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Tightening Regulations and Raising Standards in UK Marketing Communications:

the new ABPI Code of Practice (2008) explained

by Steven Gray

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Tightening Regulations and Raising Standards in UK Marketing Communications:

the new ABPI Code of Practice (2008) explained

Steven Gray

Executive summary

In the 50th year of the Association of British Pharmaceutical Industry (ABPI) Code of Practice, a new edition becomes effective on 1 July 2008. Whilst the revisions it contains are largely the direct requirements of the 2007 European Federation of Pharmaceutical Industries and Associations (EFPIA) Code, the UK still manages to introduce some unique considerations.

Changes to the code reflect an overall objective to increase transparency in the interactions between pharma and its stakeholders. Significantly, there is a clear shift of emphasis towards regulating industry communications with a broader range of stakeholders – the code no longer simply governs promotion *to* healthcare professionals (HCPs), but also looks at interactions *with* them.

The 2008 revisions are designed to tighten controls and, in the process, further improve the standards of pharmaceutical marketing communications in the UK. Areas such as donations to institutions and how the industry, in particular its representatives, engages the services of HCPs have been scrutinised, and this has led to new clauses and additional controls.

The new code will bring new challenges in implementation for pharma companies throughout the UK. This Expert Review, *Tightening Regulations and Raising Standards in UK Marketing Communications*, provides a clause-by-clause summary of the major revisions to the ABPI Code of Practice, and how these may impact industry interactions with its stakeholders. It also reviews aspects of the code that may be open to interpretation, and offers advice where scope for flexibility still remains.

This review also includes a brief summary of revisions to the constitution of the Prescription Medicines Code of Practice Authority (PMCPA), which administers the code on behalf of the ABPI, and it's procedures for managing complaints when breaches of the code have been alleged.

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Steven Gray is a specialist in healthcare sales and marketing compliance. With a strong background in sales, marketing and compliance, Steven aims to help companies implement the various industry compliance regulations in a manner that enhances their business, rather than limiting their objectives. In addition to delivering customised in-house training, Steven Gray Consulting Limited supplies a range of materials to support training managers and compliance officers run their own courses. In addition, the company provides template policies for key business areas including meetings, sponsorship and patient group interactions. More information can be found on the company website: www.stevengrayconsulting.co.uk

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Tightening Regulations and Raising Standards in UK Marketing Communications

Introduction

In the 50th year of the Association of British Pharmaceutical Industry (ABPI) Code of Practice, a new edition becomes effective on 1 July 2008.[1] The latest revisions to the code are being introduced in line with similar changes in other national codes across Europe, so that, theoretically at least, the UK code will now be more closely aligned with those of its European neighbours than ever before. However, although many of the changes are direct requirements of the 2007 revisions to the European Federation of Pharmaceutical Industries and Associations (EFPIA) Code, the UK still manages to introduce a number of unique considerations.

The underlying principle of the changes being introduced is a shift in the emphasis of the code to drive increasing transparency in the interactions between pharma and its stakeholders. The majority of the headline changes relate to declarations of interest and tighter controls for donations to institutions and to engaging the services of healthcare professionals (HCPs). The new code will bring new challenges in implementation for some companies but represent the changes necessary to meet the evolving demands of our wider stakeholders, both in the UK – and further afield.

The underlying principle of the new ABPI Code of Practice is a shift in the emphasis of the code to drive increasing transparency in the interactions between pharma and its stakeholders

The need for change

There continue to be those critics outside the industry who doubt the effectiveness of a voluntary code, and the number of breaches since the previous (2006) version[2] would indicate that the number of complaints shows no sign of abating. However, many of these breaches lead, in turn, to tighter regulations in the next version, so that standards are continually driven higher.

Two key changes that accompanied the 2006 ABPI Code of Practice facilitated a shift in the source of complaints, with campaigns to drive greater awareness of the code amongst HCPs and an obligation on pharma to attempt resolution of its differences through inter-company dialogue. The result? Increasing numbers of complaints were received from HCPs and (presumably) the number of complaints between pharma companies dropped (one assumes that a certain percentage are resolved by inter-company dialogue, although there are, of course, no figures for this). Of the 127 cases published in the official Code of Practice Review during 2007,[3] 63 were from HCPs.

It is interesting to analyse the data arising from complaints raised about industry behaviour under the code. An analysis of cases published during 2007* reveals that:

- there were 248 breaches of the code
- 36 companies were found to be in breach of the code
- the industry was brought into 'disrepute' on 15 separate occasions; 11 different companies breached clause 2, some several times
- 17 companies were found not to have maintained the high standards expected of the industry; between them, they breached clause 9.1 on 30 occasions
- 3 representatives from three different companies failed to maintain the standards expected of their profession and were ruled to be in breach of clause 15.2
- 8 companies were found to be in breach of the code on more than 10 occasions
- 1 company in particular was ruled to be in breach of the code 54 times, including four instances of bringing the industry into disrepute (clause 2) and eight failures to maintain expected standards (clause 9.1).

All complaints reviewed by the Prescription Medicines Code of Practice Authority (PMCPA), which administers the code on behalf of the ABPI, result from the belief that pharma has acted inappropriately. Whether the

* NOTE – these figures are based on cases published in Jan–Dec 2007 and thus may represent some infringements that occurred in 2006 and may *exclude* some breaches that occurred in 2007 but were not published until 2008.

code is actually breached or not, the reason for the complaint, the analysis of the facts and the report subsequently published by the PMCPA add to industry's knowledge about what is and is not deemed acceptable. And the definition of acceptability changes over time. For example, the concerns raised in 2006 about the 'hidden' influence pharma was perceived to have with patient groups led directly to the need for declarations about which groups each company supported. Many of the concerns raised over the past 2 years have given cause for reflection on the way in which industry works in partnership with the NHS and how the nature of that relationship should be declared. There has also been a need to consider the impact of wider changes in the regulatory environment, such as anti-bribery legislation (in particular the Foreign Corrupt Practices Act). Therefore, in 2008, the focus on transparency has expanded to encompass financial support for healthcare institutions and is accompanied by the establishment of guidelines to ensure that services provided by individual HCPs are properly controlled.

The 2008 ABPI Code of Practice: what's new?

New clauses

There are three brand new clauses in the 2008 code and, as a result, many clauses have been renumbered (Table 1):

- a new clause on non-interventional studies is introduced as clause 13
- a new clause focusing on the use of consultants becomes clause 20
- the information related to patient groups is enhanced, separated from the clause related to the provision of information to the public, and moved into a stand-alone clause 23.

All of these are covered in detail in the respective sections of this report.

Whilst the code itself comes into effect on 1 July 2008, there is a transition period of 4 months, so that existing materials can continue to be used until 31 October. Two particular changes have even longer implementation periods – new requirements for patient group declarations do not come into force until 31 March 2009 and new requirements for adverse event reporting statements do not need to be incorporated into existing materials until 1 July 2009.

Given the size of the code, reviewing and absorbing all the changes is no small task. Some clauses contain very minor tweaks; others have extensive additions. Thankfully, not every clause has been subjected to change! Those clauses that have changed are covered comprehensively in the following main body of this review and more information can be found on the PMCPA's website (www.PMCPA.org.uk).

Subject	ABPI Code of Practice 2008 clause no.	ABPI Code of Practice 2006 clause no.
Reprints	10	11
Material distribution	11	12
Disguised promotion	12	10
Non-interventional studies	**13 NEW**	–
Use of consultants	**20 NEW**	–
Scientific services	21	13
Public	22	20
Patient groups	**23 NEW**	–
Internet	24	21
Breach of undertaking	25	22

Table 1. Clauses in the ABPI Code of Practice that have been renumbered or that are new.

Clause 1 – Scope of the code

Additional clarity is provided concerning the scope of the code. There is confirmation that disease awareness campaigns and other market expansion activities are permissible. Additionally, the code confirms that it is acceptable to undertake joint working with health authorities and trusts by interacting with those who deliver and those who administer healthcare. This follows the publication of the joint ABPI/Department of Health toolkit: *Moving beyond sponsorship: joint working between the NHS and pharmaceutical industry*.[4] The toolkit lays down a framework for these interactions and is referred to in the supplementary information. Within the toolkit, 'joint working' is defined as: "situations where, for the benefit of patients, NHS and industry organisations pool skills, experience and/or resources for the joint development and implementation of patient-centred projects and share a commitment to successful delivery." The toolkit explains the need for a project agreement to exist between all the partners and clarifies the difference between sponsorship and joint working.

Clarity is also provided on several areas of "jurisdictional" debate – i.e. how the code applies to events and materials that are international in nature. Where international journals are concerned, the ABPI Code of Practice applies if the journal is produced in English within the UK. The code explains that the term 'produced' encompasses compilation, editing, typesetting, printing and binding – but not factors such as where the head office of the publisher is located.

There is a new paragraph in the supplementary information to clause 1.7 regarding the applicability of codes. It is a standing principle that companies are responsible for the actions of any agencies that they commission to undertake work for them. However, the code now also requires companies to take "reasonable steps" to make sure that all other parties with whom they

interact "comply with the code". Examples given include joint ventures and licensees; however, it is not stated what "reasonable steps" actually means in practice. The minimum requirement is therefore likely to be the inclusion of references to the code in any contracts. (However, some companies might also consider it appropriate to assess the training provided by their partners or even to assess their material and activities randomly.)

The code now also requires companies to take "reasonable steps" to make sure that all other parties with whom they interact "comply with the code"

Clause 3 – Marketing authorisations

There are some amendments to the supplementary information in clause 3 relating to promotion at international meetings. Essentially, more clarity has been provided regarding when products can be *promoted* in the UK (as opposed to being the subject of scientific exchange). Not only must the meeting be truly international, but the product must be licensed in the countries of a "significant proportion" of the delegates.

Instead of stating a single country in which the product is licensed, promotional material (other than promotional aids) must now bear the names of all those countries in which the product is licensed (including at least one major developed country). The requirement for material to state that registration conditions vary from country to country still stands.

Clause 4 – Prescribing information and obligatory information

Historically, the code has allowed for promotional material to bear the inverted black triangle required by the Committee on Safety of Medicines; however, this has not previously been an obligatory requirement of the code itself. Now it is.

This new requirement applies to electronic journals, abbreviated advertisements and all promotional materials (except promotional aids such as pens and pads).

A further change is made to the safety reporting requirements of the code. Previously, the code suggested some text that companies could consider using to highlight the need for physicians to report adverse events. The code now mandates the use of a specific new statement: "Adverse events should be reported. Reporting forms and information can be found at www.yellowcard.gov.uk. Adverse events should also be reported to [name of pharma company]." Sadly, this will now mean that the customer-friendly language currently used in many adverse event statements will vanish; however, at least they will all be consistently formal.

Companies also now have the choice of including a telephone number or email address for the medical information or drug safety teams.

The switch to the new text should be made as soon as possible, and must be used in all new material from 1 November 2008. However, existing material may remain in circulation until 1 July 2009 if the adverse event statement would be the only change needed to comply with the new code.

No comments are made in the supplementary information regarding the use of combined UK/Eire material, and whether it is permissible to combine both the UK and Eire safety reporting statements. Presumably, it would be permissible to add the safety reporting statement for Eire after the UK one and before the company telephone number.

Clause 9 – High standards, format, suitability and causing offence; sponsorship

Following a plethora of allegations about disguised promotion over the past few years, the way in which companies need to declare their sponsorship of third-party events and material has been tightened up. The supplementary information to clause 9.10 now requires companies to declare the "nature" of the company's involvement. In other words, companies must clearly distinguish between hands-off grants and those events that they organise themselves; and whether they paid for the lunch or for the speakers' travel costs.

Companies must clearly distinguish between hands-off grants and those events that they organise themselves

Clause 10 (previously clause 11) – Provision of reprints and the use of quotations

The text relating to provision of reprints and the use of quotations has not changed, apart from being renumbered as clause 10.

Clause 11 (previously clause 12) – Distribution of promotional material

There are two key changes to this clause, both in the supplementary information. The limit of eight mailings

per year does not apply to mailings sent about price changes, as long as the mailing does not include any product claims. However, there is an additional change that fans of e-marketing will appreciate. Emails are exempt from the limit of eight mailings per year. This is because they can only be sent with the prior permission of the recipient.

Emails are exempt from the limit of eight mailings per year (but can only be sent with the prior permission of the recipient)

Clause 12 (previously clause 10) – Disguised promotion

The activities listed as examples of "disguised promotion" have been expanded in line with the changes regarding non-interventional studies (new clause 13). Clinical experience programmes and post-authorisation studies (including retrospective ones) have been included.

Clause 13 (new) – Non-interventional studies of marketed medicines

A complete set of rules has been introduced across Europe regarding non-interventional studies. Ostensibly, the rules are designed to prevent companies inappropriately using the guise of "research" to pay for prescriptions. Clear definitions of what constitutes a non-interventional study are given in Table 2.

It is now a requirement of the code that companies must establish a scientific service that deals with the approval and supervision of non-interventional studies.

There are specific mandatory requirements for prospective non-interventional studies that companies are also "encouraged" to follow for all other types of non-interventional study, including epidemiological studies, registries and all retrospective studies.

- The medicine must be prescribed in the usual manner in accordance with the terms of its marketing authorisation
- The choice of "therapeutic strategy" for each patient is decided by "current practice" and not by a study protocol
- The prescription of the medicine must be clearly separated from the decision to include the patient within the study
- There should be no additional diagnostic or monitoring procedures (beyond those usually applied in everyday practice)
- The analysis of collected data should be according to "epidemiological methods"

Table 2. Definitions of what constitutes a non-interventional study.

The specific requirements for prospective non-interventional studies, combined with the new requirements for declaring all clinical trials (see clause 21), essentially promote the need for companies to prove the legitimacy of *all* studies, from full-blown clinical research to small phase IV primary care "clinical experience" programmes.

Clause 14 – Certification

Full electronic approval systems are now permissible thanks to a key change in the code. Previously, companies have been able to certify material electronically, but have had to complete hard-copy certificates prior to archiving. Now companies may use electronic certificates to meet the requirements of clause 14.

Where archiving is concerned, the code now clearly states that the requirement for material to be "preserved" for 3 years applies to both promotional and non-promotional material.

Clause 15 – Representatives

Representative call rates have been the subject of much discussion over the past few years, with a number of individuals expressing concern about the targets being set by their companies. Some of the concern has been caused by inconsistency in the use of terminology. This area has now been addressed in the 2008 code. Companies must clearly distinguish between call rates (i.e. unsolicited 1:1 visits) and contact rates (everything else) in all relevant briefing materials. A company might, for example, set a call rate of three calls per year for each doctor in a target list of 50 individuals. However, there might be an additional target of three further contacts per year (through interaction at meetings, or when the doctor invites the representative back for a further discussion about a product).

Additionally, companies must make sure that the targets they set for both contact rates and call rates are realistic so that representatives do not have to breach the code in order to achieve them. In practice, this is likely to mean taking account of the size of target lists and the accessibility of those targeted. For example, it would be inappropriate to expect the representative to achieve three calls on all 50 target doctors (a total of 150 calls), because if one doctor will only see the representative twice a year, then in order to achieve his/her call rate target the representative will have to make an extra call on a different target doctor, thereby exceeding the permitted maximum of three.

Clause 16 – Training

There was some confusion arising from the 2006 code about changes to the information regarding the ABPI examination for representatives. The text in this section has now been amended.

It is now clear that representatives must *sit* their exam within 12 months of employment in the industry. It is not sufficient simply to be *entered* for it. Furthermore, candidates must ordinarily still pass the exam within 2 years of starting employment in the industry. However, the Director of the PMCPA has a new discretion to allow representatives to continue employment even if they do not sit the exam within 12 months, in addition to the existing discretion to extend the period allowed to pass the exam.

Clause 17 – Provision of medicines and samples

There is a new subclause added to the rules about samples: the requirement for samples not to be provided simply as an inducement to prescribe, supply, administer, recommend, buy or sell any medicine. In addition, samples must not be given for any medicine that has been on the UK market for more than 10 years. These two new subclauses combined underline the rationale for providing samples, which is that they allow a doctor to gain familiarity with a medicine.

The final addition to this clause is in the supplementary information and clarifies that for a medicine to be regarded as a sample it actually has to contain the active ingredient, thereby removing dummy products from the requirements of the entire clause.

Clause 18 – Gifts, inducements, promotional aids and the provision of medical and educational goods and services

This revised clause contains some of the biggest changes in the 2008 code.

Clause 18.4

There has been further restriction affecting the role that representatives can play in offering therapy reviews. Essentially, if the doctor agrees "a change in medication to one of the company's products" then the representative may not offer a therapy review during that call. This is to prevent the therapy review being seen as facilitating the switch.

What is not clearly stated is what "a change in medication" means in practice. In theory, it could mean that if a doctor agrees to switch a single existing patient to a company brand, then the therapy review cannot be offered. However, it is unlikely to extend to situations in which the doctor has agreed to use the product in *newly diagnosed* patients.

New subclauses

There are also two new subclauses (18.5 and 18.6). These relate to the provision of grants and to the contracting of services from institutions, respectively. Both must comply with clause 18.4 or be for the purposes of supporting research. It is therefore to be assumed (although not explicitly stated) that all details relating to both donations and services require certification.

Subclause 18.5

Donations and grants to institutions are allowed so long as they are for the purposes of enhancing patient care, maintaining patient care whilst benefiting the NHS or to support research. Additionally, all other requirements of clause 18.4 apply. The grants must be documented and "kept on record" and must not be an inducement to prescribe, supply, administer, recommend, buy or sell any medicine.

The definition of donations and grants is not limited to money and includes benefits in kind, so companies may want to consider whether their donation policies include references to any seconded staff they have working in health institutions, etc., or any in-house printing they do on behalf of such institutions.

The supplementary information to clause 18 makes it clear that this clause relates only to grants to *institutions*; grants to individuals (travel grants, etc.) are covered in clause 19. However, there are a couple of other points worthy of note, even though they are not "requirements" as such.

Companies are "encouraged" to consider making public any donations and grants to institutions. They are also encouraged to ask the recipients to make the donations public. There is no guidance on how this might be done. Companies may, therefore, like to consider the requirement in the 2006 code to declare funding for patient groups on their website and to adopt a similar position for grants to institutions.

Companies are "encouraged" to consider making public any donations and grants to institutions

The text makes it clear that donations must comply with clause 18.4, so it is to be assumed that the requirements for clear written briefings and certification apply. In effect, this means that the terms of the donation should be subject to a contract with the recipients or that, at the very least, a letter of agreement should be sent to them when the donation is approved by the company.

Subclause 18.6

The second new subclause relates to those occasions when healthcare institutions provide services to pharmaceutical companies (e.g. the training of representatives). It also covers any other type of funding provided by a company to a healthcare institution that is not already covered by the code. Essentially, the services must be contracted and they must be for research, to enhance patient care or to benefit the NHS whilst maintaining patient care. The services must also not be an inducement to prescribe, supply, administer, recommend, buy or sell any medicine.

Minor amendments

Beyond these significant clause revisions, clause 18 has also seen a couple of more minor amendments. First, there is clarification that non-promotional quizzes are acceptable at promotional meetings. Previously, it had been thought that all quizzes and competitions were banned; however, where the intention is to test the knowledge gained at the event, and the quizzes are proper "tests of skill", these are now acceptable – as long as no prizes are offered and as long as the quiz itself is non-promotional.

In addition, there is a welcome clarification that independently produced textbooks and journals can be provided under clause 18, even if they contain the brand names of medicines produced by the company.

Clause 19 – Meetings and hospitality

The text regarding clause 19 has been amended to include training. In effect, this means that training courses sponsored by the industry fall within this clause and need not generally be regarded as "services to medicine". In addition, the supplementary information extends the range of meetings that companies can organise and sponsor to include advisory board meetings and visits to research and manufacturing facilities. It also expands the reference to clinical investigator meetings to include all stages of meetings about clinical trials, including planning, training and general investigator meetings. It also includes meetings about non-interventional trials.

While not a new requirement, the refreshed wording regarding clinical investigator meetings should prompt companies to make sure that the scope of their approval processes considers how to incorporate the activities of clinical research teams – especially when the plans include the attendance of UK HCPs at international events, owing to the need for certification.

However, the revised wording also means that visits to research and manufacturing facilities are acceptable – many companies had previously suspected that these might not be legitimate forms of education. Obviously, the agenda and rationale would still need to be meaningful.

The definition of unacceptable venues has been expanded to include "extravagant" (as well as "deluxe" and "luxurious"). This change is likely to have little impact in practice and is driven by revised wording in the EFPIA Code.

There is also a new statement in the supplementary information of this clause that companies must ***not*** sponsor or organise entertainment. It is not clear how far this will be applied in practice – the examples given include sporting or leisure events.

Clause 19 refers to the requirements for promotional material at international meetings outside the UK to bear the names of countries where the medicine is licensed and to state that registration conditions vary from country to country. If the product is not licensed in the country where the event is taking place, then that must also be stated.

There is also a new addition to the supplementary information requiring UK companies to "remind" their global and international colleagues that if UK HCPs attend, then the meeting must comply with the UK code, regardless of the country in which the event occurs.

Clause 20 (new) – Use of consultants

Clause 20 is a brand new clause. The requirements are significant and, in summary, require every payment to an HCP for services provided to the company to be contracted in writing. The clause applies broadly to speakers, advisory board consultants, chairpersons, trainers and those individuals undertaking clinical trials. Note, however, that it applies only to individuals or groups of individuals. Clause 18 covers the contracting of services from institutions.

Every payment to an HCP for services provided must be contracted in writing

There is a long list of criteria that must be applied in order to engage the services of HCPs. These include identifying a legitimate need for the service and choosing service providers that relate to that need. The choice of service provider must be made by someone with the relevant "expertise". It is not stated how this expertise will be defined, however. For example, where speaker meetings are concerned, local representatives know their customers and their capabilities; however, representatives might be deemed to be too close to the local sales targets to be sufficiently independent in their judgement. In practice, given the other requirements below, it is probably best to have any selections made by representatives checked by their line manager at the very least.

The number of service providers must be appropriate to the specified need. This means, for example, ensuring that the number of delegates on advisory boards is not too high, and making sure that a chairperson is needed, rather than appointing one automatically, regardless of the content and format of a meeting.

The written contract must be signed before the service commences – which means, for example, that speakers should not undertake any preparation before they have signed. The contract must specify the nature of the services and the basis for the payment. This does not necessarily mean that the contract must be specific to every individual event and might mean that annual contracts of a general nature are acceptable; however, the company must keep records about the services provided, as all activities will need to be referenced back to the contract in one form or another.

Once again, the engagement of the HCP must not be an inducement to prescribe, supply, administer, recommend, buy or sell any medicine. Additionally, payment must be the fair market value of the services provided. In effect, this means that two people of similar seniority performing a similar service should receive similar remuneration.

Companies are "strongly encouraged" to include in the contract the provision that the service provider should make appropriate declarations of interest when speaking/writing about relevant subjects concerning the company or its products. Whilst this is not mandatory, companies are also "strongly encouraged" to include such provisions in all contracts renewed or started after 1 July 2008, and to renegotiate existing contracts as soon as possible.

Companies are also "strongly encouraged" to make provision in the contract of any part-time employees who are practicing HCPs for the requirement to make appropriate declarations.

There is a single exemption to the requirements for contracts – one-off remote market research. So, for example, an HCP who answers a short series of questions on the internet or in a telephone call and receives a minimal amount of remuneration would be exempt. However, if that individual was regularly engaged in market research then they should be contracted. Given the requirements for confidentiality in the British Healthcare Business Intelligence Association guidelines, it is likely that companies will require their market research agencies to put such contracts in place rather than implementing them directly.

There is a single exemption to the requirements for contracts – one-off remote market research

This clause also clearly states that the relevant provisions of clause 19 apply to HCPs attending events in a consultancy or advisory capacity. However, readers should note that the PMCPA has clarified that the application of these provisions does not include limiting consultants to economy-class air travel. In other words, it is still acceptable for consultants to travel in business class (as long as they are only travelling in connection with the service; if they are contracted to speak at the beginning of a conference but then stay on for the whole conference, then they should travel out business and travel back economy).

Clause 21 (previously clause 13) – Scientific services

The clause relating to the company needing a scientific service has now been renumbered as clause 21. The title of the clause has been changed from "Scientific service responsible for information" to: "Scientific services". This is more than a tweak to the existing text. There is a whole new service to consider.

As you will have seen in the new clause 13, companies now need a scientific service to approve and supervise non-interventional studies. This might be the existing medical information service or a different team. In most companies, this new responsibility is likely to sit with the medics or medical scientists, or clinical research teams.

The new scientific service for non-interventional studies must include a registered medical practitioner (or a pharmacist) whose responsibilities will include oversight of all non-interventional studies. This oversight will include reviewing the responsibilities of all those associated with the studies, particularly representatives. The nominated medical physician (or pharmacist) must state in writing that he or she has examined the protocol for each non-interventional study and that in his/her belief it is "in accordance with the requirements of the code".

There is a clear statement in the new text that clause 14 does not apply to the examination of non-interventional studies. However, there is a new requirement to disclose details of all clinical trials (clause 21.3). The supplementary information outlines some key requirements:

- *ongoing* clinical trials must be registered within 21 days of initiation of patient enrolment
- *completed* trials for medicines licensed for use in at least one country must also be registered.

This requirement is based on a "joint position" taken by all member companies of International Federation of Pharmaceutical Manufacturers Associations some years ago, and is now enshrined in the ABPI Code for the first time (more information can be found at http://clinicaltrials.ifpma.org).[5] This joint position relates to all trials initiated on or after 1 July 2005 and defines minimum requirements, including basic information about each trial sufficient to inform interested patients (and their healthcare practitioners) how to enrol in the trial (Table 3).

- Brief title
- Trial description in lay terminology
- Trial phase
- Trial type (e.g. interventional)
- Trial status
- Trial purpose (e.g. treatment, diagnosis, prevention)
- Intervention type (e.g. drug, vaccine)
- Condition or disease
- Key eligibility criteria, including gender and age
- The location of the trial
- Contact information

Table 3. The minimum information required about a trial according to the new ABPI Code of Practice.

Each trial listed in the registry must be given a unique "identifier" to ensure transparency of clinical trial results. This unique identifier should permit registry users to track the trial through multiple databases, including clinical trial result databases.

*Statements about a trial must be factual and non-promotional and must **not** constitute promotion of the product concerned*

The above requirements will not be new to clinical research teams, but they may be new to those not familiar with clinical research. However, the ABPI Code of Practice does, of course, add a further note about the way the information is presented – the statements must be factual and non-promotional, and must ***not*** constitute promotion of the product concerned.

Clause 22 (previously clause 20) – Relations with the public and the media

The entire clause relating to the public and the media has been renumbered clause 22. The only other change to this clause is that all references to patient groups have been removed and transferred to the new stand-alone clause 23.

Clause 23 (new) – Relationships with patient organisations

This clause is dedicated to the interactions between companies and patient groups. In addition to the requirements previously stated in clause 20 of the 2006 code, there are several new obligations to consider.

Detailed guidance is now provided about the content of the written agreements that must be in place for all significant activities and ongoing relationships with patient groups (Table 4).

*Companies may not **require** that they are the sole sponsor of an activity or of the patient group itself*

Certification of the agreement with the patient group is still required. However, it should be borne in mind that the clause is now worded as though each *specific* agreement requires certification, rather than certifying a generic template. It will be possible to certify an overall agreement, however, as soon as a new activity is added, and then the amendment will also require certifying.

- Name of activity
- Names of all organisations involved in activity (including third-party providers)
- Type of activity (unrestricted grant, meeting, sponsored material, etc.)
- The objectives of the activity/material
- Roles of company and patient group
- Time frame
- Amount of funding and description of non-financial support (e.g. public relations agency time)
- A statement that all parties know that sponsorship must be clearly declared from the start of all activities
- The code or codes of practice that apply
- Signatories to the agreement
- Date of the agreement

Table 4. Mandatory items for all written agreements regarding significant activities and ongoing relationships with patient groups.

In addition, there are other aspects of this clause to consider when planning projects. For example, companies may not *require* that they are the sole sponsor of an activity – or that they are sole sponsors of the patient group itself. Companies must obtain the written permission of the patient group before they can use their logos or material. The written permission must clearly state *how* the logo or material will be used. And of course, the use of the logo must be in accordance with the code itself.

The clause specifies that, as with all sponsored materials, it is acceptable for companies to correct factual inaccuracies in patient group material, but that the company should not seek to influence the content in a manner favourable to its own interests.

However, the most significant change in this clause relates to the declarations of interaction. It is no longer sufficient simply to list the names of groups with whom the company has involvement. By 31 March 2009, the list of supported patient groups must include short descriptions of the nature of the support. The list must be published at a national or European level – and updated annually. Companies are also encouraged to ensure that up-to-date summaries are available at any time so that they can be provided in response to any enquiries they might receive. Of course, until 31 March 2009, the existing requirement for declaring a list of names remains in force.

There is one final change that will seem a little curious to many – at least until some cases are considered that clarify the exact meaning of the phrase. Companies must now *ensure* that their sponsorship is declared and that the wording reflects the nature of the involvement. This

implies a requirement for companies to do more than simply incorporate the requirement for a declaration in the contract.

> *Companies must now **ensure** that their sponsorship is declared and that the wording reflects the nature of the involvement*

Clause 24 (previously clause 21) – The internet

The major change in this clause is one of emphasis. Previously the code has made it clear that websites containing promotional material should "ideally" be access-restricted (i.e. needing a password to enter the site). From now on, all sites *must* be password-controlled – unless the site also contains information suitable for the public. Essentially, the intention is that the public should not need to enter the site (and be exposed to promotional claims) in order to get information about company products. It should be remembered that this requirement applies to sponsored sites as well as company sites.

However, there is a welcome amendment to the clause, which states that only material intended for the public must comply with the clauses relating to patients – previously the code inferred that if the public could *access* a site then the restrictions applied.

Clause 25 (previously clause 22) – Breach of undertakings

The text relating to breach of undertakings has not changed, apart from being renumbered as clause 25.

Changes to the PMCPA constitution

There are a number of changes to the constitution of the PMCPA, dealing with the procedure to be implemented when a company is alleged to have breached any of the clauses of the code. These can be summarised as distancing the PMCPA from pre-judging the outcome of any complaint. The constitution makes it clear that the role of the PMCPA is to rule on allegations on the basis of the information provided to them by complainants and members. The PMCPA does not investigate *per se*, and no longer does it judge whether there is a *prima facie* case to answer. From this point forward, if a case falls within scope, it will proceed. There is a new appeals procedure that specifically relates to the determination of whether a complaint is within scope, with the Appeal Board Chairman having the final say. Companies are required to "provide a complete response to the matters of complaint" – historically, companies have been requested to "comment". The PMCPA will then weigh the evidence before it – on the "balance of probabilities" – and rule accordingly. The usual escalation to the Appeal Board applies. However, the Appeal Board procedure has now been updated to reflect the fact that presentations to the Appeal Board may not include any new evidence beyond that previously submitted in writing.

Conflicts of interest are managed by asking all parties to declare their interest in each case and by raising any concerns about named individuals. Complainants requesting anonymity are also asked to disclose their interest in the case or company. Truly anonymous complaints will only be allowed to proceed if the quality of evidence is meaningful.

The final change is that indiscretions are now published in the nursing press, in addition to the medical and pharmaceutical press – this reflects the inclusion of a nurse on the Appeal Board.

Conclusion

The majority of significant changes to the 2008 ABPI Code of Practice represent a shift in the emphasis of the code, from promotion to HCPs, towards recognising industry interactions with HCPs and patient groups. The changes are being introduced in line with similar changes in other national codes across Europe. The new code will bring new challenges in implementation for some companies but represents the changes necessary to meet the evolving demands of our wider stakeholders, both in the UK – and further afield.

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Strategies and Solutions for Publication Planning and Execution Excellence

A KeywordPharma **Conference Insights** Review by **Elizabeth Wager** Published September 2007

ThePharmYard product code kwp018 ISBN-13: 978-1-905676-17-0

An in-depth report from The International Publication Planning Association's 5th Annual Meeting held in San Francisco, CA, 25-26 June 2007.

Executive Summary

The reputation of the global pharmaceutical industry is currently suffering, and there is public mistrust of drug companies' publication practices. The industry can only eradicate this problem through increased transparency, honesty and openness in its publications. Clearly, the provision of unbiased information to medical decision makers is essential, not only for the sake of the industry's image, but, more importantly, for the good of public health.

In an environment of rapidly changing rules and regulations, pharmaceutical companies must develop their own robust publication policies that reflect the latest guidelines. Crucially, they must also develop compliance programmes to ensure that all those working on publications not only understand company policy, but actively implement it.

This Conference Insights review provides an in-depth review of the 5th Annual Meeting of The International Publication Planning Association held in San Francisco, CA, 25–26 June 2007. It details the major challenges facing publications professionals, including the need for disclosure, transparency and compliance. It offers guidance on how to develop and implement company policy, looks at the involvement of marketing in the publication process, the growth of open-access publishing and how agencies and drug companies can develop effective partnerships.

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About the author

Elizabeth (Liz) Wager is the author of books on '*Getting Research Published: An A to Z of Publication Strategy*' and '*How to Survive Peer Review*'. She is a co-author of '*Good Publication Practice For Pharmaceutical Companies*' and the European Medical Writers Association guidelines on the role of medical writers.

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