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

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. They are minimum requirements which should be adapted to fit the arrangements at a particular company. The introduction of the new ABPI Principles should also be reflected where appropriate. The PMCPA will not adjudicate on the ABPI Principles.

Companies' Code related policies and procedures should be in line with the ABPI 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 best practice and should be adapted to fit in with the arrangements at any particular company. Paragraphs 10.4, 11.3 and 12.2 of the Constitution and Procedure for the Prescription Medicines Code of Practice Authority (PMCPA) variously authorise the Code of Practice Appeal Board or the Board of the Association of the British Pharmaceutical Industry to require an audit of a company's procedures in relation to the ABPI Code to be carried out by the PMCPA. During such audits the PMCPA will review 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.

These guidelines do not cover all aspects of the Code and are thus no substitute for a detailed study of the Code as a whole, including the supplementary information.

The 2021 Code introduces a new structure, setting the Code requirements within six sections. The first section, 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 certain information. It is important to ensure all relevant sections of the Code are referred to and complied with. The 2021 Code does not have a separate clause covering the requirements for activities etc which are carried out through the Internet, digitally etc. this is due to both the integration of these requirements in other sections of the Code as unless otherwise stated the requirements of the Code cover both print and digital.

General advice

1. 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.

a 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. 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 information on 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, in-directly or in-kind.

b 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.

c Correction: When a compliance issue is identified, (whether reported informally, via a speak up line, through monitoring activity (as above) etc) it should be responded to quickly and thoroughly. Corrective 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. Corrective actions implemented should be documented and held on record.

2 Responding to complaints

If a complaint is received from whatever 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 continue to 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.

Advice for each section of the Code

The following cover areas of the Code where the guidelines are more detailed than the requirements of the Code.

A Overarching Requirements (Grey Section)

The umbrella 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

Scope of the Code and Definition of Certain Terms

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 and have been expanded in the 2021 Code. The definitions should be referred to and applied when carrying out any activity, interaction, relationship, material, item etc. Companies should note that some definitions are different from those in previous editions of the Code for example third party which now has a specific definition and should no longer be broadly applied.

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 in nature, are detailed in Clauses 8.2 and 8.3 and their supplementary information. Other activities, interactions, relationships, materials, items etc which do not require to be certified under the Code, including corporate advertising, press releases,

market research material, financial information for shareholders and the Stock Exchange and 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.

Obligations and Responsibilities

These sections set out important aspects of the Code which either have a broad application and/or are important requirements of the Code which are essential for all those working within the pharmaceutical industry. They should be trained to all staff, third parties etc and are the foundation requirements which should be reviewed for compliance for undertaking any activity, interaction, relationship, material, item etc.

Clinical Trials (Clause 4.6)

Companies must disclose details of clinical trials in accordance with the Joint Position on the Disclosure of Clinical Trials Information via Clinical Trial Registries and Databases and the Joint Position on the Publication of Clinical Trial Results in the Scientific Literature. Companies must include on the home page of their website information as to where details of their clinical trials can be found. Further information can be found in the supplementary information to Clause 4.6.

Quality Standards

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. 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 in nature, are detailed in Clauses 8.2 and 8.3 and their supplementary information. The Code also lists certain 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.

The certification of events/meetings involving travel outside the UK, unless the company's only involvement is to support a speaker to present at the meeting, must be certified in advance as set out in Clause 8.1 or by an appropriately qualified person (AQP) signatory. That person does not need to be either a registered medical practitioner or a pharmacist registered in the UK. In deciding whether someone other than a registered medical practitioner or a pharmacist registered in the UK is appropriately qualified to certify events/meetings involving travel outside the UK, account should be taken of relevant experience both within and outside the industry, length of service and seniority.

Protocols relating to non-interventional studies have been added to Clause 8.1 of the 2021 Code and although this is a similar requirements to that of Clause 25 of the 2019 ABPI Code (in that a registered medical practitioner or pharmacist registered in the UK responsible for the oversight of non interventional studies had to state in writing that he/she had examined the protocol relating to the non-interventional study and that in his or her belief it was in accordance with the requirements of the Code) it means that all materials, activities etc which require certification by a registered medical practitioner or a pharmacist registered in the UK are consolidated into one section. Companies may decide to nominate the

registered medical practitioner, or a pharmacist registered in the UK, who was responsible for the oversight of non interventional studies under the 2019 Code as the final signatory to carry out such certification.

The names of the nominated signatories including, where applicable, the registered medical practitioner or pharmacist registered in the UK who certifies non-interventional studies for companies and the AQP signatory, must be notified in advance to the MHRA and to the PMCPA. Changes in the names of nominees must be promptly notified.

Other activities, interactions, relationships, materials, items etc which do not require 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. To aid companies determine who could perform the function of an appropriately qualified person, the supplementary information to Clauses 8.1 and 8.2 Appropriately Qualified Persons states: It is possible for a company to have different individuals who would act as an appropriately qualified persons (AQP) for examination depending on their skill sets and the material and activities etc being examined. For example an individual with proof reading skills could examine and sign the final form of printed material which has been certified electronically as set out in the supplementary information to Clause 8.1. It is unlikely that this AQP would also have the necessary skills to examine market research material to ensure it does not contravene the Code as set out under the supplementary information to Clause 8.3.

Clause 9.1 sets out that 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. such a person must have an up-to-date and detailed knowledge of the Code. It is important therefore that companies must assess and confirm the experience and knowledge of each health professional signatory (a registered medical practitioner, a pharmacist registered in the UK or in the case of a product for dental use only, a UK registered dentist), AQP signatory and AQP. Assessments which include tests are advisable with companies retaining such documentation.

Material which is certified in an electronic form and is subsequently printed, the supplementary information to Clause 8.1, sets out that provided the final electronic copy has been certified by either a registered medical practitioner or a pharmacist registered in the UK, then the final printed form can be examined and signed by an appropriately qualified person. The material will thus have a certificate and a declaration approving the final form (and cannot be used until it has such) and both must be preserved.

The names of the AQPs nominated for Examination **do not** need to be notified to the MHRA or the PMCPA.

Companies should consider having a list of the AQPs including the activities, materials etc they can examine available for staff.

Company procedures for certification must ensure that:

- promotional material is not issued until its final form has been certified in accordance with Clause 8
- the names and qualifications of signatories are notified in advance to the Advertising Standards Unit, Vigilance and Risk Management of Medicines of the Medicines and Healthcare products Regulatory Agency and to the Prescription Medicines Code of Practice Authority (Clause 8.4)

- the form of certificate encompasses at least the requirements of Clause 8.5
- material still in use is recertified at intervals of no more than two years (Clause 8.5); much more frequent recertification may be needed for some products and companies should ensure that the status of material continuing in use is kept under review
- paper or electronic copies of the certificates, together with the material in the form certified and information as to whom it was addressed, the method of dissemination and the date of first dissemination are preserved for at least three years after final use (Clause 8.6).

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 promotional 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.

Certification of Joint Ventures and Co-Promotion arrangements
In a joint venture in which a third party provides a service on behalf of a number of pharmaceutical companies, the pharmaceutical companies involved are responsible for any activity carried out by that third party on their behalf.

It follows therefore that the pharmaceutical companies involved should be aware of all aspects of the service carried out on their behalf and take this into account when certifying the material or activity involved. Similarly, if two or more pharmaceutical companies organise a joint event/meeting each company should ensure that the arrangements for the event/meeting are acceptable.

Under co-promotion arrangements or other arrangements where companies work together, such as collaborative working projects, the companies concerned can agree to have only one final signatory to certify on behalf of all the companies. Companies are advised to clearly document the various responsibilities under co-promotion arrangements. This must all be agreed beforehand and the MHRA and the Prescription Medicines Code of Practice Authority (PMCPA) must be informed in advance who the signatory will be. In the event of a complaint about material certified in this way each company involved in the project/activity would be responsible under the Code (supplementary information to Clause 8.1).

Certification of Representatives' Briefing and Training Materials
The certification requirements of Clause 8 apply also to briefing material prepared for representatives in accordance with Clause 17.9. Briefing material includes the training material used to instruct representatives about a medicine and the instructions given to them as to how the product should be promoted, how the medicine should be used etc.

Certification of Materials and Items for, or to be Passed on to Patients
Materials and Items which are provided to patients or to health professionals for them to pass on to patients must be certified in advance (Clauses 8.3, 19.2, 26.3 and 26.4); the details must be appropriately documented.

Training (Clause 9)

It should be ensured that all relevant personnel, including representatives and others retained by way of contract, concerned in any way with the preparation or approval of material or activities covered by the Code are fully conversant with the requirements of the Code and relevant legal requirements (Clause 9.1).

Company procedures should cover the training, ongoing education and individual validation on the requirements of the Code. It is recommended that key personnel also attend one of the seminars organised by the Prescription Medicines Code of Practice Authority.

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 into when a complaint is received about a representative, it is important for companies to keep records, including for the time during the Covid 19 pandemic, that each representative has either passed or complies with the Code requirements in this regard. 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 such employment and must pass it within two years of starting such employment. To be acceptable an examination must be accredited to at least Level 3 by an external awarding body recognised by Ofqual. The ABPI only offers accredited examinations. Examinations may also be offered by providers other than the ABPI (Clause 9.4).

Representatives commencing such employment on or after 1 October 2014 must take an accredited examination. There is more detail in the supplementary information to Clause 9.4.

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

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 sponsorship of attendance at meetings, whether held in or outside the UK (note the sponsorship of individual health professional and other relevant decision makers is now defined in the 2021 Code as support). Information on allowable expenditure associated with hospitality and other meeting expenses should be included. Contracted services are often included in or associated with meeting expenses in the procedure for meetings and hospitality. The remuneration for the services must be reasonable and reflect the fair market value of the services provided, further information on contracted services is set out in Clause 24 and page 5 of these guidelines.

Companies must ensure that meetings held in the UK that it plans are examined to see that they comply with Clause 10. The Code does not require the certification of meetings held in the UK.

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 (supplementary information to Clause 10.1). Meetings which involve travel outside the UK must be certified as set out in Clause 8.2 and also set out in the certification section above. This does not apply if the company's only involvement is to support a speaker to present at the meeting and there is no pharmaceutical company involvement with the meeting.

The public consultation on the 2021 ABPI Code asked respondents to comment on whether a contract should be required for all support of health professionals and other relevant decision makers to attend events/meetings and for contributions, financial or otherwise, in whole or in part provided by or on behalf of a company, towards an activity (including an event/meeting or material) performed, organised, created etc by a healthcare organisation, patient organisation or other independent organisation. There was an overwhelming response for this to be a requirement of the Code, prior to doing so it is being included in these guidelines. A requirement for a contract will be proposed for inclusion in subsequent editions of the Code. As set out previously, documentation is a key, agreements/ contracts should be in place for transactions where contributions, whether direct, indirect or in kind are made by companies.

Clause 10.7 stipulates that the cost of a meal (including drinks) provided by way of subsistence in the UK must not exceed £75 per person excluding VAT and gratuities. The supplementary information to Clause 10.7 sets out further details. The maximum of £75 plus VAT and gratuities 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.

The only items that can be provided to health professionals for them to keep are notebooks, pens and pencils for use at *bona fide* meetings and conferences etc. No individual should receive more than one notebook and one pen or pencil. The total cost of such items provided to an individual must not exceed £6, excluding VAT, and the perceived value to the recipient must be similar. They must not bear the name of a medicine or any information about medicines but may bear the name of the company providing them (Clause 10.4). They must not be provided by representatives when calling upon health professionals. They must not be given out from exhibition stands. They can be included in conference bags at independently organised meetings but cannot then bear the name of the company providing them. There is much detail in the supplementary information to Clauses 19.1, 19.2 and 10.4 and it is essential that companies familiarise themselves with it.

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.

Disclosure

Companies must publicly disclose annually financial details of support of UK health professionals and other relevant decision makers in relation to attendance at events and meetings. The annual financial disclosure of the details for contributions to costs related to events/meetings (sponsorship) paid to healthcare organisations, patient organisations or organisations managing an event/meeting on a company's behalf. Disclosure must be carried out in accordance with Clause 28.

B Promotion to Health professional and Other Relevant Decision Makers (Blue section)

Prescribing Information (Clause 12)

In certain circumstances Clause 12 of the Code allows elements of the prescribing information to be provided by way of a copy of the summary of product characteristics.

The supplementary information to Clause 12.4 covers the use of links to prescribing information. When digital material includes a link to prescribing information on another website then such a link should only be included for use when the material is generally expected to be viewed online, for example, advertisements in electronic journals, emails or electronic detail aids when used remotely and the like. This is to ensure that at the time of reading the link is active and will provide readers with the necessary information. When material is more likely to be viewed offline, such as electronic detail aids to be used by representatives when visiting health professionals, then the requisite information must be provided as part of the item itself or as a link that does not require the reader to be online.

It is helpful if promotional material which consists of more than four pages includes a reference as to where the prescribing information can be found.

Abbreviated Advertisements (Clause 13)

Abbreviated advertisements (Clause 13) must refer to a website where further information about the product can be found. This further information can consist of the prescribing information, as set out in Clauses 12.2, or the summary of product characteristics. Clause 13.4 sets out the information which must be provided in a clear and legible manner.

Representatives' Expenses (Clause 17)

The company's procedures should include clear process for the approval and payment of representatives' expenses and expenditure on meetings and hospitality and the like. The company's policies and processes 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' procedures.

Representatives' Training (Clause 17)

Procedures must ensure that:

- representatives are aware that they must maintain a high standard of ethical conduct and comply with all relevant requirements of the Code (Clause 17.2)
- representatives (including contract representatives) are adequately trained in relation to every product which they are to promote (Clause 17.1). It is important to note that representatives who take the ABPI generic representative examination are qualified to promote primarily on the basis of price, quality and availability to non prescribers. If they change role to include calling on prescribers then they are required to take the ABPI medical representatives examination. (supplementary information to Clause 9.4).

Representatives should be provided with written instructions on the application of the Code to their work even if they are also provided with a link to the Code. Their instructions should cover such matters as the company's policy and/ or procedure on meetings and hospitality, and the associated allowable expenditure, and the specific requirements for representatives. 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 17.6), to the scientific service referred to in Clause 4.1.

It should be made clear to representatives as to whether, and in what, if any, particular circumstances, they can themselves write letters (or prepare other materials) which mention particular medicines and are thus almost certain to be considered promotional material. Such material must be certified, either in advance by way of pro forma letters or by certifying each individual letter or other item and must include prescribing information in accordance with Clause 12.1.

C Interactions with Health professional, Other Relevant Decision Makers and Healthcare Organisations (Green section)

Items for Patients Support (Clause 19)

The supplementary information to Clause 19.2 refers to items for patient support which can be provided to health professionals to pass onto patients. It includes that items which are to be passed on to patients may not be given out from exhibition stands, they may be exhibited and demonstrated on stands and requests for them accepted for later delivery.

Items for patient support may be provided to health professionals by representatives during the course of a promotional call and representatives may deliver such items when they are requested by health professionals. Examples of items which might be acceptable include a peak flow meter as part of a scheme for patients to regularly record readings or a pedometer as part of a scheme to encourage exercise.

Provided that they have been appropriately documented and certified in advance as required by Clause 8.3, items for patient support which allow patients to gain experience in using their medicines whilst under the supervision of a health professional, may be made available for the use of health professionals even though they are not to be passed on to patients for them to keep. Examples include inhalation devices (with no active ingredient) and devices intended to assist patients to learn how to self-inject.

An ‘inexpensive’ item for patient support means one that has cost the donor company no more than £10, excluding VAT. The perceived value to the health professional and the patient must be similar.

Items which can be provided to health professionals, other relevant decision makers and others at events/meetings is set out in Clause 10 Meetings and Hospitality and on page 6 of these guidelines.

Information regarding material and items made available directly to patients is set out in Clause 26 and its supplementary information.

Memory sticks and other data storage devices provided in accordance with the supplementary information to Clause 19.1 must be inexpensive.

The supplementary information to Clause 19.1 deals with outcome or risk sharing agreements, patient access schemes and package deals.

Collaborative working with Organisations (Clause 20)

Collaborative working with healthcare organisations (and others) has been introduced in the 2021 Code as a means of recognising that there might be some projects which are not carried out with the NHS or cannot show a direct benefit to patients and thus could not be joint working as defined by the Department of Health and set out in the 2019 Code.

Clause 20. Collaborative Working with Organisations must enhance patient care or be for the benefit of patients, or alternatively benefit the NHS and, as a minimum, maintain patient care. Joint working must continue to be patient centred and always benefit patients and is

thus now an example of collaborative working. Some of the previous language for Medical and educational goods and services (MEGS) from the 2019 Code, Clause 19, has been adapted.

A summary of the collaborative working agreement must be publicly available before arrangements are implemented and it must be documented with a formal written agreement which is kept on record (Clause 20.3). Certain material related to collaborative working must be certified (Clause 8.3).

Companies and organisations setting up collaborative working and wanting to involve patient organisations should arrange their involvement under the requirements of Clause 24. Companies must also comply with the requirements of Clause 27.1.

The Code requires public disclosure of transfers of value in connection with collaborative working (Clause 20.5). Clause 28 sets out the requirements in relation to transfers of value provided under Clause 20.

Medical and Educational Goods and Services **-** The provision of medical and education goods and services (MEGS) under Clause 19 of the 2019 Code do not exist in the 2021 ABPI Code. These are likely to fall under donations in Clause 23 or collaborative working in Clause 20 of the 2021 Code. Information including their transition under the 2021 Code is in the supplementary information to Clauses 20 and 23.

Provision of Medicines and Samples (Clause 21)
Companies should ensure that their procedures are such as to ensure compliance with Clause 21. They should be clear as to the distinctions between samples, identification samples, titration packs and free goods etc which are described in the supplementary information to Clause 21.

Electronic signatures are acceptable in relation to requests for samples.

Not more than four samples of a particular medicine may be provided to an individual health professional during the course of a year (Clause 21.2). Samples of a medicine can be provided to a health professional for only two years after that health professional first requests samples of it. There is a special provision for the sampling of new medicines which are extensions of existing medicines (Clause 21.2).

Medicines covered by Clause 21.6 cannot be provided as samples at all.

The supplementary information to Clause 21.7 requires companies to have adequate systems of control and accountability for samples and for all medicines handled by representatives. Similarly, there should be an adequate system to control the number of samples of a particular product given to a particular health professional (Clause 21.2).

Samples must not be given for the sole purpose of treating patients (Clause 21.10).

Starter packs are not permitted (supplementary information to Clause 21). Starter packs were small packs designed to provide sufficient medicine for a primary care prescriber to initiate treatment in such circumstances as a call out in the night.

Non-Interventional Studies of Marketed Medicines (Clause 22)
A non-interventional study of a marketed medicine is a study where the medicine is prescribed in the usual manner in accordance with the terms of its marketing authorisation (Clause 1.12). The assignment of the patient to a particular therapeutic strategy is not decided by a study protocol but falls within current practice and the prescription of the

medicine is clearly separated from the decision to include the patient in the study. No additional diagnostic or monitoring procedures are applied to the patients and epidemiological methods are used for the analysis of collected data.

A company involved in non-interventional studies must have a scientific service to deal with their approval and supervision as required by Clause 4.2.

Companies must publish the summary details and results of non-interventional studies of marketed medicines completed on or after 1 May 2011 (Clause 4.7). This applies to studies with which a UK company has had any involvement. The 2008 Code encouraged companies to publish this information and this still applies to studies completed prior to 1 May 2011.

Clause 22.1, which sets out the criteria with which non-interventional studies must comply and applies to studies completed on or after 1 July 2008, though companies are encouraged to comply in relation to studies completed prior to that date.

The supplementary information to Clause 22 sets out that All non-interventional studies, including epidemiological studies and registries and other studies that are retrospective in nature are subject to Clause 24.3.

D Interactions with Health professionals, Other Relevant Decision Makers, Healthcare Organisations, Patient Organisations and the Public including Patients and Journalists (Yellow section)

The harmonisation of the three EFPIA Codes in 2019 means that requirements for certain activities which previously only applied when companies interacted with certain groups, now apply more broadly. Patient organisations and individuals representing patient organisations are now incorporated in many areas of the Code such as donations and grants, which previously only referred to health professionals, other relevant decision makers, healthcare organisations etc. Similarly, health professionals, other relevant decision makers and healthcare organisations have been incorporated into areas of the Code which previously only referred to patient organisations. Members of the public etc are now also included in the requirements for contracted services.

Donations and Grants (Clause 23)

Donations and grants are defined in Clause 1.5 as funds, benefits-in-kind or services freely given for the purpose of supporting healthcare, scientific research or education, with no consequent obligation on the recipient organisation, institution and the like to provide goods or services to the benefit of the pharmaceutical company in return. Donations and grants to individuals are prohibited. In general donations are physical items, services or benefits-in-kind which may be offered or requested. Grants are the provision of funds.

The provision of donations and grants has been expanded to patient organisations and must, among other things, only be made for the purpose of supporting healthcare, scientific research or education. A written contract is required for all donations and grants and their provision must be publicly disclosed annually, other requirements for their provision are set out in Clause 23 and its supplementary information.

Medical and Educational Goods and Services **-** The provision of medical and education goods and services (MEGS) under Clause 19 of the 2019 Code do not exist in the 2021 ABPI Code. These are likely to fall under donations in Clause 23 or collaborative working in Clause 20 of the 2021 Code. Information including their transition under the 2021 Code is in the supplementary information to Clauses 20 and 23.

Contracted Services (Clause 24)
Contracted services in the 2021 Code replaces and expands the 'Use of Consultants' in Clause 23 of the 2019 Code and now also applies to patient organisations and the public including patients and journalists.

Health professionals, other relevant decision makers, healthcare organisations, patient organisations, individuals representing patient organisations and members of the public including patients and journalists may be used as consultants and advisors for services such as speaking at and chairing meetings, involvement in medical/scientific studies, clinical trials or training services, writing articles and/or publications, participation at advisory board meetings, and participation in market research where such participation may involve remuneration and/or hospitality. The arrangements which cover genuine consultancy or other services must, to the extent relevant to the particular arrangement, fulfil all the criteria set out in Clause 24 and company procedures should ensure that the requirements of that clause are complied with.

Contracts with UK individuals representing a patient organisation should be made with a patient organisation and disclosed against the patient organisation in accordance with Clause 29. An individual representing a patient organisation is defined in Clause 1.16, which should be referred to when determining an individual's status.

To ensure alignment with EFPIA requirements Clause 24.3 of the 2021 Code replaces Clause 21 'Relationships and Contracts with Certain organisations' of the 2019 Code. This clause covers any other type of service, not otherwise covered in the Code to ensure all relevant services are covered.

The 2021 Code has expanded the requirement for all contracts and agreements with contracted individuals to include provisions regarding their obligation to declare they are a contracted individual to the company whenever they write or speak in public about a matter which is subject of the agreement or any issue relating to the company.

A requirement to annually disclose contracted services provided by the public including patients and journalists from 2022 has also been included. Further information can be found in Clause 30 and its supplementary information including the date the first disclosure is required.

E Specific Requirements for Interactions with the Public including Patients and Journalists and Patient Organisations (Pink Section)

It is important that during interactions between the pharmaceutical industry and members of the public including patients and journalists, patient organisations and individuals representing patient organisations, including when providing contracted services, set out in Clause 24, that standards are adhered to. This section of the Code sets out the standards which companies and individuals should be familiar and comply with.

With respect to relations with the public including patients and journalists (Clause 26) it is important to remember that prescription only medicines must not be advertised to the public including patients and journalists but information about them can be provided either directly or indirectly.

Any material which relates to a medicine and which is intended for patients taking that medicine must include a statement relating to the reporting of side effects. If the medicine is one which is subject to additional monitoring, then the material must include an inverted black equilateral triangle and an additional statement (Clause 26.4).

Relationships with Patient Organisations (Clause 27)
Interactions between pharmaceutical companies and patient organisations etc are common practice. The integration of these organisations into certain clauses of the Code recognises the regularity of these interactions and helps to support alignment and consistency in industry interactions. 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 eg the quality standards section which includes the requirements for all events/ meetings and hospitality. To ensure companies are clear what additional standards apply to patient organisations these have been set out in Clause 27.

F Annual Disclosure Requirements (Teal Section)

Transparency is an essential element in building and maintaining trust with stakeholders and has become one of the key pillars of the industry's reputation building activities. The public disclosure of certain transfer of value is part of a compliance journey; one which we endeavour to expand where possible; to further enhance and build on, to demonstrate that patients are at the heart of our work and interactions. The disclosures in the ABPI's Disclosure UK platform supports publication and allows for greater transparency in the healthcare arena, allowing public scrutiny and enhancing public perception.

Companies should embrace transparency and look to disclosure where possible, pro-active disclosure helps demonstrate integrity.

Certain transfers of value to health professionals, other relevant decision makers and healthcare organisations must be disclosed (Clause 28). The term 'transfer of value' is defined in Clause 1.25; this also sets out a number of matters which are not transfers of value for the purposes of the Code.

The 2021 Code continues this compliance journey with increased level of detail being required for patient organisations and the expansion of disclosure to members of the public including patients and journalists.

The transfers of value to patient organisations are set out in Clause 29. The 2021 Code requires an increased level of detail; this is driven by the integration of patient organisations to certain activities within the Code. Contracted services, donations, grants and sponsorship (including in relation to events/ meetings) provided to patient organisations. The full details for the disclosures are set out in Clause 29.2.

This information must be disclosed on the company website either on a national or European level. Each reporting period must cover a full calendar year. A template to disclose the information required in relation to patient organisations is available from the PMCPA website www.pmcpa.org.uk. The use of this template is optional.

Transfers of value made to members of the public including patients and journalists who have provided contracted services is required for the year 2022. Details for such disclosures are set out in Clause 30.

All disclosures must be made annually in respect of each calendar year and must be in the first six months after the end of the calendar year in which the transfers of value/payments were made. The information disclosed must remain in the public domain for at least three years from the time of first disclosure. Companies must document all disclosures and retain the records for at least five years after the end of the calendar year to which they relate.

A methodological note is required for each group. Each company must include a note of methodologies used by it in preparing all disclosures. Procedures should ensure that each methodological note includes:

- a general summary and/or country specific considerations
- the approach used
- how multi-year contracts, VAT, currency aspects have been treated.

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 and healthcare organisations can be obtained from the ABPI.

Suggested Standard Operating Procedures (SOPs)

Companies will have extensive policies and procedures and depending on the activities undertaken it is helpful if there are SOPs on the following 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
- Medicines and Samples
- Disclosure (Transfers of Value)
- Recall, Withdrawal and Suspension