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Increasing Transparency in Pharmaceutical Marketing Communications:

the new code from the European Federation of Pharmaceutical Industries and Associations (EFPIA)

by Joan Barnard, Rene Lai and Andrew Robson
Advisor: Paul Woods

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Increasing Transparency in Pharmaceutical Marketing Communications:

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Executive summary

The representative body of the pharmaceutical industry in Europe, the European Federation of Pharmaceutical Industries and Associations (EFPIA), issued the latest revision to its code of practice in late 2007. The EFPIA code, introduced in 1992 and last revised in 2004, does not act as a pan-European code, but is implemented through the national codes of its member organisations. The updating of these national codes in line with the new EFPIA guidelines will be completed by the end of July 2008.

Prompted by a desire to answer growing criticism of the pharmaceutical industry with a robust and effective system of self-regulation, the new EFPIA code aims to foster an environment where the public can be confident that choices regarding the medicines they are prescribed are based on individual merits and healthcare needs. As such, the need for greater transparency in pharmaceutical marketing communications is the main take-home message from the new code, which comprises revisions and clarifications designed to tighten existing regulations.

Despite this, certain aspects of the code remain open to interpretation, while other areas allow for flexibility in implementation.

This Expert Review delivers a line-by-line summary of all revisions, both major and minor, to the EFPIA code, and offers insight into the likely implications for the pharmaceutical industry and its customers. It outlines the background and principles of the new code, looks at how it will work in practice and provides guidance on its implementation.

The Review also includes details of an entirely new, separate EFPIA code, designed to regulate industry relationships with patient organisations.

In both cases, the latest EFPIA guidelines underline an increased desire for clarity and transparency in how the industry interacts with its healthcare customers.

Contents

About the authors

Dr Joan Barnard (www.joanbarnard.co.uk) is the author and publisher of 'The Code in Practice', a practical guide to the ABPI Code for Head Office staff, and 'The Code in the Field', a guide to the ABPI Code for Medical Representatives. Both books are now in their third editions and are used widely throughout the pharmaceutical industry.

Joan joined the pharmaceutical industry in 1980 and held various positions in clinical research and medical affairs, both in the UK and internationally, including 5 years as a UK Medical Director. She was a member of the ABPI Code of Practice Appeal Board for 4 years.

Joan set up her medical consultancy in 1994, specialising in the regulation of promotional activity, particularly in relation to the ABPI Code of Practice. She runs regular workshops on the code and provides guidance to a broad range of companies on interpretation and implementation of the code. She is registered with the PMCPA as a conciliator.

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Rene is a pharmacist by training and has extensive experience within the pharmaceutical industry. She was Principal Pharmaceutical Adviser, involving a diverse role within Medical Affairs, for a major blue chip company. Rene worked for an international medical consultancy to develop and manage promotional and educational meetings in the USA, Europe and South East Asia, and so developed her knowledge of the regulations and code of practice issues involved with international meetings and activities. Rene set up her own consultancy in 2002. Rene is also involved in ABPI code training run by the PMCPA.

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Andrew has worked with the ABPI code for many years. He participated in the ABPI Code of Practice Review Group that was responsible for the 2006 edition of the code.

Before establishing his consultancy in 2004, Andrew worked in the pharmaceutical industry, latterly as Director of Global Medical Information at GlaxoSmithKline. He is editor and co-author of the book 'Pharmaceutical and Medicines Information Management'.

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Increasing Transparency in Pharmaceutical Marketing Communications

Why is there a new EFPIA code?

EFPIA (The European Federation of Pharmaceutical Industries and Associations[1]) is the representative body of the pharmaceutical industry in Europe. It involves national industry associations ('member associations' and 'associations with liaison status' [Table 1]), of which there are now 32, and over 40 leading pharmaceutical companies.

The first EFPIA code took effect in January 1992. It was revised the next year to take account of new European legislation and this rather skeletal 1993 code remained in force until the end of 2005.

The 2004 revision of the code,[2] which came into effect in January 2006, was much expanded and included a number of significant changes. Although some changes were again prompted by changes in European legislation,[3] the main source of change was the EFPIA itself, as it sought to demonstrate a genuine commitment to improving self-regulation of promotional practices in Europe. As a result, much more detail was given on the acceptability of promotional claims and, in perhaps the most significant change, there was considerable strengthening of controls on meetings.

The new EFPIA code has been prompted by the desire of pharmaceutical companies to answer criticism of the industry and its practices with a system of self-regulation that can be seen as robust and effective

The new EFPIA code[4] continues this process of ongoing review and improvement. It has been prompted, not by legislative changes, but by the desire of pharmaceutical companies to answer criticism of the industry and its practices with a system of self-regulation that can be seen as robust and effective. The stated aim is "to foster an environment where the general public can be confident that choices regarding their medicines are being made on the basis of the merits of each product and the healthcare needs of patients."

It is important to remember that the EFPIA code does not act as a pan-European code under which complaints may be processed. Rather, it has its effect through the national codes of the member associations.[5] Following the finalisation of the new EFPIA code the process will now begin to update the national codes, and this should be complete by the end of July 2008.

EFPIA has also introduced a second, totally new, code that refers to relationships with patient organisations.[6] This extends significantly the scope of EFPIA self-regulatory mechanisms and includes a requirement to list publicly support that companies provide to patient organisations. Some national codes already include sections on relationships with patient organisations but for others this is new ground.

What are the key changes?

There are, again, changes which will have a significant impact not only on companies but also on healthcare professionals.

Scope

The first change to notice is the title. This used to be:

'EFPIA CODE OF PRACTICE ON THE PROMOTION OF MEDICINES'

It is now:

'EFPIA CODE ON THE PROMOTION OF PRESCRIPTION-ONLY MEDICINES TO, AND INTERACTIONS WITH, HEALTHCARE PROFESSIONALS'

The addition of 'prescription-only' is for clarification only, but the addition of 'interactions' is a significant indicator that the reputation of the industry is affected not only by what can be regarded as typical promotional activities, such as advertisements, mailings and representative visits, but also by other activities that are generally considered non-promotional. In fact arguably, it is inappropriate conduct in relation to these other activities that can be most damaging – the questionable 'seeding study' (a study conducted for no bona fide medical

Member associations		Associations with liaison status	
Austria Fachverband der chemischen Industrie Österreichs (FCIO) http://home.fcio.at/	**Netherlands** Vereniging Innovatieve Geneesmiddelen Nederland (Nefarma) http://www.nefarma.nl/	**Bulgaria** Association of the Research-based Pharmaceutical Manufacturers in Bulgaria (ARPharM) http://www.arpharm.org/	**Latvia** Association of International Research-based Pharmaceutical Manufacturers (AFA) http://www.siffa.lv/
Belgium l'Association Générale de l'Industrie du Médicament (AGIM) http://www.pharma.be/	**Norway** Legemiddelindustriforeningen – Norwegian Association of Pharmaceutical Manufacturers (LMI) http://www.lmi.no/	**Croatia** Croatian Pharmaceutical Association (CARP)	**Lithuania** Association of Representative Offices of Ethical Pharmaceutical Manufacturers (EFA) http://www.efa.lt/
Denmark Laegemiddelindustriforeningen – The Danish Association of the Pharmaceutical Industry (LIF) http://www.lifdk.dk/	**Poland** Employers Union of Innovative Pharmaceutical Companies (Infarma) http://www.infarma.pl/	**Cyprus** Association of Pharmaceutical Companies (KEFEA)	**Malta** Maltese Pharmaceutical Association (PRIMA)
Finland Pharma Industry Finland (PIF) http://www.pif.fi/	**Portugal** Associação Portuguesa da Indústria Farmacêutica (Apifarma) http://www.apifarma.pt/	**Czech Republic** Mezinárodní Asociace Farmaceutických Spolecností (MAFS) http://www.mafs.cz/	**Romania** Association of International Medicines Manufacturers (ARPIM) http://www.arpim.ro/
France Les Entreprises du Médicament (LEEM) http://www.leem.org/	**Spain** Asociación Nacional Empresarial de la Industria Farmacéutica (Farmaindustria) http://www.farmaindustria.es/	**Estonia** Ravimitootjate Liit – Association of International Pharmaceutical Manufacturers in Estonia (AIPME) http://www.rrle.ee/	**Slovakia** Association of Research Based Pharmaceutical Companies (SAFS) http://www.safs.sk/
Germany Bundesverband der Pharmazeutischen Industrie (BPI) http://www.bpi.de/ Verband Forschender Arzneimittelhersteller (VFA) http://www.vfa.de/	**Sweden** Läkemedelsindustriföreningen – The Swedish Association of the Pharmaceutical Industry (LIF) http://www.lif.se/	**Hungary** Association of Innovative Pharmaceutical Manufacturers (AIPM) http://www.igy.hu/	**Slovenia** Forum of International R&D and Development Pharmaceutical Industries (EIG) http://www.firdpc.com/
Greece Hellenic Association of Pharmaceutical Companies (SFEE) http://www.sfee.gr/	**Switzerland** Société Suisse des Industries Chimiques (SSIC) http://www.sgci.ch/	**Iceland** Icelandic Pharmaceutical Association (Frumtök) http://www.frumtok.is/	
Ireland Irish Pharmaceutical Healthcare Association (IPHA) http://www.ipha.ie/	**Turkey** Arastirmaci Ilac Firmalari Dernegi (AIFD) http://www.aifd.org.tr/		
Italy Associazione delle imprese del farmaco (Farmindustria) http://www.farmindustria.it/	**UK** Association of the British Pharmaceutical Industry (ABPI) http://www.abpi.org.uk/		

Table 1. National industry associations linked to the EFPIA.

purpose, but rather to increase use of a medicine), the 'token consultancy' (where the fee paid cannot be justified by the service provided) and the unspecified 'donation' (which cannot be guaranteed to be used for an appropriate purpose).

The scope of the new code is thus expanded so that it now addresses donations and grants, fees for service, consultancy arrangements and non-interventional studies, with detailed requirements for each of these. Further information is provided on pages 9–11.

Meetings

In line with the extended scope in relation to non-promotional activity, it is made explicit that non-promotional meetings, such as advisory board and clinical study meetings, are covered by the code in exactly the same way as promotional meetings. Further information is provided on pages 7–9.

Third parties

It is made clear that companies are responsible not only for activity that they conduct themselves but also for any activity carried out on their behalf, for example by contract sales forces, consultants, market research agencies and advertising agencies. Further, companies are considered to have a responsibility to encourage compliance with the code in situations where activity is not done on their behalf but is carried out, for example, by licensees or joint venture partners.

Transparency

This could perhaps be considered the key theme of the new code.

The demand for increased transparency is apparent in the new requirements in relation to donations and

grants to organisations, where there is now strong encouragement to make these arrangements public.

The written contract or agreement that is now required in relation to any consultancy arrangement provides clarity in terms of the services provided and the fees paid. Also, it is made clear that transparency is of importance for healthcare professionals, who are to be encouraged to declare consultancy arrangements when writing or speaking in any relevant situation.

Transparency could perhaps be considered the key theme of the new code

Which code applies and when?

One area that has not changed – some may say unfortunately – is the applicability of codes. Provisions were introduced in the last revision that within Europe (defined as the countries covered by member associations' codes) any activity is covered by the code of the country in which the activity takes place and by the code of the country in which the organising company is legally registered (or, for companies registered outside Europe, the EFPIA code).

- No promotion (of a product or indication) prior to marketing authorisation
- Consistent with the SPC
- Accurate, balanced, fair and objective
- Sufficiently complete to prompt an informed opinion
- Up to date
- Not misleading in any way
- Objective, not exaggerated
- No statement that a product has no side-effects
- No use of the word 'safe' without qualification
- No use of 'new' after 1 year
- Professional and not likely to cause offence
- Capable of substantiation
- Clear references to any published studies used
- Artwork from publications faithfully reproduced and source cited
- Directed to an appropriate audience
- Not disguised
- Prescribing information* included

**Specific requirements determined by national laws and regulations*

Table 2. Requirements for promotion (Articles 1–7).

This does not present a problem for local subsidiary activity, as these two codes will be the same. For example, a UK affiliate organising a meeting in London will be covered only by the UK code. However, it becomes more complicated when a global or international company is involved. For example, a global company headquarters registered in Germany organising a meeting in Paris will be covered by both the German and the French codes, with the more strict code requirements being followed. It becomes even more complicated if that meeting in Paris is attended by delegates from Sweden, Italy, Spain, etc. as the delegates are covered by their home country code.

Sections of the code that have not changed significantly

Promotion (Articles 1–7)

There are no major changes to the requirements for promotion. These are summarised in Table 2.

Advice on personal medical matters (Article 8)

Members of the public who request medical advice should be advised to consult a healthcare professional.

Pharmaceutical company staff (Article 17)

The code's requirements concerning representatives are essentially unchanged, although it is made clear that the new provisions in relation to non-interventional studies must be considered in relation to the representative's role. These new provisions also affect the requirements of the 'scientific service' (see Non-interventional studies, page 10).

Changes to the code in detail

Meetings (Article 9)

The 2004 EFPIA code brought significant changes to the requirements for meetings, particularly in relation to the suitability, or otherwise, of venues and hospitality (Table 3). The 2008 code is essentially unchanged in this respect, but there are other changes which are likely to have impact.

What meetings are covered?

The 2004 code referred to "All promotional, scientific or professional meetings, congresses, conferences,

symposia, and other similar events". It is now specifically stated that this also includes:

- advisory board meetings
- visits to research or manufacturing facilities
- planning, training or investigator meetings for clinical trials and non-interventional studies.

This may not be considered to represent a significant change, as the existing reference arguably covers the whole range of meetings involving health professionals. There has, however, been some variation in how this has been interpreted in practice. The new code now leaves no room for doubt that the same rules apply to all meetings, and further emphasises that the scope of the code is not only 'promotion', but also includes the much wider range of 'non-promotional' activities that companies conduct.

It is similarly made explicit that the code applies equally to health professionals attending meetings as consultants (e.g. speakers, advisory board members). There is thus no doubt that the standards of hospitality appropriate for an advisory board are no different from those appropriate for other types of meeting.

It remains the case that the code covers meetings that are organised by a company or sponsored by a company, either directly or on its behalf. The code also covers sponsorship of individual healthcare professionals to attend meetings (see page 9).

What does "extravagant" mean?

The new restriction that meeting venues should not be "extravagant" (Table 3) introduces a term that is clearly open to interpretation. So too are the terms "reasonable", "appropriate" and "renowned". It is recognised in the new requirement that member associations should provide guidance on the meaning of these terms. Each member association will decide how it will provide this guidance, whether it will be within the national code itself or as part of supplementary guidance to the code. It may also be considered that this guidance can be adequately provided through case precedent as established in published case reports.

Venue	• Appropriate • Conducive to main purpose of meeting • Not renowned for entertainment facilities • Not extravagant*
Hospitality	• Appropriate • Reasonable • Limited to main purpose of meeting • Meals, accommodation, travel, registration fees only • No sponsoring or organising of entertainment • No more than attendees would pay for themselves • Offered only to *bona fide* attendees
**New requirement*	

Table 3. Requirements for meetings (Article 9).

In addition to the likely variation among national codes in terms of how the guidance is provided, there is considerable scope for variation in the substance of guidance, both in terms of the level of detail and the interpretation of the terms. So far, most national codes have avoided specifying, for example, what would be considered an acceptable star rating of a hotel venue or the acceptable cost of an evening meal. More detailed guidance may benefit companies by removing doubt as to what is and what is not within the code and thus establishing a 'level playing field' where all companies operate to the same requirements. However, many companies appreciate that a framework of more general guidance offers flexibility, not to run roughshod over the requirements, but to be able to interpret them in relation to specific meetings. Five-star hotels may well be considered "extravagant" for the majority of meetings, but there may be occasions where the facilities required for a meeting are such that a five-star business hotel is the only viable venue. For example, for a large international meeting, ease of access for all the attendees is extremely important. This is likely to restrict location, and the requirement for facilities for large numbers may mean that a high-quality business hotel is the only reasonable option. This would still be within the spirit of the code in that the venue would be appropriate and conducive to the main purpose of the meeting.

It is therefore necessary to await the finalisation of national codes before being able to answer this question.

International events

Events that involve health professionals travelling outside their home country remain restricted to those where they can be justified logistically. Justifiable cases might occur where the audience is truly multinational, or when the purpose of the meeting requires the event to be held in another country. In such an instance, this is considered an international event.

At an international event, attendees are considered to be covered by the code of their home country – the country in which the attendee practises

At an international event, attendees are considered to be covered by the code of their home country – the country in which the attendee practises. This leads to the complicated situation where, for example, for a European meeting with an audience drawn from 10 European countries, the hospitality must be considered in relation

to those 10 country codes. All 10 codes should be similar in principle, but differences in interpretation (e.g. of what should be considered "extravagant") mean that there are likely to be significant differences in practice.

A new provision caters for situations where a product or indication may be registered in some countries but not in the country in which an international event is being held. In these circumstances, it is possible to use and distribute promotional material referring to the unlicensed product/indication provided that it is made clear that it is unlicensed and that registration conditions differ internationally. Implementation of this is likely to vary from country to country; it has already been in place for some time in the UK code, but will still not be possible in some countries where it is prohibited by legislation.

Money (Articles 10–14)

Considerable attention has been paid to the potentially thorny issue of companies transferring monies (or benefits in kind) to health professionals. The intention is to ensure that monies are fully justifiable and not some form of inducement. The code previously covered this issue only in relation to 'gifts' and sponsorship to attend meetings, but new Articles have been added. These include:

- donations and grants
- fees
- consultancy arrangements.

In essence, all transfer of monies is now covered.

Although the content of the Article dealing with gifts has barely changed, it is notable that the title has been changed from "Gifts and Inducements" to simply "Gifts". The key principle of this Article is emphasised by the following:

"No gift, pecuniary advantage or benefit in kind may be supplied, offered or promised to a healthcare professional as an inducement to recommend, prescribe, purchase, supply, sell or administer a medicinal product."

This needs to be considered as a key requirement in relation to each of the following different areas.

1. **Promotional gifts** – the use of promotional gifts is still acceptable, as long as the gift is "inexpensive", relevant to the practice of medicine or pharmacy and not of personal benefit to healthcare professionals. Member associations are now required to provide guidance on the interpretation of "inexpensive".
2. **Donations and grants** – subject to certain restrictions, donations and grants may be provided to healthcare organisations. These are defined as "institutions, organisations or associations that are comprised of healthcare professionals and/or that provide healthcare or conduct research." This therefore applies, for example, to hospitals, GP practices, professional societies and research centres.

Subject to certain restrictions, donations and grants may be provided to healthcare organisations

Any such donation or grant must in some way support healthcare or research. This offers considerable scope for company funding, ranging from provision of items of medical equipment, to support for clinical research and funding of staff.

Companies must document and keep records of all grants and donations provided, and, in line with the major theme of transparency, are encouraged to make information about these public.

Donations and grants must not be made available to individual healthcare professionals, only to organisations, as described above. Monies may be provided to individuals only if they can be justified either as sponsorship or as fees for service.

3. **Sponsorship** – sponsorship is discussed only in relation to companies providing individual healthcare professionals with funding to attend meetings or training. In doing so, the company must ensure that the criteria for the selection of recipients are appropriate, and cannot be considered an inducement. Funding can be provided only if the arrangements for the meeting, including any hospitality offered, comply with code requirements. Once more, where the meeting involves travel outside the country in which the healthcare professional practises (the "home country") then, regardless of where the meeting is held, the code that should be considered is that of the home country.
4. **Fees for service** – companies may engage healthcare organisations or individual healthcare professionals to provide a service. For healthcare organisations, the services must be provided to support healthcare or research and the arrangements must be covered by a contract.

The use of individual healthcare professionals as consultants is now covered by extensive new requirements (Table 4). These apply to healthcare professionals acting in a wide range of capacities, including:

- speakers
- chairmen
- clinical study investigators
- trainers
- advisory board members.

The requirements do not apply to participation in market research if the research is limited to one-off

- **Written contract/agreement specifying:**
  - service to be provided
  - basis for payment
- **Legitimate need for services identified**
- **Selection of consultants:**
  - based on identified need
  - decided by person with appropriate expertise
  - Number of consultants justified by identified need
- **Services provided:**
  - records maintained
  - appropriate use by company
- **Fees:**
  - reasonable
  - reflect fair market value

Table 4. Requirements for use of consultants (Article 14).

telephone interviews or questionnaires conducted via mail, e-mail or the internet and the payment is minimal, but do apply if there is more than minimal payment or if participants are consulted frequently or need to travel. Member associations are charged with providing guidance on what constitutes "minimal" payment.

The first requirement is that, before services are provided, there should be a written contract or agreement which clearly specifies the services that will be provided and the basis of payment for them. The code states that fees should be "reasonable" and that they should "reflect the fair market value" of the services. Neither of these terms is sufficiently precise to assist companies in the often difficult task of determining what fee should be paid. In particular, the concept of fair market value is open to interpretation – is it what the services should be considered to be worth, or is it what the market requires should be paid for them? This can be a particular problem when dealing with international thought leaders or with consultants operating in therapy areas where earnings are very high.

However, before embarking on any agreement, the company must identify a legitimate need for the services. It should be this need that drives the selection of consultants and the selection should be made by those who have appropriate expertise. This probably means, for example, that clinical trialists should be selected by Medical or Clinical Research staff, whereas speakers for a promotional meeting may be selected by Marketing.

The number of consultants selected should also be driven by the need. The number of clinical trialists will be determined by the patient numbers required to meet the study objective and the number involved in a market research study will be determined by the sample size required. The number of advisory board members should be limited so that each member is able to make an individual contribution to the meeting.

Companies should keep records of the services provided and the services should be made use of within the company.

Companies are "strongly encouraged" to specify, in contracts, the obligation of consultants to declare the fact of the consultancy arrangements whenever the consultant writes or speaks in public about any matter either related to the agreement or otherwise relevant to the company. This obligation is also stressed for health professionals who work part-time for a company while continuing in professional practice. Companies are encouraged not only to incorporate this into new or renewed contracts but also to renegotiate existing contracts as soon as is practicable. This, once again, returns to the theme of transparency, emphasising that health professionals, as well as companies, have responsibilities in this area.

The code restricts the transfer of monies to individual healthcare professionals to promotional gifts, sponsorship to attend meetings or training and contracted service

The code therefore restricts the transfer of monies to individual healthcare professionals to promotional gifts, sponsorship to attend meetings or training and contracted service. Other than this, monies must be transferred not to an individual but to an appropriate organisation.

Non-interventional studies (Article 15)

Another aspect of transparency is that promotion must be clearly identifiable as promotion and not disguised as something that is non-promotional. Thus, when promotional material is published in journals, it must be easily distinguishable from independent editorial material, and when a company sponsors material, either promotional or non-promotional, the material must clearly indicate that it has been sponsored by that company.

Promotion must be clearly identifiable as promotion and not disguised as something that is non-promotional

The current code already states that for any clinical assessments, post-marketing surveillance and

experience programmes and post-authorisation studies, there must be a primary scientific or educational purpose. There are now extensive requirements specifically related to non-interventional studies.

A non-interventional study is defined as a study where:

- a medicine is prescribed in line with its marketing authorisation
- the choice of treatment for any patient is based on usual practice, rather than on a trial protocol
- the decision to prescribe is unrelated to the study
- there are no requirements for procedures beyond what would be considered usual practice.

Criteria are listed for prospective non-interventional studies that involve the collection of patient data specifically for the study (Table 5). These criteria should also be applied, as far as is possible, to any other non-interventional study.

These requirements are intended to ensure that any study is a true clinical study and not a 'seeding' study, which is simply an extension of promotional activity. If representatives are involved at all, this can be only in an administrative capacity.

There is emphasis on studies being properly set up, both clinically and financially, and on results being made public. The requirements relating to disclosure of results apply to any non-interventional study completed after 1 July 2008, but companies are urged to implement them prior to this where possible. Ideally, companies should adopt the same approach to making public the results from non-interventional studies as they are obliged to follow for clinical trials.

Studies must be controlled by a company scientific service, which must operate in a similar way to the service providing information about products, and the review and approval of promotional material, and indeed may be the same service. It must include a medical doctor or pharmacist, who will certify that the protocol for a non-interventional study complies with the relevant code.

The overall effect of these requirements is that non-interventional studies must now be considered, in effect, as clinical studies.

Non-interventional studies must now be considered, in effect, as clinical studies

Samples (Article 16)

The EFPIA code asserts that a limited number of samples may be supplied "on an exceptional basis for a limited period of time only". The "exceptional basis"

- **Valid scientific purpose**
- **Written study plan/protocol**
- **Written contract between company and health professionals and/or institutes involved specifying:**
  - services provided
  - basis of payment
- **Any payment must be reasonable**
- **Review by ethics committee where possible**
- **Adherence to any regulations covering personal data privacy**
- **Study must not be an inducement**
- **Company scientific service (medical doctor or pharmacist) must:**
  - approve protocol
  - supervise study conduct
- **Summary report of study results:**
  - to company scientific service, for retention
  - to participating healthcare professionals
  - to code authorities, if requested
  - to regulatory authority if results impact on benefit/risk assessment
- **Sales representatives:**
  - administrative involvement only
  - under supervision of company scientific service
  - appropriate training
  - no link of study to promotion

Table 5. Requirements for prospective non-interventional studies (Article 15).

requirement simply reflects European Directive 2001/83/EC, but "limited time" is a new provision and could be interpreted as meaning for a limited time after launch, or perhaps for a limited time for a particular health professional. If considered necessary, national codes should provide guidance on the interpretation of "limited number" and "limited period of time". Samples should never be used as an inducement.

Regulation of industry relationships with patient organisations

Patient organisations are not referred to in the main body of the EFPIA code but are covered in a second, new EFPIA Code of Practice on Relationships between the Pharmaceutical Industry and Patient Organisations.[6] This is a simple code and operates on the same timelines as the main EFPIA code. It aims to improve transparency and respect the independence of patient groups. This code stresses the need for written agreements (which would include defining under which national code activities will be conducted if they are transnational) and requires companies to list publicly the organisations

they support, together with a short description of support provided at a national or international level. Unlike the recommendations about transparency of support for healthcare organisations, listing of support for patient organisations is mandatory. The first report must be made available no later than the end of March 2009 and should cover support commenced since or already ongoing on 1 January 2008. This is likely to mean that companies must act promptly to put in place mechanisms to capture this information across Europe. The code also aims to ensure that funding is broad; no company should insist on being the sole sponsor of a patient group or of any single project. It introduces a requirement for a written agreement if companies wish to use materials produced by a patient organisation. Patient organisation events that companies organise or sponsor are subject to the same rules about hospitality and choice of venue as those organised for healthcare professionals.

The EFPIA Code of Practice on Relationships between the Pharmaceutical Industry and Patient Organisations aims to improve transparency and respect the independence of patient groups

Guidance on information on prescription-only medicines for patients and the public

Several years ago, attempts to provide patients with rather limited information about medicines in only three therapy areas foundered because the move was considered, quite incorrectly, as a first move towards direct-to-consumer advertising. The issue remains of how pharmaceutical companies can provide patients with what they increasingly demand – high-quality information about prescription-only products – in such a way that this does not amount to promotion to the public. This is under active consideration, with the European Commission having issued a draft report on the topic.[7] However, it remains to be seen what, if any, change in legislation will be proposed.

The EFPIA has set out its position and suggestions on its website.[1] Also available is a set of principles and guidance notes on information on prescription-only medicines for patients and the public. This does not amount to a code of practice but could be a starting point for future rules governing non-promotional information. Some national codes (e.g. in the UK) already cover non-promotional information for patients but others are silent.

The law dictates that prescription-only medicines cannot be promoted to the public, but national interpretations vary, with quite different views of what should be considered non-promotional. The current inequality of access to good-quality, non-promotional information on medicines will, hopefully, be improved by the latest European initiatives. The successful operation of the two new EFPIA codes could provide a powerful argument for the benefits of self-regulation working alongside legislation.

How does the EFPIA code work?

The EFPIA code is implemented by its member associations, who must ensure that their national codes fully reflect the requirements of the EFPIA code. Each must ensure that the national code is accessible, which means, at a minimum, that it is published on the association's website.

Complaints are dealt with solely by member associations, not by the EFPIA. If a complaint is received by the EFPIA, it will be passed to the relevant member association. Each association is required to have a procedure to process complaints, and a body, comprising industry and non-industry members, to handle them. Appropriate sanctions should be applied to companies who breach the code and all significant case reports should be published.

Member associations must submit an annual report to the EFPIA Code Committee, which is similarly charged with providing an annual report to the EFPIA Board. A new development is that the EFPIA Code Committee will meet member companies at least annually to share best practice. There is also encouragement for the associations and companies to share interpretations via the International Federation of Pharmaceutical Manufacturers & Associations (IFPMA) Code Compliance network.

What are the implications for companies?

Companies will need to wait until the new EFPIA code is incorporated into their national codes before they will know exactly what the requirements are in their countries. Some member associations may issue revised codes fairly quickly but, for others, the process of revision will mean that new codes will not be available until much closer to the final implementation date of 1 July 2008. EFPIA member companies also have a commitment to implement the code in their organisations that runs parallel to the implementation by associations.

Although all national codes must incorporate all the principles of the EFPIA code, there is scope for significant differences in the detail from one country to another. In some cases, this is an inevitable result

of local legislation, which must supersede any code requirements. In other areas, there are likely to be differences in interpretation. The EFPIA code now specifically requires member associations to provide guidance on the interpretation of a number of terms:

- "appropriate", "renowned" and "extravagant" in relation to meetings
- "inexpensive" in relation to gifts
- "minimal" in relation to payment for market research
- "limited number" and "limited period of time" in relation to samples.

There are, however, many other areas of the code, perhaps most areas, where there is room for interpretation.

It would seem prudent for companies to start to think about implementing the likely changes, particularly as these may mean that their local code has to be considered in relation to activities not previously covered, and hence departments and staff possibly not previously involved. This raises management issues of awareness and training. Also, the new transparency requirements and recommendations relating to patient organisation support, healthcare organisations' grants and donations, and non-interventional studies raise significant logistic challenges that may take some time to resolve.

The changes are also likely to mean a change in how companies interact with institutions and consultants, and it would be worthwhile considering how best to communicate this to healthcare professionals. Again, perhaps, there may be a need for a programme of awareness and training.

Finally, companies need to be aware, if they are not already, of the environment in which the new EFPIA code is appearing. This is an environment of continued criticism of the industry and consequent strong commitment to ensure that self-regulation is, and is seen to be, effective. This increased emphasis on compliance is also seen beyond Europe, in the IFPMA code,[8] which has also recently been strengthened both in content and in implementation. All companies need to embrace self-regulation, both in letter and spirit.

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Further reading

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EFPIA press release 14 November 2007: 'Pharmaceutical industry interaction with patient groups - EFPIA adopts new Europe-wide code of practice'. Available at www.efpia.eu/content/default.asp?PageID=263&DocID=3490

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

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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.

Contents

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.

After obtaining a First Class zoology degree from Oxford University in 1983 she worked for Blackwell Scientific Publications, Janssen-Cilag then Glaxo-Wellcome. In 2001, she set up her own company, Sideview, which provides training, writing, editing and publication consultancy services.

She is a member of: the *BMJ*'s Ethics Committee, the World Association of Medical Editors Ethics Committee, the Council of the Committee on Publication Ethics, the editorial board of *European Science Editing* (the journal of the European Association of Science Editors) and the World Health Organization Scientific Advisory Group on trial registration.

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