
    b. avoiding unnecessary formality and adopting flexibility in the proceedings where appropriate;

c. ensuring, so far as practicable, that the parties are able to participate fully in the proceedings; and
d. avoiding delay to the case in hand and other cases, so far as compatible with proper consideration of the issues.

(3) The Health Research Authority

11. The HRA is an executive non-departmental public body, sponsored by the Department of Health and Social Care ("**DHSC**"). The HRA's mission is to make it easier to do research that people can trust.

12. Part of HRA's role, in collaboration with the Devolved Authorities, is to administer the NHS Research Ethics Committees ("**RECs**") that exist across the UK, to ensure that research proposals are ethically reviewed and approved. RECs exist to safeguard the rights, safety, dignity and well-being of research participants. RECs consist of up to 15 members, a third of whom are 'lay' - their main professional interest is not in a research area, nor are they a registered healthcare professional.

13. RECs review research proposals and give an opinion about whether the research is ethical. They also review the actual intended wording of the study and the specific participant-facing material, including CTRM. It is a REC's responsibility to determine whether public-facing information it is considering is ethical, including whether that information is non-promotional, non-coercive and not misleading as to the potential benefit.

14. RECs are entirely independent of research sponsors (the organisations responsible for the management and conduct of the research), funders and the researchers themselves.

15. The HRA also reviews generic recruitment materials (not related to any specific clinical trial) via its Generic Document Review Committee ("**GDRC**").

16. This MOU uses the term "**REC-approved**" to refer to CTRM that has been approved by a REC or by the GDRC.

Consultation with the MHRA

17. The MHRA is an Executive Agency of DHSC. The MHRA has responsibility for the UK's legal framework in relation to the regulation of medicines.

18. Although it is not a party to this MOU, the MHRA has been consulted on the principles outlined in this MOU.

19. The Parties acknowledge the statutory duties of the MHRA to ensure that advertising of medicinal products within the UK conforms with Part 14 of the Human Medicines Regulations 2012, and as the regulatory authority responsible for clinical trial approvals, oversight, and inspections under the Medicines for Human Use (Clinical Trials) Regulations 2004. The Parties may, where appropriate, consider referral to the MHRA.

Regulation of clinical trial recruitment materials

20. The Parties agree that CTRM that has been REC-approved will be regulated and adjudicated upon by the HRA; not the PMCPA. It is also important that questions and/or concerns about CTRM, including on social media, are directed to the HRA given its specific regulatory remit in this area.

21. Pharmaceutical companies must comply with all applicable laws, regulations and codes to which they are subject. However, the Parties do not consider it to be in the interests of the industry nor the wider public to have the same CTRM monitored by different regulators. The Parties agree that it is important to have this MOU to clarify which regulator will adjudicate upon this type of material. This will avoid duplication and allow industry and other stakeholders to be provided with consistent decisions and guidance in this area.

22. The Parties are satisfied that this MOU ensures that the regulation of CTRM remains robust whilst also safeguarding the regulatory independence of the PMCPA and the HRA.

23. Public-facing guidance and responses to queries in relation to CTRM will be provided by the HRA. Queries should be sent to approvals@hra.nhs.uk.

How complaints about clinical trial recruitment material will be handled by the PMCPA

24. The PMCPA commits to taking the action set out in this section of the MOU if it receives a complaint that relates to CTRM that is within the scope of the Code. Whether such a complaint should be classified as relating to CTRM or not is a matter of discretion for the PMCPA's case preparation manager. The PMCPA has previously ruled that certain CTRM (including participant information sheets and informed consent documents) is outside the scope of the Code.

25. When the PMCPA receives any complaint about a pharmaceutical company, a case preparation manager is appointed to consider the complaint in accordance with Paragraph 5 of the PMCPA's Constitution and Procedure (2024-abpi-code.pdf).

26. Paragraph 5.5 empowers the case preparation manager to decide that a matter should be dealt with by another UK authority.

27. If the case preparation manager decides that the complaint relates to CTRM that is within the scope of the Code, they must contact the relevant pharmaceutical company and ask it to confirm whether the material complained about has been REC-approved.

28. If a complaint deals partly with CTRM and partly with other matters, the case preparation manager must take all reasonable steps to divide the complaint; to allow the CTRM aspect of the complaint to be dealt with in accordance with this MOU. If the case preparation manager decides that the complaint cannot be divided in this way, they should consider the Constitution and Procedure and this MOU, to decide whether the PMCPA or the HRA is the more appropriate regulator to deal with the complaint.

Complaints about clinical trial recruitment material that has been REC-approved

29. If the pharmaceutical company confirms that the CTRM has been REC-approved, the case preparation manager must refer the complaint to the HRA via complaints@hra.nhs.uk.

30. If the complainant is contactable, the case preparation manager must:

a. inform them that the complaint should be dealt with by the HRA instead of the PMCPA, in accordance with Paragraph 5.5 of the PMCPA's Constitution and Procedure,

b. provide them with contact details for the HRA, and

c. inform them that the PMCPA's Constitution and Procedure does not provide a right of referral to an independent referee in relation to this decision.

31. If the complainant is non-contactable, the case preparation manager must send the HRA a copy of the complaint and the pharmaceutical company's confirmation that the CTRM has been REC-approved. The HRA must then consider the complaint in accordance with this MOU alongside the Research Ethics Committee Standard Operating Procedures and relevant HRA complaints policies.

32. The PMCPA case preparation manager must then close the case, meaning the PMCPA will not adjudicate on that specific complaint.

Complaints about clinical trial recruitment material that has not been REC-approved

33. If the pharmaceutical company confirms that the CTRM has not been REC-approved, the case preparation manager must consider the complaint in the usual way.

34. In accordance with Paragraph 5.13 of the PMCPA's Constitution and Procedure, when the pharmaceutical company's complete response is received, the case preparation manager must decide if there is a case for the pharmaceutical company to answer under the Code. If so, the complaint will be referred to the PMCPA Code of Practice Panel, who will issue a ruling on the matter.

35. If the case preparation manager decides not to refer the complaint to the Panel, on the basis that there is no case to answer under the Code, the complainant may:

a. disagree, in which case Paragraph 5.13 of the PMCPA's Constitution and Procedure requires that the complaint must be referred to the Panel, or

b. not disagree, in which case the case preparation manager must close the case, but refer the complaint to the HRA in case it wishes to take any action.

36. In all instances where non REC-approved CTRM has been available to participants, the case preparation manager will notify the HRA to allow the HRA to investigate the case in line with its Breach Policy and Procedure for corrective and preventative action. The PMCPA must keep HRA informed of any Panel ruling in relation to non REC-approved CTRM and the HRA must inform the PMCPA if the REC subsequently approves that CTRM. Neither Party's decision will have any effect on the other Party's regulatory independence.

37. If a complaint deals partly with REC-approved material and partly with material that has not been REC-approved, the case preparation manager must refer the complaint to the HRA.

How complaints about clinical trial recruitment material will be handled by the HRA

38. Where the HRA receives a complaint about CTRM, it must first consider whether the material complained about has been REC-approved.

39. If the material has been REC-approved, the HRA must consider the complaint in accordance with the Research Ethics Committee Standard Operating Procedures and relevant HRA complaints policies.

40. The HRA must also apply the above policies and procedures to any complaints referred to it by the PMCPA under this MOU. For cases where the material has been approved by a REC from a Devolved Administration, the HRA will liaise with the relevant appointing authority in the Devolved Administration as required.

41. If the material has not been REC-approved, the HRA must exercise its discretion to determine whether the complaint is more appropriately dealt with

by the HRA or if the complaint should be referred to the PMCPA. If the HRA refers the complaint to the PMCPA, the HRA will not adjudicate on that specific complaint however may take forward action in line with its Breach Policy and Procedure (as per paragraph 36 above).

42. The HRA may liaise with other third parties as required.

Co-operation between the Parties

43. The Parties must co-operate with each other to promote the efficient regulation of CTRM, without compromising their respective complaint procedures and regulatory independence.

44. The Parties agree to avoid unnecessary duplication by ensuring that a specific complaint in relation to CTRM is considered in accordance with the principles of this MOU, and adjudicated upon either by the PMCPA or the HRA, but not both. However, even if the PMCPA or the HRA does not adjudicate upon a complaint about a pharmaceutical company, they may still take any other action that they consider appropriate, in accordance with their powers.

Duration

45. This MOU enters into force on 1 February 2026 and remains in force until amended or revoked by the Parties.

Amendments or Termination

46. This MOU may be amended at any time by agreement between the Parties.

47. Any party may revoke this MOU by giving three month’s written notice to the other parties. If this MOU is to be revoked, the Parties must cooperate in relation to any transitional arrangements that are required for complaints that are already in the process of being adjudicated upon by the PMCPA or the HRA.

Confidentiality

48. The Parties understand and acknowledge that they may receive or become aware of Confidential Information of the other parties (which may include information where there is a duty of confidence to a third party) whether in the course of the performance of activities under this MOU or otherwise.

49. The Recipient shall treat the other Party's Confidential Information as confidential and safeguard it accordingly (which shall include complying with any protective markings on documents and instructions supplied by the other regarding such information). In particular, the Recipient shall not do anything that may place the other Party in breach of a duty of confidence owed to a third party.

50. If the Recipient is required by law to disclose Confidential Information of the other Party then it shall, as soon as reasonably practicable and to the extent permitted by law, first inform the other Party of the full circumstances of the matter and consult with the other Party about that disclosure.

51. The Recipient may disclose the Confidential Information of the other Party to the minimum number of its Representatives who need to know the same for the purpose explicitly contemplated by this MOU, provided that the Recipient:

    a. ensures that each such Representative complies with the confidentiality obligations of this MOU, and
    b. is responsible and liable for the actions and omissions of each Representative in relation to the Confidential Information as if they were the actions and omissions of the Recipient itself.

52. For these purposes, “Representatives” means, in relation to a Party, its: officers, employees, Appeal Board members, professional advisers and auditors, contractors and sub-contractors.

Data Protection

53. The Parties shall comply with all applicable data protection legislation in force in the United Kingdom.

54. Access to personal data shall be restricted to authorised personnel who require it for the performance of their duties and are subject to confidentiality obligations.

55. The Parties shall assist each other in responding to requests from data subjects exercising their rights under UK GDPR, including access, rectification, erasure, and objection.

56. In the event of a personal data breach, the affected Party shall notify the other Parties without undue delay and cooperate in managing the breach, including any required notifications to the Information Commissioner's Office.

57. Personal data shall be processed and retained in accordance with each organisation's applicable policies.

Dispute resolution

58. Any disputes arising under this MOU will be resolved through mutual consultation and negotiation between the Parties.

Legal status

59. This MOU is not intended to create any legally binding obligations between the Parties.

Signatures

(1) The Association of the British Pharmaceutical Industry
Russell Abberley
ABPI President
Date 28-Jan-2026 | 08:21 PST

DocuSigned by:
Russell Abberley
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(2) The Prescription Medicines Code of Practice Authority
Alex Fell
Chief Executive
Date 29-Jan-2026 | 12:57 GMT

DocuSigned by:
alex fell
44CBB67B4A824E9...

(3) The Health Research Authority
Stephen Tebbutt
Company Secretary
Date 28-Jan-2026 | 16:45 GMT

Signed by:
Stephen Tebbutt
20A401E13B484BC...