Comparison of the AdvaMed Code of Ethics and the IFPMA Code of Pharmaceutical Marketing Practices

Executive Summary:

The International Federation of Pharmaceutical Manufacturers & Associations (IFPMA) is the global non-profit nongovernmental organization (NGO) representing the research-based pharmaceutical industry, including the biotech and vaccine sectors. Its members comprise 25 leading international companies and 45 national and regional industry associations covering developed and developing countries. The industry's R&D pipeline contains hundreds of new medicines and vaccines being developed to address global disease threats, including cancer, heart disease, HIV/AIDS and malaria. The IFPMA Clinical Trials Portal, its Ethical Promotion online resource and its Developing World Health Partnerships information help make the industry's activities more transparent. The IFPMA strengthens patient safety by improving risk assessment of medicines and combating their counterfeiting. It also provides the secretariat for the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH).

The main objectives of the IFPMA are:

- to encourage a global policy environment that is conducive to innovation in medicine, both therapeutic and preventative, for the benefit of patients around the world;
- to contribute industry expertise and foster collaborative relationships and partnerships with international organizations, national institutions, governments and non-governmental organizations that are dedicated to the improvement of public health, especially in developing and emerging countries;
- to assure regular contact and experience-sharing and coordinate the efforts of its members towards the realization of the above objectives.

AdvaMed Code of Ethics on Interactions with Health Care Professionals	IFPMA Code of Pharmaceutical Marketing Practices	Notes
Approved: December 18, 2008, Effective July 1, 2009	Revised 2006, Effective January 1, 2007	
I. Preamble: Goal and Scope 1. Defines the terms: "**Companies**": companies that develop, produce, manufacture, and market medical products, technologies and related services and therapies used to diagnose, treat, monitor, manage and alleviate health conditions and disabilities. These products, technologies and services are defined as "**Medical Technologies".** **"Health Care Professional": (HCP)** those individuals or entities involved in the provision of health care services and/or items to patients, which purchase, lease, recommend, use, arrange for the purchase or lease of, or prescribe Companies' Medical Technologies in the United States. 2. ***Medical Technologies***: makes a distinction between Medical Technologies which are highly dependent on "hands on" HCP interaction, and drugs and biologics, which act on the human body by pharmacological, immunological or	**Preamble** • Makes the point that the ethical promotion of prescription medicines is vital to the pharmaceutical industry's mission of helping patients by discovering, developing and marketing new medicines and that ethical promotion helps to ensure that healthcare professionals and patients have access to information they need, and that medicines are prescribed and used in a manner that provides the maximum healthcare benefit to patients. • IFPMA and its members are committed to educational and promotional efforts that benefit patients and promotional programs and collaborations that enhance the practice of medicine. IFPMA also seeks to preserve the independence of the decisions taken by healthcare professionals in prescribing medicines to patients. • The IFPMA Code of Pharmaceutical Marketing Practices (the "IFPMA Code") sets forth standards for the ethical promotion of	The Preamble also includes the Objectives and Scope of the IFPMA Code. There are a number of other provisions in the preamble, including: IFPMA acknowledges the role of relevant codes of ethics developed by a number of associations and the World Health Organization. The Objectives and Scope section lists a number of exclusions: The Code does not seek to regulate the following activities: • Promotion of prescription only pharmaceutical products directly to the general public (i.e. direct to consumer advertising). • Promotion of self-medication products that are provided "over-the-counter" (OTC) without prescription, • Pricing or other trade terms for the supply of

metabolic means.

3. ***Interactions with HCPs***: explains the scope and types of interactions with HCPs.
   a) Promote the advancement of Medical Technologies
   b) Enhance the Safe and Effective use of Medical Technologies
   c) Encourage Research and Education
   d) Foster Charitable Donations and Giving

4. ***The Purpose of the Code of Ethics***: recognizes that HCP's first duty is to act in the best interest of patients, and the obligation to facilitate ethical interactions between Companies and HCPs.

5. A **footnote** notes that the principles are derived from a number of authorities, including the federal Anti-Kickback Statute. Reference to "unlawful inducement" relates to the Anti-Kickback Statute prohibitions.

pharmaceutical products to healthcare professionals, and for member companies' interactions with them.

1. Objective and Scope

Objective

The IFPMA Code sets out standards for the ethical promotion of pharmaceutical products to healthcare professionals to ensure that member companies' interactions with healthcare professionals are appropriate and perceived as such.

Scope

The following definitions are provided:

"Pharmaceutical Product" means all pharmaceutical or biological products which are intended to be used on the prescription of, or under the supervision of, a healthcare professional, and which are intended for use in the diagnosis, treatment or prevention of disease in humans, or to affect the structure or any function of the human body.

"Promotion" means any activity which is directed at healthcare professionals to promote the prescription, recommendation, supply, administration or consumption of its pharmaceutical product(s) through all media, including the internet.

"Healthcare Professional" means 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, recommend, purchase, supply, or administer a pharmaceutical product.

"Member Company" means any company that is a member of IFPMA (direct member) or a member of any association that is a member of IFPMA (indirect member).

pharmaceutical products.

- The engagement of a healthcare professional to provide genuine consultancy or other genuine services to a member company.
- The conduct of clinical trials.
- The provision of non-promotional information by member companies.

The points discussed in Section 2 of the IFPMA Code, are included in the AdvaMed Preamble.	**2 General Principles** **2.1 Basis of Interaction** Member companies' relationships with healthcare professionals are intended to benefit patients and to enhance the practice of medicine. Interactions should be focused on informing healthcare professionals about products, providing scientific and educational information and supporting medical research and education. **2.2 Independence of Healthcare Professionals** No financial benefit or benefit-in-kind may be provided or offered to a healthcare professional in exchange for prescribing, recommending, purchasing, supplying or administering products or for a commitment to continue to do so. Nothing may be offered or provided in a manner or on conditions that would have an inappropriate influence on a healthcare professional's prescribing practices. **2.3 Appropriate Use** Promotion should encourage the appropriate use of pharmaceutical products by presenting them objectively and without exaggerating their properties. **2.4 Local regulations** In all cases, all relevant laws, local regulations and industry codes must be observed and companies have a responsibility to check local requirements, in advance of preparing promotional material or events in any specific country. **2.5 Transparency of Promotion** Promotion should not be disguised. Clinical assessments, postmarketing surveillance and experience programs and postauthorization studies must not be disguised promotion. Such assessments, programs and studies must be conducted with a primarily scientific or educational purpose. Material relating to pharmaceutical products and their uses, whether promotional in nature or not, which is sponsored by a company should clearly indicate by whom it has been sponsored.	Both Codes emphasize the recognition that HCPs should make product purchase decisions with the best interest of their patients in mind. They both also discuss the advancement of medical technology as one of their goals. The IFPMA mentions company compliance with local regulations while the AdvaMed Code specifically mentions the US Federal Anti-Kickback Statute.

II. Code of Ethics Compliance

All Companies are strongly encouraged to adopt the Code and implement effective compliance programs.

1. **Annual Certification** Companies that adopt the Code are strongly encouraged to submit an annual certification that the Company has adopted the Code and has implemented an effective compliance program. Certification should be signed by the CEO and Chief Compliance Officer. AdvaMed will publish a list of Companies that have certified.

2. **Contact Information** AdvaMed member Companies must, and non-members may supply contact information for the Company's Compliance Department or anonymous hot line to facilitate reporting of possible violations. AdvaMed will publish this information.

3. **Elements of an Effective Compliance Program**: Companies are strongly encouraged to follow the seven elements of an Effective Compliance Program.
   a) Written policies and procedures;
   b) Designated compliance officer and compliance committee;
   c) Conduct effective training and education;
   d) Develop effective lines of communication (including an anonymous reporting function);
   e) Conducting internal monitoring and auditing;
   f) Enforcing standards through well-publicized disciplinary guidelines; and
   g) Responding promptly to detected problems and undertaking corrective action.

4. ***Note:*** Companies adopting the Code shall communicate the principles of the Code to their employees, agents, dealers and distributors with the expectation that they will adhere to the Code. Companies shall encourage ethical business practices and socially responsible industry conduct and shall not engage in any

The IFPMA Code Preamble includes the following as relates to Code Compliance

Member associations are required to accept the conditions of the IFPMA Code and, subject to local laws and regulations, adopt codes that meet local requirements but are consistent with, and as comprehensive as, the IFPMA Code.

IFPMA member companies must comply with applicable national codes or where there are no local codes or appropriate laws and regulations, the IFPMA Code acts as a default code.

Member companies are accountable for addressing and correcting infringements under relevant codes. They should also ensure that internal structures and procedures are created to ensure responsible and ethical promotional activities. Companies not in membership with IFPMA may elect to be subject to the IFPMA Code and its complaints handling processes.

The IFPMA is open to receive genuine complaints from any source on any aspect of the IFPMA Code, in accordance with its operating procedures. Where it is determined that there has been a breach of the IFPMA Code, the objective is to correct the matter as rapidly as possible.

10. Infringement, Complaints, and Enforcement

10.1 Complaints
Genuine complaints relating to infringements of the IFPMA Code are encouraged. Detailed procedures are set out in Appendix 1: Operating Procedures of the IFPMA Code. (See Notes in next column.)

10.2 Measures to Ensure and Enforce Compliance
Each member association should strongly encourage its member companies to adopt procedures to assure adherence to its national code. While strong local legal and regulatory mechanisms and vigorous government enforcement may obviate the need for compliance mechanisms in some countries, member associations are

Compliance with the IFPMA Code is addressed in the Preamble, in Section 10 and in Appendix 1 which includes Operating Procedures that provide detailed information with regard to processing allegations of violations. Following is a synopsis of the Principles and Procedures.

1. Principles

The Code is stated as being applicable in territories where no national code has been adopted as well as where there are national codes adopted by member associations but the alleged violating company is not a member of that association.

2. The Procedure for Code Complaints

The Procedure for Code Complaints explains how complaints are processed, including but not limited to the following:

Validation to ensure it is a genuine matter submitted in good faith,

Referral of the matter to senior management of the company,

Time Limits for responses from companies, usually expected in 30 calendar days,

Company Response indicating action to remedy the matter where a company acknowledges a breach of the IFPMA Code,

Adjudication of cases where a company disputes the allegation, and

Appeal where a company disagrees with the decision of the IFPMA.

3. Use of the Complaint Procedure

The IFPMA Code complaint procedure is open to any healthcare professional, a company or member of the public, acting in good faith within the spirit and intentions of the IFPMA Code. This Subsection provides the details on how to submit complaints and the required information to be submitted.

unlawful inducement.	encouraged, where appropriate, to include provisions intended to assure compliance with their national codes. The IFPMA recognizes, however, that local laws and practices vary widely and will affect the types of compliance provisions, if any, that may be adopted.	
III. Company-Conducted Product Training and Education 1. The Code defines: ***Training***: training on the safe and effective use of Medical Technologies ***Education***: communicating information directly concerning or associated with the use of Companies' Medical Technologies, e.g., information about disease states and benefits to certain patient populations. **FDA Required Training** The Code points out the FDA often mandates training and education to facilitate the safe and effective use of Medical Technologies. 2. Companies should adhere to the following principles concerning training and education: a) **Conducive Setting** Programs should be conducted in a setting conducive to the effective transmission of information. Settings may include clinical, educational or conference sites including hotels and other meeting facilities. They may also include the HCPs site. b) **Hands on Training** Training should be conducted at training facilities, medical institutions or laboratories. Training staff should be qualified. Sales employees may conduct the training if they have the technical expertise. c) **Modest meals and refreshments** may be provided if they are modest in value and subordinate in time to the training or education. d) **Travel and Lodging** Out-of-town travel and modest lodging may be provided the HCPs if there are objective reasons to support the need. e) **No Guests** Meals, refreshments, travel	**7. Interactions with Healthcare Professionals** **7.1 Events** 7.1.1 Scientific and Educational Objectives The purpose and focus of all symposia, congresses and other promotional, scientific or professional meetings (an "Event") for healthcare professionals organized or sponsored by a company should be to inform healthcare professionals about products and/or to provide scientific or educational information. 7.1.2 Events Involving Foreign Travel No company may organize or sponsor an Event for healthcare professionals that takes place outside of their home country unless it is appropriate and justified to do so from the logistical or security point of view. International scientific congresses and symposia that derive participants from many countries are therefore justified and permitted. 7.1.3 Promotional Information at Events Promotional information which appears on exhibition stands or is distributed to participants at international scientific congresses and symposia may refer to pharmaceutical products which are not registered in the country where the Event takes place, or which are registered under different conditions, provided that a number of conditions are observed: • The meeting should be a truly international, scientific Event with a significant proportion of the speakers and attendees from countries other than the country where the Event takes place; • Promotional material (excluding promotional aids) for a pharmaceutical product not registered in the country of the Event should be accompanied by a suitable statement indicating the countries in which the product is registered and make clear that such product is not	**Section 7 of the IFPMA Code, Interactions with Healthcare Professionals, discusses the principles of ethical interactions during promotional, scientific or professional meetings and symposia. Although the IFPMA Code does not have specific subsections that correlate with certain parts of the AdvaMed Code, they provide guidance in those areas as well. Section 7 will be referenced in those other areas.**

and lodging may be provided only to HCPs with a *bona fide* reason to attend the training.	available locally; • Promotional material which refers to the prescribing information (indications, warnings, etc.) authorized in a country or countries other than that in which the Event takes place but where the product is also registered, should be accompanied by an explanatory statement indicating that registration conditions differ internationally; and • An explanatory statement should identify the countries in which the product is registered and make it clear that it is not available locally. **7.2 Sponsorship** Member companies may sponsor healthcare professionals to attend Events provided such sponsorship is in accordance with the following requirements: • The Event complies with the hospitality requirements in this Code as described in 7.5; • Sponsorship to healthcare professionals is limited to the payment of travel, meals, accommodation and registration fees; • No payments are made to compensate healthcare professionals for time spent in attending the Event; and • Any sponsorship provided to individual healthcare professionals must not be conditional upon an obligation to prescribe, recommend or promote any pharmaceutical product. **7.3 Guests** Companies should not pay any costs associated with individuals accompanying invited healthcare professionals. **7.4 Payments for Speakers and Presenters** Payments of reasonable fees and reimbursement of out-of-pocket expenses, including travel and accommodation, may be provided to healthcare professionals who are providing genuine services as speakers or presenters on the basis of a written contract with the company at the Event. **7.5 Hospitality** 7.5.1 Appropriate Venue	

	All Events should be held in an appropriate venue that is conducive to the scientific or educational objectives and the purpose of the Event or meeting. Companies should avoid using renowned or extravagant venues. 7.5.2 Limits of Hospitality Hospitality should be limited to refreshments and/or meals incidental to the main purpose of the Event and should only be provided: • to participants of the Event and not their guests; and • if it is moderate and reasonable as judged by local standards. 7.5.3 Guidance from Member Associations Member associations are encouraged to provide written guidance on the meaning of the terms "moderate", "modest" and "reasonable", and the meaning of the terms "renowned" and "extravagant". As a general rule, the hospitality provided should not exceed what healthcare professional recipients would normally be prepared to pay for themselves. 7.5.4 Entertainment No stand-alone entertainment or other leisure or social activities should be provided or paid for by member companies. At Events, entertainment of modest nature which is secondary to refreshments and/or meals is allowed.	**Also see Q&A 14 of the IFPMA Code, beginning on page 10.**
IV. Supporting Third-Party Educational Conferences *Bona fide* independent, education, scientific and policymaking conferences include educational conferences include conferences sponsored by national, regional, or specialty medical associations and conferences sponsored by accredited continuing medical education providers. Companies may support these through: **Conference Grants** Grants must be provided to the conference sponsor to reduce conference costs, or to training institutions to allow attendance by medical students, residents, fellows and other		**See pertinent subparts of Section 7 of the IFPMA Code, "Interactions with Healthcare Professionals", beginning on page 5.**

HCPs in training.
Grants may be provided when:

a) The gathering is primarily dedicated to promoting objective scientific and educational activities, and
b) The training institution or conference sponsor selects the attending HCPs in training.

- Grants should be paid ONLY to organizations with a genuine educational function
- The may be used to reimburse legitimate expenses for *bona fide* educational activities.
- The conference sponsor controls the selection of program content, faculty, methods and materials.

Conference Meals and Refreshments
Companies may provide:

- Funding to conference sponsors to support the provision of meals and refreshments to conference attendees
- Meals and refreshments themselves if they are provided:
  (1) To all HCP attendees (note exception below)
  (2) Consistent with applicable standards established by the conference sponsor and any accrediting body.

  Note: meals and refreshments provided to fewer than all HCP attendees must meet all the principles stated in Section VIII of the Code, and must be modest in value, subordinate in time and focus to the purpose of the conference and separate from the educational portion of the conference.

Faculty Expenses Grants may be made for reasonable honoraria, travel, lodging and modest meals for *bona fide* faculty members.

Advertising Companies may purchase

advertisements and lease booth space for Company displays.		
V. Sales, Promotional, and Other Business Meetings Companies may conduct business meetings with HCPs: a) **Business Discussion** Discuss Medical Technology features, sales terms or contracts b) **Meals** Occasional modest meals and refreshments may be provided c) **Travel** When necessary, (e.g., plant tours or demonstration of non-portable equipment) reasonable travel costs and lodging may be provided d) **No Guests** Meals, refreshments, travel or lodging may not be provided for guests of HCPs or anyone without a *bona fide* interest in the information being shared at the meeting.		**See pertinent subparts of Section 7 of the IFPMA Code, "Interactions with Healthcare Professionals", beginning on page 5.**
VI. Consulting Arrangements with Health Care Professionals Companies may pay HCP consultants fair market value for services that fulfill a legitimate business need and do not constitute an unlawful inducement. The following standards apply: • **Agreements** should be written and describe all the services to be provided. Clinical research services should have a written research protocol. • **Legitimate need** for the services should be identified and documented in advance of any arrangements. • **Selection** should be based on the consultant's qualifications and expertise to meet the defined need. • **Compensation** should be fair market value and not based on past, present or anticipated business. • **Expenses** Companies may pay for actual, reasonable and documented expenses, including travel, modest meals and lodging,	**6. Consultancy Agreements** Q: In the absence of any formal industry guidelines or local laws, how should companies interact with healthcare professionals who are offering legitimate consultancy services? A: It is appropriate for consultants who provide services to be offered reasonable compensation for those services and to be offered reimbursement for reasonable travel, lodging, and meal expenses incurred as part of providing those services. Compensation and reimbursement that would be inappropriate in other contexts can be acceptable for genuine consulting arrangements. Token consulting or advisory arrangements should not be used to justify compensating healthcare professionals. The following factors support the existence of a genuine consulting arrangement (not all factors may be relevant to any particular arrangement): • a written contract which specifies the nature of the services to be provided and the basis for payment of those services;	Although the issue of consulting arrangements with HCPs is not addressed in the body of the IFPMA Code, Q&A #6 deals with this topic and the principles track with those of the AdvaMed Code.

incurred by the consultant to carry out the arrangement. • **Venue** and circumstances of any meetings should be appropriate for the subject of the consultation, and conducive to the effective exchange of information. • **Meals and refreshments** should be modest in value and subordinate in time and focus to the primary purpose of the meeting. Recreation or entertainment should not be provided. • **Sales Involvement** Sales personnel may provide input about the suitability of proposed consultant, but should not control or unduly influence the selection decision. **Provisions on Payment of Royalties** Companies should enter into a royalty arrangement only where the HCP makes a novel, significant or innovative contribution to the development of a product, technology, process or method. Calculation of royalties should preserve the objectivity of medical decision-making and avoid the potential for improper influence and should not be conditioned on a requirement to purchase, order or recommend the Company's product or technology or a requirement to market the product or technology upon commercialization. Companies may elect to enter into separate agreements with HCPS for marketing services and are strongly encouraged to consider the appropriateness and practicality of excluding the HCP consultant's purchases from the calculation of royalty payments.	• a legitimate need for the services has been clearly identified in advance of requesting the services and entering into arrangements with the prospective consultants; • the criteria for selecting consultants are directly related to the identified purpose and the persons responsible for selecting the consultants have the expertise necessary to evaluate whether the particular healthcare professionals meet those criteria; • the number of healthcare professionals retained is not greater than the number reasonably necessary to achieve the identified purpose; • the retaining company maintains records concerning and makes appropriate use of the services provided by consultants; and • the hiring of the healthcare professional to provide the relevant service is not an inducement to prescribe a particular product. **IFPMA does not discuss the payment of royalties to HCPs.**	
VII. Prohibition on Entertainment and Recreation Companies should not provide or pay for any entertainment or recreational event or activity for any non-employee HCP. Examples include: golf, skiing. Hunting, sporting equipment and leisure or vacation trips. Such events or items should not be provided	**7.5.4 Entertainment** No stand-alone entertainment or other leisure or social activities should be provided or paid for by member companies. At Events, entertainment of modest nature which is secondary to refreshments and/or meals is allowed. **Q&A 14, Entertainment**	IFPMA mentions restriction on entertainment in Section 7, Subpart 7.5.4, Interactions with Healthcare Professionals. Q&A #14 provides greater detail and gives additional guidance.

regardless of: (1) Their value, (2).whether the HCP is a speaker or consultant, or (3) whether the entertainment or recreation is secondary to an educational purpose.	Q: The IFPMA Code prohibits stand-alone entertainment, leisure or social activities but allows entertainment of modest nature in conjunction with meals, etc., which is secondary to the main purpose of the event. How should companies interpret this in practice? A: When a company organizes a meeting and refreshments are provided, e.g., an evening meal for a meeting stretching over more than one day, it would be permitted to provide some background music during the meal or to have an interlude when some local singers perform. However it would not be appropriate for a company to fund attendance at a concert by those same performers as this would be self standing and not incidental to the refreshments and the IFPMA Code also prohibits the purchase of entertainment tickets. A self standing sightseeing tour would not be permitted but this would not prohibit a commentary about sights of interest en-route to a restaurant. The 'modest nature' of the entertainment may be interpreted as prohibiting high profile, inappropriate or expensive entertainers - even if their performance is secondary to a necessary meal. So an appearance by a well known TV or pop star would not be considered as modest whereas a folk dance display or performance by a local singer would be acceptable as entertainment for a meal interlude.	
VIII. Modest Meals Associated with Health Care Professional Business Interactions Modest meals may be provided as an occasional business courtesy involving the presentation of scientific, educational, or business information, consistent with the following limitations: **Purpose** The meal should be incidental to the *bona fide* presentation of scientific, educational or business information, and should provided in a manner conducive to the presentation. It should not be part of an entertainment or recreation event. **Setting and Location** The setting should be conducive to *bona fide* scientific, educational or business discussion. Meals may occur at the HCP's place of business, however, if that place is		**See pertinent subparts of Section 7 of the IFPMA Code, "Interactions with Healthcare Professionals", beginning on page 5.** **Also see Q&A 14 of the IFPMA Code, beginning on page 10.**

not available or conducive to such discussions, meals may be provided off-site. Examples include: (1) where the medical technology cannot easily be transported to the HCP's location, (2) when it is necessary to discuss confidential product development or improvement information, or (3) where a private space cannot be obtained on site. **Participants (No Guests)** Meals may be provided only to HCPs who actually attend the meeting, and may not be provided for an entire staff where everyone does not attend the meeting, i.e., no "dine and dash" programs. Meals may not be provided for guests of HCPs or any one not having a *bona fide* professional interest in the information being shared.		
IX. Educational items; Prohibition on Gifts • Items that benefit patients or serve a genuine educational function occasionally may be provided to HCPs. • Items should have a FMV of less than $100, except text books and anatomical models. • Items must not be capable of non-educational or non-patient-related uses. • Non-educational branded promotional items may not be given to HCPs, even if of minimal value and related to the HCPs work or benefit patients. • Items such as wine, flowers, cookies, gift baskets, holiday gifts etc., or cash or cash equivalents are not permitted.	7.6 Gifts and Items of Medical Utility **7.6.1 Cash** Payments in cash or cash equivalents (such as gift certificate) must not be offered to healthcare professionals. **7.6.2 Personal Gifts** Gifts for the personal benefit of healthcare professionals (including, but not limited to, music CDs, DVDs, sporting or entertainment tickets, electronic items) must not be provided or offered. **7.6.3 Promotional Aids** Promotional aids or reminder items may be provided or offered to healthcare professionals and appropriate administrative staff, provided the gift is of minimal value and relevant to the practice of the healthcare professional. **7.6.4 Items of Medical Utility** Items of medical utility may be offered or provided free of charge provided that such items are of modest value and are beneficial to the provision of medical services and for patient care. **7.6.5 Cultural Courtesy Gifts** In some countries, if allowed under local law and in accordance with local practice, an inexpensive gift not related to the practice of medicine may be given on an infrequent basis to healthcare professional in	In the IFPMA Code, Section 7, Interactions with Healthcare Professionals, Subsection 7.6, deals with Gifts and Items of Medical Utility.

	acknowledgment of significant national, cultural or religious holidays. **7.6.6 Guidance on Values** Member associations shall provide guidance using local currency, on the precise value for the following: • "minimal" value for promotional aids and reminder items in 7.6.3 above; • "modest value" for items of medical utility in 7.6.4 above; and • "inexpensive" for customary gifts in 7.6.5 above. Member associations shall also clearly define what constitutes significant national, cultural or religious holidays or Events, as referred to in 7.6.5 above.	
X. Provision of Coverage, Reimbursement and Health Economics Information Companies may provide accurate and objective reimbursement information on their products to HCPs, professional or patient organizations, patients and payors as follows: • Identifying the clinical value of their technologies and services • Collaborating on joint advocacy on coverage, reimbursement and health economics issues • Providing information indentifying coverage, codes and billing options regarding technologies on which they may be used • Providing information about the economically efficient use of their technologies • Providing information related to available reimbursement revenues and associated costs • Providing information relating to changes in coverage or reimbursement amounts • Providing support in the appropriate and efficient use of their technologies • Assisting to obtain coverage decisions and in the preparation and submission of coverage requests, prior authorizations and appeals. Companies may not interfere with HCPs independent clinical decision making or provide information as an unlawful inducement or suggest mechanisms for billing for unnecessary services or	**No Equivalent Section**	

fraudulent practices to achieve inappropriate payment.		
XI. Research and Educational Grants and Charitable Donations Companies may provide such grants and donations but not as an unlawful inducement. Companies should: a) Adopt objective criteria that exclude purchasing value of the recipient b) Implement procedures to ensure such grants are not used as an unlawful inducement c) Document such grants and donations. Companies' sales personnel may provide input to, but not unduly influence grant and donation decisions or recipient selection. **Research Grants** should have well-defined objectives and milestones and may not be linked to purchases of Medical Technologies **Educational Grants** companies may make such grants to conference sponsors or training institutions but not to individual HCPs • *Advancement of Medical Education* Companies may make grants to support genuine education of medical students, residents and fellows (See also Section IV) • Public Education- Companies may make grants to support patient or public education on health care topics **Charitable Donations** Companies may make donations to organizations with *bona fide* charitable missions such as supporting indigent care, or patient and public education.	**No Equivalent Section**	**See pertinent subparts of Section 7 of the IFPMA Code, "Interactions with Healthcare Professionals", beginning on page 5.**
XII. Evaluation and Demonstration Products This section of the Code discusses the provision of evaluation and demonstration products and is not intended to address any other arrangement. **Evaluation Products**: • Provided at no charge to assess	**8. Samples** **8.1 Samples Permitted** In accordance with local laws and regulations, free samples of a pharmaceutical product may be supplied to healthcare professionals in order to enhance patient care. Samples should not be resold or otherwise misused.	

functionality and to determine future purchase and use of that product • Expected to be used in patient care a) *Single Use/Consumable/Disposable*- may be provided in quantity reasonably necessary for adequate evaluation *b) Multiple Use/Capital*- furnished only for the time reasonably necessary for adequate evaluation. The terms of such an evaluation should be set in writing, Companies should retain title to the product, and the product should be removed promptly upon completion of the evaluation. **Demonstration Products:** • Typically unsterilized single-use products typically used for HPC and patient awareness, education and training. • Not expected to be used in patient care. • Identified as not intended for patient use and typically designated as "Sample," or "Not for Human Use," on the packaging and/or other documentation that accompanies the product. Companies should provide HCPs with documentation disclosing the no-charge status of evaluation and demonstration products.	**8.2 Control and Accountability** Companies should have adequate systems of control and accountability for samples provided to healthcare professionals including how to look after such samples whilst they are in possession of medical representatives.	
No Equivalent Section	**3. Pre-Approval Communications and Off-Label Use** No pharmaceutical product shall be promoted for use in a specific country until the requisite approval for marketing for such use has been given in that country. This provision is not intended to prevent the right of the scientific community and the public to be fully informed concerning scientific and medical progress. It is not intended to restrict a full and proper exchange of scientific information concerning a pharmaceutical product, including appropriate dissemination of investigational findings in scientific or lay communications media and at scientific conferences. Nor should it restrict public disclosure of information to stockholders and others concerning any pharmaceutical product, as may be required or desirable under law, rule or regulation.	

No Equivalent Section	**4. Standards of Promotional Information** **4.1 Consistency of Product Information** It is understood that national laws and regulations usually dictate the format and content of the product information communicated on labelling, packaging, leaflets, data sheets and in all promotional material. Promotion should not be inconsistent with locally approved product information. Healthcare professionals in developing countries should have access to similar data to those being communicated in developed countries. **4.2 Accurate and Not Misleading** Promotional information should be clear, legible, accurate, balanced, fair, objective and sufficiently complete to enable the recipient to form his or her own opinion of the therapeutic value of the pharmaceutical product concerned. Promotional information should be based on an up-to-date evaluation of all relevant evidence and reflect that evidence clearly. It should not mislead by distortion, exaggeration, undue emphasis, omission or in any other way. Every effort should be made to avoid ambiguity. Absolute or all-embracing claims should be used with caution and only with adequate qualification and substantiation. Descriptions such as 'safe' and 'no side effects' should generally be avoided and should always be adequately qualified. **4.3 Substantiation** Promotion should be capable of substantiation either by reference to the approved labeling or by scientific evidence. Such evidence should be made available on request to healthcare professionals. Companies should deal objectively with requests for information made in good faith and should provide data which are appropriate to the source of the inquiry.	
No Equivalent Section	**5. Printed Promotional Material** Where local regulations or codes are in force which define requirements, those take precedence. **5.1 All Printed Promotional Material, including Advertisements**	

	All printed promotional materials other than those covered in 5.2 below must be legible and include: • the name of the product (normally the brand name); • the active ingredients, using approved names where they exist; • the name and address of the pharmaceutical company or its agent responsible for marketing the product; • date of production of the advertisement; • "abbreviated prescribing information" which should include an approved indication or indications for use together with the dosage and method of use; and a succinct statement of the contraindications precautions and side effects. **5.2 Reminder Advertisements** A "reminder" advertisement is defined as a short advertisement containing no more than the name of the product and a simple statement of indications to designate the therapeutic category of the product. For "reminder" advertisements, "abbreviated prescribing information" referred to in 5.1 above may be omitted.	
No Equivalent Section	**6. Electronic Materials, Including Audiovisuals** The same requirements shall apply to electronic promotional materials as apply to printed materials. Specifically, in the case of pharmaceutical product related websites: • the identity of the pharmaceutical company and of the intended audience should be readily apparent; • the content should be appropriate for the intended audience; • the presentation (content, links, etc.) should be appropriate and apparent to the intended audience; and • country-specific information should comply with local laws and regulations.	