Guidelines on Company Procedures Relating to the 2024 ABPI Code of Practice for the Pharmaceutical Industry

These guidelines are intended to be read in conjunction with the 2024 ABPI Code and are not a substitute for a detailed study of the Code, including the supplementary information. The guidelines have been edited down from previous editions to remove text that repeats the wording in the Code clauses and supplementary information.

1. Introduction

It is important for companies to have policies and standard operating procedures (SOPs) to communicate corporate standards, expectations, and behaviour. These might be a mixture of global, regional and local SOPs. Company documents should support compliance, ensure consistency, manage risk, and provide a platform for continuous improvement. It should be clear and apparent to all staff which requirements are relevant to their role.

Companies' ABPI Code related policies and procedures should be in line with the Code requirements but of course companies are fully entitled to have policies and procedures that impose higher standards than the ABPI Code. The ABPI Code reflects and extends beyond relevant UK legislation and ensures that the ABPI meets its commitments to implement other codes, such as the IFPMA and EFPIA Codes.

These guidelines are regarded as good practice and should be adapted to fit in with the arrangements at any particular company. The ABPI Principles should also be reflected where appropriate. The PMCPA will not adjudicate on the ABPI Principles.

The Appeal Board may require an audit of the company's procedures in relation to the Code to be carried out by the PMCPA and, following that audit, decide whether to impose additional requirements on the company concerned to improve its procedures in relation to the Code. Audits form a critical part of self-regulation in the UK and are an effective method of supporting a company to bring its compliance programme to the expected standard.

The ABPI Board may request an audit of a company's procedures in relation to the Code to assist in deciding whether to suspend or expel a company from the ABPI, or to remove it from the list of non-member companies which have agreed to comply with the Code.

During such audits the PMCPA will review company culture as well as a company's policies and SOPs, and their implementation, including but not limited to those relating to the Code. A company's website may also be reviewed and should be up to date and accurate at all times. It is likely that an audit would also include a discussion about the company's implementation of the ABPI Principles.

The first section of the Code, Overarching Requirements, provides umbrella

requirements under which companies should work, for example, it includes the scope of the Code, definition of certain terms, obligations, responsibilities as well as quality standards. The subsequent four sections provide requirements by audience and the final section sets out the requirements for disclosure of transfers of value. It is important to ensure all relevant sections of the Code are referred to and complied with.

2. General advice

a) Compliance Programme

Companies should have a compliance programme which should cover, as a minimum, three main areas: prevention, detection and correction. A broad range of relevant staff, including those with roles covered by the various process and systems, should be involved in creating, developing and monitoring compliance programmes.

i. **Prevention**: as a minimum this involves having robust and comprehensive policies and procedures (SOPs) covering all aspects of the Code relevant to the company. Comprehensive, consistent, and accurate content is key to good procedural documentation and helps staff be confident and know what is expected of them. These should be signed off by senior management and held on record. Such documents should engage staff and must be easily accessible for staff.
Senior staff in the company should be accountable for the compliance programme. A compliance committee, which involves the general manager and other senior staff, is helpful to oversee and support the compliance programme. Training, including a means to ensure staff know what training applies to their role, ongoing education and individual validation should be provided for all Code related policies and SOPs with the appropriate documentation and retention. Training on policies and procedures should be part of companies' staff onboarding processes. There should be regular communications on the compliance programme. This should be supplemented with regular updates, including discussion forums to cultivate the appropriate compliance and ethical decision making culture in addition to reinforcing best practices, providing updates, changes to policies and procedures and learnings from cases.

   Documentation is key. Companies should have processes and systems which support the appropriate management of documentation, including retention, this is particularly important for all financial contributions made by companies whether made directly, indirectly, or in- kind.

ii. **Detection:** Companies are encouraged to develop a monitoring programme. This can help in the identification of risk areas, support quality reviews and determine where additional work may be required**.** Regular monitoring and reporting of the results to relevant staff to support continuous improvement is a way to demonstrate commitment to self- regulation. The Medicines and Healthcare products Regulatory Agency (MHRA) also considers that regular monitoring and acting on the outcomes can be helpful to companies.

   Companies should strongly encourage a speak up culture and ensure that staff are confident to speak up and encouraged to do so. In addition to informal conversations, access to confidential resources should be available and regularly communicated to staff including details of the company whistleblowing policy.

iii. **Correction**: When a compliance issue is identified (whether reported informally,

through a deviations management process, via a speak up line or through monitoring activity, etc.) it should be responded to quickly and thoroughly. Corrective and preventative actions should be developed, implemented, and tracked to confirm they have been effective and should, as far as possible, ensure similar issues do not happen in the future. The actions implemented should be documented and held on record.

b) Responding to complaints

If a complaint is received, from any source, companies must ensure that their investigation into the matter(s) is thorough and the response provided is comprehensive and accurate. Effective self-regulation relies on companies providing full and accurate information from the outset.

Each company must have a senior employee who is responsible for ensuring that it meets the requirements of the Code (Clause 3.7). Unless other formal arrangements have been made by a company, it will be assumed that the responsible person is the managing director or chief executive or equivalent.

If a complaint is made to the PMCPA, the Code of Practice Panel and the Appeal Board will make rulings based on the requirements of the Code and will not adjudicate on the ABPI Principles, although each might comment in this regard.

In the event of a company being found in breach of the Code, its procedures should ensure that relevant information about the matter is communicated internally to all appropriate members of staff. Procedures must be in place to ensure that activities, materials, items, etc. found to be in breach of the Code, and any similar activity, material, item, etc. in any format, are quickly stopped and/or taken out of circulation, not forgetting those stored electronically and/or in the hands of others, such as printers and agencies, or verbal claims which may be used by representatives. The procedure should cover how to recall, withdraw and suspend materials, items, etc. including the timelines for each. It is important for the reputation of the industry that companies comply with undertakings. Inadequate action leading to a breach of undertaking is likely to be in breach of Clause 2.

Companies should keep written records of the action taken to recall, suspend or withdraw activities, material, items, etc. found in breach of the Code.

3. Advice for particular sections/clauses of the Code

Please read in conjunction with the Code and its supplementary information, which is not repeated here.

a) Overarching Requirements (Grey Section Clauses 1-10)

The overarching requirements need to be considered in relation to all activities and materials in scope of the Code. These requirements are broad in their application and should form the foundation of all training programmes on the Code. The overarching requirements are grouped in three subsections:

- Scope of the Code and Definitions of Certain Terms
- Obligations and Responsibilities
- Quality Standards

Clause 1.1 and its supplementary information provide guidance in relation to the scope of the Code and understanding is key. The Code covers matters that are not necessarily related to promotion.

The definition of certain terms is an important component of the Code. It is helpful if company policies and procedures use the same definitions as in the Code to avoid confusion.

Companies are responsible for all activities, interactions, relationships, materials, items, etc. covered by the Code; those which must be certified, including those that are non-promotional, are detailed in Clauses 8.1, 8.2 and 8.3. Other activities, interactions, relationships, materials, items, etc. which are not required to be certified under the Code, including corporate advertising, press releases, market research material, financial information for shareholders and the Stock Exchange and written responses to unsolicited enquiries from the public, etc., should be examined by a signatory or an appropriately qualified person (AQP) to ensure that it does not contravene the Code or relevant statutory requirements.

Account should be taken of the fact that non-promotional material could be used or made available in such a way that it would be considered promotion.

Certification and Examination (Clause 8)

Certification and examination are mechanisms to ensure that materials and activities are carefully checked prior to use. Procedures must ensure that no activity is commenced, or material is used or issued prior to certification or examination (depending on the Code requirement). As set out above companies are responsible for all activities, interactions, relationships, materials, items, etc. covered by the Code. Those which must be certified, even if they are non-promotional, are detailed in Clauses 8.1, 8.2 and 8.3. The supplementary information to Clause 8.3 lists examples of materials and activities which should be examined prior to use. Companies should remember they will be held responsible for an activity or material, not mentioned under certification or examination, covered by the Code.

For materials/activities that are required to be certified under the Code, each certificate should bear a reference number with the same reference number appearing on the material, item, etc. in question or some other means so that there can be no doubt as to what has been certified and the certificate can be matched to the material. A particular reference number should relate to only one item, material, etc. Different sizes and different layouts of a piece of material should be separately certified and each should have its own unique reference number.

Companies should bear in mind that material covered by the Code must be up-to-date at the time that it is sent or used or, in the case of a journal advertisement, at the publication date of the journal.

The names and qualifications of nominated signatories to be sent to the MHRA and PMCPA (via the web portal) are those of the registered medical practitioner or the pharmacist registered in the UK or, if the product is for dental use only, a UK registered dentist as set out in Clause 8.1, and the AQP signatory as set out in Clause 8.2.

It is the responsibility of the pharmaceutical company to ensure individuals nominated as signatories meet the qualification requirements stated in Clause 8 and its supplementary information.

Relevant staff should be made aware who are the nominated signatories for the company.

The names of the AQPs carrying out Examination **do not** need to be notified to the MHRA or the PMCPA. However, companies should consider maintaining a list of the AQPs including the activities, materials, etc. they can examine, which is made available to staff.

Companies should assess and confirm the experience and knowledge of nominated signatories and AQPs. Assessments which include tests are advisable with companies retaining such documentation.

Training (Clause 9)

All relevant personnel, including representatives and members of staff and others retained by way of contract, concerned in any way with the preparation or approval of material or activities covered by the Code must be fully conversant with the Code and the relevant laws and regulations.

Company procedures should cover the training, ongoing education and individual validation on the requirements of the Code.

Companies should provide opportunities for all relevant personnel to receive regular ongoing Code related training and updates, especially those involved in the certification and examination of materials, activities, items, etc. including having adequate arrangements in place to ensure that any information as to changes to the Code, etc. including reports of decided cases, are circulated to relevant personnel in a timely manner.

All personnel (and others retained by way of contract) must be fully conversant with pharmacovigilance requirements relevant to their work and this must be documented (Clause 9.2). Companies should consider making knowledge of, and compliance with, their obligations in relation to both the Code and pharmacovigilance requirements part of the annual appraisal process for relevant employees.

Clause 9.4 sets out the requirements relating to the need for representatives to pass an appropriate examination. Examination status is enquired about when a complaint is received about a representative. It is important for companies to keep records in relation to each representatives' examination status. Companies should bear in mind the broad definition of a representative in Clause 1.19 of the Code when determining which personnel require the examination as it could cover the activities of those employees that companies might not call representatives. Companies should have appropriate procedures in place to ensure that representatives enter for the examination on the earliest practicable date. Representatives must take the examination in their first year of employment and must pass it within two years of starting such employment, whether continuous or otherwise and irrespective of whether with one or more companies.

An appropriate examination can be either the relevant ABPI examination or an examination of at least the same standard which covers similar content and learning material as the corresponding ABPI examination.

Representatives who have passed the examination will still need to continue to have up-to-date knowledge about the products they promote, the industry, the NHS, the Code and the legal requirements and therefore will require regular ongoing training.

Meetings and Hospitality (Clause 10)
Company procedures should set out its requirements on meetings and hospitality for the company's own meetings, those which it sponsors and the support of attendance at meetings, whether held in or outside the UK. Information on allowable expenditure associated with hospitality and other meeting expenses should be included in procedural documents. Contracted services may be associated with meeting expenses and this should be covered in a procedural document.

Meetings held outside the UK are not necessarily unacceptable but there have to be valid and cogent reasons for the use of a venue outside the UK (see supplementary information to Clause 10.1).

Where a company provides support to an individual health professional or other relevant decision maker to attend an event/meeting there must be a written agreement in place setting out what has been agreed, including the categories of cost such as registration fees, accommodation and/or travel. The rationale for the decision to provide support to an individual health professional or other relevant decision maker to attend an event/meeting should be documented prior to the provision of the support. This requirement was newly added to the 2024 Code having previously been included in these guidelines.

Documentation is important and written agreements should be in place for all transactions where contributions, whether direct, indirect or in kind are made by companies.

Companies should remind their affiliates that the ABPI Code must be complied with if UK health professionals attend meetings which they organise regardless of whether such meetings occur in the UK or abroad. The maximum of £75 plus VAT and gratuities for subsistence does not apply to meetings held in European countries where the national association is a member of EFPIA. The local limit would apply instead. Information is available at www.efpia.eu.

Representatives' Expenses
The company's policies/procedures should include clear processes for the approval and payment of representatives' expenses and expenditure on meetings and hospitality and the like. These policies/procedures should include the requirement for the audit of representatives' expenses either on a systematic or random basis to check the nature and value of the expenditure and ensure it was in accordance with the requirements of the Code and company policies/procedures.

b) Promotion to Health professional and Other Relevant Decision Makers (Blue section Clauses 11-17)

Prescribing Information (Clause 12)
Companies should have clear processes and procedures in place regarding updating prescribing information, including the assessment of changes to an SPC, timelines for updating the prescribing information and withdrawal of materials, etc. and roles and responsibilities.

The 2024 Code allows prescribing information on certain materials to be provided by way of a clear and prominent Quick Response (QR) Code. Details are in Clause 12 and its supplementary information.

Representatives' Training (Clause 17)
Representatives (including contract representatives) must be adequately trained in relation to every product which they are to promote (Clause 17.1). Representatives should be provided with written instructions on the application of the Code to their work even if they are also provided with a copy of the Code. Their instructions should cover such matters as the company's policy/procedure on meetings and hospitality and the associated allowable expenditure, and the specific requirements for representatives, including frequency and manner of calls on prescribers. It should be made clear how representatives must, without delay, forward any information which they receive in relation to the use of their company's medicines, particularly reports of adverse reactions (Clause 17.5), to the scientific service referred to in Clause 4.1.

It should be made clear to representatives whether or not they are permitted to prepare materials (including emails) themselves that mention particular medicines and so are almost certain to be considered promotional material. The particular circumstances, if any, in which this would be allowed must be made clear. Such material must be certified, either in advance by way of templates with instructions regarding which fields can be changed (e.g. name) or by certifying each individual email/letter or other item, and must include prescribing information and the adverse event reporting statement in accordance with Clause 12.

Promotional material for use by representatives should be accompanied by briefing material to instruct representatives on its appropriate use, including mandatory information to be communicated e.g., prescribing information.

c) Interactions with Health professionals, Other Relevant Decision Makers and Healthcare Organisations (Green section Clauses 18-22)

Prohibition on Inducements and Inappropriate Payments and the Provision of Items to Health Professionals and Other Relevant Decision Makers (Clause 19)

The supplementary information to Clause 19.1 refers to package deals. There are many different types of package deals. Some may involve the use of third party organisations. Some may involve patient contact (e.g. homecare services). Some package deals require the disclosure of transfers of value. It is important that companies have clear policies/procedures in place, which cover the different types of package deals offered by the company, with clearly defined roles and responsibilities.

d) Interactions with Health Professionals, Other Relevant Decision Makers, Healthcare Organisations, Patient Organisations and the Public, Including Patients and Journalists (Yellow section Clauses 23-25)

Contracted services (Clause 24)
Companies may require the services of various types of consultants, as referred to in Clause 24. Procedures should ensure that a written agreement is executed in advance of the commencement of any work covered by that agreement. Where such services include participation at a meeting which requires pre-work, it is important that the agreement is executed prior to commencement of any pre-work.

Companies will be held responsible for what contracted speakers say at their meetings. Speakers should be adequately briefed on the requirements of the Code in advance of the meeting.

e) Specific Requirements for Interactions with the Public, Including Patients and Journalists, and Patient Organisations (Pink section Clauses 26-27)

Relations with the Public, Including Patients and Journalists (Clause 26)
Given the prohibition on advertising prescription only medicines to the public, pharmaceutical companies should ensure that they have appropriate social media policies, etc. in place, that cover both business and personal use of social media. It is important that all personnel receive training on the company's personal use of social media policy given most people have social media accounts. Given the large number of complaints that the PMCPA receive in this area, it would be advisable that such training was regular and included some form of knowledge-check. If an employee's personal use of social media was found to be in scope of the Code, the company would be held responsible.

Companies should also refer to the PMCPA Social Media Guidance published on the PMCPA website.

Relationships with Patient Organisations (Clause 27)
Interactions between pharmaceutical companies and patient organisations, etc. are common practice. Maintaining the required high standards in these interactions is essential with many of the requirements in the overarching requirements section of the Code being applicable. To ensure companies are clear what additional standards apply to patient organisations these have been set out in Clause 27 and 29.

f) Annual Disclosure Requirements (Teal Section Clauses 28-31)

Transparency is an essential element in building and maintaining trust with stakeholders and is a key ABPI principle. Disclosure of transfers of value allows for greater transparency of the relationships that pharmaceutical companies have in the healthcare arena, allowing public scrutiny and enhancing public perception.

The ABPI data sharing agreement must be signed by each company disclosing its transfers of value on the ABPI's Disclosure UK platform. Arrangements for uploading the data and checking it with health professionals, other relevant decision makers and healthcare organisations can be obtained from the ABPI.

The 2024 Code now makes it a requirement for companies to submit links via the relevant Disclosure UK gateway to take visitors from Disclosure UK to the patient organisation and public, including patients and journalists, disclosure information on the company's website.

4. Suggested Standard Operating Procedures (SOPs)

Companies should have extensive policies and procedures in relation to the Code. Depending on the activities undertaken by a particular company, it is helpful if there are SOPs on the following Code related topics:

- Certification and Examination
- Meetings and Hospitality

- Donations and Grants
- Collaborative Working (which will include Joint Working)
- Contracted Services
- Working with Patient Organisations
- Interactions with Members of the Public including Patients and Journalists
- Representatives' Training
- Representatives' Expenses
- Advance Notification and The Legitimate Exchange of Medical and Scientific Information
- Medical Science Liaisons/ field based medical personnel
- Medicines and Samples
- Disclosure (Transfers of Value)
- Recall, Withdrawal and Suspension of Materials, etc.
- Business and Personal use of Social Media