



EUROPEAN FEDERATION
OF PHARMACEUTICAL
INDUSTRIES AND ASSOCIATIONS

Today's research, tomorrow's cures

**EFPIA CODE OF PRACTICE ON THE
PROMOTION OF MEDICINES**

Adopted by EFPIA (2004 edition)*

* As adopted by the Board on 19/11/2004

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INTRODUCTION

The European Federation of Pharmaceutical Industries and Associations (“**EFPIA**”) is the representative body of the pharmaceutical industry in Europe. Its members are the national industry associations of over twenty pharmaceutical producing countries in Europe and over forty leading pharmaceutical companies. EFPIA’s primary mission is to promote the technological and economic development of the pharmaceutical industry in Europe and to assist in bringing to market medicinal products which improve human health worldwide.

EFPIA and its members are conscious of the importance of providing accurate, fair and objective information about medicinal products so that rational decisions can be made as to their use. With this in mind, EFPIA has adopted the EFPIA Code of Practice on the Promotion of Medicines (the “**EFPIA Code**”).¹ The EFPIA Code reflects the requirements of Council Directive 2001/83/EC, as amended, relating to medicinal products for human use (the “**Directive**”). The EFPIA Code fits into the general framework established by the Directive, which recognises the role of voluntary control of advertising of medicinal products by self-regulatory bodies and recourse to such bodies when complaints arise.

EFPIA encourages competition among pharmaceutical companies. The EFPIA Code is not intended to restrain the promotion of medicinal products in a manner that is detrimental to fair competition. Instead, it seeks to ensure that pharmaceutical companies conduct such promotion in a truthful manner, avoiding deceptive practices and potential conflicts of interest with healthcare professionals, and in compliance with applicable laws and regulations. The EFPIA Code thereby aims 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.

¹ Adopted in 1991 at the initiative of the European pharmaceutical industry, the EFPIA Code took effect on 1 January 1992. On 31 March 1992, the Council of the European Communities adopted Council Directive 92/28/EEC to govern the advertising of medicinal products for human use in European Community Member States. The EFPIA Code was therefore adapted in 1992 to make it fully consistent with Directive 92/28/EEC. The revised version of the EFPIA Code took effect on 1 January 1993. In November 2001, Council Directive 2001/83/EC superseded Council Directive 92/28/EEC. Council Directive 2001/83/EC was amended in 2004 by Council Directive 2004/27/EC. The EFPIA Code was further revised in 2004 to adopt various improvements and to make it fully consistent with Directive 2001/83/EC, as amended. This revised version of the EFPIA Code was adopted by EFPIA on 19 November 2004 and will take effect as early as possible but no later than 31 December 2005.

SCOPE OF THE EFPIA CODE OF PRACTICE

The EFPIA Code covers the promotion to healthcare professionals of prescription-only medicinal products. “**Promotion**”, as used in the EFPIA Code, includes any activity undertaken, organized or sponsored by a pharmaceutical company, or with its authority, which promotes the prescription, supply, sale, administration or consumption of its medicinal product(s). “**Medicinal products**”, as used in the EFPIA Code has the meaning set forth in Article 1 of the Directive. The EFPIA Code covers promotional activity and communication directed not only to doctors but also those directed towards any member of the medical, dental, pharmacy or nursing professions or any other person who in the course of his or her professional activities may prescribe, purchase, supply or administer a medicine (each, a “**healthcare professional**”).

The EFPIA Code covers all methods of promotion including, but not limited to, oral and written promotional activities and communications, journal and direct mail advertising, the activities of medical sales representatives, internet and other electronic communications, the use of audio-visual systems such as films, video recordings, data storage services and the like, and the provision of samples, gifts and hospitality.

The EFPIA Code is not intended to restrain or regulate the provision of non-promotional medical, scientific and factual information; nor is it intended to restrain or regulate activities directed towards the general public which relate solely to non-prescription only medicines. EFPIA, however, acknowledges that some member associations address these activities in their respective national codes, and encourages other member associations to do so, where appropriate.

The EFPIA Code does not cover the following:

- the labelling of medicinal products and accompanying package leaflets, which are subject to the provisions of Title V of the Directive;
- correspondence, possibly accompanied by material of a non-promotional nature, needed to answer a specific question about a particular medicinal product;
- factual, informative announcements and reference material relating, for example, to pack changes, adverse-reaction warnings as part of general precautions, trade catalogues and price lists, provided they include no product claims;
- non-promotional information relating to human health or diseases;

- activities which relate solely to non-prescription only medicinal products;
- non-promotional, general information about companies (such as information directed to investors or to current/prospective employees), including financial data, descriptions of research and development programmes, and discussion of regulatory developments affecting the company and its products.

Attached to the EFPIA Code are: Annex A, the “Implementation and Procedure Rules” which set forth the framework for the implementation of the EFPIA Code, the processing of complaints and the initiation or administration of sanctions by member associations; and Annex B, the “Guidelines for Internet Websites Available to Healthcare Professionals, Patients and the Public in the EU” which provide guidance to member associations and companies with respect to the content of websites containing information on medicinal products subject to prescription.

APPLICABILITY OF CODES

The EFPIA Code sets out the minimum standards which EFPIA considers must apply. In a manner compatible with their respective national laws and regulations, member associations must, at a minimum, adopt in their national codes provisions no less rigorous than the provisions contained in the EFPIA Code. Member associations are encouraged to tailor their national codes to adapt to national conditions and to adopt additional provisions which extend further than the minimum standards included in the EFPIA Code.

EFPIA member companies must comply, and must ensure that their respective subsidiaries comply, with applicable codes (as defined below) and any laws and regulations to which they are subject. Member associations must establish adequate procedures for ensuring that their respective member companies comply with applicable codes.

*Promotion which takes place within Europe must comply with applicable laws and regulations. In addition, promotion which takes place within Europe must also comply with each of the following “**applicable codes**”:*

(a) (i) in the case of promotion that is undertaken, sponsored or organized by a company located within Europe, the member association national code of the country in which such company is located; or (ii) in the case of promotion that is undertaken, sponsored or organized by a company located outside of Europe, the EFPIA Code; and

(b) *the member association national code of the country in which the promotion takes place.*

*In the event of a conflict between the provisions of the applicable codes set forth above, the more restrictive of the conflicting provisions shall apply. For the avoidance of doubt, the term “**company**” as used in this EFPIA Code, shall mean any legal entity that organizes or sponsors promotion which takes place within Europe, whether such entity be a parent company (e.g., the headquarters, principal office, or controlling company of a commercial enterprise), subsidiary company or any other form of enterprise or organization.*

To facilitate compliance with applicable codes, each member association must establish adequate procedures for ensuring that each of its member companies complies with the requirements of such member association’s national code and any other member association’s national code which may be applicable to its conduct, even if the member company does not belong to the other member association. Additionally, all international events (as defined in the EFPIA Code) must be notified to any relevant local subsidiary or, alternatively, local advice taken.

The spirit, as well as the letter of the provisions of the EFPIA Code must be complied with. For example, companies should apply consistent standards to their relationships with healthcare professionals, particularly with respect to gifts and hospitality. EFPIA also encourages compliance with the letter and spirit of the provisions of the International Federation of Pharmaceutical Manufacturers Associations (“**IFPMA**”) Code of Pharmaceutical Marketing Practices where applicable.

PROVISIONS OF THE EFPIA CODE OF PRACTICE

ARTICLE 1

MARKETING AUTHORIZATION

Section 1.01. A medicinal product must not be promoted prior to the grant of the marketing authorization allowing its sale or supply or outside of its approved indications.

Section 1.02. Promotion must be consistent with the particulars listed in the summary of product characteristics of the relevant medicinal product.

ARTICLE 2

INFORMATION TO BE MADE AVAILABLE

Section 2.01. Subject to applicable national laws and regulations, all promotional material must include the following information clearly and legibly:

- (a) essential information consistent with the summary of product characteristics, specifying the date on which such essential information was generated or last revised;
- (b) the supply classification of the product; and
- (c) when appropriate, the selling price or indicative price of the various presentations and the conditions for reimbursement by social security bodies.

Section 2.02. Subject to applicable national laws and regulations, where an advertisement is intended only as a reminder, the requirements of Section 2.01 above need not be complied with, provided that the advertisement includes no more than the name of the medicinal product or its international non-proprietary name, where this exists, or the trademark.

ARTICLE 3

PROMOTION AND ITS SUBSTANTIATION

Section 3.01. Promotion must be accurate, balanced, fair, objective and sufficiently complete to enable the recipient to form his or her own opinion of the therapeutic value of the medicinal product concerned. It should be based on an up-to-date evaluation of all relevant evidence and reflect that evidence clearly. It must not mislead by distortion, exaggeration, undue emphasis, omission or in any other way.

Section 3.02. Promotion must be capable of substantiation which must be promptly provided in response to reasonable requests from healthcare professionals. In particular, promotional claims about side-effects must reflect available evidence or be capable of substantiation by clinical experience. Substantiation need not be provided, however, in relation to the validity of elements approved in the marketing authorization.

Section 3.03. Promotion must encourage the rational use of medicinal products by presenting them objectively and without exaggerating their properties. Claims must not imply that a medicinal product, or an active ingredient, has some special merit, quality or property unless this can be substantiated.

Section 3.04. When promotion refers to published studies, clear references should be given.

Section 3.05. Any comparison made between different medicinal products must be based on relevant and comparable aspects of the products. Comparative advertising must not be misleading or disparaging.

Section 3.06. All artwork, including graphs, illustrations, photographs and tables taken from published studies included in promotional material should:

- (a) clearly indicate the precise source(s) of the artwork;
- (b) be faithfully reproduced; except where adaptation or modification is required in order to comply with any applicable code(s), in which case it must be clearly stated that the artwork has been adapted and/or modified.

Particular care must be taken to ensure that artwork included in promotion does not mislead about the nature of a medicine (for example whether it is appropriate for use in children) or mislead about a claim or comparison (for example by using incomplete or statistically irrelevant information or unusual scales).

Section 3.07. The word “safe” must never be used to describe a medicinal product without proper qualification.

Section 3.08. The word “new” must not be used to describe any product or presentation which has been generally available, or any therapeutic indication which has been generally promoted, for more than one year.

Section 3.09. It must not be stated that a product has no side-effects, toxic hazards or risks of addiction or dependency.

ARTICLE 4

USE OF QUOTATIONS IN PROMOTION

Section 4.01. Quotations from medical and scientific literature or from personal communications must be faithfully reproduced (except where adaptation or modification is required in order to comply with any applicable code(s), in which case it must be clearly stated that the quotation has been adapted and/or modified) and the precise sources identified.

ARTICLE 5 ACCEPTABILITY OF PROMOTION

Section 5.01. Companies must maintain high ethical standards at all times. Promotion must: (a) never be such as to bring discredit upon, or reduce confidence in, the pharmaceutical industry; (b) be of a nature which recognises the special nature of medicines and the professional standing of the recipient(s); and (c) not be likely to cause offence.

ARTICLE 6 DISTRIBUTION OF PROMOTION

Section 6.01. Promotion should only be directed at those whose need for, or interest in, the particular information can reasonably be assumed.

Section 6.02. Mailing lists must be kept up-to-date. Requests by healthcare professionals to be removed from promotional mailing lists must be complied with.

Section 6.03. Subject to applicable national laws and regulations, the use of faxes, e-mails, automated calling systems, text messages and other electronic data communications for promotion is prohibited except with the prior permission, or upon the request, of the recipient.

ARTICLE 7 TRANSPARENCY OF PROMOTION

Section 7.01. Promotion must not be disguised.

Section 7.02. Clinical assessments, post-marketing surveillance and experience programmes and post-authorization studies must not be disguised promotion. Such assessments, programmes and studies must be conducted with a primarily scientific or educational purpose.

Section 7.03. Where a company pays for or otherwise secures or arranges the publication of promotional material in journals, such promotional material must not resemble independent editorial matter.

Section 7.04. Material relating to medicines and their uses, whether promotional in nature or not, which is sponsored by a company must clearly indicate that it has been sponsored by that company.

ARTICLE 8
NO ADVICE ON PERSONAL MEDICAL MATTERS

Section 8.01. In the case of requests from individual members of the general public for advice on personal medical matters, the enquirer should be advised to consult a healthcare professional.

ARTICLE 9
EVENTS AND HOSPITALITY

Section 9.01. All promotional, scientific or professional meetings, congresses, conferences, symposia, and other similar events (each, an “**event**”) organized or sponsored by a company must be held in an appropriate venue that is conducive to the main purpose of the event and may only offer hospitality when such hospitality is appropriate and otherwise complies with the provisions of any applicable code(s).

Section 9.02. No company may organize or sponsor an event that takes place outside its home country (an “**international event**”) unless:

- (a) most of the invitees are from outside of its home country *and*, given the countries of origin of most of the invitees, it makes greater logistical sense to hold the event in another country; or
- (b) given the location of the relevant resource or expertise that is the object or subject matter of the event, it makes greater logistical sense to hold the event in another country.

Section 9.03. Hospitality extended in connection with promotional, professional or scientific events shall be limited to travel, meals, accommodation and genuine registration fees.

Section 9.04. Hospitality may only be extended to persons who qualify as participants in their own right.

Section 9.05. All forms of hospitality offered to healthcare professionals shall be reasonable in level and strictly limited to the main purpose of the event. As a general rule, the hospitality provided must not exceed what healthcare professional recipients would normally be prepared to pay for themselves.

Section 9.06. Hospitality shall not include sponsoring or organizing entertainment (e.g., sporting or leisure) events. Companies should avoid using venues that are renowned for their entertainment facilities.

Section 9.07. Companies must comply with guidance concerning the meaning of the term “reasonable”, as used in this Article 9, as provided in, or in connection with, any applicable code(s).

ARTICLE 10 GIFTS AND INDUCEMENTS

Section 10.01. No gift, pecuniary advantage or benefit in kind may be supplied, offered or promised to a healthcare professional as an inducement to prescribe, supply, sell or administer a medicinal product.

Section 10.02. Subject to Section 10.01 above, where medicinal products are being promoted to healthcare professionals, gifts, pecuniary advantages or benefits in kind may be supplied, offered or promised to such persons only if they are inexpensive and relevant to the practice of medicine or pharmacy.

Section 10.03. Except where they carry all the information stipulated in Section 2.01 above, gifts may bear no more than the name and logo of the company and the name of the medicinal product, or its international non-proprietary name, where this exists, or the trademark.

Section 10.04. Gifts for the personal benefit of healthcare professionals (such as tickets to entertainment events) should not be offered or provided.

Section 10.05. Companies must comply with guidance concerning the meaning of the term “inexpensive”, as used in this Article 10, as provided in, or in connection with, any applicable code(s).

ARTICLE 11 SPONSORSHIP OF HEALTHCARE PROFESSIONALS

Section 11.01. Companies must comply with criteria governing the selection and sponsorship of healthcare professionals to attend events as provided in, or in connection with, any applicable code(s). Funding must not be offered to compensate merely for the time spent by healthcare professionals in attending events. For the avoidance of doubt, this Section 11.01 is not intended to prohibit the extension of hospitality to healthcare professionals in accordance with Article 9 hereof.

ARTICLE 12

SAMPLES

Section 12.01. In accordance with national and/or Community laws and regulations, a limited number of free samples of a particular medicinal product may be supplied to healthcare professionals who are qualified to prescribe that medicinal product in order to familiarise them with the product; but only in response to a written request, signed and dated, from the recipient.

Section 12.02. Companies must have adequate systems of control and accountability for samples which they distribute and for all medicines handled by its representatives.

Section 12.03. Each sample shall be no larger than the smallest presentation on the market.

Section 12.04. Each sample must be marked ‘free medical sample– not for resale’ or words to that effect and must be accompanied by a copy of the summary of product characteristics.

Section 12.05. No samples of the following medicinal products may be supplied: (a) medicinal products which contain substances defined as psychotropic or narcotic by international convention, such as the United Nations Conventions of 1961 and 1971; and (b) any other medicinal products for which the supply of samples is inappropriate, as determined by competent authorities, from time to time.

ARTICLE 13

PHARMACEUTICAL COMPANY STAFF

Section 13.01. (a) Each company shall ensure that its sales representatives, including personnel retained by way of contract with third parties, and any other company representatives who call on healthcare professionals, pharmacies, hospitals or other healthcare facilities in connection with the promotion of medicinal products (each, a “**medical sales representative**”) are familiar with the relevant requirements of the applicable code(s), and all applicable laws and regulations, and are adequately trained and have sufficient scientific knowledge to be able to provide precise and complete information about the medicinal products they promote.

(b) Medical sales representatives must comply with all relevant requirements of the applicable code(s), and all applicable laws and regulations, and companies are responsible for ensuring their compliance.

(c) Medical sales representatives must approach their duties responsibly and ethically.

(d) During each visit, and subject to applicable laws and regulations, medical sales representatives must give the persons visited, or have available for them, a summary of the product characteristics for each medicinal product they present.

(e) Medical sales representatives must transmit to the scientific service of their companies forthwith any information they receive in relation to the use of their company's medicinal products, particularly reports of side effects.

(f) Medical sales representatives must ensure that the frequency, timing and duration of visits to healthcare professionals, pharmacies, hospitals or other healthcare facilities, together with the manner in which they are made, do not cause inconvenience.

(g) Medical sales representatives must not use any inducement or subterfuge to gain an interview. In an interview, or when seeking an appointment for an interview, medical sales representatives must, from the outset, take reasonable steps to ensure that they do not mislead as to their identity or that of the company they represent.

Section 13.02. (a) All company staff, and any personnel retained by way of contract with third parties, who are concerned with the preparation or approval of promotional material or activities must be fully conversant with the requirements of the applicable code(s) and relevant laws and regulations.

(b) Every company must establish a scientific service in charge of information about its medicinal products. This scientific service must include a doctor or, where appropriate, a pharmacist who will be responsible for approving any promotional material before release. Such person must certify that he or she has examined the final form of the promotional material and that in his or her belief it is in accordance with the requirements of the applicable code(s) and any applicable advertising laws and regulations, is consistent with the summary of product characteristics and is a fair and truthful presentation of the facts about the medicine.

(c) Each company must appoint at least one senior employee who shall be responsible for supervising the company and its subsidiaries to ensure that the standards of the applicable code(s) are met.

ARTICLE 14

SANCTIONS

Section 14.01. In the event that a breach is established pursuant to the procedures of its national code, each member association shall require from the offending company an immediate cessation of the offending activity and a signed undertaking by the company to prevent recurrence. Each member association shall also include in its national code provisions governing the imposition of sanctions for breaches of its national code. Sanctions should be proportionate to the nature of the infringement, have a deterrent effect and take account of repeated offences of a similar nature or patterns of different offences. A combination of publication and fines is generally considered to be the most effective sanction; however, each member association may use any other effective sanction to enforce its national code. Each member association should consider any applicable legal, regulatory or fiscal requirements which would affect the nature of sanctions which may be imposed. Where publication or fines are not permitted due to applicable legal, regulatory or fiscal requirements, member associations should impose the best alternative effective sanction.

IMPLEMENTATION AND PROCEDURE RULES

The Implementation and Procedure Rules set forth herein establish the framework for the implementation of the European Federation of Pharmaceutical Industries and Associations (“**EFPIA**”) Code of Practice on the Promotion of Medicines (the “**EFPIA Code**”), the processing of complaints and the initiation or administration of sanctions by member associations.

SECTION 1. *Member Association Implementation.* Each member association is required to:

- (a) establish national procedures and structures to receive and process complaints, to determine sanctions and to publish appropriate details regarding the same including, at a minimum, a national body of the member association that is designated to handle complaints and consists of a non-industry chairman and, besides any industry members, membership from other stakeholders;
- (b) ensure that its national code, together with its administrative procedures and other relevant information, are easily accessible through, at a minimum, publication of its national code on its website; and
- (c) prepare, and provide to the EFPIA Code Committee (defined below), an annual report summarizing the work undertaken by it in connection with the implementation, development and enforcement of its national code during the year.

SECTION 2. *EFPIA Code of Practice Committee Implementation and Key Tasks.*

- (a) The EFPIA Code of Practice Committee (the “**EFPIA Code Committee**”) shall assist member associations to comply with their obligations under Section 1 above.
- (b) The EFPIA Code Committee will be composed of all the national code secretaries, and chaired by the EFPIA Director General, assisted by one person from the EFPIA staff.
- (c) As a key part of its role of assisting member associations in their national code compliance activities, the EFPIA Code Committee shall monitor the adoption of compliant national codes. The EFPIA Code Committee will not participate in the adjudication of any individual complaint under any national code.

(d) The EFPIA Code Committee shall publish an annual code report (the “**EFPIA Code Report**”) which summarizes the work and operations which have taken place in connection with the implementation, development and enforcement of the various national codes during the applicable year, based on the country reports provided by the member associations pursuant to Section 1(c) above.

(e) On an annual basis, the EFPIA Code Committee shall (i) advise the EFPIA Board of its work and operations and the work and operations of the member associations, as summarized in the member association annual reports and (ii) review with the EFPIA Board any additional recommendations to improve the EFPIA Code with a view towards increasing transparency and openness within the pharmaceutical industry and among member associations and companies.

SECTION 3. *Reception of Complaints.*

(a) Complaints may be lodged either with a member association or with EFPIA. Adjudication of complaints shall be a matter solely for the national associations.

(b) Complaints received by EFPIA shall be processed as follows:

(i) EFPIA will forward any complaints it receives (without considering their admissibility or commenting upon them) to the relevant member association(s).

(ii) EFPIA will send an acknowledgement of receipt to the complainant, indicating the relevant national association(s) to which the complaint has been sent for processing and decision.

In addition, upon receipt by EFPIA of multiple external complaints (i.e. several complaints on the same or similar subjects lodged from outside the industry against several subsidiaries of a single company), EFPIA will communicate these complaints to the national association either of the parent company or of the EU subsidiary designated by the parent company.

SECTION 4. *Processing of Complaints and Sanctions by Member Associations.*

(a) Member associations shall ensure that industry and non-industry complaints are processed in the same manner, without regard to who has made the complaint.

(b) Complaints will be processed at the national level through the procedures and structures established by the member associations pursuant to

Section 1(a) above. Each member association's national body shall take decisions and pronounce any sanctions on the basis of the national code in force in its country.

(c) Where a complaint fails to establish a *prima facie* case for a violation of an applicable code, such complaint shall be dismissed with respect to that national code. Member associations may also provide that any complaint which pursues an entirely or predominantly commercial interest shall be dismissed.

(d) Each member association should establish effective procedures for appeals against the initial decisions made by its national body. Such procedures and appeals should also take place at the national level.

(e) National committees shall ensure that any final decision taken in an individual case shall be published in its entirety or, where only selected details are published, in a level of detail that is linked to the seriousness and/or persistence of the breach as follows:

(i) in cases of a serious/repeated breach, the company name should be published together with details of the case;

(ii) in cases of a minor breach, publication of the details of the may exclude the company name; and

(iii) in cases where the relevant national body concludes that there is no breach, no publication of the case is necessary.

**GUIDELINES FOR INTERNET WEBSITES AVAILABLE TO
HEALTHCARE PROFESSIONALS, PATIENTS AND THE PUBLIC IN
THE EU**

The Guidelines for Internet Websites Available to Healthcare Professionals, Patients and the Public in the EU set forth herein are intended as a supplement to the provisions of the European Federation of Pharmaceutical Industries and Associations Code of Practice on the Promotion of Medicines (the “**EFPIA Code**”). Member associations and companies may find it necessary to adapt these guidelines to meet their particular requirements or needs and are encouraged to adopt additional measures which extend further than the provisions included in these guidelines.

SECTION 1. *Transparency Of Website Origin, Content And Purpose.*
Each website shall clearly identify:

- (a) the identity and physical and electronic addresses of the sponsor(s) of the website;
- (b) the source(s) of all information included on the website, the date of publication of the source(s) and the identity and credentials (including the date credentials were received) of all individual/institutional providers of information included on the website;
- (c) the procedure followed in selecting the content included on the website;
- (d) the target audience of the website (e.g., healthcare professionals, patients and the general public, or a combination thereof); and
- (e) the purpose or objective of the website.

SECTION 2. *Content Of Websites.*

- (a) Information included in the website shall be regularly updated and shall clearly display, for each page and/or item, as applicable, the most recent date as of which such information was up-dated.
- (b) Examples of the information that may be included in a single website or in multiple websites are: (i) general information on the company; (ii) health education information; (iii) information intended for healthcare professionals (as defined in the EFPIA Code), including any promotion; and (iv) non-promotional information intended for patients and the general public about specific medicinal products marketed by the company.

(i) General information on the company. Websites may contain information that would be of interest to investors, the news media and the general public, including financial data, descriptions of research and development programmes, discussion of regulatory developments affecting the company and its products, information for prospective employees, etc. The content of this information is not regulated by these guidelines or provisions of medicines advertising law.

(ii) Health education information. Websites may contain non-promotional health education information about the characteristics of diseases, methods of prevention and screening and treatments, as well as other information intended to promote public health. They may refer to medicinal products, provided that the discussion is balanced and accurate. Relevant information may be given about alternative treatments, including, where appropriate, surgery, diet, behavioural change and other interventions that do not require use of medicinal products. Websites containing health education information must always advise persons to consult a healthcare professional for further information.

(iii) Information for healthcare professionals. Any information on websites directed to healthcare professionals that constitutes promotion (as defined in the EFPIA Code) must comply with applicable code(s) (as defined in the EFPIA Code) and any other industry codes of practice governing the content and format of advertisement and promotion of medicinal products. Such information must be clearly identified as information for healthcare professionals, but need not be encrypted or otherwise restricted.

(iv) Non-promotional information for patients and the general public. Subject to any applicable national laws and regulations, websites may include non-promotional information for patients and the general public on products distributed by the company (including information on their indications, side-effects, interactions with other medicines, proper use, reports of clinical research, etc.), provided that such information is balanced, accurate and consistent with the approved summary of product characteristics. For each product that is discussed, the website must contain full, unedited copies of the current summary of product characteristics and patient leaflet. These documents should be posted in conjunction with other information about the products or be connected with that discussion by a prominent link advising the reader to consult them. In addition, the website may provide a link to the full, unedited copy of any public assessment report issued by the Committee for Medicinal Products for Human Use or a relevant national competent authority. Brand names should be accompanied by international non-proprietary names. The website may include links to other websites containing reliable

information on medicinal products, including websites maintained by government authorities, medical research bodies, patient organisations, etc. The website must always advise persons to consult a healthcare professional for further information.

SECTION 3. *E-mail Enquiries.* A website may invite electronic mail communications from healthcare professionals and patients or the general public seeking further information regarding the company's products or other matters (e.g., feedback regarding the website). The company may reply to such communications in the same manner as it would reply to enquiries received by post, telephone or other media. In communications with patients or members of the general public, discussion of personal medical matters must be avoided. If personal medical information is revealed, it must be held in confidence. Where appropriate, replies shall recommend that a healthcare professional be consulted for further information.

SECTION 4. *Links From Other Websites.* Links may be established to a company-sponsored website from websites sponsored by other persons, but companies should not establish links from websites designed for the general public to company-sponsored websites that are designed for healthcare professionals. In the same manner, links may be established to separate websites, including websites sponsored by the company or by other persons. Links should ordinarily be made to the home page of a website or otherwise managed so that the reader is aware of the identity of the website.

SECTION 5. *Website Addresses In Packaging.* Subject to any applicable national laws and regulations, uniform resource locators (URLs) of company-sponsored websites that comply with these guidelines may be included in packaging of medicinal products.

SECTION 6. *Scientific Review.* Companies should ensure that scientific and medical information prepared by them for inclusion in their websites is reviewed for accuracy and compliance with the applicable code(s). The scientific service established within the company pursuant to those provisions of the applicable code that adopt Section 13.02 of the EFPIA Code may perform this function, or it may be entrusted to other appropriately qualified persons.

SECTION 7. *Privacy.* The website must conform to legislation and applicable codes of conduct governing the privacy, security and confidentiality of personal information.