

For immediate release: 13 December 2023

ABPI and PMCPA consult on changes to the pharmaceutical industry code of practice

Proposals to update the 2021 ABPI Code of Practice for the pharmaceutical industry are being consulted on by the Association of the British Pharmaceutical Industry (ABPI) and the Prescription Medicines Code of Practice Authority (PMCPA) from today.

The ABPI Code embodies the pharmaceutical industry's commitment to operate in a professional, ethical, and transparent manner. It is the cornerstone of the UK system of industry self-regulation [1].

The ABPI Code regulates the promotion of prescription medicines to UK health professionals, industry interactions with health professionals, and the provision of information about prescription-only medicines to the public, including patients, journalists, and patient organisations. It includes and extends beyond UK law and is administered by the PMCPA.

The consultation starts today and will finish on 29 February. The [consultation contains proposals](#) [2] to change specific clauses in the Code, as well as changes to the Constitution and Procedure of the PMCPA.

Proposals to change specific clauses in the Code include:

- **Clause 5.1** has been updated to emphasise the requirements upon companies to ensure high standards are maintained, with the separation of expectations of the company and the requirements for company employees. The requirement to have robust policies and Standard Operating Procedures (SOPs) which include corporate standards, expectations and behaviours, and training have been brought into this clause. It also incorporates company responsibility for third-party providers and those retained by way of contract.
- **Clause 8.1** – has been updated to provide clarity around representative briefings – while not promotional material, they are associated with promotion and should be certified under this clause.
- **Clause 8.2** – has been updated to introduce more categories which can be certified by a non-medical signatory (previously referred to as an AQP signatory) while ensuring the training and validation/re-validation of those signatories is set to the same high standard as medical signatories.
- **Clause 10** – clarity has been provided to support companies in assessing the appropriateness of meetings and events including the requirement to include a written agreement where support is provided to individual health professionals and the requirement for an education needs assessment to be conducted.
- **Clause 12** – a complete review and update has been carried out on Clause 12 to include the use of QR codes to access Prescribing Information from printed materials –

this is also to future proof the clause. These changes were developed in full consultation with the Medicines and Healthcare products Regulatory Agency. (MHRA)

- **Clause 27 - supplementary information** – new supplementary information has been added to this clause to provide clarity on the different arrangements between companies and patient organisations.
- **Clause 28 – supplementary information** – updates include strengthening the requirement to seek a legal basis to disclose Transfers of Value (TOVs) to named individuals and clarity regarding operational timelines for disclosure in advance of the final June deadline for publication.
- **Clauses 29 & 30 – supplementary information** – updated to clarify the timelines for disclosing Transfers of Value (ToVs) made to patient organisations and the public, including patients and journalists, and the provision of links to this information via the Disclosure UK platform.
- **General** – Expired clauses from the 2021 Code, put in place to manage the transition from the 2019 Code have been removed from the 2024 Code with a cross reference back to the appropriate previous Code.

Summary of key changes to the Constitution and Procedure of the PMCPA

- Clarification of the nature and scope of the reporting relationship between the ABPI and the PMCPA Director, and between the Appeal Board and the PMCPA Director for the operations of the complaints process.
- The introduction of an ‘overriding objective’ provisions for ‘case management directions,’ and a new ‘set aside’ provision for procedural error. These are designed to clarify procedures to ensure the complaints process is being administered fairly and as intended.
- The introduction of an abridged complaints procedure that meets certain specified criteria. The abridged process will allow the PMCPA the flexibility to continue to assess more serious complaints in full and with the full range of potential sanctions available but deal with less serious infringements in a proportionate and resource-efficient manner.
- Clarification of the continued acceptance of anonymous complaints, while also encouraging complainants to raise issues with the company first, and to provide contact details to fully participate in the process.
- Clarification of the decision rights between the ABPI Board and the Appeal Board in relation to suspension and expulsion from membership of the ABPI. This makes clear that the ABPI Board must ratify the recommendation made by the Appeal Board unless there was an error made by the Appeal Board in formulating its recommendation, or the recommendation is manifestly disproportionate.
- In recognition of the increase in complexity of complaints over time, an extension in the time permitted for companies to provide a response to a complaint (increase to 15 working days rather than 10 working days), which allows companies more time to submit a robust response.
- Administrative charges paid by respondent companies for cases where a breach of the Code is ruled will be payable within 30 calendar days rather than 20 working days to simplify credit control.

Dr Amit Aggarwal, Executive Director of Medical Affairs at the ABPI said: “This consultation aims to tighten up and simplify some elements of the Code itself, while strengthening the powers of the PMCPA as a robust and efficient regulator.

“The use of QR codes on printed materials to access prescribing information is an example of the continuous process of modernising the Code, which will give healthcare professionals greater ease of reference to essential and up-to-date information for their work.

“Putting these proposals into action will help us make sure that industry continues to be governed by the strongest ethical framework.”

Alex Fell, Director of the PMCPA, said: “We are pleased to share these proposals for public consultation and encourage stakeholders to respond. The changes proposed to the ABPI Code include the modernisation of certain clauses, particularly for digital activities and strengthening code requirements in other areas.

“The proposed changes to the Constitution and Procedure are designed to strengthen and simplify how self-regulation operates including delivery of a robust, timely and proportionate complaints procedure.”

The consultation will run until 29 February 2024. Comments will then be considered by the PMCPA. The 2024 Code will be published in Q2 2024 to come into force three months after publication date. The current 2021 ABPI Code of Practice will remain in force until then.

Ends

Notes to Editors

[1] The current [ABPI Code of Practice is here](#). It is a condition of membership of the ABPI that pharmaceutical companies abide by the Code. In addition to the ABPI Member companies, around 100 additional pharmaceutical companies in the UK have signed up to self-regulation and are under the jurisdiction of [the PMCPA](#).

[2] The [consultation materials are here](#).

Media enquiries

ABPI Press Office, T: +44 (0)20 7747 7147 (24hrs), E: pressoffice@abpi.org.uk

About the Association of the British Pharmaceutical Industry (ABPI)

The ABPI exists to make the UK the best place in the world to research, develop and use new medicines and vaccines. We represent companies of all sizes who invest in discovering the medicines of the future.

Our members supply cutting edge treatments that improve and save the lives of millions of people. We work in partnership with Government and the NHS so patients can get new

treatments faster and the NHS can plan how much it spends on medicines.

Every day, we partner with organisations in the life sciences community and beyond to transform lives across the UK. www.abpi.org.uk

About the PMCPA

The Prescription Medicines Code of Practice Authority (PMCPA) is the self-regulatory body which administers the Association of the British Pharmaceutical Industry (ABPI) Code of Practice for the Pharmaceutical Industry, independently of the ABPI. It was established by the ABPI on 1 January 1993.