AIFD Code of Good Promotional Practice and Good Communication

Association of Research-Based Pharmaceutical Companies (AIFD) Code of Practice on the Relations with Healthcare Professionals and Organizations, Communication with Patients Associations, Use of Digital Platforms and the Promotion of Medicinal Products for Human Use to Physicians, Dentists and Pharmacists

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For access via the internet:				
www.AIFD.org.tr/pdf/tanitim_ilkeleri.pdf (Turkish)				
www.AIFD.org.tr/pdf/tanitim_ilkeleri_eng.pdf (English)				

Differences of 4.1.1 version from 4.1.0 version:

Supplementary text 14.5. Promotion and Distribution by Sweepstakes, Quizzes during congresses
Supplementary text 15.21.2. Promotional Activities Organized in Clinics
Supplementary text 19.7.3 Suggested Approach in Invitation of Media Representatives
Three additional Q&A in Appendix IV: AIFD User Guide on Digital Communication
All updated (as of July 16,2013) MoH TITCK Guidelins related to the Regulation.
Annex XIII: Selected articles of the Regulation on the Ethical Conduct of Civil Servants and the Rules and Procedures for Application

AIFD Code of Ethics and Promotion

Members of the Association of Research-Based Pharmaceutical Companies (AIFD), that conduct medical and biopharmaceutical researches for the purpose of providing service upon offering high quality treatment opportunities to patients, manufacture, investigate, promote, distribute and sell their drugs in compliance with ethical principles as well as the applicable norms and procedures in the fields of medicine and healthcare.

The Key Principles listed below and presented also at the beginning of the IFPMA Code of Practice are the cornerstones of the vision paper that shape the AIFD 2013 Code of Good Promotional Practice and Good Communication and constitute its philosophical and ethical infrastructure. Code of Promotional Practice does not provide an answer for each situation and problem to arise. In case of a matter not included into this document or where it is necessary to perceive the essence of the code, these guiding Key Principles will assist companies and their representatives to proceed in tandem with all their stakeholders on the right ethical path.

1. The healthcare and well-being of patients are the first priority of pharmaceutical companies.

2. Pharmaceutical companies will conform to high standards of quality, safety and efficacy as determined by regulatory authorities and will try to outperform them.

3. Pharmaceutical companies' interactions with stakeholders must at all times be conducted in an ethical, appropriate and professional level. Nothing should be offered or provided by pharmaceutical companies in a manner or on conditions that would have or perceived as having an inappropriate influence.

4. Pharmaceutical companies shall offer product data and information that are accurate, balanced and scientifically valid.

5. Promotion must be ethical, accurate, balanced and must not be misleading. Promotional materials and the information contained therein shall be offered in a manner so as to substantiate the evaluation of the benefits and risks of the product in an independent and proper manner, and help the rational use of drugs.

6. Pharmaceutical companies will respect the privacy and confidential personal information of patients and healthcare professionals to whom they provide service.

7. All pharmaceutical clinical trials and scientific research conducted, sponsored or supported by pharmaceutical companies shall be conducted with the intent to develop knowledge that will benefit patients and advance science and medicine. Pharmaceutical companies are committed to the transparency of industry-sponsored clinical trials conducted on humans.

8. Pharmaceutical companies should adhere to both the letter and the spirit of applicable industry codes. To achieve this, pharmaceutical companies will ensure that all relevant personnel are appropriately trained.

Sincerely,

Alp Sevindik

AIFD Secretary General and Chief Operating Officer

AIFD Code of Good Promotional Practice and Good Communication

Pharmaceutical promotion is among the key activities in our sector. It is crucial for our physicians to follow up developments, receive information on new drugs and enhance the access opportunities of patients to drugs.

2013 Edition of the Code of Promotional Practice reflects the determination of all members of the Association of Research-Based Pharmaceutical Companies to maintain the standards in our industry at least at the same level with that in the European Union.

The Code of Practice has been prepared and updated in compliance with the following references:

- Regulation on the Promotional Activities for Medicinal Products for Human Use of the Ministry of Health, published in the Official Gazette dated 26/08/11, with No. 28037, amended with the Official Gazette dated 14/10/2012, with No. 28441, as well as its Guidelines and Directives (the whole of which shall be referred to as "Regulation" hereinafter);
- The articles and amendments relating to promotion in the Directives of the European Parliament and Council, dated 06/11/2001, with No. 2001/83/EC and 2004/27/EC, on Medicinal Products for Human Use;
- Amendments in the EFPIA 2011 (**E**uropean **F**ederation of **P**harmaceutical **I**ndustries and **A**ssociations) "Code of Practice on the Promotion of Prescription-Only Medicines" and the "Code of Practice on the Relationships with Patient Organizations";
- IFPMA 2012 (**I**nternational **F**ederation of **P**harmaceutical **M**anufacturers & **A**ssociations) Code of Pharmaceutical Marketing Practice;
- Regulation on the Ethical Conduct of Civil Servants and the Rules and Procedures for Application (published in the Official Gazette dated 13/04/2005);
- Turkish Medical Association Declaration on Physician-Pharmaceutical Industry Interactions (May 2010);
- TTB-UDEK Ethics Working Group on Physician-Pharmaceutical Industry Interactions Guidance (October 2009)

The first edition of the Code was approved at the AIFD Board of Directors Meeting of 28/01/2004 and became effective on 01/04/2004. This updated edition approved at the AIFD General Assembly on 25/05/2012 will become effective as of 01/01/2013, including also the latest amendments performed in the Regulation on 14/10/2012. From this date onwards, promotional activities should be performed in compliance with this new text and the materials used as well as the activities organized should not be in breach of this new text.

AIFD Code of Good Promotional Practice is intended to provide guidance to member companies in the interpretation of the Regulation on the Promotional Activities for Medicinal Products for Human Use of the Ministry of Health and its associated Guidelines, and also to serve as a guide in the implementation of higher ethical marketing and promotional approaches comprised in the texts of IFPMA and EFPIA Codes, WHO Codes and the relevant EU Directives and adopted in the field of pharmaceutical marketing.

When the interpretation of the Code needs to be adapted to situations not stipulated in the Code, primarily the national laws and regulations as well as the Regulation, guidelines, directives and resolutions of the Ministry of Health, and consequently IFPMA and EFPIA Codes shall be taken into consideration. In disputable cases and where necessary, the decisions and views of the AIFD Good Promotional Practice Committee, AIFD Secretary General, AIFD Board of Directors, Public Ethics Board and the Turkish Medicines and Medical Devices Agency (TİTCK) of the Ministry of Health of the Republic of Turkey shall be sought.

AIFD Code of Practice Panel (CPP-TİDK) AIFD Code of Practice Appeal Board (CPAB-TİTEK) and AIFD-IEIS Joint Supervisory Panel and Joint Appeal Board have been established in order to overview the full implementation of the Code, as indicated in the annexed Standard Implementation Procedure.

The text of the Code has been organized in separate sections. Remarks, Descriptions and Justifications are provided below each article.

Articles of the Regulations and Guidelines to which reference is made are shown next to the related Articles of the Code in smaller font sizes; e.g. (Reg.Art.10).

INTRODUCTION

The Association of Research-Based Pharmaceutical Companies (AIFD) is a non-profit association established in 2003 by research-based pharmaceutical companies operating in Turkey, with the objective of ensuring access to new and original drugs in Turkey and contributing to the provision of effective solutions for health issues. AIFD is a member of EFPIA (The European Federation of Pharmaceutical Industries and Associations) and IFPMA (The International Federation of Pharmaceutical Manufacturers and Associations).

AIFD's vision is to become a "solution partner" for our country's health sector as well as our Government in overcoming the challenges experienced in the field of health upon providing innovative therapeutic proposals.

AIFD's mission is to enhance access to innovative products, technology and information for Turkish medical community, strive to establish an "ethical and transparent" environment in the field of healthcare and contribute to the health sector of our country.

The promotion of prescription drugs to physicians, dentists and pharmacists constitutes a natural and key step within the process of discovery, development and marketing of drugs. Promotion aims to ensure that the data, information and remarks obtained from laboratory and clinical trials requiring years of work and high expenditures, are promptly disseminated to healthcare professionals via modern communication techniques. The role of scientific promotion cannot be denied in the rational use of drugs.

With the awareness of their scientific, social and economic responsibilities in the field of healthcare, Research-Based Pharmaceutical Companies believe to hold an *obligation* and *responsibility* to provide to healthcare professionals the information obtained from their research on medicinal products for human use.

AIFD promotes free competition among pharmaceutical companies. AIFD Code of Good Promotional Practice is not intended to restrain promotion in a manner that is detrimental for fair competition and restrict the right of patients to access novel therapies. Instead, it seeks to ensure that pharmaceutical companies conduct promotion by reflecting the facts, avoiding deceptive practices and behavior that may appear to give rise to a conflict of interests with healthcare professionals, upon taking into account applicable laws and regulations. The environment of trust intended to be fostered by the AIFD Code is thereby an environment where the choice of the drugs used in the treatment of patients is made only on the basis of their personal health needs and the merits of each therapeutic method and instrument.

In all their activities, Research-Based Pharmaceutical Companies agree on the need to define high standards and fully respect these. They are convinced that, as far as their promotion and overall marketing activities are concerned, the present Code of Promotional Practice, which promotes self-discipline and self-regulation, is the right tool and defines the process that best serves the interest of the public and companies in the long term.

Commitments of AIFD Members

"The fundamental objective of all rules governing the production, distribution, marketing and administration of medicinal products should be to safeguard public health. However, this objective should be attained by means that do not hinder the development of the pharmaceutical industry and trade."

"The control to be imposed on the industry and trade by the state should not exclude the voluntary control of the promotion of medicinal products by self-regulatory bodies, the intervention of and recourse to such bodies, if such a mechanism is present."

In the update of the Code, above quoted texts from the EU Directive with No. 2001/83/EC and the vision and mission statements of AIFD have been used as guidance.

Scope of the AIFD Code

AIFD Code of Good Promotional Practice encompasses the relations and interactions between the companies operating in the pharmaceutical industry and healthcare professionals, the promotion of prescription drugs and drugs included into the reimbursement system to physicians, dentists and pharmacists as well as the relations and interactions between pharmaceutical companies and patient organizations. The AIFD Code is applicable for AIFD-member companies, their affiliates or companies acting in tandem with them and other companies operating in the field of pharmaceutical promotion in cooperation with member companies and that have agreed to act in accordance with the AIFD Code.

When communicating and interacting with healthcare professionals and patient organizations, AIFD member companies are committed to observe the highest ethical standards and implement them in a transparent manner in addition to complying with legal requirements. AIFD members are also determined to display the necessary effort to ensure that their interactions with healthcare professionals and patient organizations are not perceived negatively by health authorities, healthcare professionals, the public opinion and their own employees.

Pharmaceutical companies that are members of AIFD accept to adhere with the Code of Practice presented in this document and the decisions of the AIFD Code of Practice Panel, Code of Practice Appeal Board, AIFD-IEIS Joint Code of Practice Panel and Joint Appeal Board.

AIFD Code of Good Promotional Practice is binding on all members

AIFD Code of Good Promotional Practice is binding on all member companies. Also new members shall accept to act in line with the Association Charter as well as the AIFD Code of Promotional Practice and the decisions of the Code of Practice Panel. Amendments in the AIFD Code of Good Promotional Practice shall become binding for all member companies upon being adopted in the Board of Directors and approved in the General Managers meeting. The text shall be submitted for approval in first upcoming AIFD General Assembly. Breach of the Code of Good Promotional Practice will be construed as breach of the Charter.

AIFD shall take care that the Board decisions monitoring the implementation of the AIFD Code of Practice do not violate the Law on the Protection of Competition. Due to the nature of the business, companies operating in the pharmaceutical industry accept that the commercial and promotional freedom generally granted to other sectors of the business world is restricted by universally accepted rules.

AIFD member companies shall adopt necessary measures to ensure that those working for them and on their behalf, including their contractors, consultants, market research companies, advertising agencies, tourism and congress organization companies, sales representatives working on contract and the like, act in compliance with the AIFD Code of Practice. Member companies shall also take relevant steps to ensure that third parties in the position of a JV or licensor, not included into the definitions provided above but engaged in activities in the pharmaceutical sector that may be encompassed by the scope of the relevant Code of Practice with a member company, act in line with Code of Practice.

The AIFD Code of Practice does not restrain member companies from establishing more stringent rules in line with laws and international obligations or their own ethical regulations. On the contrary, such types of implementations are encouraged by AIFD.

Certainly, the laws and regulations to be issued by the Ministry of Health, other relevant Ministries, Regulatory Institutions and Bodies supersede the AIFD Code and it is mandatory to adhere with the norms stipulated by laws and regulations.

In their activities outside Turkey, member companies shall act in line with the applicable Codes of AIFD, EFPIA, IFPMA, PhRMA, and where available, the norms (Guidelines and Codes) of the pharmaceutical company organizations of the host country where the activity is conducted. Before organizing an international activity, the contacted affiliate in the host country, or in its absence, the Pharmaceutical Company Organization

in that country shall be informed about the activity to be organized and obtain information about the implemented rules.

The AIFD Code of Practice, Code of Practice Panel and the Appeal Board take their power to sanction from the goodwill, mutual tolerance and adherence to ethical norms of AIFD members that are committed to AIFD's vision and respectful of laws.

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Article 1- Purpose and Scope

Purpose

1.1. This Code is based on the Regulation defining the promotional rules aimed at providing rational use of medicinal products for human use and is prepared for the purpose of ensuring that member companies comply with the rules stipulated in the Regulation and to be adhered to (Reg.Art.1.1), as well as internationally accepted high ethical standards in marketing these products and preserve the level attained.

Scope

1.2. This Code comprises the promotion of medicinal products for humans to physicians, dentists and pharmacists. (Reg.Art.2.1)

1.3. The Code also comprises the provision of information to healthcare professionals, assistant healthcare personnel and administrative healthcare personnel with regard to the administration of products to patients, the aspects to be considered during the administration, adverse events and similar topics.

1.4. In addition to promotional activities, the AIFD Code also encompasses the relations and interactions between member companies and physicians, dentists and pharmacists and the chambers, associations, federations or platforms (organizations) established by them or of which they are members; including, but not limited to some pharmaceutical research contracts, service, service agreements and protocols; some aspects of clinical drug trials, ethically important aspects of non-interventional pharmaceutical studies; relations with healthcare professionals to take part in the consultancy and advisory boards of companies.

1.5. The communication, interaction and contracts to be established between member companies and patient associations and organizations are evaluated within the scope of the AIFD Code.

1.6. Furthermore, including but not limited to, sponsorship declarations (Article 8), certain aspects of the procurement of drugs and samples (Article 13) and provision of information to the general public and information provided directly or indirectly to the general public (Article 18) also fall under the scope of the Code.

1.7. The AIFD Code is not intended to restrain the transmission of medical, scientific and tangible information to healthcare professionals, as long as they do not have a promotional purpose.

1.8. The promotion of products registered or permitted within the scope of the Regulation on Traditional Herbal Medicinal Products, shall be conducted in compliance with the Promotion Regulation and AIFD Code of Promotional Practice. (THMP Regulation, Article 29)

1.9. The Code does not encompass *the public promotion* in line with laws of medicinal products for human use which have received registration or permit to be introduced into the market so as to be sold without prescription, and which are not reimbursed.

1.10. The promotion of enteral nutritional products included into the scope of reimbursement, except for taste samples, are covered by the scope of this Code.

1.11. Priority of the Regulation and Laws: Where an amendment is made in relevant Laws or Regulations, in case of any conflict in the content of guidelines, directives and circular letters intended for implementation and the AIFD Code, the legislation of the Ministry of Health shall be taken as basis.

Remarks, Descriptions and Justifications

1. Scope of the Code

The Code is binding on AIFD member companies. Other non-AIFD companies that have declared in writing that they will comply with this Code are also evaluated within this scope.

This Code comprises the promotion of medicinal products for human use, intended or directed to physicians, dentists and pharmacists in Turkey.

The Code comprises the following;

a) Promotion to physicians, dentists and pharmacists;
b) Promotion to physicians, dentists and pharmacists in Turkey, regardless of their nationality;

c) Promotion conducted at international meetings held in Turkey;

d) Promotion conducted in meetings held outside Turkey for healthcare professionals practicing their profession in Turkey.

e) Promotion made at international meetings outside Turkey, intended at those practicing their profession in Turkey is included into the scope of this Code; however, such meetings should also comply with the rules of the host country. The most stringent rule shall apply.

1.4. Some rules of the Code are not directly associated with promotion. Details on those to whom promotion can be made, reduced samples can be given and information may be provided and similar topics are described in detail in the relevant articles.

Article 2- Discredit to, and Reduction of Confidence in, the Industry

Promotional activities conducted, methods applied or materials used in promotion must never be such as to bring discredit upon, or reduce confidence in, the pharmaceutical industry. Companies and AIFD should closely monitor promotional activities in order to ensure this.

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2. Preservation of Reputation and Confidence

This article is positioned at the beginning of the Code as it constitutes the reason for the preparation of the Code.

Top management of each AIFD member company should display utmost care to ensure that any department or employee of the company, starting with the behavior and activities of medical sales representatives; any person or organization affiliated with the company via a service contract; all activities and behavior that may be associated with the company, including the methods used, regardless of whether they are intended for promotion or not, comply with the letter and spirit of the Code.

Article 3- Definitions

For the purposes of this document, the following terms shall apply:

3.1. Promotion: All informative activities organized by registration/permit holders or in the name or with the name, upon the request, with the contribution or support of registration/permit holders on the medical-scientific characteristics of medicinal products for human use covered by this Regulation, as well as the activities of product promotion representatives within this framework, advertisements published in medical or professional books or journals, announcements made through direct mailing or the press, or other means of communication, and scientific/educational activities, meetings and similar events. (Reg.Art.4.1.g)

The Code regulates the following activities, including but not exclusive of:

a) All promotional and informative activities intended for physicians, dentists and pharmacists, about the medical-scientific features of medicinal products for human use;
b) Informative activities about product administration on topics such as the administration and side effects of products, intended for healthcare professionals other than physicians, dentists and pharmacists;
c) All activities of Product Promotion Representatives intended for physicians, dentists and pharmacists, including the use of promotional materials and verbal promotion;
d) Advertisements to be placed on medical and professional books and journals;
e) Advertisements made via direct mailing;
f) Advertisements to be placed via the press and other communication media;
g) Company sponsored activities and company activities conducted by using digital environment and social media;
h) Activities involving reminder promotion;
i) Distribution of free samples;
j) Reasonable support and hospitality provided for promotional purposes;
k) Direct or indirect organization (via another establishment) or sponsorship including the organization or sponsorship of scientific, educational and promotional meetings attended by healthcare professionals; payment of relevant travel, accommodation costs and congress registration fees;
l) Participation in fairs and exhibitions, use of audio cassettes, films, records, tapes and video recordings; use of promotional materials such as radio, television, internet, electronic media, interactive data systems, audio or video CDs, DVDs, flash disks and the like;
m) Programs and materials intended for patient education (Reg.Art.4.1.ğ)
n) Provision of inducements in cash or in kind, encouragement of the recommendation, procurement, prescription, use, sale, purchase of drugs via proposal or commitment*.

3.2. The following items are not encompassed by the promotion on which this Code applies:

a) Public promotion of traditional products not registered by the Ministry of Health;

b) Promotion of baby food and baby nutritionals not included into the scope of medical baby food;
c) Distribution of taste samples aimed at promoting the rational product use of enteral nutritional products;
d) Promotion of kits, in vitro diagnostic tests, medical devices, equipment and supplies which may be sold directly to the public;
e) Promotion of lenses and lens solutions;
f) Promotion of healthy life products and foods;
as well as;
g) Replies and correspondence related to the questions raised by healthcare professionals or relevant administrative staff or to the scientific messages conveyed by them as a question or comment; (including letters published in professional journals which are related with the subject matter or inquiry, and which are accurate, do not mislead and are not promotional in nature);
h) Factual, accurate and informative announcements and reference materials associated with registered products, such as package modifications, adverse reaction warnings, commercial catalogues and price lists, provided that they do not comprise any claim related with the product;
i) Trade practices comprising prices, discounts or sales conditions;
j) Summary of Product Characteristics (SmPCs);
k) Labeling on drugs, Patient Information Leaflets;
l) Statements provided on the lay press and television for the general public, relating to human health or diseases, provided that they do not make any direct or indirect reference to products;
m) Information about companies, not comprising pharmaceutical promotion (such as information directed to investors, information for employees and job applicants, data on the financial status of the company, information on R&D programs, information on regulatory and affiliated development that may affect the company and its products)
n) Corporate promotions.

3.3. Medicinal Product for Human Use/Product/Preparation/Drug: Any branded or unbranded active substance or combination of substances of natural and/or synthetic origin, administered to humans, including biological products, enteral nutritional products, medical baby food, traditional herbal medicinal products and immunological products; granted registration/permitted by the Ministry, for the purpose of treating and/or preventing a disease, making a diagnosis or restoring, correcting or modifying a physiological function by exerting a pharmacological, immunological or metabolic action; (Reg.Art.4.1.b)

3.4. Prescription product: Medicinal product that requires a prescription so as to be sold at pharmacies, that should not be sold without prescription or needs to have a prescription to be reimbursed even if it is sold without prescription;

3.5. Registration/Permit/Marketing Authorization: Registration granted by the Ministry for medicinal products for human use, biological products, vaccines and traditional herbal medicinal products and their marketing and permits granted for enteral nutritional products and medical baby food; (Reg.Art. 4.1.d)

3.6. Sales Permit: The certificate of conformity to be obtained upon submitting the sample of the final market presentation form of the product to the Ministry following the issuance of the Registration or Permit for the product; (Registration Reg.Art.26),

3.7. Promotional Materials: (Reg.Art.4.1.ğ; 8.1) Promotional materials comprise materials or tools in compliance with the Regulation..(Reg.Art.8.1)

Promotional materials refer to any material used in promotion or advertising, directly via sales representatives, including but not exclusive of:

a) Printed materials such as books, booklets, medical journals, brochures and advertisements, providing sufficient and necessary information regarding the product;
b) Audio-visual materials presented in storage media such as flash disks and CDs/DVDs;
c) Audio-visual materials such as films, slides, video shoots, databanks and electronic media including the internet;
d) Any type of publications and materials that may be used as a source of information/data/reference by relevant circles;
e) Free samples in reduced package quantity;
f) Programs and materials intended for patient education;

g) Reminder items such as pens, penholders, notepads and calendars that can be used by healthcare professionals and do not exceed a modest monetary value (2.5% of the monthly minimum gross wage or 20 TL.) (Reg.Art.4.1.ğ);

3.8. Healthcare Professionals:

3.8.a. Physicians, dentists, pharmacists (According EU and Turkish health legislations, promotion can only conducted towards physicians, dentists and pharmacists.)

3.8.b. Nurses and midwives,

3.8.c. Members of other professions defined in supplemental Article 13 of Law No. 1219, of 11/4/1928, on the Practice of Medicine and Branches of Medicine; (See App IX) (Reg.Art. 4.1.f)

3.9. Product Promotion Representative/Medical Sales Representative/Medical Representative: A person holding a certificate of qualification and promoting a medicinal product for human use to physicians, dentists and pharmacists by direct calls; (Reg.Art. 4.1.h)

3.10. Certificate of Qualification: A certificate issued by the Ministry to graduates of Medical Promotion and Marketing Programs at universities directly, or to anyone who successfully passes an examination given, or commissioned to be given, after Ministry-approved in-service training.(Reg.Art. 4.1.ı)

3.11. Health Journalist: A journalist or media reporter working at an accredited press agency, newspaper, periodical or audio-visual broadcaster, dealing only or mainly with health news;

3.12. Summary of Product Characteristics (SmPCs): The document prepared for healthcare professionals as part of the Registration Dossier, containing the indications of the registered/permitted product and minimum information on the product; (Reg.Art. 4.1.c),

3.13. Abbreviated SmPCs: Succinct information relating to the drug that should be present in all promotional materials except for those described in detail in Article 5.2 and defined in Articles 6.2 and 14.4;

3.14. Package Information Leaflet (PIL): The leaflet prepared in accordance with the SmPCs of the product, in a manner so that it is comprehensible by patients, for the purpose of informing patients about the product and which is required to be inserted inside the package of the product; (Reg.Art. 4.1.ç),

3.15. Scientific Service: The body (bodies) responsible for supervising the conformity of the promotions and other activities conducted by the company to Laws, Regulations and the Code of Practice;

3.16. Registration/Permit Holder/Pharmaceutical Company/Company: Real persons or legal entities for whom a registration/permit is issued by the Ministry for their products; (Reg.Art. 4.1.e)

3.17. Regulation: Regulation on the Promotional Activities for Medicinal Products for Human Use, published in the Official Gazette No. 28037, of 26/08/2011, and whose amendments have been published in the Official Gazette No. 28441, of 14/10/2012; as well as the Guidelines and Directives published in association with the Regulation;

3.18. Law: Law No. 1262 on Pharmaceutical and Medicinal Preparations, Decree Law No. 663, of 02/11/2011, on the Organization and Duties of the Ministry of Health and its Affiliated Bodies and also the European Union Directive 2001/83/EC (and the directives amending this directive), indicating when reference is made;

3.19. Calendar Year: The period between January 1 and December 31;

3.20. Ministry: The Ministry of Health and the relevant bodies of the Turkish Medicine and Medical Device Agency (TİTCK-TMMDA) (Reg.Art. 4.1.a; 17.1).

3.1. Promotion: The words referred to as "advertising" and "promotion" in the EU directives and EFPIA documents are expressed as "Promotion" in the Regulation and the AIFD Code.

3.1.b. Advertisements in Journals: The Code applies to the advertising of drugs in professional publications which are printed in Turkey and/or are intended for Turkish readers. Journals produced in Turkey as a sister publication of an international publication are also included into the scope of this Code.

Journals, vademecum-type and similar publications with the stated objective of being directed to physicians, dentists and pharmacists, but which are available at places open to general public are not suitable for the advertisement of drugs according to the

Regulation or this Code. Member companies should refrain from advertising in such publications in case they are sold at places open to general public. (See Article 6.3 below)

3.1.n. Definition: To define a material does not mean that the material or activity defined is regarded suitable or is approved. Thus, the definition in the sub-article should be interpreted from this perspective. The activities defined in this sub-article are definitely incompatible with the Regulation and ethical norms.

3.2.2. Promotion of Over-the-Counter (*OTC*) Drugs to Physicians, Dentists and Pharmacists: The promotion of medicinal products for human use to physicians, dentists and pharmacists is carried out in accordance with the AIFD Code of Promotional Practice.

3.2.2.a. Promotion to the General Public: AIFD Code of Promotional Practice does not comprise the promotion of OTC products to the general public.

3.2.2.b. Traditional Drugs: Substances of herbal or natural origin without an indication, generally sold at herbalists, grocery stores and markets, that are not among medicinal products for human use for which the Ministry of Health issues a registration or permit.

3.2.2.h. Replies Prepared for Frequently Asked Questions: Replies prepared in response to frequently asked questions from healthcare professionals may be drafted (or printed) in advance, provided that they are used only when directly associated with a specific question. These replies should not have the appearance of a promotional material.

3.2.2.j. Trade Practices: Trade practices, as long as they remain purely within the framework of the trade practice and are not intended for promotion, are outside the scope of this Code. In terms of the image perceived by the public, management of companies should monitor trade practices closely in order to prevent misevaluations and unfair criticisms towards the pharmaceutical industry and trade.

3.2.2.l. Relevant provisions of the Regulation and guidelines should be observed for labels and package inserts.

3.3.1. Definition of "Substance": Any substance with a human origin (human blood and products obtained from human blood), animal origin (microorganisms, whole animals, parts of organs, animal secretions, toxins, extracts, blood products), herbal origin (microorganisms, plants, parts of plants, herbal secretions, herbal extracts) or chemical origin (elements, naturally forming chemical materials and chemical products obtained by chemical change or synthesis). (Regulation on the Registration of Medicinal Products for Human Use, Article 4.e)

3.3.2. Traditional Herbal Medicinal Product: Preparations where the medicinal herbs included into their composition are bibliographically proven to be used in Turkey or EU member states for at least fifteen years and for thirty years in the other countries prior to the date of application; which are designed or intended to be used without the diagnosis and supervision or prescription of therapeutic follow-up of a physician due to their composition and intended use, which avail of special indications compliant with traditional medicinal products and are administered orally, externally or via inhalation, with special administrations only at specifically indicated doses and posology. (Regulation on Traditional Medicinal Herbal Medicinal Products ,Official Gazette, October 6, 2010, Article 4.f)

3.5. Marketing Authorization: This term has been used in the Code in line with the term in the EU acquis communautaire.

3.8. Healthcare Professionals (Reg. Art. 4.1.f)**:** Supplemental Article 13 of Law No. 1219 of 11/4/1928 on the Practice of Medicine and Branches of Medicine has stipulated that "Healthcare professionals other than physicians and dentists cannot plan a treatment and write prescription upon making a diagnosis for a disease". In line with the EU acquis, the Regulation restricts the "promotional" activities of pharmaceutical companies with those who hold the power to write a prescription (i.e. physicians and dentists) and pharmacists.

3.8.c. Healthcare Professionals, Nurses, Midwives, Health Operators, Health Technicians: The Regulation does not allow any promotion to healthcare professionals other than physicians, dentists and pharmacists but it does allow information to be transmitted to these individuals about the administration and side effects of products, provided that the authorized physician is informed thereof and has granted his/her approval.

3.11. Summary of Product Characteristics: "SmPCs" is used in the Code as defined in Article 3.11. (See Article 11 of the Law on the Registration of Medicinal Products for Human Use.)

3.13. Patient Information Leaflet (PIL): The content of the Patient Information Leaflet should be prepared in accordance with the Regulation on the Packaging and Labeling of Medicinal Products for Human Use and the Standard Evaluation Procedure of Patient Information Leaflets.

Article 4- Promotion

4.1. Promotion of prescription-only medicinal products for human use can only be made to physicians, dentists and pharmacists. (Reg.Art.5.1)

4.2. The promotion of medicinal products for human use not registered or permitted in accordance with the relevant legislation (whose registration has not been approved) (Reg.Art.6.2.a) or the off-label promotion of medicinal products for human use registered or permitted in accordance with the relevant legislation other than the areas of use defined in their SmPCs approved by the Ministry (Reg.Art.6.2.b), shall not be conducted except for the following two exceptions (Reg.Art.6.2).

4.2.1. Promotions conducted in international congresses held in Turkey are not in the scope of this article. (Reg.Art.6.2)

4.2.2. The information personally provided by a Scientific Service Officer of the registration/permit holder, upon the written request of a healthcare professional physician, dentist or pharmacist is not in the scope of this article. (Reg.Art.6.2)

4.3. The promotion of a medicinal product should be consistent with the information, data and details provided in the updated Summary of Product Characteristics (SmPCs) approved by the Ministry. (Reg.Art.6.3)

4.4. Promotion should assist healthcare professionals in establishing their own views regarding the therapeutic value of the product, be informative, evidence-based, accurate, consistent with scientific facts, reliable, fair and objective and contain sufficiently complete and clear medical information about the characteristics of the product. (Reg.Art.6.4)

The referred promotion should conform not only to legal requirements, but also to high ethical standards and be in good taste.

4.5. The promotion of drugs should be conducted in an objective and unexaggerated manner and shall encourage the rational use of products.

4.6. Promotion should not be made by conveying misleading, exaggerated information or information with no proven accuracy that may lead to unnecessary encouragement of the use of the medicinal product for human use or give rise to unanticipated risks. (Reg.Art.6.6)

4.7. Information and claims which are misleading, exaggerated or whose accuracy is not sufficiently proven should not be used in promotion. Healthcare professionals should not be misled by distortion, exaggeration, undue emphasis of information or by any other method. Claims presented should not be stronger than the current scientific evidence.

4.8. The perceived monetary value of reminder call items should not exceed the limit determined by AIFD.

4.9. Healthcare professionals cannot take part in the promotion of medicinal products for human use unless a permit is obtained from the Ministry. Likewise, also legal entities such as associations or foundations cannot take part in the promotion of these products, unless permitted by the Ministry. (Reg.Art.5.4)

4.1.1. Promotion. This article highlights the fact that the promotion of medicinal products for human use can be conducted only to the Healthcare Professionals (physicians, dentists and pharmacists) allowed to receive promotion of drugs as indicated in the Regulation and the supplemental Article 13 of Law No. 1219, of 11/04/1928, on the Practice of Medicine and Branches of Medicine.

4.1.2. Member companies shall also act in compliance with this Code of Promotional Practice when they promote non-prescription medicinal products for human use to physicians and pharmacists, in addition to the promotion of prescription drugs.

4.2.1. Promotion of Products or Indications Not Registered in Turkey in International Meetings Held in Turkey

a) In accordance with the relevant legislation, medicinal products for human use and/or indications which have not been registered or permitted in Turkey, are allowed to be promoted to healthcare professionals upon opening a booth in international congresses organized in Turkey, as per clause 2 in Article 6. This permit applies only for large-scale international congresses.

b) It should clearly be specified on the booth and/or in the satellite symposia that these products or indications are not registered in Turkey. The relevant product booth should bear the statement: *"This product (or indication) is not registered in Turkey and in every country. Check the drug compendium in your country or consult our company before prescribing it*" or a similar message.

4.2.2. Scope: Both registered and permitted products are covered by this Article. The terms Registration and Permit are defined in further detail in the Registration Regulation of the Ministry of Health.

4.2.3. Scope of Prohibitions: It is forbidden to promote products, galenic forms, packages not registered in Turkey in accordance with the current legislation or unapproved indications.

4.2.4. Promotion shall not be initiated prior to the receipt of Registration or Permit.

4.2.5. Teaser campaigns can be initiated before the grant of registration so long as they do not contain the trade name or INN and company with the letter and spirit of the Code.

4.2.6. According to the joint interpretation of AIFD and EFPIA, the legitimate sharing of medical and scientific findings and information about the product on medical platforms during the developmental process of a drug prior to the receipt of a registration, is not prohibited provided that no promotion is made.

4.2.7. Information provided personally by the Scientific Service Officer of the registration/permit holder upon the written request of the healthcare professional, dentist or pharmacist, are not included into the scope of the restriction in this article. (Reg.Art.6.2) Product promotional representatives cannot promote to physicians indications which have not been registered in Turkey.

4.2.8. Sharing scientific information regarding non-registered products/indications with physicians and pharmacists participating in a multi-centered clinical trial, is not considered a breach of the Code or Regulation. However, open meetings with the intention of detecting new potential clinical investigators, cannot be used to disseminate non-registered indications or products.

4.2.9. Legitimate sharing of information on a scientific platform:

Based on the practices and accepted views in the US Food and Drug Administration (FDA) and Europe, legitimate platforms have been defined by AIFD as follows:

a) Independent peer-reviewed journals and other similar scientific publications;
b) Scientific and medical meetings organized independently from the influence of sponsoring companies and the posters or verbal presentations in these congresses;
c) Satellite symposia included into the program by the scientific organizing committee of the congress, organized and sponsored by companies within the scope of meetings and congresses defined above;

4.2.10. Information share in above-mentioned platforms may be provided to the physicians who are not subscribed to the relevant journal or have not attended the relevant congresses, only upon their written request, by the Scientific Service of the relevant company as a reprint or on electronic media.

4.2.11. Sharing of literature comprising also products and indications not yet registered/approved in Turkey **upon written request** is possible, as long as the referred information is provided upon the written request of healthcare professionals, the information is conveyed personally by the Scientific Service Officer, that **it is clearly indicated on** the reprint of the literature shared or **the Turkish translation** prepared in the same format **that the product or indication is not registered in Turkey** upon written request and that the non-registered product or indication is not promoted visually or verbally during this communication.

4.2.12. Notifying Relevant Institutions About New Products and New Indications

The information and product claims sent for commercial purposes to Health Authorities and Health Insurance Boards in order to shed light on the preparation of their budget for the upcoming years and their reimbursement assessments does not mean the Code has been breached.

4.5. Unless proven, it should not be even implied that the product or its active substance has a different characteristic, superiority or quality. Due effort should be displayed so as to avoid ambiguity.

4.9. Any image reflected by healthcare professionals that may give rise to the perception of mutual interest in the films, videos and audio-visual media production prepared for the purpose of promoting medicinal products for human use is against the Regulation of the Ministry of Health. However, filming speeches or presentations delivered by scientists who are healthcare professionals and showing these again upon adding creative scenes for enhancing the interest or emphasis or shortening them in due form are not included into the scope of this article and interviews compiling the views on disputable therapeutic methods and edits are not encompassed by this scope as long as they are scientific in content.

Article 5- Abbreviated summary of product characteristics and Other Mandatory Information

5.1.1. Abbreviated summary of product characteristics listed in Article 5.2, should be provided in a clear and legible manner in all promotional materials of medicinal products for human use, except for abbreviated advertisements (see Article 6) and promotional materials indicated in Article 14.4.

5.1.2. Abbreviated summary of product characteristics should constitute a whole with the promotional materials.

5.2. Abbreviated summary of product characteristics should consist of the following:

(i) Commercial name of the medicinal product;

(ii) INN (*International Nonproprietary Names*) or approved generic names of the active substance(s);

(iii) Quantity of active substances in its composition in a single unit dose (quantitative composition);

(iv) Content in the package of the commercial form;

(v) At least one registered indication in compliance with the updated SmPCs;

(vi) Route of administration and dosage;

(vii) Dosage and method of use;

(viii) Major side effects and precautions to be adopted;

(ix) Major interactions, incompatibilities;

(x) Contra-indications, warnings and conditions to be observed during the administration of the product (pregnancy, lactation, driving);

(xi) Other information to be requested by the Ministry or other authorized bodies or regulatory authorities (overdose, storage conditions, shelf life, reimbursement conditions of the Social Security Institute) and other warnings to be included in promotions;

(xii) Name and address of the manufacturer, importer or distributor;

(xiii) Registration date and number;

(xiv) The statement reading, "Please contact our company for detailed information";

(xv) Legal classification (prescription or non-prescription, red and green prescription categories, narcotics, controlled drugs);

(xvi) Public sales price of commercial forms (including VAT) and the approval date of the price;

(xvii) Tracking code/number of the material and the printing date (or intended usage date) of the materials;

(xviii) The date of preparation and/or latest date of update of the SmPCs taken as basis in the information of the materials.

5.3. The information specified above in relation with the dosage, method of use, side effects, precautions, contra-indications and warnings should be placed in such a position in the promotional material so that their association with the claims and indications relating to the product are easily seen by the reader.

5.4. Furthermore, the generic name of the drug should appear at a legible size on the promotional material, immediately adjacent to the most prominent display where the commercial name is presented.

5.5.1. In audio-visual materials such as films, video recordings and the like and information in interactive data systems, abbreviated summary of product characteristics should be provided in compliance with either one of the following routes:

- By a document which is made available to all persons to whom the material is shown or sent, or
- By being included on an audio-visual recording or interactive data system itself.

5.5.2. When the abbreviated summary of product characteristics is included into an interactive data system, instructions for accessing it should be clearly displayed.

5.6. In case the promotional material is presented over the internet, there should be clear and prominent statement as to where to find the abbreviated summary of product characteristics.

5.7. In case of journal advertisements where the abbreviated summary of product characteristics does not appear on the same spread, a reference to where it can be found should appear on the outer edge of the page in a legible manner.

5.8. Promotional materials other than advertisements appearing in professional publications should include the date on which the promotional material was drawn up or last revised.

5.1.1. Abbreviated SmPCs: Each promotional material related to a drug should contain mandatory information. Abbreviated summary of product characteristics should be consistent with the SmPCs related with that drug.

5.1.2. Abbreviated SmPCs in Meetings and Exhibitions: Mandatory information about the products promoted on posters and exhibition panels at meetings should be provided either directly on the posters or panels or at the company booth. If the abbreviated summary of product characteristics is available at the company booth, this should be indicated on the posters or panels.

5.2.1. Abbreviated summary of product characteristics should be compliant with the relevant Regulations (Regulation on Packaging and Labeling), Guideline and Notifications issued by the Ministry of Health; applicable legislation should be followed.

5.2.2. Legibility of Abbreviated SmPCs: Abbreviated SmPCs comprise the essential information that should be provided in promotional materials. As the information on promotional materials is included for the purpose of conveying information to physicians, dentists and pharmacists, its legibility should be ensured.

5.2.3. Legibility is not simple a question of font size. The following recommendations will help to enhance legibility.

a. The font size should be such that a lower case "c" is no less than 1 mm in height.
b. Sufficient space should be left between the lines to facility easy reading.
c. A legible font style should be used.
d. There should be adequate contrast between the color of the text and the background. Dark print on a light background (preferably white background) should be preferred.
e. Starting each section on a new line helps legibility.

Article 5.2.ii. Approved INN: Some substances may have two or more commonly used INNs (generic names); in such cases, the generic name more commonly used in the European Union is recommended. In any case, the generic name used in the updated SmPCs should be used.

Indicating the open or closed chemical name or formulation or omitting the generic name even though it exists is considered a breach of the Code.

Using color and font that makes it difficult for the generic name to be read is also considered a breach of the Code.

5.2.iii. Quantitative List Related with the Dosage: The dosage should be clearly indicated. Showing the amount in each dosage form on the promotional materials is preferable (per tablet, per vial, etc.). For creams and similar packages (or where suitable), content per ml, 100 gr. or 100 ml should be indicated. It is also accepted to indicate the amount inside the inner package volume in special cases.

5.2.v. Registered Indications: It is preferable to list all indications of the product; however, mentioning only those indications which are under active promotion in the promotional materials is also a wide practice. In such cases, the dosage indicated should fully comply with the indications specified. Most frequently seen adverse events and relevant warnings associated with usage in these indications should also be clearly indicated.

5.2.vii. Mode of Administration of the Drug: In case of possibility of the form of the drug to cause confusion (genital tablets, hemorrhoid creams and suppositories, hair lotions in vial form, etc., the mode of administration should be clearly indicated on the promotional material and even more prominently on the package and Patient Information Leaflet.

5.2.x. Contra-indications, Warnings, Precautions, Adverse Effects and Major Interactions: It is suggested to list all contra-indications, warnings, precautions, side effects and major interactions, as these should be reminded to prescribers. It is the duty of the Scientific Service of the company to ensure that relevant information is included.

5.2.xvi. Information on Reimbursement and Prices: Within the framework of a rational use of drugs, in addition to the approved sales prices of the product and/or different doses, forms and packages, also their cost for the social security institutions may be indicated on the promotional materials. As the price update indicated in the abbreviated SmPCs may be performed when the material is prepared, it would be beneficial to provide an explanation such as "for current sales price of the product see: www.ourcompany.com.tr/price" for those who would like to see the price changes that have occurred after the date indicated next to the price.

5.2. xvii. Tracking Code and Printing Date: Some companies prefer to provide as the tracking code the intended date of usage while others prefer to indicate the printing date. Bot hare acceptable, as long as the date of update of the latest SmPCs taken as basis for the information used in the material is indicated.

5.4. "Immediately Adjacent": "Immediately adjacent" means almost touching the brand name from above, below or on the side.

5.5. Abbreviated Summary of Product Characteristics on Audio-Visual Materials: It is preferable to include such information on the recording, as mentioned in the second paragraph.

5.8. Dates on Inserts: As an insert is not regarded as an associated part of a professional publication, it should therefore bear the date on which it was drawn up or last updated.

Article 6- Full and Abbreviated Advertisements, Journal Advertisements

6.1. A full advertisement is the one that includes promotional claims for the use of products. Full advertisements should comprise all the mandatory information listed above in Article 5.2.

6.2. Abbreviated advertisement or reminder advertisement is defined as a short advertisement appearing only in medical journals, comprising the brand name of the product, the INNs of the active substances and the name of the company, and not including any claims.

It is sufficient for reminder advertisements to include the following:

a) Brand name of the drug,
b) Generic names of the active substances,
c) Name and address of the manufacturer, importer or registration holder,
d) The statement of the prescriber, reading "Please consult our company for further information".

6.3. Advertisements of prescription drugs may be published only in medical, scientific and commercial journals sent of distributed under subscription to physicians, dentists and pharmacists. (Reg.Art.5.3)

6.4. Advertisement of prescription drugs cannot appear in newspapers, magazines, television, radio and similar media open to the general public. (Reg.Art.5.3)

6.5.1. Advertisements made in newspapers/journals with the permission of the Ministry, declaring the market introduction of a new medicinal product/form to healthcare professionals, are outside the scope of this provision. (Reg.Art.5.3)

6.5.2. In case the registration/permit holder wishes to declare the market introduction of the product to healthcare professionals via a press release, permission should be obtained from the Turkish Medicines and Medical Devices Agency upon submitting an authentic copy of the advertisement text.(Reg.Art.11.2, Press Release Guidelines Article 4.3) No artwork or illustration is allowed in such type of advertisements.

6.5.3. The press release may be published once on the same day in all daily media organs. It may be published once in periodical printed media organs within 30 days as of the date of permission. (Reg.Art.11.2)

6.5.4. The size of the press announcement to be published in newspapers may not exceed 1/8 of the full page of the newspaper. This activity is not regarded as promotion of a medicinal product for human use. (Reg.Art.1.2)

6.6. Corporate advertisements, where there is no open, hidden or covered promotion of medicinal products for human use, can be placed in newspapers and printed and audio-visual media.

6.7. Corporate advertisements are not under the scope of this Code.

6.1. Company Address: The inclusion of telephone and fax numbers as well as the internet access addresses in full, abbreviated and reminder advertisements and promotional materials, that may enable physicians and pharmacists to reach the company more rapidly, is becoming more widespread. The internet address or the full address may be provided in reminder advertisements and promotional materials.

6.2. Reminder Advertisements: In case of reminder advertisements relating to drugs in organizers and desk pads, the associated abbreviated SmPCs should appear on them.

6.3. Definition of a Professional Publication: "Sent or distributed to subscribers" are the keywords in this article.

A positive list of medical, scientific and commercial journals eligible for advertisement in compliance with the Regulation is prepared with the contribution of companies.

It is recommended for advertiser to make a standard written contract with the publishers of the periodicals (and drug compendia) and to advertise in journals which commit that the copies containing the drug advertisement will not be distributed or sold to the general public.

Periodicals should be asked to include on the cover of the periodical in a visible manner the statement "Reserved for Physicians, Dentists and/or Pharmacists".

Even if they claim to be professional in content, publications sold in areas open to the general public are not suitable for the advertisements of prescription drugs. Advertisements in such publications are considered by AIFD as a breach of the Regulation and the Code of Promotional Practice.

6.5.2.1. Press Releases: (Press Release Guidelines Article 4.3.b)

i) Should not be colored

ii) Should not exceed 1/8 (A5 page size) of the full page size of a newspaper
iii) Should use the same typeface on the package which has been approved by the Agency,
iv) Should not contain information/articles not included on the package approved by the Agency.

6.5.2.2. Documents to Be Submitted in the Press Release Applications: (Press Release Guidelines Article 5)

a) An authentic copy of the press release,
b) Photocopy of the registration,
c) The latest approved sales permit and sample of the annexed package,
d) In the applications for co-promoted products, the approval letter obtained by the registration holder company from the relevant unit.

Article 7- Information, Claims, Citations and Comparisons, Disparaging References

7.1. In case of request by a physician, dentist or pharmacist, or the company owning the product with which comparison is made, the relevant company should submit, without delay, information, claim and evidence of the comparison relating to the drugs it markets.

7.2. Information, Claims and Comparisons Used in Promotion

a) Information, claims and comparisons used in promotion should be accurate, provable, sufficient, balanced, fair, objective and unambiguous, be based on an up-to-date evaluation of the evidence at hand and clearly reflect that evidence.

b) Information, claims and comparisons should not be misleading directly or by implication; they should not mislead healthcare professionals by distortion, exaggeration, undue emphasis or in any other way.

c) Any type of information appearing on the promotional material should be designed in a manner so as to enable the healthcare professional to establish his/her own view independently with regard to the therapeutic and diagnostic value of the relevant medicinal product. (Reg.Art.6.4)

7.3. Comparisons between different medicinal products should comprise "comparative features". Comparison can be made in a promotional material as long as;

a) It is not misleading,
b) Drugs or services for the same needs and purposes are compared,
c) Relevant, proven and significant features are compared,
d) Comparisons are not used to create confusion on purpose,
e) Pejorative or derogatory statements are not included regarding the competing product or brand,
f) Unfair advantage is not taken from the reputation of a competitor.

7.4. Any claim, information or comparison presented should be provable. Side effects and adverse events should be supported with clinical experience. Additional reference is not required for the information and data included into the SmPCs of the product.

7.5. References to and Citations from Congress Abstracts and Posters

Publication abstracts published in abstract books of national and international congresses as well as posters accepted to be displayed in such congresses can be used as source in promotions within two years following the congress date.

7.6. When the promotional material refers to a published study, clear references should be specified.

7.7. When the promotional materials refer to "data on file", the section relating to the claim in this data should be provided without delay upon the request of physicians, dentists and pharmacists.

7.8. Use of Drug Substitution Rules of an Institution in Promotional Materials

The drug substitution rules of an institution cannot be used for promotion. However, it is allowed to inform physicians and pharmacists in an institution where substitution rules are applied, about the substitution rules implemented in that institution.

7.9. Use of Scientific Citations (References)

7.9.1. In case promotion is made with a documentation prepared with materials using citations, tables and other visual materials from medical journals or other scientific studies, these materials should be faithfully reproduced, providing full reference to relevant resources. (Reg.Art.6.5) In case it is required to make a change for the purpose of achieving compliance with the Code of Promotional Practice, it should be clearly stated in the material that the citation has been adapted, modified, shortened or adjusted, and the source should clearly be indicated.

7.9.2. The texts, illustrations, tables, pictures and graphs should conform to the Code. If the whole text, graph or table has not been taken from a publication, it should be clearly indicated that it has been modified and adapted.

7.9.3. Graphs and tables should be faithfully reproduced and the source should be clearly indicated. Graphs and tables should be presented in such a way as to give a clear, accurate and balanced view about the relevant topic.

7.9.4. The graphs, patterns and pictures to be used should not give a wrong idea about the use of the product (e.g., use in children) and should not contain comparisons that may be misleading (e.g., statistically insignificant information, incomplete information or misleading scales); promotion should not be conducted by using alluring images which are not directly associated with the product itself. (Reg.Art.6.6)

7.9.5. Citations from medical and scientific literature or personal communication should faithfully reflect the intended meaning of the author.

7.9.6. Utmost care should be displayed to avoid ascribing claims or views to authors in the promotional materials, when these no longer represent the current views of the authors concerned.

7.9.7. All information and claims about side effects and adverse events should reflect current available data. It cannot be claimed that a product *has no* side effects, toxic hazards or risks of addiction.

7.10. The words "safe" and "reliable" should be used only when substantiated with sufficient and valid evidences.

7.11. The word "new" should not be used to describe any product or form or therapeutic indication which has been available in Turkey for more than twelve months.

7.12. Exaggerated or all-embracing claims (the most superior, the most reliable, the most effective, perfect, unique, etc.) should not be used, except for those cases where they relate to a clear and sufficiently proven fact about the drug.

7.13. Pejorative, unfair or negative statements should not be used about the products and activities of other companies.

7.14. Physicians, dentists, pharmacists or their clinical and scientific views should not be referred to in a derogatory manner.

7.15. Copyrights of Reprints and Citations

Copyrights of publishers and investigators should be observed.

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7. Information, Claims and Comparisons: Pharmaceutical promotion should be compliant with Law No. 4077 on the Protection of Consumers, especially with Article 16, as much as with the relevant legislation of the Ministry of Health.

7.2. Misleading Information

The Scientific Service of companies should take into account the following points:

i. Claims of superiority in relation with the weight of active substance are generally meaningless.
ii. Data obtained from in-vitro studies, studies conducted on healthy volunteers and animals should be used carefully, ensuring that the meaning is preserved and not disrupted.
iii. Economic evaluation of drugs: Pharmaco-economic findings should be used carefully and should not be exaggerated.
iv. A totally new clinical or scientific view: Until a clinical or scientific topic is generally accepted, particular care should be displayed to ensure that this topic is treated in a balanced manner in promotion.
v. Unfounded comparisons: A drug should not be described as "better" or "stronger" without openly identifying the compared product.
vi. As with any comparison, price and cost comparisons should also be accurate, fair and balanced and comparison criteria such as similar duration of treatment, cost for patients and the social security institution, the comparison should not be misleading.
vii. Statistics used should be accurate. Statistical significance should be watched for. The accuracy of statistics should be evaluated before being used as a basis for the promotional material.

7.2.c. It is not necessary for all the outcomes in the publication referred to in the promotional materials prepared to be presented to physicians in the same material. Main findings, data and judgements in the articles taken as reference should be presented in a balanced manner in the promotional material.

7.3.e. Trade names should not be used in comparisons. (This restriction is stipulated in legislation.)

7.4.a. Reference to Publications: Articles published in peer-reviewed scientific medical periodicals or periodicals with reliable scientific integrity and reputation may be used in promotion. The claims used should be in line with the updated SmPCs approved by the Ministry.

Unregistered indications cannot be promoted even if they are included into a publication.

7.4.b. Claims should be substantiated by literature from peer-reviewed journals. References should always be provided for all promotional claims, on the front or back page or inside the material. Reference should be provided also fort the slogan appearing on the cover page of the promotional material, unless the text used in this slogan is not included into the SmPCs of the drug.

7.5. Congress Abstracts and Posters: Publication abstracts of a congress may be used in promotional materials, as long as they are in line with the SmPCs and are not older than two years (date of congress being day zero).

"Submitted papers" should not be used as reference in promotion.

7.6. Citation of References: All sources used as basis for promotional materials and which have been cited, should be clearly indicated.

Examples:
Published articles: Authors, Title of Article, Name of Periodical, Year, Volume, Page.
Unpublished congress abstract:
Authors, Title of Article, Document Name, Venue and Name of Congress, Congress Date, Publication Date of Abstract Book.
Internet references:
Title of Article, Authors, Document Name, Website Reference, Date of Document Access.

7.7. Data on File: If Data on File is used in promotion for backing a claim, this should be proven. In case the company does not want to reveal the data on file, this data should not be used in promotion.

Substitution rules: Replacement rules

7.9. Graphs, Illustrations and Texts: Care should be displayed to ensure that graphs are not misleading; it should not cause any warning or contra-indication to be overlooked.

Titles and coordinates of tables and graphs should be specified adequately and accurately. Adaptation as such should not distort or modify the meaning of the graph.

7.9.3.1. Special attention should be displayed so that the placement of the tables and graphs taken from different publications or meta-analyses on a page of the promotional material (or visual presentation) does not mislead healthcare professionals or causes the information provided in publications to be inquired unfairly.

7.9.3.2. It should be observed that information not directly related with the prodct being promoted could be misperceived due to the place and style of presentation, even if taken from reliable scientific sources and is correct in itself.

7.9.6. Current Opinion of Authors: Nowadays when data interpretation and information are changing rapidly, companies should verify that the author's current opinion about a dated paper reflects his/her view before a publication is approved for distribution as an updated source of information or reprint. Use of claims which are known to be no longer valid is regarded as a breach of the Code.

7.10. Use of the Terms "Safe, "Reliable" and "Effective": The word "safe" may only be used when substantiated with appropriate and valid evidences. Otherwise, it is regarded as misleading information. "Safe" should not be used instead of "reliable".

A quote from a published paper as "safe and effective" is not acceptable even if it is an accurate reflection of the intention of the author, because the Code does not allow the use of these words in this manner. A citation from a reputable publication or author may be violating the Code.

1. It should be clearly indicated whether what is described as "new" is a new dosage form, a new commercial presentation of a known molecule or a galenical form or strength.

7.12. Superlatives: If to be used, superlatives should clearly identify what is defined and its boundaries.

7.13. Disparaging and Humiliating Texts: Most pharmaceutical promotions contain comparisons with other products and, due to the nature of promotion, such comparisons are generally made to show a superiority of the product promoted over its competitors. Such types of comparisons with the product of another company are accepted within the scope of the Code, provided that such references are accurate, balanced, fair, updated and verifiable. Unjustified texts in which the products or activities of a competitor are unfairly criticized are prohibited under this article.

7.14. Disparaging and Humiliating Statements: Unless fully proven, scientific opinions should be criticized with disparaging and humiliating statements.

7.15. Copyrights

Copyrights of the publications used should be observed. The dissemination, duplication and processing rights of the publications to be used should comply with the current Law on Intellectual Property Rights. Headquarters of multinational companies may obtain copyrights and translation rights of certain papers and books on a global scale. It is the responsibility of the Scientific Service to verify that copyrights are observed in each and every case.

Before translating, duplicating, distributing the literature used in promotion, it should be inquired whether it is necessary to obtain permission of the copyright holder or their representative; the legal departments in headquarters, company attorneys and, where necessary, copyright holders should be contacted.

Third party service providers should be warned against potential violations of copyrights.

Article 8- High Standards, Format, Suitability; Offensive Behavior; Sponsorships, Hidden and Disguised Promotion

8.1. It should be aimed to maintain high standards at all times.

8.2. Promotional materials and activities,

a) Should not bring discredit upon, or reduce confidence in the pharmaceutical industry and trade;
b) Should be conducted and prepared upon recognizing the special nature of drugs and the professional characteristic of the audience to whom they are directed;
c) Should not be likely to disturb anyone.

8.3. Promotional materials should not imitate the logos, forms, slogans or general designs used by other companies or in a manner that may give rise to confusion.

8.4. Promotional materials should not include any reference to regulatory authorities, unless such authorities specifically require this.

8.5. Exaggeration in the form and cost of promotional materials should be avoided.

8.6. Postcards, other mailings exposed to the public, envelopes or wrappers should not bear characteristics that may be regarded as an advertisement to the general public.

8.7. Telephone, text messages, e-mails, telephone messages, fax messages and similar messages should not be used for promotional purposes, except when requested or with prior permission of the recipient.

8.8. Clear Declaration of Sponsorship: In case of any company sponsorship of activities and materials relating to drugs and their use, whether promotional in nature or not, this sponsorship should clearly be indicated.

8.9. In order to protect the integrity of the research when a market research is conducted, the company name may not be revealed, but it should be indicated that his research is conducted with the request or support of a pharmaceutical company.

8.10.1. Rule of Transparent Conduct of Promotion: Companies should not make hidden or disguised promotion.

8.10.2. Clinical assessments, post-marketing surveillance programs, experience programs and post-registration studies including those that are retrospective in nature should not target disguised product promotion. The primary target of such types of programs, assessments and studies should be scientific and educational.

8.10.3. Promotional papers and articles published by the monetary support or other type of sponsorship of a company should not be published in a manner so as to resemble an independent assessment paper.

8.11. The preparation and conduct of market researches, post-marketing surveillance studies, post-registration studies and similar activities should not be promotional in nature. These studies should be conducted for the purpose of gathering information about the product of the company or competing products and carried out for scientific and educational purposes.

8.12. Post-marketing studies should not be carried out as promotion under the appearance of a research and for influencing physicians.

8.13. Food products should not be distributed during promotion.

8.14. Healthcare professionals should disclose any sponsorship received from registration/permit holders:
a) At the end of every article they author,
b) At the beginning of every speech/presentation they deliver.
(Reg.Art.6.9)

8.1. and 8.2. Compliance with High Standards: The special characteristic of medicinal products for human use and the level of professionalism of the physicians, dentists and pharmacists, to whom the promotional materials are presented, require the standards of pharmaceutical promotion to be more sensitive compared to other general advertisements and promotions. The use of some promotional tools, means or techniques, which are regarded as acceptable in other products, in pharmaceutical promotion is thus regarded as unsuitable.

8.4. Reference to Regulatory Authorities: References such as "FDA Approved, EMEA Approved" are not regarded as suitable by the Ministry.

8.6. Wrappers and Plastic Bags: This topic is covered in Supplemental Information in Article 14.3.

8.7. Unsolicited Messages: In case a recipient wants her/his name to be removed from mailing lists, this request should be fulfilled without any delay.

8.8. Financial Support (Sponsorships): This sponsorship includes non-promotional materials and activities, sponsorships to patient organizations and websites. The name of the pharmaceutical company providing direct or indirect sponsorship and the nature of the sponsorship should be clearly indicated during the activity and in documents, in line with the restrictions of the Competition Authority and the legislation on sponsorships.

8.10. Hidden Promotion and Disguised Promotion Under the Appearance of Editorials: Advertisements should not be published under the appearance of editorials.

Hidden or disguised pharmaceutical promotion under the appearance of a news or report should not be performed.
Sponsorships should be described. .
Promotional purpose should not be sought during researches. Proving commitment to the letter of the current rules may not be accepted as a proof that the spirit of this Code is complied with.

8.11. Market Research: Market research should involve the collection and analysis of information and be objective.

The use of statistical data and information may have a promotional purpose. These two phases should be separated from each other.
The use of IMS grid sales data in promotions does not conform to the Code.
It should be verified whether market research materials, from internal and external resources, violate the Code.
The reliability of the source from which the data is obtained does not guarantee conformity to the Code.

8.14. Obligation of Healthcare Professionals to Declare the Sponsorship Received: As clause 9 of Article 6 in the Regulation imposes the obligation for healthcare professionals to declare **any type of sponsorship** received at the end of the paper each time they write a paper and at the beginning of the speech/presentation each time they deliver a speech/presentation, it would be suitable to remind this obligation to each healthcare professional, before he/she receives the sponsorship.

Article 9- Distribution of Promotional Materials

9.1. Mailing lists should be kept up-to-date. Requests for being removed from the physical or electronic mailing lists, other than those to be used for adverse effect notification and urgent warnings, should be forthwith fulfilled.

9.2. Promotion should only be directed at healthcare professionals who are interested or are assumed to be interested in the topic or who need to be informed about it.

9.3. Respect for the Confidentiality of the Information Collected

The personal data collected from healthcare professionals cannot be used for purposes other than the purpose of collection and cannot be shared with third parties without the permission of these persons.

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9. Mailing: The volume and frequency of the printed promotional materials or electronic mails sent to physicians, dentists and pharmacists should be at a reasonable level.

Non-promotional mailings such as drug safety, notification of adverse events or price lists are not encompassed by the restriction. In cases such as adverse reactions and urgent warnings, relevant measures should be adopted to ensure rapid access to physicians and pharmacists.

9.2. Restriction of Promotion to Interested Physicians: This article relates to the restriction of the promotional activities of companies to selected interest groups. Promotion or reminder items directed to those working in clinics may not be appropriate for administrative staff. A promotional brochure which is sufficient and meaningful for one specialty may not be meaningful for another branch.

No such restriction applies to non-promotional materials such as drug safety, notification of adverse events or price lists.

Article 10- Scientific Service and Its Duties

10.1.1. Registration/permit holders should establish a Scientific Service within the company to work in line with the principles set forth below and be responsible for the information about marketed medicinal products. A competent person should be appointed to deal with such activities. (Reg.Art.11.1)

10.1.2. Every company should establish, according to its organizational structure and requirements, an authorized Scientific Service in charge of pharmaceutical promotion and pharmaceutical information, all materials and activities to be used in promotion as well as the approval and proper conduct of non-interventional pharmaceutical studies. The duties of the Scientific Service may be shared by one or multiple units or persons.

10.2. The Scientific Service ensures that the promotion of medicinal products, the registration of which is held by that company, conforms to the specified terms of the Regulation and the Code. (Reg.Art.11.5.a)

10.3. The Scientific Service verifies and certifies that the product promotion representatives employed by the company are adequately trained, that they are regularly updated and fulfill the obligations expected from them.

10.4. In case of request by the Ministry, the Scientific Service officer supplies all documents and information regarding promotional activities. (Reg.Art.11.5.b)

10.5. The Scientific Service officer ensures that the decisions adopted by the Ministry concerning the promotion of medicinal products are fully implemented. (Reg.Art.11.5.ç)

10.6. Samples of all promotional materials to be used should be preserved for at least two years so as to be presented to the Ministry upon request. (Reg.Art.11.5.c)

10.7. The information provided directly by the Scientific Service Officer about a product or indication not registered in Turkey upon the written request of a physician, dentist or pharmacists who is a healthcare professional is not covered by the promotional restriction stipulated in clause 2 of Article 6 in the Regulation. (Reg.Art.6.2)

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10. Scientific Service: AIFD member companies should communicate to AIFD General Secretariat an up-to-date list of the names, of the Scientific Service Officer appointed (Medical Director, Medical Manager, Regulatory Affairs Manager, Compliance Officer or other officers regarded suitable by the company), their summary CVs, emergency phone numbers and e-mail addresses.

10.1.2.a. The Scientific Compliance Officer of the company should be kept responsible for observing the conformity of all promotional materials to be used to the Code of Promotional Practice, before their distribution and the activities to be conducted, as well as their approval. Such person should certify that he/she has examined the final version of the material, and that in his/her belief the material or activity is compliant with the Code of Promotional Practice and any laws and regulations, are consistent with the SmPCs, and that information presented about the product is communicated in an accurate, balanced and realistic manner.

10.1.2.b. A physician or pharmacist should be responsible in the Scientific Service for the preparation and implementation of non-interventional studies. Such person should certify that he/she has examined the protocol of the non-interventional study and that in his/her belief and scientific experience it is in accordance with the Code of Promotional Practice and any applicable laws and regulations and is consistent with the SmPCs of the product.

10.6. Archiving Samples of Materials: With regard to the samples of promotional materials to be archived, practically at least two (2) physical samples of each material should be kept (one for submission to the Ministry upon request and the other to be kept in the archives).

It should be taken into account that the two-year preservation period begins as of the last wide usage of the material.

Records of documents about all promotional materials used, the amounts utilized, the period of usage and target groups should be kept properly. Notifications submitted in the digital environment and the accessible samples of promotions should also be preserved in accordance with archiving rules.

Article 11- Internal Approval Process of Promotional Materials and Activities

11.1. Promotional materials shall not be used and promotional activities shall not be performed before their conformity to the Code is approved by the Scientific Service Officer. No changes can be made afterwards on the approved materials. This rule applies also for promotional materials prepared in a digital environment.

11.2. The Scientific Service should approve all activities falling under the definition of "promotion", including meetings and sponsorships, in addition to promotional materials.

11.3. Materials used continuously should be re-approved at least every two years to ensure that their content continues to conform to the Regulation and Code.

11.4. Companies should preserve all certificates of approval and relevant materials for at least two years after the final use of approved materials.

11.5. Training, Monitoring and Certification of the Code of Promotional Practice

11.5.1. It is the responsibility of the Scientific Service to ensure that all company staff, including contracted parties, concerned with pharmaceutical and company promotion, in areas such as the preparation and approval of promotional materials; communication of information to physicians, dentists and pharmacists; submission of requested information to the relevant units of the Ministry of Health; activities for informing the general public; as well as employees of advertising agencies working in the preparation of these promotional materials; those working in market surveys and CROs are adequately informed about the work they will perform in relation with the terms and conditions of this Code and Regulation, Guidelines, Directives and any other applicable laws and regulations.

11.5.2. Training, monitoring and certification shall be conducted by authorized departments under the surveillance of the Scientific Service. The training of product promotion representatives is described in Art. 12.

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11. Internal Approval Process: The fact that many tasks and responsibilities are assigned to the Scientific Service with this article does not intend to intervene to business process of companies. Companies may arrange their business, approval and follow-up processes and powers as they deem suitable.

11. A senior employee should be appointed by the company to be responsible for supervising the compliance of the company with the Code of Promotional Practice and relevant laws and regulations.

11.1.a. The approval process is conducted for the purpose of ensuring full conformity of promotions with this Code and relevant Regulations and Guidelines.

11.1.b. Approved materials shall not be altered after the approval; if changes are necessary, the approval process should be repeated..

11.1.c. The approval form for promotional materials should certify that the signatories have examined the final form of the material and that it is in accordance with the Code in their belief.

11.2. Entry into the System and Approval of Meetings in Conformity with the Guidelines: Meeting and participant information that need to be entered into the system of the Ministry of Health in accordance with the new Regulation and relevant Guidelines should be carefully followed by the top management of the company in order to avoid being subjected to severe sanctions. Conformity with the restrictions stipulated in Article 15 is the responsibility of the Scientific Service on behalf of the registration/permit holder.

11.4. Preservation of Documents and Materials: Companies should note that the Ministry is entitled to request at any time any information about a promotion, including the content, form, method of dissemination and the first date of dissemination (first sentence of Article 12 in the Regulation). Companies are advised to keep a reference archive, at all times, in electronic format.

11.5. Certification of Trainings (Documentation and Approval): Trainings to be conducted on the Code of Promotional Practice should be documented, as with all other trainings. An adequate process is applied by each company to serve this purpose. It is adequate for the list of signatures of participants, documenting that they participated at the meeting, and documents showing that they have received the information conveyed and sufficiently benefited from the training/information, to be preserved in a suitable environment (as hard copy or soft copy).

Companies may regard sufficient for certification also participation in training meetings provided by AIFD or upon the approval of AIFD about the Code of Promotional Practice.

12- Product Promotion Representatives, Proficiency and In-Service Training

12.1. Member companies should ensure that their representatives responsible for the promotion and sales of their products, including those working under contract, or representatives of other companies responsible for calling on and making promotion to hospitals and other healthcare facilities on behalf of their company are adequately trained on applicable laws, Regulations, guidelines, health and advertisement regulations, AIFD Code of Promotional Practice and the relevant Regulation. The Scientific Service should document and certify that an adequate and appropriate training has been provided.

12.2. Companies are responsible for the activities of their product promotion representatives. The registration/permit holder and the relevant product promotion representative are jointly responsible for the promotion made by product promotion representatives. (Reg.Art.10.2)

12.3.1. Product promotion representatives are obliged to undergo basic and necessary in-service trainings/trainings deemed suitable by the Ministry, directly themselves, or by their company where they are employed or by means of procurement of services by their company, comprising also the legal and ethical framework of the service (Reg.Art.10.1.b) and receive a certificate of qualification issued by the Ministry. (Reg.Art.10.1.b) (To apply as of 01/01/2015.)

12.3.2. These certificates of qualification apply until the end of the fourth calendar year; product promotion representatives who would like to continue working in a pharmaceutical company should receive a new certificate prior to the expiration of this period. (Reg.Art.10.1.b) (To apply as of 01/01/2015.)

12.3.3. Persons holding at least a high school degree who were employed as a product promotion representative after 01/01/2015, are eligible to apply for a qualification certificate by presenting documentation of their having successfully passed an examination to be held for this purpose. (Reg.Art.10.1.c)

12.3.4. For university graduates holding a "Medical Promotion and Marketing" degree, a qualification certificate shall be issued upon submission of their diploma, without further examination. (Reg.Art..10.1.ç) The certificates of qualification issued for graduates of "Medical Promotion and Marketing Program" at universities are not required to be renewed [at the end of the fourth calendar year] within this scope. (Reg.Art.10.1.b)

12.3.5. Registration/permit holders should record their product promotion representatives employed and to be employed into the electronic registry system of the Ministry. A "Product Promotion Representative Identification Card", with a format determined by the Ministry, shall be issued to product promotion representatives holding a certificate of qualification and who are registered into the system. (Reg.Art.10.1.d).

12.3.6. Companies shall not employ as a product promotion representative persons without a Product Promotion Representative Identification Card. (Reg.Art. 10.1.e) (Valid as of 010/1/2015.)

12.3.7. It is mandatory for companies to notify the Ministry within twenty days when product promotion representatives quit their job for whatever reason or start working. (Reg.Art.10.1.f) (Valid as of 01/01/2015.)

12.3.8. Product promotion representatives may provide service to multiple registration/permit holders. The responsibility rests with the registration/permit holders and the rights arising from the contracts of registration/permit holders are reserved. (Reg.Art.10.1.g)

12.3.9. The procedures and principles relating to the training, documentation and records of product promotion representatives are arranged by the relevant Guidelines.

12.4. Product promotion representatives should be fully and sufficiently equipped with relevant scientific data and information about the products which they are promoting; (Reg.Art.10.1.a) the provision of suitable basic and in-service continuous training is ensured by their company to serve this purpose.

12.5.1. Product promotion representatives shall not promote any product or the like to healthcare professionals other than physicians, dentists and pharmacists. (Reg.Art.10.1.ğ)

12.5.2. The promotional materials relating to the product being promoted shall not be delivered to persons other than physicians, dentists and pharmacists. (Reg.Art. 10.1.i)

12.5.2. Product promotion representatives may provide information also to healthcare professionals other than physicians, dentists and pharmacists on topics such as the administration and side effects of products,

provided that the relevant department authority/responsible physician is informed and has granted his/her approval. (Reg.Art.10.1.ğ)

12.6. They are obliged to convey the information to be used during their promotion to physicians, dentists and pharmacists, substantiated with a promotional material, where necessary, upon transmitting fully and accurately any positive or negative data to be known about the product. (Reg.Art.10.1.h)

12.7.1. When fulfilling their duties in a responsible manner, product promotion representatives should always act in line with high ethical standards and the Code of Promotional Practice.

12.8. In line with applicable laws and regulations, the Summary of Product Characteristics of each product promoted should be made available by the product promotion responsible so as to be presented upon request to the physicians, dentists or pharmacists called upon.

12.9. Product promotion representatives should forthwith forward to the relevant Scientific Service and Product Safety Officer of their company the adverse effects/events reported to them with regard to the product during the product promotion. (Reg.Art.10.1.ı)

12.10. The frequency, timing, duration and style of calls by product promotion representatives to physicians, dentists, pharmacists, in private surgeries, pharmacies, hospitals and other healthcare facilities should be organized in a manner so as to avoid causing inconvenience for physicians, dentists, pharmacists and patients. The following rules apply in order to enable product promotion representatives promote medicinal products for human use in public healthcare facilities during working hours: (Reg.Art.10.3)

12.10.1. Product promotion representatives should indicate at the beginning of the call the company and/or registration/permit holder that they represent and show their Product Promotion Representative Identification Card. (Reg.Art.10.3a) (Valid as of 1/1/2015.)

12.10.2. The relevant administrator of each healthcare facility providing public service should allocate the most suitable time, upon observing the working order of healthcare professionals to ensure that product promotion representatives conduct their product promotion call. This allocation should not disrupt the training services and healthcare services provided to patients. (Reg.Art.10.3.b)

12.10.3. Product promotions shall not be conducted in emergency services and during patient-seeing hours in out-patient departments. (Reg.Art.10.3.c)

12.11. No money or similar fees shall be requested, by any means whatsoever, even under the name of donation or similar names, from product promotion representatives that call on a healthcare facility in order to make promotion, for their entry in that facility. (Reg.Art. 10.4) In case of such a request, companies or their representatives shall not make any payment.

12.12. Product promotion representatives should not induce or offer incentives or benefits in kind to physicians, dentists or pharmacists in order to be able to call on them. No fee should be offered or paid in return for the duration of the call.

12.13. Companies should prepare training-guidance materials for their product promotion representatives with regard to the technical aspects of each drug promoted. Such materials should conform to the relevant requirements of this Code.

12.14. Training-guidance materials should not contain any material that may cause the breach of the Code directly or indirectly, or should not encourage a behavior that may be perceived in this manner.

12.15.1. Posters or similar promotional materials, that may be perceived as product promotion, should not placed, hung and/or adhered in public healthcare institutions. (Reg.Art.10.5)

12.15.2. However, posters and similar promotional materials to be used in campaigns held by the Ministry for the purpose of promoting health, such as vaccination campaigns, combat against epidemics, smoking and obesity remain outside the scope of this provision. (Reg.Art. 10.5)

12.16. Product promotion representatives shall not contact directly patients and patients' relatives.

12.17. Invalidation of the Certificates of Product Promotion Representatives:

a) In case of breach in the promotions made by a product promotion representative – during the valid term of the certificate of qualification issued by the Ministry – first the product promotion representative is warned by the Ministry;

b) In case of repetition, the certificate of qualification is suspended for a period of three months,

c) In case of continuation of the breach, the certificate of qualification is suspended for a period of one year.

d) Product promotion representatives whose certificate of qualification has been suspended shall not work during this period and,

e) the company of employment takes back the Product Promotion Representative Identification Card. (Reg.Art.13.4)

Article 12- Product Promotion Representatives: It is advised for companies to include also compliance with the code of ethics into their employment contracts to be signed with the product promotion representatives (PPRs).

12.1. Contracted staff: Persons not included into the payroll of the company, but who work under contract via a third party company.

12.3. Certificate of Qualification of Product Promotion Representatives: This implementation described in detail in Article 10 of the Regulation shall become effective as of 01/01/2015. According to Provisional Article 1 of the Regulation, the procedures and principles relating to the implementation calendar of this implementation will be prepared by the Ministry until 30/06/2013 and will be announced on the website of the Ministry. AIFD Code of Promotional Practice will be forthwith arranged in a manner so as to encompass these amendments as well and be published upon receiving the relevant approvals.

12.7. Product Promotion Representatives; High Ethical Standards: In medical and sales and marketing trainings, companies should highlight the characteristic of pharmaceutical promotion where medical information with commercial purposes is presented and the rational use of drugs is given priority.

12.8. EFPIA-compliant text. SmPCs to be distributed to physicians should be up-to-date. Such information may be in printed form or stored in other modern communication media (CDs, flash disks, company website) and distributed accordingly. In case of request of a printed form by the person to whom promotion is made, this request should be forthwith fulfilled.

12.9. Collection of Adverse Events Reports from Physicians, Dentists or Pharmacists: The collection process of adverse events (and side effects) notification reports should be included into the basic training package of product promotion representatives.

12.10. Text compliant with the Regulation, EFPIA Code and TTB (Turkish Medical Association) Declaration of Physician-Pharmaceutical Industry Interactions.

12.13. Training-Guidance Materials for Product Promotion Representatives: Companies should prepare such materials in a manner so as to avoid misunderstandings and misinterpretations.

12.16. Product Promotion Representatives Shall Not Contact Patients Directly Under Any Circumstance: The role of trainers of prescribed special administration devices and that of product promotion representatives should certainly be distinguished. Companies are advised to recruit separate teams for patient trainings.

During the time allocated for patient training, no promotional material or any material that may be interpreted as such should be available, and no activity that may be interpreted as such should be conducted.

Training on the use of administration devices of drugs prescribed to patients (such as insulin pumps, etc.) should be carried out by teams without sales responsibility; these teams should preferably be composed of nurses.

Company representatives (or those contracted by the company) are strictly forbidden to contact and establish relations with patients and patients' relatives in case of assistance on patients' medical reports, prescriptions and other documents as well as similar situations. Product promotion representatives shall not be involved in activities such as finding patients for researches.

Article 13- Distribution of Free Samples

13.1. Free samples are provided for the purpose of enabling prescribing physicians and dentists to get acquainted with the product, without the obligation of obtaining permission from the Ministry.

13.1.1. Samples shall not be distributed for the treatment of patients.

13.1.2. Promotional samples may not be used as a research product in clinical trials. (Reg.Art.9.1.g)

13.1.3. Samples shall not be distributed with the purpose of increasing the sale, procurement, use, recommendation of a drug.

13.2. Registration/permit holders shall set up and appoint qualified persons for an adequate system of records and control, for the production, importation and distribution of free promotional samples. Upon demand, these records shall be submitted to Ministry officials in the format – electronic or hardcopy – determined by the Ministry. (Reg.Art.9.1.a)

13.3. The recording system should also be arranged in a manner so as to enable a sound tracking indicating that the samples have been delivered in accordance with the AIFD sample distribution standard.

13.4. Registration/permit holders shall establish a system and formulate a process to enable the safe withdrawal of free samples where necessary. (Reg.Art.9.1.e)

13.5. It is essential that no barcodes/datamatrixes are used on the packages of promotional samples. In cases of presence of a barcode/datamatrix on the packages of Free Promotional Samples to be distributed, a written permission shall be requested from the Ministry along with its justification. The sale of samples shall be prevented in the Drug Tracking System of the Ministry. (Reg.Art.9.1.e)

13.6. Free samples contain a reduced amount. However, samples of enteral nutritional products and products that cannot be reduced, due to technical reasons, shall not be bigger than the size of the smallest package marketed. (Reg.Art.9.1.b)

13.7. The statement reading "Promotional sample, not for resale" shall be placed on at least one surface of the outer package of promotional samples in a marked manner. Where it is not possible to print it, the same statement shall be included also in the inner package. (Reg.Art.9.1.c)

13.8. A copy of the PIL and/or SmPCs will always be presented, if available, along with the promotional sample. (Reg.Art.9.1.ç)

13.9. Samples of products containing psychotropic and narcotic substances within the scope of the United Nations Single Convention of Narcotic Drugs of 1961 and the United Nations Convention of Psychotropic Substances of 1971 (Reg.Art.9.1.d) and samples of other products where the distribution of samples is not regarded as suitable by competent authorities shall not be distributed or supplied.

13.10. Samples may be given only to prescribing physicians and dentists. (Reg.Art.10.1.i)

13.11. Samples of prescription products shall not be distributed in congress booths.

13.12. Sample Distribution Rules in the Regulation

13.12.1. Free product samples may be distributed for each medicinal product for human use as of its market introduction date, at an amount to be calculated as follows:

13.12.2. At an amount not to exceed 5% of the total annual sales upon tracking the monthly sales realizations in the first calendar year;

13.12.3. At an amount not to exceed 5% of the sales amount of the previous [calendar] year in the second calendar year;

13.12.4. At an amount not to exceed 3% of the sales amount of the previous years in the third, fourth and fifth calendar years;

13.12.5. At an amount not to exceed 1% of the sales amount of the previous year each year after the fifth calendar year.

13.13. AIFD Sample Distribution Rules:

13.13.1. The reduced sample of a product may be provided to a healthcare professional authorized to write prescriptions (a physician or dentist) upon his/her first dated and signed written request, for the purpose of enabling him/her get acquainted with the drug, for a period of only 2 years (24 months) at an amount not exceeding 4 (four) per year (4 x 2 years rule). The same rule applies also for new drugs*(See Article 13.13.3).

13.13.2. The total number of samples that may be distributed any year for a product shall not exceed the total amount specified by the provisions of the Regulation according to the sales of the previous year and no more than 4 samples shall be provided to a physician who makes a request.

13.13.3. *A "new drug" is a product newly issued a registration for its market introduction with an indication upon a registration application or which has been permitted to be prescribed in a new indication in addition to an existing registration. New dosage forms and new trade commercial forms registered in existing indications shall not be regarded as a new drug.

13.13.4. Taste samples of enteral nutritional products are not encompassed by AIFD's 4x2 restriction.

13.13.5. Abovementioned distribution rules for reduced samples shall be applied by AIFD members as of July 1, 2012.

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13. Samples: In accordance with EU directives and the EFPIA Code, distribution of free samples in a reduced amount of prescription drugs may only be allowed in exceptional cases to prescribers (physicians and dentists), for a limited period of time and in a limited amount, upon a written, dated and signed request. Although a restriction is imposed on the amount of samples to be distributed by the legislation of the Republic of Turkey, the period of distribution is not restricted, provision of samples to pharmacists is not prevented and distribution is not bound to the written, dated and signed request of physicians and dentists.

13.1. Free goods distributed to pharmacies upon indicating this on the dispatch notes and invoices are not considered free samples and are not included into the scope of this Code. Free Goods (FG) should be indicated on the invoice in line with the applicable laws and regulations.

13.1.2. Drugs provided to physicians or clinics for research purposes or in starter kits for initiating the treatment should not be delivered in their original commercial packages; their packages should not bear any price tags or commercial drug barcodes.

13.2. Samples should be preserved in similar conditions with sales products during the period until they are distributed.

13.3.1. Companies should have a suitable recording, tracking and control system that is detailed enough to ensure the recall of samples like commercial drugs

13.3.2. Recording, tracking and control systems should include starter kits and the drugs used in trials.

13.4. Free samples should be prepared and distributed in a manner so as to avoid the prevention of their sale. Samples packages should not bear any price tags, commercial barcodes or commercial datamatrixes. The outer package should include relevant information for the production process, withdrawals and inventory tracking.

13.5. Documents to be Submitted in the Applications for Receiving a Distribution Permission for Free Samples

a) Sample specimen (2),
b) Photocopy of registration,
c) Latest approved sales permit and annexed package sample,
d) Latest certified patient information leaflet (along with its letter of conformity),
e) In the applications for co-promoted products, letter of approval received by the registration holder company from the relevant department for co-promotion.

13.12.1. Market introduction date of the medicinal product for human use: As the registration date and the date of inclusion into the reimbursement list may differ, the market introduction date is accepted as the date on which the company has registered its drug into the Drug Tracking System.

13.13. Supply of Samples to Pharmacists: In line with EFPIA's interpretation of the EU Directive, AIFD does not regard suitable the supply of samples of prescription drugs to pharmacists.

13.13.1. Distribution of samples upon the written, dated and signed request of physicians: EFPIA's rules envisage the distribution of samples "upon the unsolicited request of physicians". Therefore, physicians should submit their request in writing, with a date and sign it.

13.13.2. Amount of samples that may be distributed in the co-promotion of the same product by two companies: The total amount of samples that may be distributed for a product distributed or promoted by more than one company under the same trade name shall not exceed the amount specified in the relevant articles. (5%-3%-1% and 4x2 rules shall apply)

13.13.4. Distribution of taste samples of enteral oral nutritional products: Enteral oral nutritional products are products mostly covered by reimbursement, and used by persons who have issues in being nourished with natural products or routes. As it is highly important to enable the user (patient) taste the flavor and smell added to facilitate drinking of products in terms of rational treatment, it is a generally accepted practice to leave product taste sample to administering physicians for their use before writing a prescription. Continuous distribution of taste samples of oral enteral products is possible upon recording the sample distributed for tracking purposes, provided that the upper limit indicated in the Code of Promotional Practice is not surpassed.

13.12. Calculation of the amount of free samples to be distributed (percentage of the sales of the previous year: In accordance with the Regulation, the annual amount of free samples of medicinal products for human use distributed annually as of January 2013 shall not exceed the amount to be found according to the calculation method presented in the following table as of the market introduction date of the relevant product. The enforcement of this provision shall be initiated as of the market introduction date for each medicinal product for human use. (Reg.Art.9.1.f, Guidelines on the Distribution of Free Promotional Samples)

Paragraph (f) in the 1st clause of Article 9 regarding free samples in the Guidelines shall be as follows:

First Calendar Year:

A. If the market introduction date (first record on the Drug Tracking System) *is within the first 6 months* of the 1st calendar year, samples may be distributed at an amount not exceeding 5% of the total annual domestic unit sales figure of the same year upon tracking the annual sales realizations.

B. If the market introduction date is within the second 6 months of the 1st calendar year, this shall be regarded as the "first calendar year" until the end of the following calendar and samples may be distributed at an amount not exceeding 5% of the total annual domestic unit sales figure upon tracking the monthly sales realizations.

Example A: For a product introduced into the market on 30.06.2012, the 1st calendar year is 2012.

Example B: For a product introduced into the market on 01.07.2012, the 1st calendar year is 2013. Free promotional samples at an amount not exceeding 5% of the 18-month total sales figure may be distributed upon tracking the monthly sales of a total of 18 months "in the first calendar year" for this example.

Second Calendar Year:

A. If the product has been introduced into the market within the first 6 months of the previous year, samples may be distributed without exceeding 5% of the total annual domestic sales figure calculated on the basis of a *1-year projection* of the total domestic sales figure *with direct proportion*.

B. If the product has remained in the market for a complete calendar year in the previous year, samples may be distributed without exceeding 5% of the total annual domestic unit sales figure.

Example A: For a product introduced into the market on 30.06.2012, it is calculated as 5% of the 1-year sales figure obtained upon making a projection with direct proportion on a total of 6 months and 1 day in 2012 which is the 1st calendar year.

One-year sales figure is calculated as follows:

[(Unit sales figure of 6 months and 1 day) / 6,033] X 12 =" projection of the total sales figure in the 1st calendar year"

Example B: For a product introduced into the market on 01.07.2012, the first calendar year is 2013. The amount of samples that may be distributed in 2014 is calculated as 5% of the total unit sales figure in the calendar year 2013.

Third, Fourth and Fifth Calendar Years:

Samples may be distributed without exceeding 3% of the total annual domestic unit sales figure of the previous year.

Sixth, Seventh and Consecutive Calendar Years:

Samples may be distributed without exceeding 1% of the total annual domestic unit sales figure of the previous year.

Article 14- Promotional Materials, Medical & Educational Materials and Donations

14.1.1. When promoting medicinal products for human use to physicians, dentists and pharmacists, no gift, benefit, whether in cash of in kind, may be provided, committed or even offered to these persons or their administrative staff, except for reminder items complying with the boundaries defined in Article 14.3, for the prescription, procurement, use or recommendation of a drug.

14.1.2. Referred healthcare professionals shall not accept or request any inducement during the promotional activities directed to them. (Reg.Art. 6.8)

14.2. The Positive List, which was applicable in the AIFD Code of Promotional Practice from 2004 to 2011, **has been revoked.**

14.3.1. With regard to reminder items related with a specific product or directed for general use, the referred materials may be distributed, provided that they are associated with the profession or duties of physicians, dentists or pharmacists and also bear a modest monetary value.

14.3.2. Reminder call materials should be designed in a manner so that they cannot be in places open to the general public and assist physicians, dentists and pharmacists in exercising their profession and/or their provision of services to patients.

14.3.3. Company representatives should take relevant measures to ensure that promotional materials are not displayed in a manner that may be visible for patients in the healthcare facilities. (Reg.Art. 8.3)

14.4. If the reminder promotional material contains only the following, it is not necessary for the mandatory information specified in Article 4.2 to be written:

a) Brand name of the drug;
b) INN of the active substance;
c) Name and address of registration holder/manufacturer.

14.5. No promotion or service shall be provided to healthcare professionals through **sweepstakes, games of chance or prizes from such games**. (Reg.Art. 6.7)

14.6. Tickets to entertainment venues, personal care products and similar gifts for personal benefit shall not be offered or provided.

14.7. Medical Publications, Books and Journals

14.7.1. AIFD Code of Promotional Practice does not restrict companies from preparing medical publications, publish medical journals and distribute medical books and journals to physicians, dentists and pharmacists.

14.8. Donations

Donations provided in accordance with laws and regulations are not considered as gifts under Article 14 of the AIFD Code.

14.8.1. Donations Provided to Public Healthcare Institutions or Organizations:

Registration/permit holders can make donations to the following public healthcare institutions or organizations, provided that they fulfill the following requirements: (Reg.Art.6.10)

a) Prior permission is received from the administrative authority supervising the recipient organization, institution or family health center,
b) Tender award decisions for products covered in this Regulation are not influenced by the donation,
c) The donation does not lead to any unethical conduct which may be associated with product purchase,
ç) The donation does not encourage prescribing a specific human medicinal product,
d) The underlying intention is to promote either of research, training, patient wellbeing or care provided to patients,
e) The donation will be utilized by not any individual person, but the entire organization or institution,
f) Only the name of the registration/permit holder, and not of the product, may appear on the donated materials,
g) The donation is entered in the official books of the registration/permit holder,

ğ) Any donation of medicinal products, laboratory kits or similar items for use in clinical research is made directly to the principal investigator.

14.8.2. Sponsorships and Donations Directed to Health and Research & Development

Donations and sponsorships can be provided under the following conditions to non-profit organizations, associations, foundations that are composed of physicians, dentists and pharmacists and/or organizations providing healthcare or conducting research that comprises them, and which are not covered by another section of the AIFD Code of Promotional Practice:

a) It is provided for the purpose of supporting research on health or the provision of a specific public health service;
b) The donator/sponsor is registered on the official records;
c) The written commitment of the institution receiving the sponsorship/donation, indicating that the sponsorship will be included into their records and will be declared to the public, has been obtained;
d) It is not directed to the inducement for the recommendation, prescription, purchase, sale, distribution, promotion or use of a drug or drugs;
e) The personal or scientific educational expenses of the persons identified are not covered via "conditional donation".

14.8.3. Personal donation shall not be made to directly or indirectly to healthcare professionals.

14.8.4. Sponsorship for the participation of healthcare professionals to national or international activities is covered by Article 15.

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14. Promotional Materials and Donations

14.2. The implementation of the Positive List, which was included into the 2004-2011 editions of the AIFD Code of Promotional Practice, **has been revoked.**

14.3.a. "Modest value" is defined by the Ministry as 2.5% of the applicable minimum gross monthly wage. This limited is accepted as 20 TL for AIFD members.

14.3.b. In the design of reminder items; common sense, aesthetics and ethics and the review of the materials distributed by the company and its competitors and the decisions adopted by the relevant committees of AIFD shall provide guidance.

A material bearing only the company logo, or "corporate promotion" activities conducted for the purpose of announcing the name of the company and not directed to physicians, dentists and pharmacists or those who influence drug purchasing and selection policy with their decisions are not included into the scope of the restrictions mentioned above. However, indirect promotion of drugs is clearly banned. Therefore, the fact that corporate promotional activities are not included into the scope cannot be interpreted in a manner to lead to the activities banned by the Code.

14.3.c. Plastic Bags and Wrappers Distributed to Pharmacies: Plastic bags, wrappers and similar materials distributed to pharmacies by pharmaceutical companies cannot be used for the promotion of prescription-only medicinal products. Non-prescription drugs do not fall under the scope of this article.

14.3.d. Printing Brand Names and Promotional Messages on Official Documents: It is forbidden to print the brand names of drugs or messages reminding them on official documents, prescription stubs or materials to be distributed to children or to the public. Company logo may be printed to indicate a sponsorship.

14.4. Company Address: Inclusion of telephone and fax numbers as well as the website address as the company contact information of the company in full, abbreviated and advertisements is becoming more widespread. Providing only the website address in reminder items is sufficient.

14.5. Promotion and Distribution by Sweepstakes: Use of games of luck in promotional activities has been forbidden by the Regulation.

Scientific quizzes can be organized during congresses. The prizes to be presented at the end of these are restricted to items described in Articles 14.3.1. and 14.7. The value of prizes (inclusive of the books) presented in connection with scientific quizzes organised in any platform (at Internet, in congresses, satellite symposia, company booths or others), shall not exceed the modest value as defined in Annex It is not suitable to present gifts by sweepstakes at the end of the quiz.

14.7.a. **Scientific Books and Journals, medical Educational Materials and Services:** AIFD does not equate reminder items with educational materials and services. Books and journals that may contribute to healthcare and provide contribution to the medical knowledge of physicians, dentists and pharmacists may be supplied and distributed; journal subscriptions may be provided for the benefit of the physicians at clinicians, if at a reasonable level. Distribution of books and journals should not be made to induce prescription of a drug or a range of drugs of a company. Provision of books and journals should not put physicians, dentists and pharmacists under the pressure to reciprocate and should not be complimentary.

14.7.b. Scientific Books and Journals: Scientific books and journals are not subjected to monetary restriction. AIFD, advises its members to refrain from practices that may be regarded as exaggerated, give rise to misinterpretations or appear exaggerated in the distribution of books and journals.

14.7.c. Provision of Medical and Educational Goods and Services: Provision of such types of goods and services should not be performed in a manner so as to encourage the prescription, procurement, recommendation or purchase of any drug. These may include the company logo but not the name of a drug.

14.8. Donations: Donations should be limited to public institutions and non-profit healthcare organizations. The eventual "perception" of donations should always be taken into consideration.

14.8.1.h. **and 14.8.2.c.:** EFPIA and AIFD obliges member companies to make a transparent declaration to the public about donations and sponsorships provided throughout the year. As indicated in the relevant article (Article 21), as of 2013, AIFD members shall be obliged to declare donations to be provided to patient associations and payments made in return for services to be received from associations.

Article 15- Scientific and Educational Meetings and Hospitality

15.1. Scientific and educational meetings such as congresses, seminars and symposia, including those providing financial contribution by companies, are the most appropriate settings for conveying existing medical information or disseminating rapidly and accurately new information and experiences, for the purpose of introducing a new medicinal product or a product in use and are also suitable platforms for promoting collegiality among colleagues.

15.2. Scientific and educational activities regarding the promotion of a medicinal product for human use shall not be used for a purpose other than conveying existing medical information and/or presenting new information. (Reg.Art.7.1)

15.3. Companies may sponsor healthcare professionals in scientific meetings, promotional meetings, scientific congresses, educational meetings and similar meetings; they may provide hospitality at the degree allowed by laws and regulations.

15.4. Activities related to hospitality and hosting in events directed to promotion shall not make secondary the purpose of the meeting. Such meetings should be organized in proper venues, style and level. Hospitality should always be at a reasonable level and carry secondary importance compared to the main purpose of the meeting and should not be seen exaggerated for that setting. Time allocated for hospitality shall not exceed the time dedicated for the scientific activity.

15.5. Hospitality activities sponsored by companies should be limited to genuine registration fee of the scientific part of the meeting, reasonable accommodation, transportation and meal costs.

15.6. Care should be displayed to ensure that the sponsorship and costs are at a reasonable level; these should not at a level that may be regarded as excessive by the participants and the general public.

As a general rule, hospitality costs should not be above a level that may be afforded by the invitees themselves.

15.7. Companies shall not cover directly or indirectly the transportation and accommodation costs of the participants attending the scientific and educational activities organized for the purpose of promoting their medicinal products for human use. (Reg.Art.7.1)

15.8. Registration/permit holders may sponsor healthcare professionals for participating in scientific meetings such as congresses or symposia taking place in or outside the country on the following conditions: (Reg.Art.7.2)

15.8.1. Rules relating to meeting sponsorships apply for all healthcare professionals providing service in Turkey. (Guidelines 1.6)

15.8.2. The meeting should be related to the area of specialty/role of the relevant healthcare professional. (Reg.Art.7.2.a)

15.8.3. A healthcare professional may benefit from the sponsorship of companies for three times in total within the same calendar year. (Reg.Art.7.2.b)

15.8.4. A registration/permit holder may provide participation sponsorship to a healthcare professional for maximum two of these three sponsorships within the same calendar year. (Reg.Art.7.2.b)

15.8.5. A healthcare professional may use only one right of these three sponsorships as a participant within the same calendar year for meetings held abroad. (Reg.Art.7.2.b)

15.8.6. In scientific meetings, the restrictions specified in clause b) of article 7.2 in the Regulation shall not apply for a) the speaker, b) investigator presenting a paper. (Reg.Art. 7.2.b)

15.8.7. Meetings of investigators, sponsored by the registration/permit holder, held in Turkey or abroad in connection with a national or international multicenter clinical trial, will not be considered attendance to a congress or symposium. Any application submitted to the Ministry for such meetings will include a clear description of the meeting's nature and it will be indicated that the meeting being held is for the aforesaid purpose. (Reg.Art.7.4)

15.8.8. Sponsorship should be provided to the organization(s) holding the meeting and directly to a person. (Reg.Art.7.2.c)

15.8.9. Registration/permit holders are obligated to notify the Ministry of particulars of sponsored healthcare professionals according to the Guidelines that will be subsequently issued to regulate these issues. The Ministry will collect this information in a database. (Reg.Art.7.3)

15.9. "Educational Activities" held by registration/permit holders and where there is no product promotion, are shall be evaluated separately if a separate application is made; in case of receipt of Ministerial consent, it will be possible to cover transportation and accommodation costs of healthcare professionals participating in such type of educational activities without the restriction of Article 7.2.b of the Regulation. (Guidelines 3.1.4)

15.10.1. Non-healthcare professionals may not be invited to the meetings, nor may their expenses be covered; however, guests of honor are excluded from this provision. (Reg.Art. 7.6) Hospitality and financial contribution should not cover persons other than those presenting a scientific study in scientific congresses, those participating in meetings for educational purposes and relevant administrative staff. Accompanying persons (for example spouses) who are not actively participating in the referred scientific meetings, even if they are physicians, dentists or pharmacists, shall not be covered.

15.10.2. Persons appointed by the Ministry may attend such meetings with or without prior notification for inspection purposes. (Reg.Art. 7.8)

15.11. Participation of a healthcare professional in a meeting or sponsorship of such participation shall not be bound to the commitment of prescribing specifically a drug or the products of a company or having achieved a certain amount of sales. The level of hospitality should not be associated with the previous services of the healthcare professional as a prescriber.

15.12.1. Hospitality or sponsorship should not comprise vacations, participation in sports competitions and offering of entertainment to healthcare professionals.

15.12.2. Companies should not use excessive, grandiose, extravagant venues and facilities that are immediately associated with recreational activities and should refrain from organizing or sponsoring, directly or indirectly, activities that may be described as such or similar activities.

15.12.3. Except international meetings that are held each time in a different country, no meeting can be held or sponsored by registration/permit holders at seaside resorts or skiing resorts during the high season. The high season periods will be announced on the Ministry's website. (Reg.Art. 7.5)

15.13. Whether for promotional purposes or scientific and professional in nature, all meetings, congresses, conferences, symposia, workshops and similar meetings (each defined as an "event"), including but not limited to advisory board meetings, research and production facility calls, planning and training meetings of clinical trials and non-interventional trials, researcher meetings and workshops and such, organized or sponsored by a company or on behalf of a company, should be held in a suitable place, time and setting, in line with the rules specified above, be directed to fulfill the main objective of the meeting, should comprise hospitality only when needed and if adequate, and conform with the letter and spirit of the Code of Promotional Practice.

15.14. Sponsorships Provided to Associations and Clinics

Conditions and restrictions relating to the sponsorships and donations to be made to specialty associations established by healthcare professionals and hospital clinics are described in Articles 17 and 14.8.

15.15. Requirement of Including a Session on the Rational Use of Drugs in Sponsored Meetings: *(See Article 17.3)*

A session on the "rational use of drugs", related with the topic of the meeting, shall be included into the program of at least 60% national congresses and similar meetings lasting more than 6 hours, which are organized, sponsored or otherwise contributed by registration/permit holders. The content of the presentations to be delivered in this session shall be within the framework of the educational materials and diagnostic and therapeutic guidelines approved by the Ministry and be submitted to the Ministry in the form of a end of meeting feedback as indicated in the relevant Guidelines. (Reg.Art. 7.7)

15.16. Meetings Held Abroad and Hospitality

No company may organize or sponsor meetings abroad, barring the following exceptions:

a) If the meeting is international, where it is more suitable to hold the meeting abroad for logistic reasons, due to the fact that majority of the participants (invitees) are coming from other countries;

b) If the sources or specialties associated with the subject matter or objective of the meeting make it preferable to hold the meeting in another country due to logistic reasons.

15.17. Planning, Reporting and Monitoring of Sponsored Meetings in Turkey and Abroad; Obligations

15.17.1. Congresses, symposia, seminars and similar meetings to be organized or supported by registration/permit holders will be communicated to the Ministry. (Reg.Art. 11.3)

15.17.2. At least fifteen working days prior to each meeting, it is mandatory to report to the Ministry the content of the meeting, the list of potential participants, expense items and events to be performed; notifications where the document entry has been performed and no response is received from the Ministry within ten working days, this will be regarded as approved application. (Reg.Art. 11.3)

15.18. Archiving of Meeting Programs, Materials and Names of Participants Sponsored

15.18.1. Upon the realization of the meetings they have sponsored, registration/permit holders shall submit to the Ministry in detail latest within one month and in line with the Code of Promotional Practice, the list of participants, expense items and the events performed, in the specified format and on digital media. (Reg.Art. 11.4)

15.18.2. Copies of information and documents presented to participants should be preserved by the relevant registration/permit holder for a period of two years for submission to the Ministry upon request. (Reg.Art. 11.4)

15.19. International medical meetings organized in Turkey and outside Turkey and directed to physicians, dentists and pharmacists are included into the scope of this Code.

15.20. Compensation of the Time Spent

No payment shall be made to physicians, dentists or pharmacists in order to compensate for the time they have spent for attending a conference or meeting. (Reg.Art.6.8) No fee shall be offered or paid to physicians, dentists or pharmacists for the time of call in the institution where they work.

15.21. Sponsored Meetings, Their Announcements and Abstracts

When a meeting is sponsored by pharmaceutical companies, this information should be clearly indicated in all of the announcements to be made relating to the meeting, in the abstracts and proceedings to be published.

Names of sponsoring companies should be printed in a manner so as to enable participants and readers to notice it immediately.

15.22. The registration, accommodation, transportation expenses of healthcare professionals to participate in the sponsored meetings should be paid by companies to the congress and the relevant organization holding the congress and not directly to the participants. (RegçArt.7.1.c.)

Assessment of whether an meeting or event is acceptable in terms of this Code of Ethics may be determined with the answers to be given to the Ethical Screen ® composed of the four following questions:

1) Is this event in line with laws and regulations? ***(Standards)***
2) Is this event balanced and fair? Would you feel disturbed if the competing company (someone else) did it? ***(Sense of justice)***
3) Would our company and our invitees feel disturbed if all the details of this event were heard by the public? **(Feelings and Ethical Values)**
4) To what degree will the "**perceived facts**" in this meeting or event match our aimed "**objective facts**"?

15. Meetings and Hospitality: Hospitality refers to the reasonable, actual registration expenses, travel costs and accommodation expenses relating to the meeting to be attended by the person sponsored.

It is a generally accepted practice to pay a reasonable "honorarium" to the guest speakers invited to the meetings organized by a company in addition to covering his/her travel expenses and accommodation costs. The restrictions and terms of the Ethical Behavior Principles for Public Officers should be complied with.

Companies may sponsor a wide range of meetings. These may range from lunchtime audio-visual presentations at hospitals, meetings in training centers, meetings with meals for new products, courses, meetings for those conducting a clinical trial, meetings for patient support groups, satellite symposia held under the sponsorship of a company in national and international meetings organized by independent bodies.

The following basic principles should be complied with in the organization of any meeting:

a. The meeting should have a clearly defined scientific content;
b. The hospitality associated with the meeting should be secondary to the nature of the meeting, be at a certain quality, suit the invitees and not be out of proportion for that setting;
c. The financial support provided to the invitees for hospitality should not cover accompanying persons. In cases where the accompanying person is also a physician, dentist or pharmacist and is qualified to be invited to the meeting, he/she should be invited separately.
d. The Regulation does not allow the coverage of the expenses of the accompanying person, including his/her travel and accommodation costs.

15.4. Appropriate Venue, Style and Level:

a) Conditions stipulated in this article apply also for sponsorships. For example, no sponsorship shall be provided to stage performers in the congress or meeting sponsored.
b) In case of events that may be perceived to be under the sponsorship of companies and are against the Code are included into the meeting program, companies should refrain from providing sponsorship.
c) Hospitality that may appear excessive, such as "hospitality suites" outside the congress area, exaggerated catering even is inside and around the booth area and such, should be avoided. Even if it is appropriate to serve tea, coffee, frut juice and petit-fours, pastry before/after the satellite symposium or reasonable snacks such as sandwiches during lunch break, serving cocktails and alcoholic drinks is not regarded as appropriate.

15.8.5. Contracted speakers in scientific meetings and educational activities are not regarded as "participants" and will not be subject to the restriction in this article.

15.8.7. and 15.22. Prohibition of direct sponsorship of persons: Oil, taxi and similar additional expenses paid personally by participants who did not use a ticketed transportation vehicle shall not be covered.

15.10. Text to be used in the invitations of all organizations sponsored by a company:

It is mandatory to use at the right size (at least 11 as font size; see also the explanation in Article 5.2.3) the following text in the invitations of meetings and organizations organized or sponsored by companies, placed in a section and manner ensuring that the recipient of the invitation may see it immediately and easily, and written with easily legibly fonts:

> **"**Dear…., According the Promotional Regulation of the Ministry of Health and affiliated AIFD Code of Promotional practice, pharmaceutical companies shall not provide any financial contribution to persons other than those delivering a scientific work in scientific congresses, such as abstracts, publications or posters and those participating in the meetings for educational purposes. Contributions to be made to persons outside this scope are subjected to severe legal sanctions. We therefore kindly ask you not to bring your companion to the meeting and affiliated activities. We thank you for your sensitivity and support you will display with regard to the preservation of high standards of the healthcare sector.
>
> This invitation is for one person only.
>
> Sincerely"

15.10. Protocol Invitees: the local top officials of the location where the meeting is held and their spouses that attend the inauguration of the meeting are the officials of the Ministry of Health approved by the Ministry.

15.12. Hospitality and Sponsorships

a) No social programs shall be organized, under any condition, during the flow of the scientific programs of the congress, including satellite symposia.
b) Activities organized or sponsored as part of social responsibility projects, are acceptable provided that they remain within the scope of corporate promotion and are not directed to healthcare professionals.

15.12.1. Unacceptable Activities

c) Pharmaceutical companies shall not organize social, sportive meetings or leisure programs for healthcare professionals. (Gala dinners and inaugural cocktails should also be evaluated within this scope.)
d) Calls and invitations which are sportive or entertainment-oriented in nature (such as tickets to sports activities, movie or theatre tickets and recreational trips) are not suitable.
e) Invitation and sponsorship of famed persons (such as singers, artists, entertainers, etc.) whose objective is only to enhance the interest towards a satellite symposium or a meeting are not regarded as suitable.
f) Companies should not undertake, directly or indirectly, sponsorship of dinners, inaugural and closing cocktails and "gala dinners" in congresses and should not provide support that may be used for this purpose.
g) Social activities organized with a reasonable budget, featuring music or folkloric performances of local (or young) artists, photograph shows or short films or a guest speaker at dinner, or similar activities may be approved, provided that they comply with the spirit of the this article and the restrictions mentioned above.

15.12.3. High season

a) It is not suitable to organize scientific meetings for physicians, dentists or pharmacists in water sports locations and resorts in coastal towns during summer months, and within or near winter sports facilities in winter months or to sponsor the meetings organized under these conditions.

b) The Ministry of Health of the Republic of Turkey has declared that the Ministry does not regard it suitable for pharmaceutical companies to organize meetings and/or contribute to the scientific meetings organized in ski centers between December 1 and March1, and in coastal holiday resorts between June 1 and September 1.

Even if they are declared as "international", meetings organized each year in Turkey on the dates and locations mentioned above are also regarded to fall into this scope and are not deemed suitable. (Promotion Guidelines of 21.12.2011)

c) International meetings documented to be organized each year (or at regular intervals) in different countries are outside the restriction mentioned above.

15. Definitions: Guiding definitions on the meaning of adjectives such as "reasonable", "appropriate", renowned", "excessive", "grandiose", "extravagant", "renowned with its activities" "modest", "acceptable", "logical" and "symbolic" are prepared by AIFD's Good Promotional Practices Committee. The referred definitions are provided in *App I.*

15.15.1. Session of the Rational Use of Drugs: (Guidelines on the Rational Use of Drugs)

In the scientific congresses sponsored by pharmaceutical companies, it is not suitable to make requests about the program other than for satellite symposia according to WMA (World Medical Association), TTB (Turkish Medical Association); IFPMA; EFPIA and AIFD.

Congress organizing committees should plan a session on the rational use of drugs in congresses. One of the prerequisites for companies to be able to sponsor or a congress or meeting is to include a session into the congress program which is compliant with the Ministry's Guidelines on the Rational Use of Drugs. This rule should be reminded to all medical and pharmaceutical professional associations organizing congresses. This rule should be reminded to all medical pharmaceutical professional associations organizing congresses.

15.15.2.1 Meetings to Include the Session of the Rational Use of Drugs: The Session on the Rational Use of Drugs should be included into national meetings exceeding six hours.

Of drug promotion activity (drug promotion booth, banners, brochures and similar promotional activities) is to be conducted within the program of the meeting or in areas that may be seen by meeting participants, in national meetings, sponsored by registration/permit holders, organized under the name of a congress, symposium, seminar, workshop etc., lasting 6 hours in total from the opening until the end, a session on the Use of Rational Drugs, relating to the topic of the meeting shall be in included.

15.15.2.2. Registration/permit holders that have provided sponsorship to the meetings availing these characteristics in a calendar year, should ensure the inclusion of a "Session on the Rational Use of Drugs" in at least 60% of the meetings sponsored in this manner.

15.15.3. Session on the Rational Use of Drugs

15.15.3.1. The session should last at least 30 minutes. No promotion or direction should be made towards the registration/permit holder or a specific product in the Session on the Rational Use of Drugs.

15.15.3.2. The content of the presentations to be included into the session on the Rational Use of Drugs is prepared within the framework of the educational materials and diagnostic therapeutic guidelines approved by the Ministry, in line with the principles of the Use of Rational Drugs.

15.15.3.3. The presentations to be included into the session on the Rational Use of Drugs should contain at least the content of the "Sample presentation for Sessions on the Rational Use of Drugs" available on the official website of the Rational Use of Drugs, at www.akilciilac.gov.tr**.** In addition to this standard presentation, the content of the sessions should be enriched with various aspects of the rational use of drugs and/or one or multiple topics covered by the meeting.

15.15.4.1. Principles of Notification: Registration/permit holders should submit the notifications to be made to the Ministry about meetings within the timeframe specified in the Regulation. It should be declared in these notifications that a "Session on the Rational Use of Drugs" will be held in the meeting.

When submitting the relevant application as per the "Regulation on the Promotional Activities for Medicinal Products for Human Use" for the meeting to be conducted, the presentations to be used in the Session on the Rational Use of Drugs should be added in electronic environment via the official website of the Turkish Medicine and Medical Device Agency.

15.15.4.2. The program of the meeting should always contain the statement "A Session on the Rational Use of Drugs is included in this meeting in accordance with the regulation issued by the Ministry of Health on the promotional activities of medicinal products for human use".

15.15.4.3. The presentations used in the sessions shall be collected in the pool of educational tools for the Rational Use of Drugs. The content of these presentations may be shared in other meetings for the purpose of disseminating the Rational Use of Drugs, provided that written permission is obtained from the copyright owners and reference is provided.

15.16. Meetings and Hospitality Outside Turkey

a) It cannot be stated that it is not suitable for pharmaceutical companies to organize meetings for physicians, dentists and pharmacists outside Turkey. However, as emphasized by EFPIA, there should be valid and justifiable reasons for the meetings abroad. Whether in Turkey or abroad, the overall cost, the facilities provided by the organization, specifics of the theme of the meeting, qualifications of the participants (audience), transportation, communication, hospitality provided and similar topics should be taken into account in the educational programs.

b) As with any other scientific meeting, the aspect to attract the invitees should be the program of the meeting rather than the hospitality offered or the location of the meeting.

c) International meetings organized by the headquarters of international companies may be regarded as compliant with this rule if it is logistically more suitable to hold the meeting abroad and where at least more than half of the participants are from outside Turkey.

d) Technical details of the international nature of the meeting shall not constitute a reason for not complying with the restrictions mentioned in this article.

e) In order to prevent an act which is non-compliant with the rules stipulated in the Regulation on the Ethical Code of Public Officers, published in April 2005, it should be appropriately reminded to invitees who are public officers that it should obtain a permission from their institution for attending the meeting. It should be taken into account that the Ministry of Health requests a tangible evidence from companies regarding this topic within the scope of assessments or investigations.

f) Before attending an international meeting in Turkey or organizing a meeting for their own invitees in Turkey, it would be beneficial for multinational companies to consult their representatives in Turkey or AIFD in order to obtain information about the current applicable rules.

15.20.1. Compensation of the Time Spent: It is stipulated in clause 8 of Article 6 in the Regulation that no benefit in cash or in kind may be provided, offered or promised when making promotion to physicians, dentists or pharmacists.

15.20.2. It is also stipulated in the same article that physicians, dentists and pharmacists shall not accept or request any inducement.

15.21. Sponsored Meetings, Their Announcements and Notifications: Companies providing sponsorship for organizations such as meetings or symposia or providing financial support to their publications and undertaking the distribution of reports or newsletters should pay attention to the fact that these reports may have the characteristics of a promotional material and that they should comply with this Code.

The names of sponsoring companies should be clearly indicated and there should not be the possibility or suspicion of a disguised promotion.

15.21.1. Inspection of Organizations by the Scientific Service: Companies shall do whatever is necessary in order to ensure that all events which they plan to organize, contribute to or support are in compliance with the Code. Meetings planned, attended or sponsored outside Turkey are also encompassed by this Code.

15.21.2. Promotional Activities Organized in Clinics: Obligation to notify TITCK as stated in Article 15.8.9 does not cover the activities organized by the company personnel within the clinics or the events/activities organized by the Healthcare Professionals of the said clinic as speakers or organisers themselves.

15.21.3. Archiving Meeting Programs, Materials and Names of Sponsored Participants: In National and International meetings held by independent organizations, in which a company has not financially supported all of the events, it is sufficient to archive only the names of participants that have received the financial support of that company, the official program of the meeting and samples of documents distributed by the company.

15.21.4. Detailed notifications to be submitted pursuant to the meeting should be performed in accordance with the guidelines and circulars of the Ministry.

Article 16- Interactions with Consultants

16.1. Companies may receive consultancy support from healthcare professionals. Service may be purchased from healthcare professionals, either individually or in groups, as speakers or session/meeting moderators, to contribute to scientific/medical trials, Phase I-IV clinical studies, to guide or conduct these, to provide training to company employees or other healthcare professionals, or to participate in the advisory board of a company or in market surveys; the travel and accommodation costs may be covered if they are traveling to offer these services and remuneration can be made to them on the basis of a contract.

16.2. Consultancy or other service purchases that fulfill all of the following conditions, qualify as acceptable:

a) The company's need for the referred service and consultancy should be clearly identified before contacting the consultant, requesting the service and initiating talks with potential consultants.
b) Characteristics of the services to be provided and the criteria of remuneration for such services and to be made in accordance with article g) mentioned below should be included in a written contract or agreement before starting to receive services.
c) The criteria used for selecting a consultant should fulfill the need which has been identified. Persons appointed for selecting consultants should have the qualification, knowledge and skills to assess whether the relevant healthcare professionals meet these criteria.
d) The number of healthcare professionals hired as consultants should not be greater than the number required for fulfilling the need identified and achieving the goal.
e) The company requesting consultancy should keep records demonstrating that they have received services offered by consultants and used these in line with their needs.
f) The payments in cash or in kind to be made to healthcare professionals for the services requested by a company should not aim to induce healthcare professionals to recommend, prescribe, purchase, procure, sell or administer any product.
g) The payment made for the consultancy or services should be at a reasonable level and reflect the market value of those services. It is not allowed to prepare on-paper agreements to justify any payment to be made to healthcare professionals.

16.3. Service Contracts

Service or funding under contract may be provided to companies, institutions, organizations, associations, foundations and establishments established by or involving healthcare professionals and not encompassed by any other section of the AIFD Code of Promotional Practice, only under the following conditions:

a) If the service or funding is provided for the purpose of supporting a research, training or healthcare service, and;

b) If the service or funding is not directed to induce the recommendation, prescription, purchase, sale, distribution, promotion or use of a drug or some drugs.

16.4. Principles on Payments to Clinical Trials

AIFD member companies are advised to make payment through the following means for clinical trials they are sponsoring, in compliance with relevant laws and regulations:

16.4.1. Payments for Clinical Trials should be made in accordance with one of the following options.

16.4.1.1. Payment to Revolving Capital

In accordance with Law No. 2547, of November 4, 1981, on Higher Education Board, the investigator fee to be paid at the end of the trial may be deposited to the revolving capital payment office of the Institution or the bank account of the relevant revolving capital upon indicating the protocol no. and/or name of investigator.

16.4.1.2. Payments (In Kind) Made for the Purchase of Medical Devices/Materials/Supplies, etc.

16.4.1.2.1. Purchasing medical devices and/or equipment for improving the clinic at a price corresponding to the amount to be calculated according to the fee indicated in the relevant Contract of the clinical trial is allowed, provided that the Institution concerned or its Department Directorate writes a receipt or records these as fixture.

16.4.1.2.2. Kits/supplies not part of the inventory may be purchased if this is indicated in the relevant clinical trial contract. Relevant materials are identified with a letter of request from institutions. A suitable delivery document is obtained against these materials, in line with the relevant processes of the Institution and the transaction is documented.

16.4.1.2.3. Payment of Participation Fees for Scientific and Educational Meetings in Turkey/Abroad

Sponsorship for Scientific and Educational Meetings in Turkey/abroad may be provided to investigators and/or assistant investigator(s) at a fee corresponding to the amount to be calculated according to the price indicated in the relevant contract of the clinical trial. Approval of the authorizing officer or his/her assistant is required in such cases.

16.4.2. Unacceptable Payment Types

In line with applicable laws and regulations, AIFD does not support the following payment means by its member companies in return for the clinical trials they sponsor:

16.4.2.1. No direct payment shall be made to the personal accounts/companies of the study team/investigator, assistant investigator, etc.) involved in the clinical trial.

16.4.2.2. No device/instrument/materials etc. shall be bought for the personal use of the study team involved in the clinical trial.

16.4.2.3. In accordance with "Law No. 5072, of 22.01.2004, on the Interactions of Associations and Foundations with Public Institutions and Bodies", honorarium per patient deserved upon the completion of patient recruitment in clinical trials shall not be directed to Foundations and Associations.

16.4.3. Payments to Speakers in the Research and Training Program

A consultancy fee may be paid to healthcare professionals who are trainer speakers in the "Clinical Trial Training Program" held by AIFD member companies, provided that all of the following requirements are fulfilled and that these are clearly indicated in the contract to be signed. Companies shall make the payments in line with their internal procedures.

16.4.3.1. Speaker fee of the speaker working in a public healthcare institution on a full time basis should be deposited to the Revolving Capital of his/her Institution.

16.4.3.2. If the healthcare professional is working on a part-time basis, or is working in a private institution or in his/her private practice, payment should be made against a Self-Employment Invoice.

16.4.3.3.1. The training may be conducted during the weekend or outside working hours.

16.4.3.3.2. In case payment is made against a Self-Employment invoice, the speaker should not use his/her official title indicating the association with his/her institution during the training.

16.4.3.4. Proposals on the methods for detecting the honorarium to be paid to the speaker healthcare professionals that will participate in the Training Programs of Investigators are provided in *APP I*.

16.4.3.3.2. Healthcare professionals who cannot take their speaker fee from the revolving capital of the institution shall not use their official titles indicating their association with their institution in their speeches and presentations (such as University XYZ, Department of XYZ, Clinic Chief of Hospital ABC). Acquired titles regarded suitable by TTB (such as Dr., Assoc. Prof., Prof.) may be used. Affiliated may be indicated in publications. TTB's Ethical Directive regarding this topic should be taken into consideration.

Article 17- Interactions with Associations and Societies of Healthcare Professionals and Congress Organizing Agencies

17.1. Pharmaceutical companies and associations may establish scientific or promotional communication and relations with professional institutions and specialty associations founded by healthcare professionals. National and international scientific meetings (congresses) involving a high attendance are organized by companies specialized in the organization of meetings. Due to the special requirements of the healthcare sector and especially of pharmaceutical companies, the rules to be complied with by pharmaceutical companies should be known also by professional associations of healthcare professionals and companies organizing meetings and be applied as strictly.

17.2. Competence of Companies Organizing Meetings

Tourism and organization companies providing service in the organization of scientific, educational and promotional meetings held or sponsored by companies shall be responsible for ensuring that their employees are sufficiently informed about the relevant parts of the job they will perform in this Code and relevant regulation, guidelines and other laws and regulations. Conformity with IPCAA principles should be requested from organizing companies.

17.3. Requirement of a Session on the Rational Use of Drugs (See Article 15.5.)

Sponsoring companies should monitor whether the session on the "Rational Use of Drugs", required to be included in national and international congresses as of June 1, 2012 in accordance with the Regulation, is included into the scientific program of the congress in compliance with the relevant Regulation. AIFD recommends that no sponsorship is provided by companies for congresses whose scientific program does not include a Session on the Rational Use of Drugs as of June 1, 2012.

17.4.1. The organizing company is the principal responsible for the conformity of the content of satellite symposia to laws and regulations and AIFD Code of Promotional Practice.

17.4.2. The topics and speakers of the satellite symposia sponsored by companies are to be included into the scientific program of the congress upon being approved by the Scientific Board of the Congress. The Scientific Board of the Congress should have approved the scientific quality of the topics and speakers of satellite symposia as with all other sessions.

No company shall raise the condition of being the exclusive sponsor of an association or any large project/even if proposed by the company itself)

Article 18- Non-Interventional Studies Conducted with the Drugs Available in the Market

18.1. Definition

Non-interventional studies are studies in which data relating to a spontaneously prescribed drug on patients whose treatment is ongoing in accordance with up-to-date diagnostic and therapeutic guidelines in approved indications of a marketed drug and which do not influence the diagnosis or therapeutic choice and administration of the physician applying the therapy. The purpose of non-interventional studies is to observe the therapeutic conditions under the routine administration of a drug by a physician and patient and to obtain additional information about the drug over wider audiences compared to clinical trials.

18.2.1. As a principle in non-interventional studies, the treatment of the patient should be initiated prior to the decision to be recruited into the study. Inclusion of the patient into a treatment strategy should be decided according to the therapeutic need and according to the trial protocol.

18.2.2. Prescription of a drug and inclusion of a patient in a non-interventional study are two separate topics that should be distinguished from each other. This distinction may be achieved by the enrollment of a patient in a study only after the initiation of his/her treatment. (GNISCD - Guidelines on Non-interventional Studies Conducted with Drugs, 7.3)

18.2.3. A drug should not be prescribed for the purpose of including a patient in a non-interventional study. (GNISCD, 7.2)

18.3. Prospectively planned non-interventional studies directed at gathering findings from physicians, dentists, pharmacists, participating physicians or physician groups may be conducted in compliance with the provisions and restrictions of up-to-date text of the "Guidelines on Non-interventional Studies Conducted with Drugs", published by the Ministry and other relevant applicable laws and regulations.

18.4.1. Non-interventional studies shall not be designed and conducted by the marketing and sales departments of pharmaceutical companies. Such type of studies designed and/or monitored by marketing departments is accepted as a Non-Ethical Promotional Activity and the relevant laws and relevant laws and regulations shall apply.

18.4.2. Product promotion representatives shall not be included into the conduct and monitoring of non-interventional studies.

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18. Non-Interventional Studies

As far as allowed by the study protocol and to the degree of compliance with the applicable laws and regulations, companies are advised to act in line with this article also in epidemiological studies and other studies involving retrospective collection of information such as collection of data relating to treatments applies in the past or are still ongoing. In any case, all these studies should be conducted in line with Article 16.3 of this Code of Promotional Practice (Service Contracts).

18.3. Non-interventional studies planned prospectively for the collection of findings from physicians, dentists, pharmacists, participating physicians or physician groups may be conducted if they fulfill the following requirements. Provisions and restrictions in the current text of the "Guidelines on Non-Interventional Studies Conducted with Drugs" (GNISCD), published by the Ministry, as well as the other applicable laws and regulations shall be complied with in addition to those specified in this article.

Non-interventional studies should be planned and conducted in order to achieve a scientific objective; the boundaries, objectives and methodological nature of non-interventional studies shall be determined in accordance with the relevant legislation.

(a) (i) The trial should avail of a written study plan (protocol) and (ii) there should be a written contract signed between the physicians, dentists or pharmacists to conduct the study and/or the healthcare institutions where the study will be conducted and the company sponsoring the study, and the service expectations to be included into the "Study Plan" as well as details of the service payments to be determined in accordance with the following article c) should be clearly specified;

(b) Any payment to made should be compliant with the relevant laws and regulations, at a reasonable level, reflecting the fair market value of the service rendered;

(c) Non-interventional studies should be reported to the Ministry and the study should not be initiated before obtaining the relevant permit; if non-interventional studies need to be examined by the ethical committee, relevant applications should be submitted and permits should be obtained;

(d) Laws and regulations regarding general and ethical principles on patient information, Patient Consent and the protection of patients recruited to the study (and the applicable laws and regulations on the privacy of personal information, collection of personal information and the use of such information should be complied with;

(e) The sponsoring company should not conduct a non-interventional study with a promotional objective or to be perceived as such. A study should not constitute an inducement to recommend, prescribe, purchase, supply, sell or administer a particular drug;
(f) Study protocol should be approved and supervised by the Scientific Service;
(g) An outcome report should be prepared on the conduct of the non-interventional study and its results: the study results should be analyzed by or on behalf of the sponsoring company and summaries thereof should be made available within a reasonable period of time to the company's Scientific Service. All documents of the non-interventional study should be preserved for a period of at least 5 (five) years for later access and further evaluation;
(h) The company should send the summary report to the physicians, dentists and pharmacists that participated in the study and present this report, upon request, to self-regulatory bodies of the industry (AIFD Code of Practice Panel) responsible for supervising the correct implementation of the Code of Promotional Practice;
(i) If the study shows results that are important in terms of the benefit-risk assessment of the relevant product, the summary report should be submitted to the Ministry;
(j) In case an approved study cannot be started for any reason or terminated before completion, this should be reported to the Ministry along with its justifications.

18.3.h.: Sharing the results of non-interventional studies with physicians, dentists and pharmacists
Companies should comply with these rules relating to non-interventional studies in a manner so as to cover studies completed latest after July 1, 2008. Adherence is advised to companies also for those completed before this date.

Furthermore, companies are also encouraged to publicly disclose the summary details and results of non-interventional studies in line with the obligation to disclose to the public.

Article 19- Relations with the General Public and Media

(*Interactions with patient associations are covered in Article 21)*

19.1. Any promotion of medicinal products for human use to the general public through any public media or communication channels, including the internet, is prohibited, whether directly or indirectly, or through placement in programs, movies, TV series, news reports or similar media. (Reg.Art.5.3)

19.2. Relations with Healthcare Professionals Other Than Physicians, Dentists and Pharmacists

Pharmaceutical promotion shall not be conducted to persons other than physicians, dentists and pharmacists; however, information may be provided on topics such as the administration and side effects of products also to healthcare professionals other than physicians, dentists and pharmacists, provided that the relevant department officer/responsible physician is informed and grants approval. (Reg.Art. 4.1.f; 4.1.g,5.1;10.1.ç)

19.3. Information to the general public may be provided on products that will be used in cases that are important for public health, such as vaccination campaigns and fight against epidemics or in other campaigns run by the Ministry to promote health upon permission of the Ministry and within the confines of principles and procedures set by the Ministry for such products. (Reg.Art.6.1)

19.4. Companies are liable for the information provided to public relations agency about their products.

19.5. Relations with Pharmacies

Pharmacy window decorations for prescription only drugs shall not be used. Promotion of prescription only drugs to the general public in shall not be conducted in pharmacies**.**

19.6. Relations with Wholesalers and Their Personnel

Meetings with wholesalers and their personnel should be conducted in such a way to avoid breaching this Code of Promotional Practice.

19.7. Relations with Medical Reporters

Meetings with health journalists should be conducted in such a manner so as to avoid breaching this Code of Promotional Practice.

19.8. Company-Sponsored Hot Lines

Use of live or pre-registered answering hot lines sponsored directly or indirectly by companies is permitted, provided that no promotion is made on these lines and only medically qualified personnel answers.

19.9. Not Providing Any Advice on Personal Medical Matters

In case of requests from the general public on personal medical matters, the inquirer should be advised to consult a healthcare professional.

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19. Relations with the Society and Media

19.1. No prescription medicinal product or sample in reduced quantity may be distributed directly or indirectly to the general public for promotional purposes.

19.3.1. Vaccination Campaigns: The INN of products, company name and logo may be in vaccination campaigns approved by the Ministry of Health.

19.3.2. Campaigns Aimed at Promoting Health: The Regulation allows information to be provided to the general public about products in campaigns conducted by the Ministry.

19.5. Relations with Pharmacies: Commercial relations with pharmacies and pharmacists are excluded from the scope of this Code. Interactions other than commercial relations with pharmacies and pharmacists shall be taken up in another Guideline.

19.7.1. Relations with Medical Reporters: Procedures concerning relations with health journalists on a regular basis, also covering medical congresses and symposia, shall be prepared after consultation with the Ministry and in line with the best practices in the EU.

19.7.2. Press Conference: Corporate press conferences are excluded from the scope of the Code of Promotional Practice.

It is allowed to place press advertisements in compliance with the relevant legislation for the purpose of informing healthcare professionals on drugs newly introduced into the market.

Press conferences can be held in order to inform the general public about announcements to be made in line with the relevant laws and practices (adverse events, warnings on the use of drugs, recall related information, etc.); it should be ensured that the information and images to be provided in the press conferences are not perceived as pharmaceutical promotion and that they do not appear as pharmaceutical promotion on the press.

19.7.3. Suggested Approach in Invitation of Media Representatives: In cases where a pharmaceutical company invites a media/press member to a training, information sharing meeting or a research or production facility visit, the invited press/media representatives should be briefed by the host company prior to the visit, about the restrictions peculiar to the healthcare sector and particularly pharmaceutical industry , informing them about the legislation, regulations, national and international business self regulations and ethics codes restricting the placement of texts and visuals that could be interpreted as product promotion in public media, even if such information is placed in the media beyond the control of the pharmaceutical company concerned.

Article 20- Internet, Digital Platforms and Social Media

(Annexed AIFD User Guide on Digital Communications in the Pharmaceutical Sector, where detailed explanation on this article is provided, is a complementary part of the AIFD Code of Promotional Practice. The content of the Article and Guide shall be updated in line with the developments in the digital environment. Amendments shall be binding for all members upon being accepted by the Board of Directors and approved in the General Managers meeting. Updated texts will be submitted for approval in the first upcoming AIFD General Assembly.)

20.1. Introduction:

A major responsibility of the pharmaceutical industry is not only to ensure that the society receives high quality and reliable medicinal products and that these products are used in a rational manner, but also to facilitate sharing of data, findings and information they possess on products and areas of research using current communication technologies, in compliance with promotional ethics. Pharmaceutical companies utilize digital communication options by adhering with applicable laws and their own internal rules and especially avoiding approaches that may be perceived as pharmaceutical promotion towards the public.

20.2. Principle of Transparency and General Rules

20.2.1. Pharmaceutical companies may create internet websites in accordance with laws and regulations directed at communication with their stakeholders. **Internet websites of companies fall into the scope of AIFD Code of Promotional Practice.**

20.2.2. Companies shall be responsible for the websites and social media accounts they have established or which have been prepared on their behalf. Relevant measures should be adopted to ensure that there is no content which may be perceived as pharmaceutical promotion towards the public is the websites they support or in their social media accounts.

20.2.3. **Protection of Visitor Information:** Personal information collected from visitors in the websites established by companies or on their behalf should be kept confidential. The website should be arranged and managed in accordance with national laws and regulations and international rules with regard to the protection of the confidentiality, safety and privacy of personal information. The privacy policy of the website, terms of use and the management of information should be clearly indicated.

20.2.4. Scientific Consistency: The content of websites should be informative, accurate, up-to-date, balanced, reliable, fair, objective, clear and easily comprehensible. All information presented on the website of the company should be appropriate, medically and scientifically accurate and up-to-date; the information of the website should be revised by the relevant responsible departments in the company in line with AIFD Code of Promotional internal company rules and should not be published before the receipt of necessary approvals.

20.2.5. Every website should have a homepage; discernibly containing the following information:

20.2.5.1. Name of company that owns the website; relevant mail/e-mail addresses and telephone numbers for contact with regard to the website;

20.2.5.2. Name of company sponsoring the website; relevant mail/e-mail addresses and telephone numbers for contact with regard to the website;

20.2.5.3. Sources of the information provided on the website, edition/publication dates of sources and, where necessary, description of persons and institutions from whom the information on the website has been obtained;

20.2.5.4. Purpose and target audience(s) of the website (e.g. physicians, pharmacists, patients, patients' relatives or the general public);

20.2.6. Information intended for healthcare professionals (physicians, dentists and pharmacists) and information for the general public should be separated into two sections and the statement "This section is intended for physicians/pharmacists" should be included at the top of the section prepared for the healthcare professionals to whom promotion is allowed.

20.2.7.1. The homepage and the name of the website shall not contain any product name or any statement which may be interpreted as product promotion.

20.2.7.2. Website names should be selected in compliance with the Code of Promotional Practice; websites named with product name whose promotion to the general public is not suitable is not deemed appropriate by AIFD.

20.2.8. Information on the website should be regularly updated; the latest date of update should be indicated in a visible manner for each section, page and/or item, where necessary.

20.2.9. Information intended for physicians, dentists and pharmacists on the website and information for the general public should be published prior to the revision of the relevant departments of the company in accordance with AIFD's rules and company's internal rules and the receipt of relevant approvals. The information should be prepared under the supervision of the Scientific Service.

20.2.10. Links from this website to other sites on the internet should be made carefully. In case of presence of information what may be perceived as promotion of the products of the company on the website to which a link is provided (even if this is a website open to the general public and not sponsored by the company) the responsibility lies with the company providing this link.

20.2.11. Compliance of the content of the website to which a link is provided with the code of promotion and whether the website the link directs to the correct address should be regularly verified.

20.2.12. It is advised not to provide links to dynamic websites with dynamic content, such as 'blogs' or 'forums', wherein information constantly changes and conformity to the code of promotion is difficult to verify and it is recommended for companies not to sponsor such websites. In case such links are provided, the responsibility of verifying compliance with the Code of Promotional Practice lies with the company.

20.2.13. Users should be given clear indication when they are directed to a website to a non-company website from any of its websites of the company of a website sponsored by the company.

20.2.14. The following recommendation should always be included on each page containing health information open to the general public, other than the corporate pages of the company (e.g. sections highlighting company principles, section for job application, etc.): "**Information on this website shall not replace consultation with a physician or pharmacist. Consult a physician and/or pharmacist for further information".**

20.2.15. Websites may contain information about diseases, disease prevention, screening and therapeutic methods and other information aimed at protecting public health.

20.2.16. Any mention of therapies should reflect balanced and up-to-date information, and include no element of pharmaceutical promotion and/or references to a specific drug.

20.2.17. In addition to medical therapy, also other rational therapeutic methods including diet, behavior modification therapies and similar prevention and therapeutic methods may be explained on the website.

20.2.18. Each member company, when they become aware of the existence of a website administered in a non-conformant manner which may be perceived as being sponsored by them, should take prompt legal action to cease activity of such website. Such applications should be documented at a level that may provide proof of action to AIFD or other relevant authorities upon request.

20.2.19. AIFD User Guide on the Digital Communication Practices in the Pharmaceutical Sector: The "AIFD User Guide on the Digital Communication Practices in the Pharmaceutical Sector" presented in APP X of the Code of Promotional Practice has been prepared for the purpose of explaining in detail Article 20 to company employees responsible for digital communication and marketing practices and third parties commissioned by the company and to complement the AIFD Code of Promotional Practice.

Content of Websites

20.3. General Information About Companies, Corporate Websites

Company websites may contain financial information that may interest investors, investments and information of the state of registrations, HR job opportunities and job application sections, press releases and declarations of the company not involving product promotion intended for the general public, product lists and prices, areas of specialty, information about health conditions, advancements in the medical field, contact details and similar information in conformity with Good Promotional Practices. This information does not fall under

the scope of Code of Promotional Practice and laws and regulations on pharmaceutical promotion, provided that they do not contain content and form which may be perceived as pharmaceutical promotion.

20.4. Health-Related Information

Websites may contain information on diseases, prevention of diseases, screening and therapeutic methods and other information aimed at protecting public health. In case of any mention of therapies should not contain any information that may be interpreted as pharmaceutical promotion and be balanced and reflect the facts. In addition to medical therapy, other therapeutic methods including diet, behavioral change therapies and similar therapeutic methods may be described on the website.

20.4.1. Information offered on drugs that may be accessed by the general public over the internet should be compliant with Article 18 of the Code.

20.4.2. Accessible sources should be given as reference for information relating to the general public and descriptions on diseases.

20.4.3. Content of information provided should be suitable for the target audience.

20.5. Websites Prepared for Patients and the Society, Not Containing Any Product Promotion and Intended to Provide Information on the Topic of Health

20.5.1. Public promotion of medicinal products for human use which are not reimbursed and are registered so as to be sold without prescription does not fall under the scope of the Code of Promotional Practice. The promotion of these products should be compliant with current and laws and regulations.

20.5.2. A company may provide information about its drugs towards the general public upon using the company website, provided that this is compliant with laws and regulations. Pharmaceutical companies may develop and promote websites and social medial platforms for the purpose of information the patients and the society on diseases and current medical applications.

20.5.3. No section of these websites should contain information that may be interpreted as pharmaceutical promotion or no direct association should be made between disease information and the drugs of the company.

20.5.4. Pages intended for patients should include the statement "Information on this website does not replace consultation with a physician or pharmacist" and the recommendation "Consult a physician and/or pharmacist for further information" should be included, at all times, on each relevant page.

20.5.5. The brand names should not be used in a manner on pages which are open to the general public that may be perceived as promotional; in special cases where their use is necessary, the INN (International Nonproprietary Name) should always be specified.

20.6. Web pages Intended for Healthcare Professionals and Containing Also Product Promotion

20.6.1. Product promotion which may be performed over the internet or upon using the digital environment should be compliant with the AIFD Code of Promotional Practice. Information approved by the Ministry and conflicting with the SmPCs should not be used for product promotion – even if approved in other countries.

20.6.2. Access to promotional materials of prescription medicines and medicinal products for human use the public promotion of which is legally allowed, should only be allowed for physicians, dentists and pharmacists. It should be clearly indicated that information in these sections is intended only for physicians, dentists and pharmacists. An effective process (a blocking warning, password or approval mechanism) should be used to prevent access of others in the sections and pages intended for physicians, dentists and pharmacists. It is the responsibility of the relevant company to employ sufficient safeguards for ensuring and documenting that the person entering the website is a physician, pharmacist or dentist.

20.7. Applications via Electronic Mails

20.7.1. A company may utilize the electronic mailing system or social media to learn the views of the physicians, dentists, pharmacists and the general public on its website as well as its products. The replies of the company to these messages should be compliant with the same rules that apply for the replies to inquiries and requests that may be submitted by telephone, mail or other media.

20.7.2. Private information to be obtained from the general public, patients and healthcare professionals should be used for promotional or other purposes and relevant laws and regulations should be observed.

20.7.3. In correspondences to be received from patients and the general public via electronic mails from the websites of companies, discussion of private health issues of individuals should be avoided and these individuals should be advised to consult a physician or a pharmacist.

20.7.4. Relevant arrangements should be made to enable the receipt of adverse event reports about products on company websites.

20.8. Links to Other Websites

20.8.1. Links can be provided from a website established or sponsored by the company to other websites sponsored by the company or other websites; links can be made, in accordance with relevant rules, from the website of others to the website of the company.

20.8.2. In case of links to dynamic websites such as 'Blogs' or 'Forums', wherein the conformity of the constantly changing content with the code of promotional practice is difficult to verify, it is the responsibility of the relevant company to ensure their conformity with the Code of Promotional Practice.

20.8.3. Websites and social media allowing submission of free text should be regularly monitored for potential adverse event reports.

20.8.4. When providing links to other websites, there should be a warning indicating that the information on the websites to which a link is provided is not under the responsibility of the pharmaceutical company, that their content may differ from the texts approved by the Ministry of Health and that these websites may not be compliant with the laws and regulations of the Republic of Turkey.

20.9. Inclusion of the Web Address on the Packages of Drugs: Links to the website of the company or websites sponsored by the company may be included on drug packages.

20.10. Social Media Applications: Media applications towards healthcare professionals or the general public should comply with the Code of Promotional Practice.

20.11. Digital-Based Promotional Methods

20.11.1. Promotional activities using digital technologies shall be conducted within the framework of applicable rules for printed materials, in line with AIFD's Code of Good Promotional Practice.

20.11.2. Sources used in promotional activities (papers, posters, etc.) and information regarding a drug (patient information leaflet, summary of product characteristics and product monographs, etc.) may be stored in the device used for promotion. Upon request, references may be shared with physicians, dentists or pharmacists, taking care that the relevant reference copyright, if available, are not violated.

20.11.3. Content should be archived for at least three years, in a manner so as to enable its future retrieval, assessment and evaluation in the event of objections raised for noncompliance with the AIFD Code.

20.11.4. Virtual Congresses: Virtual congresses may be organized or sponsored upon complying with the restrictions laid down in relevant articles of the AIFD Code of Promotional Practice (articles 15 and 16). In such meetings, the type and scope of sponsorship should be clearly disclosed. When compiling and releasing speeches or correspondences from the meeting, the sponsoring company should care that the Code of Promotional Practice is respected and that scientifically accepted references etc. are included,

20.12. Sharing Information via Digital Communication Means

20.12.1. The company or companies sponsoring the scientific or promotional activities in the electronic environment (virtual congresses and similar events) should be clearly disclosed.

20.12.2. The content to be shared should not be disseminated before being subjected to an internal approval process similar to the one followed for printed materials.

20.12.3.1. Before sharing the content, permission of the recipient or group of recipients should be obtained for sending it.

20.12.3.2. Warnings such as "unsubscribe" and/or "report unwanted message" should be included at the bottom of all digital content sent.

20.12.4.1. Use of "Share" or "Like" in promotional messages: Physicians and pharmacists should be allowed to share promotional company messages in social media by mistake. Considering that in the event of electronic journals and similar content provided by pharmaceutical companies being shared in social media or via other methods, such texts may be seen in areas open to the general public, product promotion or product names should not be mentioned. The content intended for production promotion, prepared for Healthcare Professionals should only be shared in social media upon making entry with a username and password.

20.12.4.2. Use of "Share" or "Like" in non-promotional messages: Links such as "share" or "like may be used in e-journals published by pharmaceutical companies or via their sponsorship and which do not comprise any pharmaceutical promotion or content that may be perceived as such.

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20. Internet, Digital Platforms and Social Media

20.2.2. In order to avoid the inclusion of content which may be perceived as pharmaceutical promotion to the general public on the websites and social media accounts sponsored by companies, contracts where the sensitive areas are clearly indicated are expected to be made. It should be clearly indicated on the contact that companies shall forthwith terminate their sponsorship in case of noncompliance with the contract and the conduct or recommendation of pharmaceutical or therapeutic promotion on social media.

20.2.6. Although there is no legal restriction, AIFD advises companies not to websites with the brand names. On the other hand, it is recommended for brand owners to obtain the rights for using the name of websites bearing a brand name in order to prevent third parties to get the rights of these websites.

20.2.12a. Links provided from the website to other websites should be made carefully. In case of information on the website to which a link is provided and which may be perceived as promotion of the products of the company, it should not be forgotten that the company providing the link shall be responsible for this content.

20.2.12b. Compliance of the content of the website to which a link is provided with the code of promotional practice and whether the website the link directs to the correct address should be regularly verified.

20.2.19. Websites created by third parties upon using the company name: In case companies are informed about the existence of a website that may be perceived as a site sponsored by them, they should resort to legal means in order to stop the activity of this website.

20.6.2. Access of physicians, dentists and pharmacists (P.D.P) to promotional company websites: In line with applicable laws and regulations in Turkey and the European Union, pharmaceutical companies shall conduct promotion of prescription drugs only and exclusively to physicians, dentists and pharmacists (P.D.P.). Based on this principle, each and every company is expected to adopt effective measures in order to prevent the access of those who are not physicians, dentists or pharmacists (P.D.P.) to companies' promotional websites or sections of such websites on internet. Using only a statement as "Intended for physicians, dentists and pharmacists" shall not be sufficient, warnings such as "Are you a P.D.P?" or "Declare that you are a P.D.P." should not be accepted as an "effective measure mentioned above. Statement is fundamental in terms of legal liabilities; however, AIFD's ethics approaches envisage that companies will act with a sustainable liability of business ethics beyond the legal liability of companies.

When registering to the website for the first time, in addition to information such as name, surname, institution, etc., it is recommended to use difficult declaration methods such as asking information such as the specialty of the P.D.P. and/or his/her diploma number and/or school of graduation, and creating options only for PDPs. It is appropriate for company employees to enter the website of their own company. Reasonable measures to be adopted may be identified with the principle of "acting as a prudent merchant" (New Turkish Commercial Code No.6102 Article 18/2).

Article 21- Guidelines on the Relations Between Pharmaceutical Companies and Patient Associations

21.1. Introduction

It is recognized that patient organizations, which represent patients and/or patients' caregivers or which have been established for fulfilling their requirements (associations, platforms) and the companies in the pharmaceutical sector have common areas of interest.

21.2. Scope

These Guidelines cover the relationships between patient organizations and pharmaceutical companies or their intermediary third parties or companies cooperating (funding) on their behalf. Patient organizations are defined as non-profit organizations (and the umbrella organizations they have established), mainly composed of patients or their caregivers, that represent and/or support patients and/or caregivers and/or aimed at supporting them.

21.2.1. Relationships with international patient organizations, if to be maintained in Turkey or will cover patients and/or their caregivers stationed in Turkey, shall be conducted in accordance with this article. Otherwise, the most stringent code, be it the EFPIA Code or the AIFD Code, shall be applied. The scope of an "activity" includes any relationship (including the provision of funding) between the company and the organization.

21.3. Prohibition of the promotion or prescription-only drugs to the general public applies.

21.4. Written Agreements

When pharmaceutical companies provide financial support, significant indirect support and/or significant non-financial support to patient organizations, they should have in place a written agreement. This should state the amount of funding and also the purpose (e.g. unrestricted grant, specific meeting or publication, etc). It should also include a description of significant indirect support (e.g. the donation of public relations agency's time and the nature of its involvement) and significant non-financial support. Each pharmaceutical company should have an approval process in place for these agreements.

A template for written agreements is available in APP. III.

21.5. Use of Logos and Proprietary Materials

Pharmaceutical companies should obtain the written permission of the relevant patient organization in order to use its proprietary materials, logos or symbols. In seeking such permission, the specific purpose and places where the symbols will be used should be clearly indicated.

21.6. Editorial Control

Pharmaceutical companies should not seek to influence the text of patient organization material they sponsor in a manner favorable to their own commercial interests. This does not preclude companies from correcting factual inaccuracies. In addition, at the request of Patient Organizations, companies may contribute to the drafting of the text from a fair and balanced scientific perspective.

21.7. Transparency

21.7.1. Each company should make publicly available a list of patient organizations to which it provides financial support and/ or a significant direct or indirect non-financial support. This description should be sufficiently comprehensive and clear to enable an ordinary reader perceive the nature and dimension of the support provided to the company. The description should always include the monetary value of the financial support and the amount of invoiced costs. In case of significant non-financial support difficult to be defined in monetary terms, non-monetary support received by the patient association should be defined explicitly. This information may be provided on a national or European level and be updated at least once a year.

21.7.2. Companies should take relevant action to ensure that their sponsorship is always clearly indicated and announced by patient organizations at the beginning of activities.

21.7.3. Each pharmaceutical company should publicize the list of patient organizations to which it provides significant service under contract. This description should be comprehensive and clear enough to ensure that an ordinary reader perceives the nature and dimension of the services provided by the company to the patient organization and its importance to the association, without the obligation to disclose confidential information. Companies should publish the total amount paid to each patient association during that reporting period on a national scale and as a total for Europe and update this information at least once a year.

21.8. Contracted Services

21.8.1. Service contracts between patient organizations and companies may be signed, provided that these contracts aim to support public health or researches.

21.8.2. Patient associations may provide contracted services by participating as a specialist in advisory board meetings or being a speaker. Consultancy or other services performed in compliance with all of the following requirements will be acceptable:

a) A written contract or agreement is made in advance of the commencement of services, which specifies the nature of the services to be provided and criteria of payments to be made in return for these services and identified in accordance with article g) indicated below.
b) The company's need for the referred service and consultancy should be clearly identified before contacting the consultant, requesting the service and initiating talks with potential consultants.
c) The criteria used for selecting a consultant should fulfill the need which has been identified. Persons appointed for selecting consultants should have the qualification, knowledge and skills to assess whether the persons from whom consultancy service will be received meet these criteria.
d) The dimension of the service received should not be greater than what is required from a rational perspective for meeting the need identified and achieving the goal.
e) The company requesting consultancy should keep records demonstrating that they have received services offered by consultants and used these in line with their needs.
f) The company should not expect the Patient Association to support a drug in return for having requested a service.
g) The payment made for consultancy or services should be at a reasonable level and reflect the market value of these services. It is not allowed to prepare on-paper agreements to justify any payment to be made to the association.
h) In the contracts signed with Patient Associations, companies should be insistent on obliging the authorities of the association to declare that they have provided paid service to the company in any occasion where they make a speech in front of the public or provide a written statement with regard to any topic related with the company.
i) Each company should publish the list of patient associations from which they have received paid service in the previous term, as indicated in Article 21.7.3. above, as well as the amount they have paid, and update this list at least once a year.

21.9. Exclusive Sponsorship

No company should raise the condition of being the exclusive sponsor of a patient organization or any large project (even if proposed by them).

21.10. Events and Hospitality

a) Scientific, business-oriented and specialty-focused events and meetings sponsored by a company and organized by that company, physician associations or patient organizations should be held in proper venues, the style and level and hospitality and hosting activities should be aimed at achieving the main objective of the meeting and these should not take place in locations that are associated with excessive, extravagant and entertainment activities.
b) Hospitality provided by a pharmaceutical company to a patient association or its members should always be at a reasonable level and should not make the main purpose of the meeting secondary, whether the meeting is organized by the pharmaceutical company or the patient association.
c) Hospitality costs should be restricted to travel costs, meals, accommodation and the genuine registration fee of the meeting.

d) Hospitality should be restricted only to persons identified as participants. In case of clear health problems (such as disability), the travel, meal, accommodation costs and registration fee of the supporting person may be covered.
e) Hospitality or sponsorship should not comprise holidays, participation in sports competitions or offering entertainment.
f) No company may organize or sponsor meetings abroad, barring the following exceptions:
    i. If the meeting is international, where it is more suitable to hold the meeting abroad for logistic reasons due to the fact that majority of the participants (invitees) are coming from other countries;
    ii. If the sources or specialties associated with the subject matter or objective of the meeting make it preferable to hold the meeting in another country due to logistic reasons.

21.11. Inspection and Enforcement

The processes, standard operation procedures and sanctions indicated in APP II shall be applied about companies violating this Code.

21: Guidance on the Relations between Pharmaceutical Companies and Patient Associations

This article has been prepared in conformity with the text of the *EFPIA Code of Practice on Relationships between the Pharmaceutical Industry and Patient Organizations-The EFPIA Patient Organization (PO) Code*", published as a separate Code and most recently updated in June 2011.

EFPIA and AIFD have adopted the Code of "Relations Between the Pharmaceutical Industry and Patient Associations" in order to maintain in an ethical and transparent manner the relations between the pharmaceutical industry and patient organizations. The Standard Enforcement Procedure, presented in APP. II shall be observed with regard to Enforcement and Sanctions.

This Code builds upon the following principles that EFPIA, together with pan-European patient organizations, subscribed to:

1. The independence of patient organizations, in terms of their political judgement, policies and activities, shall be assured.
2. All partnerships between patient organizations and the pharmaceutical industry shall be based on mutual respect, with the views and decisions of each partner having equal value.
3. The pharmaceutical industry shall not request, nor shall patient organizations undertake, the promotion of a particular prescription-only medicine.
4. The objectives and scope of any partnership shall be transparent. Financial and nonfinancial support provided by the pharmaceutical industry shall always be clearly acknowledged.
5. The pharmaceutical industry welcomes broad funding of patient organizations from multiple sources.

21.4. Template for Contracts to be Signed Between Pharmaceutical Companies and Patient Organizations

When pharmaceutical companies provide financial support, significant indirect support and/or significant non-financial support to patient organizations and associations, a written contract should be signed between the organization and the company. In case the support is not directly provided by the company, it is recommended that the intermediaries are also signatories to the agreement.

The sample contracted presented in App. III contains the key points that need to be included into a written contract that regulates the relations between pharmaceutical companies and patient organizations. The template may be used in its entirety or be adapted. The template contract aims to lay down in writing the goals to be decided between both parties, in line with EFPIA's and AIFD's Code of Promotional Practice.

21.4. Definition of a Significant Support: In case given support has provided meaningful contribution to the activities of the relevant organization or it is believed that such support will be provided and in case the patient organization has little or no possibility to achieve the said project without this support, there is a "significant support". Direct or indirect financial and monetary supports should always be declared and be announced to those affected by the activity or receiving the service

21.7.2. and 21.7.3. Transparency: The monetary value of the support and contributed as well as the contract services provided to sponsored patient organizations should be published for the first time at the end of the first quarter of 2013, covering the contributions of 2012.

21.7.3.1. Transparency: Article entitled "Transparency in EFPIA Code on Interactions with Patient Organizations, updated in 2001

:a) Each company should make publicly available a list of patient organizations to which it provides financial support and/or significant indirect/non-financial support. This should include a description of the nature of the support that is sufficiently complete to enable the average reader to form an understanding of the significance of the support. The description should include the monetary value of financial support and of invoiced costs. For significant nonfinancial support that cannot be assigned a meaningful monetary value the description should describe clearly the non-monetary benefit that the patient organization receives. This information may be provided on a national or European level and should be updated at least once a year.(***Footnote:*** The requirement to include the monetary value of support should be made by companies for the first time by the end of the first quarter of 2013 (covering activities commenced as of, or ongoing on, 1 January 2012).

b) Companies should ensure that their sponsorship is always clearly acknowledged and apparent from the outset.

c) Each company should make publicly available a list of patient organizations that it has engaged to provide significant contracted services. This should include a description of the nature of the services provided that is sufficiently complete to enable the average reader to form an understanding of the nature of the arrangement without the necessity to divulge confidential information. Companies should also make public the total amount paid per patient organization over the reporting period. (Footnote: The requirement to include details of contracted services should be made by companies for the first time by the end of the first quarter of 2013 (covering activities commenced as of or ongoing on January, 2012). The requirement to include details of contracted services should be made by companies for the first time by the end of the first quarter of 2013 (covering activities commenced as of or ongoing on January 1, 2012).

Article 22- Promotional and Sales Activities Commissioned to Third Parties

22.1. If a company uses third party services for activities related with promotion falling under the scope of this Code, it shall also carry the whole responsibility of the actions and results arising from commissioning third parties to do the job.

22.2. Activities planned or conducted by advertising agencies, advertising consultants, research organizations and public relations agencies as well as similar companies on behalf of the registration holders shall be under the responsibility of the employer pharmaceutical company.

22.3. Co-promotion

Registration holders shall be fully responsible of all activities, unless it is clearly stated otherwise in the co-promotion contract. It should be ensured that AIFD Code of Promotional Practice is complied with in the distribution of samples.

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22. Activities Commissioned to Third Parties

22. Contract sales forces are also evaluated under this article.

22.2.1. To avoid misunderstandings, the projects should be assigned with clearly defining contracts.

22.2.2. It would be beneficial to include a text similar to the one provided below into the contract:

Service providing COMPANY/AGENCY hereby accepts, declares and commits that it shall not publish the names of products, brands, visual materials, videos, photographs and similar materials as well as any content such as name of drug and name of molecule which is carried and may be perceived as pharmaceutical promotion towards the general public or any photograph, video and similar content relating to an activity organized by the PHARMACEUTICAL COMPANY or in relation with the PHARMACEUTICAL COMPANY, in the websites and social networking media of the COMPANY/AGENCY or of third parties, for any reason whatsoever. This commitment of the COMPANY/AGENCY shall continue indefinitely even if this contract is terminated. The COMPANY/AGENCY hereby accepts, declares and commits that it shall forthwith pay any fine, compensation, etc. that the PHARMACEUTICAL COMPANY may have to pay due to this sharing as a result of the violation of this provision and compensate all damages of the PHARMACEUTICAL COMPANY arising from this situation. The COMPANY/AGENCY hereby accepts, declares and commits that it shall make necessary warnings to its employees for the compliance with this provision and that in the event of violation of this provision by its employees, it shall forthwith pay any fine, compensation, etc. that the PHARMACEUTICAL COMPANY may have to pay due to this sharing as a result of the violation of this provision and compensate all damages of the PHARMACEUTICAL COMPANY arising from this situation. As an exception to this article, in cases that do not fall under the scope of pharmaceutical promotion to the general public, the COMPANY/AGENCY may share or broadcast such information upon the written preliminary permission of the PHARMACEUTICAL COMPANY.

Article 23- Training on Raising Awareness and Good Promotional Practice

23.1. Within the framework of applicable laws and regulations, AIFD adopts facilitating measures and provide development and training opportunities in order to raise the awareness of the management and employees of member companies about the Code of Good Promotional Practice, contribute to trainings on the Code of Ethics, ensure the correct interpretation of the Code and prevent breaches of the Code. To serve this purpose, it makes necessary amendments in the Code of Good Promotional Practice and contributes to the correct interpretation of the Code upon following the national legislation promulgated by the Ministry of Health, other Ministries and institutions, as well as international legislative amendments, particularly those in the European Union, the rules and comments of IFPMA and EFPIA, of which it is a member, and the developments and trends in the industry, upon paying particular attention to those of the Turkish Medical Association (TTB).

23.2. AIFD,

a) Makes proposals, programs and publications to ensure better perception and enforcement of the Code of Promotional Practice;

b) Organizes training seminars directed to its stakeholders;

c) Establishes interactions with physician organizations, advertising agencies, congress organizers and tourism companies as well as other stakeholders including associations, syndicates and similar organizations founded with the same purpose to share its own views and approach about the special character, rules and restrictions of the pharmaceutical sector;

d) Establishes a platform that enables rules to be interpreted according to changing conditions,

e) Develops common operating proposals, provided that these are compliant with Competition Law. Such proposals are put into practice with the consent of the AIFD Secretary General and the approval of the AIFD Board of Directors; when ratified at the General Assembly, proposals are added to the AIFD Code of Promotional Practice.

23.3. AIFD shares and discusses its comments through the IFPMA CCN (*Code Compliance Network*) with the organizations in other countries and pharmaceutical industry organizations to contribute to the global Code of Good Promotional Practice.

Article 24- Following Up of the Enforcement of the Code and Monitoring of Promotion

24.1. The Ministry may monitor, ex-officio or upon receipt of a complaint, the promotional activities as well as any material and method used in promotion. (Reg.Art.12.1)

24.2. The Ministry may request, ex-officio or upon receipt of a complaint, for the cessation or cancellation of the promotional activities which do not comply with the principles stipulated in this Regulation or deemed inappropriate for public health. Any request of the Ministry to that effect should be fulfilled forthwith. (Reg.Art.12.1)

24.3.* AIFD may empower a committee to be established or a third party, with the duty to monitor the conduct of promotional activities, any material or method used in promotion.

24.4.* AIFD may request a member company, ex-officio or upon receipt of a complaint, to cease or cancel promotional materials which it believes are not complying with the terms, goals or spirit of the Code of Good Promotional Practice or are deemed as inappropriate, and to refrain from repeating the activity where breach is observed or revise the promotional activities and report the corrections made to the AIFD General Secretariat.

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24. Competition Law

Articles **24.3.* and 24.4.*** shall become effective upon application is made to the Competition Board for the establishment of negative facts.

24. Sanctions:

Sanctions should be proportionate to the weight and nature of the breach, have a deterrent effect and become more severe where repeated offences or patterns of offences are observed.

b) Announcement and publication of the sanctions are deemed as the most deterrent method. Other sanctions in line with applicable legislation that will not discredit the reputation of the pharmaceutical industry may be applied.

c) To increase awareness, the AIFD Code of Promotional Practice and Standard Operating Procedure will be available on AIFD's website in Turkish and English.

Article 25- Breach of the Code of Promotional Practice

The process of handling breaches to the Code within AIFD as well as processes relating to complaints and objections are detailed in the "AIFD Code of Promotional Practice; Committees, Sanctions and Enforcement - Standard Operating Procedure for Complaints" presented in *APP II*.

Article 26- Regulatory Sanctions

26.1. A criminal complaint may be filed to Public Prosecution Offices in order to execute legal actions in line with general provisions against those who have acted and conducted an activity in breach of the provisions stipulated in this regulation, according to the nature of their actions.

a) Turkish Penal Law with No. 5237, of 26/9/2004,
b) Law No. 4077, of 23/2/1995, on the Protection of Consumers,
c) Law No. 4054, of 7/12/1994, on the Protection of Competition,
d) Law No. 6112, of 15/2/2011, on the Establishment of Radio and Television Enterprises and Their Broadcasts,
e) Law No. 1262 on Pharmaceutical and Medical Preparations, and
f) Relevant provisions of other laws and regulations. (Reg.Art.13.1)

Disciplinary action may be initiated about healthcare professionals before their affiliated institutions and professional organization. (Reg.Art.13.1)

26.2. Restriction of Congress Sponsorships and Organization of Meetings:

In the event of any provision stipulated in Article 7 of the Promotional Regulation comprising scientific and educational meetings, the registration/permit holder shall be issued a warning by the Ministry. In the event of a

recurring breach, the Ministry may ban the relevant company from taking par tor supporting any congress or symposium activity for a period of one year. (Reg.Art.13.2)

26.3. Marketing Restrictions

In the event of a product promotion of a medicinal product for human use breaches the Regulation, the registration/permit holder will be issued a warning; in the event of its recurrence, promotional activities shall be suspended for three months and if continued, for a period of one year (Reg.Art 13.3)

26.4. Banning Product Promotion Representatives in Promotional Breaches

a) In the event of promotional breaches by product promotion representatives – within the period of validity of the certificate of qualification issued by the Ministry – firstly the product promotion representatives shall be warned by the Ministry;

b) In the event of recurring breach, the certificate of qualification shall be suspended for a period of three months,

c) In the event of continuation of breach, it shall be suspended for a period of one year.

d) Product promotion representatives whose certificate of qualification has been suspended, shall not work during this period, and

e) their company of employment shall take back the Product Promotion Representative Identification Card. (Reg.Art 13.4)

26: Administrative Sanctions: Administrative Fines stipulated in Law No. 4054 on the Protection of Competition, and issued by the COMPETITION AUTHORITY, have been raised with Law No. 5728 and the scope has been widened. In case of breach of competition, fines are imposed executives as well as employees without the power to represent the company. Irregularity fines on Executives, which were present in the previous version, continue to be applicable, while the statute of limitation in fines has been revoked.

APPENDIX I

DEFINITONS and REMINDER ITEMS

Reminder items that may be used in promotion constitute the subject matter of Article 14.2 of the Code. More detailed information is provided in this Appendix.

Small items used as reminders should be suitable for medical use or use in pharmacies when providing service to patients and have a "modest monetary value". The limit of the modest monetary value is defined by AIFD as no more than 20 TL per item. The Regulation has determined the monetary value of reminder call items as 2.5% of the applicable minimum monthly wage. (Reg.Art 8.2) The limit which is more stringent should be applied.

The positive list has been revoked with this Code.

Definitions Made and Payment Limits Proposed by AIFD Good Promotional Practice Committee:

These definitions do not aim to direct the market, but to set a benchmark for the definitions to be identified and applied by each company as an example.

"Reasonable": Meals, accommodation and meeting facilities **at the market value of the region and not be perceived as luxurious;** coach services with accredited travel safety; train tickets; economy class plane tickets;

"Appropriate", "Acceptable", "Logical": Limits which are acceptable for the "common man";

"Renowned": performers who have gained fame in the field of popular culture;

"Grandiose", "exaggerated", extravagant", "renowned with its activities": Locations and accommodation facilities that describe themselves with these or similar adjectives, comprising areas and accommodation facilities wherein or in the immediate vicinity of which games of luck are played and which are regarded as exaggerated according to EU standards (such as golf courses);

"Modest": For reminder call items with a market unit value of maximum 20 TL; (the Regulation has determined the monetary value of reminder call items as 2.5% of the applicable minimum monthly wage). The limit which is more stringent should be applied by AIFD members.

"Symbolic": Items with no market value, but bearing a symbolic value, such as plaques, commemorative plates and paper weights.

The fair market value of the honorariums to be paid to physicians, dentists or pharmacists engaged as speakers shall be determined upon taking a benchmark. The fair market value is calculated on criteria such as the salaries or fees of speakers, whether the speech is based on their own studies, the need for a wide literature screening, the qualification of the speaker as a reference person in his/her topic on a local, national and global scale and fair market values in Turkey and across the world.

If no monetary restriction has been imposed on the distribution of medical scientific books and medical journals, exaggerated payments that may be regarded excessive and give a wrong impression should be avoided.

Negative List:

The materials listed below shall not be distributed to physicians, dentists or pharmacists.

1) Any size refrigerator or cooler
2) TV sets
3) Video, DVD, VCD, CD-players
4) Air conditioners
5) Car accessories
6) Hair dryers
7) Thermos bottles

APPENDIX II

AIFD CODE OF PROMOTIONAL PRACTICE: COMMITTEES, SANCTIONS AND ENFORCEMENT
Standard Operating Procedure for Complaints; Constitution and Operation
Edition 4.1.0; Applicable as of January 1, 2013.

1. Introduction

1.1. Code of Promotional Practice of the Association of Research-Based Pharmaceutical Companies (AIFD) has been developed by the Good Promotional Practice Committee (GPP). In addition to providing a wide communication platform among all member companies, the Committee is also responsible for providing advice, guidance and training on the Code of Practice, interpreting the Code under changing conditions and updating the Code where necessary. The Committee also acts as a negotiator/mediator between companies, where required, and to regularly improve the assessment system for complaints and warnings that may be raised by all relevant parties, particularly by member pharmaceutical companies, other pharmaceutical companies, healthcare professionals, the general public, media, health authorities and politicians.

1.2. Complaints which are raised on promotional materials, promotional activities and the methods covered by the Code are evaluated by the Code of Practice Panel (CPP) and the Code of Practice Appeal Board (CPAB). Board Members, AIFD Secretary General, CPP and CPAB members can request for an ex-officio initiation of investigations without waiting for a complaint.

1.3. Names of individuals outside the pharmaceutical industry and trade, who have raised a complaint, shall be kept confidential. In cases where the respondent company cannot give an answer without learning the identity of the complainant, the name of the complainant may only be disclosed upon his/her approval.

2. Structure and Responsibilities

2.1. AIFD Good Promotional Practice Committee (GPP) is responsible for the management and development of the Code of Practice, including provision of advice, guidance and training on the Code.

2.2. GPP selects its Chairperson and two Vice Chairpersons in the first meeting of each year and communicates their names to the AIFD Secretary General. The duties of the Chairperson and Vice Chairpersons are described in the relevant Standard Operating Procedure.

2.3. GPP is composed of two representatives from each company, preferably one representative who is from the Medical Department, Regulatory Affairs Department or is the Compliance Officer, and one representative from the Marketing/Sales of Legal Affairs Department. Names of GPP members are communicated to the AIFD General Secretariat by General Managers. There is no limitation for participation in GPP meetings. However, in case of voting, each company has the right for a single vote.

2.4. GPP may exchange views with CPP, CPAB and AIFD Board of Directors about any matter concerning the Code or its enforcement.

2.5. Enforcement decisions adopted by GPP (Good Promotional Practice Committee) shall become part of the Code of Practice upon being approved by AIFD Board of Directors. Breaches to the enforcement decisions approved by AIFD Board of Directors and, where necessary, by General Managers, fall under the jurisdiction of the Code of Practice Panel (CPP). Breaches to such decisions shall be discussed and settled in the Code of Practice Panel, ex-officio or upon application.

3. Code of Practice Panel (CPP) – Constitution and Operation

3.1. Member companies are asked by the AIFD Board to nominate two candidates, one from the Medical, Compliance or Regulatory Affairs Department, and one preferably from the Marketing & Sales Department. Preferably, candidates should have an experience of at least five years in the industry.

3.2. The list of nominees (e.g. 38 from Medical/Regulatory Affairs Departments and 38 from Marketing & Sales or other Departments, listed in two separate columns) are circulated to member companies. Each company is requested to vote for 9 candidates from the Medical list and 9 candidates from the Marketing list. Companies cannot vote for their own candidates.

3.3. AIFD Secretary General presents to the Board top-voted 15 Marketing and top-voted 15 Medical candidates. AIFD Board selects five permanent and six substitute members from the list, observing that no company is represented by more than one member, that there are at least two candidates among permanent members and three candidates among substitute members from the Marketing list and ensuring that previous experience in the Committee is carried over to the next term.

3.4. AIFD Secretary General proposes three candidates each for the Independent Expert and Independent Physician/Pharmacist memberships of the Panel and submits these to the Board of Directors. AIFD Board appoints one of these candidates as the permanent Independent Expert member, one as the permanent Independent Physician/Pharmacist member and the other four persons as substitute consultant members.

3.5. CPP is composed of the following eight members:

- AIFD Secretary General or Deputy Secretary General as his/her proxy (Non-voting Chairperson of the Panel),
- Five executive members selected from companies (at least two from the field of marketing/sales),
- One Independent Physician/Pharmacist member,
- One Independent Expert member.

AIFD Committee Officer and the Chairman of GPP may also participate in the meetings, without voting right, upon the invitation of the AIFD Secretary General.

3.6. It is composed of six substitute member company representatives, three elected from the Medical list and three from the Marketing list, and four independent substitute members appointed as described above.

3.7. CPP members serve for a term of two years. Membership of company representatives may be renewed once.

3.8. Six members, including the chairperson, form the quorum, and decisions are adopted by the majority votes of members with the right to vote. At least one member each from Medical, Marketing and Independent member categories should be present to be able to start the meeting.

3.9. Company representative substitute members are invited to every meeting to safeguard quorum; they may contribute to deliberations like permanent members. In decisions where consensus cannot be reached, decisions are taken by counting the votes of permanent members or their substitutes. At the beginning of each meeting, the Chairperson determines which members hold the right to vote.

3.10. CPP convenes at least four times a year, or whenever required, for the assessment of the complaints made under the Code.

3.11. Membership of permanent members, who fail to participate in three consecutive meetings without an adequate justification, is dropped and he/she is replaced by the next highest voted substitute from the same category. The same procedure is followed in case a member resigns.

3.12. The Chairperson may receive external consultancy support in any field. Consultants may participate in CPP meetings upon the invitation of the Chairperson, but they do not have any right to vote.

3.13. CPP appoints one or more CPP rapporteurs among its permanent and substitute members to carry out the preliminary review, and where necessary, a brief investigation on the cases received.

3.14. AIFD Secretary General provides the necessary administrative support to CPP.

4. AIFD Code of Practice Appeal Board (CPAB), AIFD-IEIS Joint Boards - Constitution

4.1.1. AIFD Code of Practice Appeal Board is composed of twelve members as mentioned below:
- AIFD Secretary General (Non-voting Chairperson of the Board),
- Two members from AIFD Board of Directors and/or Board of Inspection,
- Two company representative members from CPP,
- Three independent expert members from medical, pharmaceutical sciences and marketing fields,
- Two legal experts
- One representative of TTB (Turkish Medical Association),
- One representative of TEB (Turkish Pharmacists' Union).

4.1.2. CPAB members are elected by AIFD's Board of Directors.

4.1.3. Cases that could not be settled at CPP level or have been appealed are resolved by CPAB. The decisions of CPAB are final.

4.2. AIFD-IEIS Joint Panel - Constitution

4.2.1. Complaints raised by IEIS members about AIFD members are evaluated at CPAB. (Likewise, complaints raised by AIFD members about IEIS members are evaluated at the IEIS Panel.) In case the complainant IEIS member is not satisfied with the decision adopted at AIFD, the decision is reviewed again at CPP. If the complainant objects once again to the decision, the matter is evaluated at the AIFD-IEIS Joint Panel. Similar process is observed in the complaints of AIFD members about IEIS members.

4.2.2. Joint Panel is formed when need arises.

4.2.3. The Boards of Directors of AIFD and IEIS elect the members to refer to the Joint Panel.

4.2.4. The Joint Panel is constituted of the following nine members:
- AIFD Secretary General,
- IEIS Secretary General,
- Two company representative members from AIFD CPAB,
- Two members from IEIS Supervisory Board for the Code of Promotional Practice,
- Three independent expert members to be jointly nominated by AIFD and IEIS, with at least one from the medical field and the other from the pharmaceutical field.

4.2.5. The Joint Panel operates similarly to CPAB. Chairmanship is held in turns, by the Secretaries General of these two associations.

4.3. AIFD-IEIS Joint Appeal Board - Constitution

4.3.1. Joint Appeal Board is formed when need arises.

4.3.2. Board of Directors of AIFD and IEIS select their members to be referred to the Joint Appeal Board.

4.3.3. Joint Appeal Board is composed of the following eighteen members:
- AIFD Secretary General,
- IEIS Secretary General,
- Four members from AIFD Board of Directors or Practice Panels or CPAB,
- Four members selected by the IEIS Board of Directors,

- Four independent expert member to be jointly selected by AIFD and IEIS,
- Two legal experts,
- One TTB representative,
- One TEB representative.

4.3.4. The Board operates similarly to CPAB. Chairmanship is held in turn, by the Secretaries General of the two associations.

4.3.5. Cases may be submitted to the Joint Appeal Board upon the joint decisions of the Secretaries General of two associations.

4.3.6. Decisions adopted in the joint board are final.

5. AIFD Code of Practice Appeal Board (CPAB) - Operation

5.1. AIFD Appeal Board convenes, where needed, to assess the objections under the Code and any other matter which relates to the Code.

5.2. The meetings may begin with the attendance of the Chairperson and five voting members. Decisions are taken by majority voting.

5.3. If a Board member is involved in a case either as a complainant or respondent, he/she is replaced by another Board member.

5.4. The Chairperson of the Appeal Board may receive consultancy support in any field. Consultants may participate in meetings, but have no voting rights.

5.5. When an objection is evaluated, representatives of both complainant and the respondent companies are invited to the meeting and make their case in person.

5.6. CPAB decisions are final.

6. Complaint Handling Process

6.1. Complaints between AIFD members should first be sought to be reconciled between relevant companies, by informing in writing their General Managers as well.

In case of failure to reach a satisfactory result latest within two weeks, application can be made to CPAB.

6.1.1.Complainant company may apply directly to AIFD in case the material or activity constituting the complaint has already been subject of correspondence between the two relevant companies, and complaint was not filed because of settlement between companies, but the material was used again consequently (if it is repeated despite the commitment in case of an activity); or due to a similar complaint filed against the company, CPP decided that a breach was committed and asked the material/activity to be ceased, but activity was repeated despite this; or the activity assumed to be in breach of the Code is about to be performed and there is limited time to stop it.

6.2. In case of complaints filed by an AIFD member about a non-member company, the enforcement of the method described in 6.1 is advised.

6.3. In case notifications or complaints filed to AIFD by healthcare professionals, patient associations or the general public, via electronic mail or media, AIFD Secretary General shall initiate transactions on an ex-officio basis.

6.4. Submission of Complaints to AIFD and CPP

6.4.1. Notifications and complaints filed by AIFD members should address the AIFD Secretary General, be signed by the relevant General Manager and comprise at least the following information:

a- Name of respondent company; correspondence address if this is not a member of AIFD;
b- Date of complaint;
c- Material(s) or activity (activities) subject to complaint: At each case, details about the activity, printed material of other evidences subject to the complaint, should be clearly indicated, and where possible, a sample and evidence or color copy should be attached to the complaint file;
d- Summary of the complaint: At each case, a summary description should be provided, indicating the articles breached in the Code by the subject matter of the complaint. In the event of miscitations from medical publications, the referred publications and misquoted sections should be clearly marked. If the referenced publication is an article, the article itself, and if it is from a book, adequate reference and the photocopy of the relevant section should be attached to the complaint.
e- Period during which the material subject to the complaint has been used; the locations and dates, in case of an activity;
f- In case solution-seeking steps indicated above in article 6.1 have been taken, their documents (copies of the letter submitted to the company subject to the complaint and the response from that company; dates, relevant parties involved and short summaries of verbal communications, if any).

6.4.2. Each complaint file should be submitted in 5 copies. It is recommended to send the files also in electronic format.

6.5. Establishment of the Case

6.5.1. When the notification about a breach of the Code or complaint reaches AIFD, the General Secretariat conducts the examination described below in 6.5.2 and it is ensured that the complaint is placed on the agenda of CPP. Where deemed necessary, AIFD Secretary General may change the priority of the agenda or call for an urgent meeting (Urgent Evaluation Process).

6.5.2. When the complaint notifying that the Code has been breached reaches AIFD, the validity of the following is verified first:
a- The matter is included into the scope of the Code,
b- The information on the application letter is sufficient to establish the case as indicated in Article 6.4,
c- One single complaint letter may comprise multiple cases of breach; for example, the complaint may relate to several breach allegations for different products of the company within the scope of the same activity or to multiple activities conducted for the same product in different times and locations. Taking into account the severity of the matters and whether there is recurrence of breach, AIFD decides to treat the activity or materials subject to complaint as a single case or convert these into separate files and treat them as separate cases. The Secretary General holds the discretionary power to decide on this matter.
d- All of the items indicated above in Article 6.4 shall be taken into account for each case.

6.5.3. In case the complaint file is regarded as incomplete, the complainant is requested to complete the file; the complaint is not processed until the completion of the file.

6.5.4. The process mentioned above is applied in notifications between AIFD member companies. In complaints received from non-AIFD member companies, media and third parties and institutions, action is taken upon evaluating whether the complaint is under the scope of the Code and whether there is sufficient information on the file for enabling CPP to take a decision.

6.5.5. Complaints from members, complaints from non-member companies and complaints from healthcare professionals, the general public, other institutions and organizations or the media, are processed according to the same procedure without discrimination.

6.5.6. In case the complaint received does not demonstrate that the Code of Practice has been breached or no convincing evidence can be submitted, the case is closed and the complainant is duly informed thereof.

6.5.7. In case of complaints where the entire or predominant goal is to taint the commercial reputation of a company, which have been filed for commercial interests, or similar complaints, the file is closed and both parties are informed about the reasons of closure.

6.6. Time Limit

Any complaint about promotional materials or activities will not be taken into consideration where the use or conduct of such materials or activities was ceased since a period longer than twenty-four months.

6.7. Request of Respondent's Answer

6.7.1. Even if the breach of the Code is evidently seen, AIFD shall not conclude the case directly.

6.7.2. A copy of the complaint file is sent to the respondent company along with a cover letter and a written response is requested. Information and documents may be requested by telephone or a face-to-face meeting at this phase, if deemed necessary.

6.7.3. If the complaint relates to the information, assertions and claims in the promotional material about the product, the complainant is responsible for submitting the documents that will prove such claim. Alleged company is responsible for providing the references, documents, scientific publications and/or technical reports on which claims in the promotional materials are based.

6.8. Grant of Time

6.8.1. Alleged company should provide a response to AIFD latest within ten working days. If no answer is provided during this period, the process continues without further waiting. However, upon the reasonable justified request of the relevant company and the qualification of the case as urgent, additional time may be granted.

6.8.2. CPP should finalize complaints received latest within ninety days upon their submission.

6.9. Preliminary Review

6.9.1. The file containing the complaint and the response are evaluated as part of the preliminary review by the CPP rapporteur. The rapporteur may contact concerned parties, where deemed necessary, visit company's premises and the site of the event, collect information from witnesses and concerned parties, request information and views from the relevant parties; the report is prepared based upon evidences at hand.

6.9.2. If the complaint concerns a matter similar to one which was the subject of a previous ruling, it may be reviewed upon making reference to the relevant decision. If the material is not used again or alleged activity is not repeated, the case is reviewed on the file without requesting the presence of relevant parties. Relevant parties are informed about the decision previously adopted about the same matter. The decision does not conclude that this is a new breach of the Code; the file is closed, but recorded.

6.9.3. If the complaint is the same as a case previously adjudicated, this is indicated in the report of the rapporteur.

6.9.3.1. Where the activity or material subject to the complaint is repeated after the decision for stopping it, the case is considered as a new case.

6.9.3.2. When multiple companies file a complaint about the same material or activity at the same time or collectively, the files may be merged. If the complaints are not related to different aspects, a single rapporteur's report is written.

6.9.4. The file concerning the case and the rapporteur's report are submitted to the Practice Panel.

6.10. Review by Practice Panel

6.10.1. Complaint files subjected to the preliminary review are placed on the agenda according to the date of receipt of complaints. In urgent cases, the Chairperson may propose a change in the order of the agenda or call for an urgent meeting.

6.10.2. The agenda and reports are distributed to members at least two working days prior to meeting date under normal conditions. Only the rapporteur's report is sent to the relevant parties.

6.10.3. CPP evaluates the complaints on the basis of submitted files.

6.10.4. Where deemed necessary by Practice Panel members or the Chairperson, relevant parties may be invited to the meeting to present their cases verbally and respond to questions. As deemed suitable by the Chairman, both parties may participate in the meeting together or be invited in the room separately. During the allocated time, first the representative of the complainant company, and consequently the representative of the respondent company present their cases. Meetings are conducted according to generally accepted meeting order rules.

6.10.4.1. If more than one company places a complaint about the same activity or material, these complaints may be merged. All parties may be invited to the room at the same time to present their cases.

6.10.5. Panel members may ask questions to the representatives of both parties and request additional documents. In case CPP wishes to take a decision after seeing the documents or making an additional investigation, the meeting may be adjourned and the examination may be resumed in the subsequent meeting. In such case, the parties may not be invited again and the examination is continued on the basis of the file.

6.10.6. Company representatives are invited out of the meeting room after presentations and questions. Unless the Chairman decides otherwise, representatives of companies, who are either from the complainant side or the respondent side, are also permanent or substitute members of CPP and are present in the meeting, are invited out of the meeting room as well.

6.10.7. If during the examination or discussion of a case, the rapporteur or a CPP member comes across a situation which is not mentioned in the complaint, but may be interpreted as a breach of the Code of Practice, CPP examines this matter and requests additional information from the respondent company, where necessary. In case time is requested for the preparation of a response, the case is finalized at a later date, upon the examination of documents, preparation and distribution of a new rapporteur's report, where necessary, and listening to relevant parties.

6.10.8. Pursuant to the discussion of the files and other matters in the panel, separate voting is made for each agenda item and decisions are taken according to the majority of those present in the meeting. Names of voters are not indicated in the decisions of the panel. When decisions are taken by majority of votes, the number of votes is specified.

6.10.9. Results of the evaluation made by CPP are recorded and a separate case report is prepared for each case.

6.10.10. If the complaint is submitted also to the Ministry of Health, the Competition Authority or to Court, in addition to being submitted to AIFD, CPP closes the case until a legal ruling is made and a decision is adopted by the Ministry of Health or the Competition Board. Likewise, in the event of cases where it is understood that these have previously been submitted to court or about which a complaint has been submitted also to the Ministry, CPP closes the file. In case of the verdict of the Court or decision of the Competition Authority or the Ministry of Health is against the respondent member company, the Secretary General presents the case to the attention of the Board of Directors.

7. Code of Practice Panel (CPP) Decision Process

7.1. The evaluation and the final report are submitted in written form to the relevant parties with the signature of the Secretary General, along with a cover letter, irrespective of whether a sanction is applied or not.

7.2. In case CPP decides that the Code has been breached, both parties are informed in writing about this decision, the sanction and the reasoning behind the decision; the company subjected to sanction is requested to stop the activity or the use of the material and implement additional sanctions, if there are any.

7.3. Monitoring of Sanctions

7.4. Where the Panel rules that there is no breach of the Code, the complainant and the respondent parties are informed in writing about the decision and its reasons.

7.5. The respondent company has maximum ten working days to provide to AIFD's Secretary General a written undertaking signed by the General Manager, indicating the time when the referred promotional activity or the use of the relevant material has been stopped, and stating that corrective measures have been adopted to prevent the breach from being repeated, with clear details about the measures adopted.

7.6. Both the complainant and the respondent companies may object to the ruling within ten days of the notification of the ruling, clearly indicating the reasons of the objection. Decisions not objected to within ten days become final.

7.7. In case of objection, the file is reviewed again at CPP. CPP reviews the objection letter on the basis of the file or, where deemed necessary, upon hearing the representatives of the relevant company/companies and adopts a decision. The new decision is communicated to the relevant parties as described above.

7.8. Relevant parties may object again to the CPP decision adopted upon the first objection, indicating the reasons of the objection. In this case, the objection is submitted to the Appeal Board (CPAB). Decision of the Appeal Board is final.

8.0 Decisions of the Code of Practice Appeal Board (CPAB)

The decisions and methods of the Appeal Board resemble those of CPP.

9. Sanctions

9.1. Attention should be paid to ensure that sanctions are proportionate to the severity of the breaches.

9.2. Necessary measures shall also be taken to assure that sanctions have a deterrent effect, and that an effective deterrence is achieved in case the company repeats offences on a specific product or displays general attitude or indifferent behavior, thus continuing to commit a breach.

9.3. During the evaluation of the respondent company's behavior relating to the Code or a specific case, CPP or CPAB may decide to implement more sanctions to that company, where deemed suitable, in case of bad intention and repetition of the offences despite warnings.

9.4. In all cases, CPP and CPAB and, where necessary, AIFD Board of Directors and the General Assembly shall apply the following sanctions:

- Concern Letter,
- Admonition,
- Warning,
- Condemnation,
- Strong Condemnation,
- Temporary Suspension from Association Membership,
- Expulsion from the Association.

9.5. The following additional sanctions may also be applied:

- To stop the use of a material or repetition of an activity;
- To ask the relevant company to collect the materials;
- To publish the decision adopted for the company, with details in proportion with the mistake made,
- To require an audit of the company's processes regarding the breached Code and request improvements where necessary; to require an audit to be made by persons or institutions to be appointed by AIFD where the costs are covered by the company to be audited,
- To request the company to issue a corrective declaration and publish a corrective statement in publications intended for physicians, dentists and pharmacists,
- To inform in writing headquarters of Multinational Companies,
- To inform in writing the other international institutions (EFPIA, IFPMA, PhRMA, etc.) about the breach,
- To inform the Ministry of Health or the Competition Board or both about the breach of the Code of Practice and the company's nonconformity to the Code.

9.6. AIFD Board of Directors, in line with the proposal of EFPIA, is authorized to institute sanctions aimed at stopping repeated and proliferating offences that are proportionate for stopping such misbehavior.

9.7. In case of multiple complaints about the same matter, all complaints may be handled in a single session.

10. Case Reports

10.1. At the conclusion of a case under the Code, both the complainant and the respondent are informed about the result verbally at the end of the meeting; consequently, it is communicated in writing to the General Managers of both parties upon adding the final case reports.

10.2. The case report includes the name of the company subjected to the complaint, summary of the complaint and of the decision adopted in the meeting. In case of factual errors in the rapporteur's report, these are corrected and the report is re-distributed.

10.3. Summaries of all case reports are submitted to the attention of the AIFD Board of Directors, on a regular basis.

10.4. At the end of each year, AIFD General Secretariat publishes, with adequate details, the reports of all cases handled and finalized during that year, upon considering the severity level of each case, trends, obstinate behavior and recurrences; the Secretariat proposes to the AIFD General Assembly, amendments in the Code of Practices, that may further promote transparency and ethical practices in the pharmaceutical industry and between members. The summary report is submitted to EFPIA Code of Practice Panel and IFPMA. The following are taken into account in publishing the reports:

10.4.1. In severe or repeated breaches, details about the case and the name of the company will be indicated in the publication.

10.4.2. In case of a minor breach or where there is no breach, the name of the company and details referring to the company may be excluded in the case report.

10.5. Each year, AIFD shares its own experience on Good Promotional Practices with EFPIA Code Committee and IFPMA Code Compliance Network (CCN) and the other associations within the pharmaceutical industry and benefits from their experiences.

10.6. AIFD publishes on its website English summaries of case reports which may be of interest in the international circles in order to contribute to the exchange of information with IFPMA and EFPIA.

11. Reconciliation

11.1. Companies requiring a conciliator for reaching an agreement on topics of dispute related with promotion may contact GPP Representatives, CPP members or the AIFD General Secretariat.

11.2. AIFD member companies may forward the enquiries about Code of Promotional Practice to CPP or GPP and request for their consultancy.

12. Modifications of the Code, Constitution and Operation of Panels

12.1. The Code of Practice, Constitution and Operation of the Panels may be modified by AIFD's Board of Directors. Changes are submitted to the approval of the next AIFD General Assembly.

13.0 Summary Table of the Complaint Process

Table 1: Summary Table of the Complaint Process

If Complainant is	**If Respondent is**	**The matter shall be resolved as follows:**
An AIFD member	An AIFD member	Between companies; *Otherwise*, AIFD CPP handles the case.
AIFD member	IEIS or TISD member	Between companies; *Otherwise*, CPP prepares a draft case report; passes the case to IEIS or TISD, follows outcome.
An IEIS or TISD member	An AIFD member	CPP handles the case
An AIFD member	None	CPP handles the case; where deemed necessary, suggests direct appeal to the Ministry of Health or the Competition Authority.
A Healthcare Professional	An AIFD member	CPP handles the case.
A Member of public or media	An AIFD member	CPP handles the case.

14.0 Summary Table of CPP and CPAB Sanctions

Table 2: Summary Table of Sanctions

Sanction	*Severity score*	*Additional Communication*	*If repeated within 12 months*	*Decision Taken by:*
Concern Letter	**1**			CPP-CPAB
Admonition *Severity Level:1-2*	**5**		3 admonitions= 1 warning	CPP-CPAB
Warning *Severity level:2-3*	**15**	.	3 admonitions = 1 condemnation	CPP-CPAB
Condemnation *Severity level:2-3*	**45**	Decision communicated to healthcare professionals	2 condemnations = 1 severe condemnation	CPP-CPAB or AIFD Board of Directors
Strong Condemnation *Severity level:2-3*	**90**	Communication to IFPMA and the headquarters of the relevant company	2 severe condemnations = Temporary suspension from AIFD	AIFD Board of Directors
Temporary Suspension	**180**	Information is provided to IFPMA and EFPIA.		AIFD Board of Directors and General Assembly
Expulsion from AIFD		Ministry will be informed; press release will be issued.		AIFD General Assembly

APPENDIX III

TEMPLATE FOR WRITTEN AGREEMENTS BETWEEN PHARMACEUTICAL COMPANIES AND PATIENT ORGANIZATIONS

When pharmaceutical companies provide financial support, significant indirect support and/or significant non-financial support to patient organizations and associations, a written contract should be signed between the organization and the company. In case the support is not provided directly by the company, it is recommended that the intermediaries are also signatories to the agreement.

The following template contract contains the key points that need to be included into a written contract that regulates the relations between pharmaceutical companies and patient organizations. The template may be used in its entirety or be adapted according to requirements. The template contract aims to lay down in writing the goals to be decided between both parties, in line with EFPIA's and AIFD's Code of Promotional Practice.

Name and short description of the activity;

Names of partnering organizations (pharmaceutical company (companies), patient organization, and where applicable, third parties that will be brought in to help, as agreed by both the pharmaceutical company and the patient organization);

Definition of the activity (information on whether the activity is an unconditional and non-refundable grant, the meeting aimed, publication, event, participants, etc.)

Objectives and goals of the activity;

Distribution of roles, duties and responsibilities undertaken by the pharmaceutical company and patient organization;

Term of validity of the contract;

Amount of financial support provided by the contract;

Description of significant indirect/non-financial support (e.g. public relations agency's time, free training opportunities, participation in congresses and meetings organized by the company, advertising agency services, correspondence and support in interactions with national and international institutions, secretarial services, web page design, etc.);

Joint determination of all parties on the fact that that sponsorship should be announced in a transparent manner and declared to all stakeholders including the general public;

Mention that AIFD Code of Promotional Practice shall apply in the activity;

Names and titles of representatives signing the contract;

Date of contract.

APPENDIX IV

AIFD USER GUIDE ON DIGITAL COMMUNICATION APPLICATIONS IN THE PHARMACEUTICAL SECTOR

(This Guide is a study document established on the rules stipulated in Article 20 and comprising the points that need to be considered in the use of digital media in the pharmaceutical sector. The content may be updated in time in line with the developments in the digital environment. Amendments in the Guide shall become binding for all members upon being approved in the Board of Directors and ratified in the General Managers Meeting. The text will be submitted for approval in the next AIFD General Assembly.)

The Turkish pharmaceutical sector, as in many other countries, operates subject to strict oversight. Code of Practice (http://www.AIFD.org.tr/Hakkimizda/Tanitim-ilkeleri.aspx) of the Association of Research-Based Pharmaceutical Companies is a detailed self-supervision and communication document, covering promotion of prescription drugs to healthcare professionals, communications to and interactions with patient groups, and how health information qualified for public consumption should be used by pharmaceutical companies. In Turkey, public promotion of prescription drugs is prohibited by law.

Whereas Digital Communication is the general name given for communication through new communication channels which are gather under internet pages, social networking sites (e.g. Facebook, YouTube), microblogs (e.g. Twitter), user forums, sites developed also with the contribution of users (e.g. Wikipedia, *Ekşisözlük* - Sourtimes), and services such as text messages or multimedia messages which are sent through mobile phones, which are open to technological development and content supervision is generally difficult or impossible.

Pharmaceutical companies are seeking ways to utilize the benefits of digital communication means, while maintaining compliance with applicable laws and internal rules and avoiding to be perceived as promoting drugs to the general public.

This document is prepared as a guide for the enforcement of Article 20 of the AIFD Code of Promotional Practice, focusing on Digital Communication and Media, upon taking into account the internal company rules of AIFD members. Employees of AIFD member companies who are responsible for digital communication applications and third parties appointed by companies are expected to observe the AIFD Code of Promotional Practice and this guide.

This Guide covers the following topics under these headings:

1. The Principle of Transparency and General Rules
2. Corporate Websites
3. Websites Prepared for Patients and the General Public, Not Comprising Any Promotion and Aimed At Providing Information on Health
4. Websites Prepared for Healthcare Professionals, Comprising Also Product Promotion and Intended for Promotion or Training
5. Computerized or Web-Based Promotional Methods
6. Applications in the Use of Social Media
7. Information Sharing via Digital Communication Tools

The final section includes answers to frequently asked questions. Subheadings cover a general description of the section and Good Promotional Practices.

Fundamental Rules

Digital Communications should be compliant with the general rules that are binding on the pharmaceutical sector as well as the letter and spirit of the AIFD Code of Promotional Practice.

Companies should comply with the rules to be imposed by public institutions on the use of internet, rulings about the use of internet and international Good Practices with regard to the content and use of internet.

Companies shall be responsible for the activities conducted in the digital environment on their behalf, including third party activities.

1. Principle of Transparency and General Rules

1.1. Pharmaceutical companies may establish websites in compliance with laws and regulations, directed at communication with their stakeholders.

1.2. Personal information collected from visitors should be kept confidential. The website should be arranged and managed in accordance with national laws and regulations and international rules with regard to the protection of confidentiality, safety and privacy of personal information.

1.3. Companies are responsible for the websites and social media accounts established by them or created in their name upon their request. Relevant measures should be adopted to ensure that there is no content which may be perceived as pharmaceutical promotion to the general public in the websites or social media accounts which they sponsor.

1.4. Content of websites should be informative, accurate, current, balanced, reliable, fair and objective, clear and readily comprehensible

1.5. Every website should have a homepage. The following information should discernibly be contained on the website:

1.5.1. Name of website owner; street/e-mail address, telephone numbers for contact about the website

1.5.2. Name of the company sponsoring the website; street/e-mail address, telephone numbers for contact about the website

1.5.3. Sources of the information provided at the website, edition/publication dates of resources and a description of persons or entities (those who sent this information) from whom the information provided on the website was obtained, where required.

1.5.4. Purpose and target audience(s) of the website (e.g. physicians, pharmacists, patients, patient relatives or the general public)

1.6. Website names should be selected in accordance with the Code of Promotional Practice; AIFD does not consider appropriate a website named after a product whose promotion to the general public is not suitable.

1.7. The homepage and the name of the website shall not contain a statement which may be interpreted as a product name or product promotion**.**

1.8. Information offered on the website should be reviewed by the relevant departments of the company in line with internal company rules and relevant approvals should be obtained.

1.9. Information offered on the website should be regularly updated, with clear references to the last revision date for each section, page and/or article, as applicable.

1.10. Information aimed at healthcare professionals (physicians, dentists and pharmacists) and the general public should be separated in two sections, with the section aimed at physicians, dentists and pharmacists clearly marked on top with the statement "This section is intended for physicians/pharmacists".

1.11. Links from this website to other sites should be made carefully. In case of presence of information what may be perceived as promotion of the products of the company on the website to which a link is provided (even if this is a website open to the general public and not sponsored by the company) the responsibility lies with the company providing this link.

1.11.1. Compliance of the content of the website to which a link is provided with the code of promotional practice should be ensured and it should be regularly verified whether the link directs to the correct address.

1.11.2. It is advised not to provide links to dynamic websites with dynamic content, such as 'blogs' or 'forums', wherein information constantly changes and conformity to the code of promotion is difficult to verify and it is recommended for companies not to sponsor such websites. In case such links are provided, the responsibility of verifying compliance with the Code of Promotional Practice lies with the company.

1.12. Users should be given clear indication when they are directed to a website to a non-company website from any of its websites of the company of a website sponsored by the company.

1.13. The following recommendation should always be included on each page containing health information open to the general public, other than the corporate pages of the company (e.g. sections highlighting company principles, section for job application, etc.): "**Information on this website shall not replace consultation with a physician or pharmacist. Consult a physician and/or pharmacist for further information"**.

1.14. Websites may contain information about diseases, disease prevention, screening and therapeutic methods and other information aimed at protecting public health.

1.15. Any mention of therapies should reflect balanced and up-to-date information; pages open to the general public and patients should not include any pharmaceutical promotion and/or direction to a specific drug.

1.16. In addition to medical therapy, also other rational therapeutic methods including diet, behavior modification therapies and similar prevention and therapeutic methods may be explained on the website.

1.17. Each member company, when they become aware of the existence of a website administered in a non-conformant manner which may be perceived as being sponsored by them, should take prompt legal action to cease activity of such website. Such applications should be documented at a level that may provide proof of action to AIFD or other relevant authorities upon request.

2. Corporate Websites

2.1 Company websites may contain financial information that may interest investors, investments and information on the stage of registrations, HR job opportunities and job application sections, press releases and declarations of the company not involving product promotion and intended for the general public, product lists and prices, areas of specialty, information about health conditions, advancements in the medical field, contact details and similar information in conformity with the Code of Good Promotional Practice. This type of information does not fall under the scope of the Code of Promotional Practice and laws and regulations on pharmaceutical promotion, provided that there is no content and form which may be perceived as pharmaceutical promotion.

3. Websites Prepared for Patients and the General Public, Not Comprising Any Promotion and Aimed at Providing Information on Health

3.1. Promotion to the general public of non-reimbursed medicinal products for human use registered to be sold without prescription does not fall under the scope of this Code of Promotional Practice. These products should be promoted in accordance with current laws and regulations.

3.2. Pharmaceutical companies may develop and promote websites and social medial platforms for the purpose of informing the patients and the society on diseases and current medical applications.

3.3. The general criteria to be used in assessing such activities will be to ensure that the information provided on pages available to the general public is provided in limited form, as stipulated by national legislations, promotional regulations, Codes of the European Union, EFPIA and IFPMA and other laws and regulations generally accepted in the pharmaceutical sector.

3.4. Content and level of the information provided should be suitable for the target audience.

3.5. Sources should be referenced for information relevant to the general public and for any remarks made on diseases.

3.6. No section of these pages should contain information that may be interpreted as product promotion or enable a direct or indirect association between disease information and the drugs of companies.

3.7. The statement "**Information on this website shall not replace consultation with a physician or pharmacist.**" should be included on pages intended for patients and relevant pages should contain, at all times, the recommendation reading, "**Consult a physician and/or pharmacist for further information".**

3.8. Companies should stay clear of discussions involving individuals' health problems in e-mail correspondence received from patients or the general public originating from websites, and advise such persons to consult with their physicians or pharmacists.

3.9. Websites allowing submission of free text messages should be regularly monitored for potential adverse event reports.

4. Websites Prepared for Healthcare Professionals, Comprising Also Product Promotion and Intended for Promotion or Training

4.1 Information aimed at healthcare professionals (physicians, dentists and pharmacists) and the general public should be separated in two sections, with the section aimed at physicians, dentists and pharmacists clearly marked on top with the statement "This section is intended for physicians/pharmacists".

4.2. An effective process (e.g. a blocking warning, password, approval mechanism) preventing access of others should be used at the entry point of the section and any pages aimed at physicians, dentists and pharmacists. The responsibility rests with the company to employ sufficient safeguards for ensuring and documenting that the person is a member of the healthcare profession.

4.3. Where a website, or page, aimed at physicians, dentists and pharmacists contains product-related information or promotional elements, compliance with the code of promotional practice, regulations, and all relevant rules should be ensured as applicable for promotion through conventional means.

4.4. Electronic mailing systems used at company websites should be regularly monitored for potential adverse reports.

4.5. Requests received from healthcare professionals for literature and professional information should be documented and addressed by the company in an appropriate manner.

4.6. If information is requested from physicians on the website, such as contact details or affiliated institution and areas of professional interest, such information should be compliant with the guidelines and be in line with the format approved by the company's legal department. Confidentiality of information collected should be respected.

4.7. Prior written permission of physicians, dentists and pharmacists – with wet signature or digitally approved - should be obtained, in line with laws and regulations, for subsequently contacting them for promotional purposes using their contact details collected (e.g., e-mails or text messages).

4.8. Accessible and reliable sources should be referenced for information offered on the website and for any remarks made about a disease.

4.9. No information that contradicts the Ministry-approved patient information leaflet and SmPCs should be used - even if these are approved in other countries.

4.10. In addition to the SmPCs (Summary of Product Characteristics), also the Patient Information Leaflet (PIL) prepared for patients should be included among the information relating to products presented on the website intended for healthcare professionals.

4.11. If a section is included where physicians can exchange views, the moderation rules for this section should be clearly stated in the website's terms and conditions for use (that the comments will be monitor to verify their compliance with the Regulation and the Code of Promotional Practice, the route to be pursued for adverse event reports, etc.).

5. Computerized and Virtual Web-Based Promotional Methods

5.1 Promotional activities using computers should be performed in line with the same rules that apply to printed materials according to AIFD's Code of Good Promotional Practice. In case the content of the promotional material is to be shared as a whole or in part, an internal review process should be applied for modification.

5.2. Resources used in promotional activities (e.g., articles, posters, etc.) and information relating to drugs (such as patient information leaflets, summary of product characteristics and product monographs) may be stored in the device used for promotion. Upon request, resources may be shared with physicians, taking care not to infringe any copyrights.

5.3. Content should be archived in a manner that allows future retrieval. Disputed portions of the content should be available in the event of objections raised for noncompliance.

5.4 **Virtual Congresses:** Virtual congresses may be held or sponsored, subject to the restrictions laid down in the relevant articles (i.e. Articles 15 and 16) of the AIFD Code of Promotional Practice. In such meetings, the type and scope of sponsorship should be clearly disclosed. If speeches or correspondence from the meeting will be published, they should comply with the Code of Promotional Practice, the

references should be included in the publications according to scientific practice and the copyrights of authors should be preserved.

6. Use of Social Media Applications

6.1 Ensuring effective and useful utilization of social networking applications with user-generated content, such as Facebook, Twitter, Linked-in, YouTube and blogs, is gradually gaining more importance in the context of today's communications. In a sector like the pharmaceutical sector, which is subject to a large number of arrangements such as laws, regulations and company procedures, company employees have several obligations in this field:

6.2. Respectful, honest and transparent communication is essential.

6.3. There should be no sharing of information, visuals, photographs, slide shows, videos or links by persons not authorized by the company. In any case, any information shared should be compliant with the applicable laws on capital market, competition law and the laws and regulations of the Ministry of Health.

6.4. All company employees should maintain the attitude they display vis-à-vis the general public also in the virtual environment of the internet; behavior which is not regarded appropriate in real life should not be displayed also in the virtual network considering that one's identity is hidden.

6.5. Conduct that may lead to personalization of the debate should be avoided and relevant measures should be adopted to ensure that the preparation and dissemination of emotionally disturbing messages for others is avoided.

6.6. Mechanisms should be in place to prevent unwanted or abusive messages.

6.7. Care should be taken to be transparent as far as possible in social media communications and the author should clearly state his/her identity and the company for which he/she works. In difficult circumstances, company's compliance officer should be notified.

6.8. True identity should not be withheld unless justified, and care should be taken to ensure that identity is clearly indicated under every message. Even when nicknames are used, conduct should take account that true identity may be revealed when necessary.

6.9. When a negative comment is noticed by a company employee against the company or its products, he/she should notify appropriate designated functions within the company (social media responsible, corporate communications, compliance officer etc.); if the message is related to an adverse reaction, the officer responsible for drug safety should be strictly notified thereof.

6.10. Any messages or texts communicated by pharmaceutical sector employees over social media channels concerning their companies, drugs and competitors' drugs should be compliant with the rules applicable to other media. No expression or statement which should not be spoken to healthcare professionals during face-to-face interactions should be used at social media channels.

6.11. All company employees should always apply their companies' rules of ethical conduct. It should be remembered that any "status," "tweet," or "comment" released over the social media will be publicly available.

6.12. Unauthorized persons should strictly refrain from introducing themselves as an official company spokesperson.

6.13. Confidential information qualified "for internal use only" concerning the company or its products should never be discussed on public forums; only released/publicized information should be shared.

6.14. When an adverse reaction report is detected in a digital environment, concerning any company product, the Drug Safety Department should be promptly notified, following company procedures.

6.15. No groups or accounts involving the name of the company or a product should be started on Twitter, Facebook or similar environments without informing the Social Media and/or Corporate Communications Department.

6.16. Company employees should not share any information which may be perceived as promotion of prescription drugs in their accounts in social media.

6.17. Frequently, a company opens a global or local official Facebook and Twitter account for sharing recent developments and follow such developments; it is the responsibility of the company that has opened the account to monitor the conformity of the information shared with laws and regulations in Turkey.

6.18. Blogs: A blog (short form of weblog) is and site where additions can be made frequently made. Blogs are websites that facilitate persons interested in the same topic to express their views on the internet, communicate and establish relations with each other. You may find below the adapted version of the view of the ABPI (Association of the British Pharmaceutical Industry) on whether it is suitable for

pharmaceutical companies to use or sponsor blogs or establish relations with healthcare professionals or patients via blogs according to the Code of Promotional Practice:

6.18.1. Article [8.8] of the Code of Promotional Practice calls for the clear indication of company sponsorship in all sponsored activities and materials. This rule applies also for the internet. If a company sponsors a pharmaceutical or therapeutic website, it should ensure that the information therein complies with laws and regulations and the Code of Promotional Practice. It is not acceptable for add links, information or material about an unregistered indication of a drug of the company in a blog sponsored by that company and it may be deduced that the company is making an off-label promotion of the product or is acting as an intermediary for the dissemination of such information. By definition, everyone may contribute as they wish on blogs (and social media "walls") and express their views and proposals freely. If a blog intends the discussion of drugs or in case the therapeutic views about a drug is expected to be expressed in the blog, pharmaceutical companies are advised not to sponsor such sites as they may not guarantee the conformity of their content with the Code of Promotional Practice."

6.19. Likewise, even if it is possible to make corporate promotion on Twitter, in case of a pharmaceutical promotion not intended for the general public, considering that not all followers of the message will be HCPs or due to the potential of the message to be re-tweeted and reach also persons other than physicians, dentists and pharmacists, it may be understood that this environment is not suitable for pharmaceutical promotion.

7. Information Sharing via Digital Communication Tools

7.1. Advancements in technology and rapid transformation in the healthcare sector provide pharmaceutical companies with the opportunity to reach healthcare professionals, other health sector employees, healthcare institutions, patients and patients' relatives upon employing state-of-the-art equipment and means. Electronic communication methods (e-newsletters, e-zines, virtual congresses, etc.) are becoming common place. Such methods should be used carefully and meticulously by the pharmaceutical sector within the framework of the general rules mentioned below.

7.2. During any type of communication in pharmaceutical promotion or with healthcare professionals, companies should act with the awareness that they should be compliant with the letter and spirit of the AIFD Code of Promotional Practice when using the digital environment, as with other media channels.

7.3. The sponsor of any electronic promotional activity including virtual congresses should be clearly indicated.

7.4. Content sharing should be made in compliance with the classification group of stakeholders. For example, an e-newsletter prepared for physicians or pharmacists and containing product promotion should not be sent to patients and patients' relatives.

7.5. The content to be shared in the internet environment should not be published prior to being subject to an internal company approval process similar to the one pursued for printed materials.

7.6. Before sharing a promotional content, permission of the recipient or the group of recipients should be obtained for sending it. Notices such as "unsubscribe" or "report unwanted message" should be included at the bottom of all digital content.

7.7. In publications such as e-newsletters and e-zines intended for healthcare professionals (physicians, dentists, pharmacists) only to whom pharmaceutical promotion can be made, it should be clearly indicated that such information can only be shared with physicians, dentists and pharmacists; that appearance of such content on Facebook, YouTube, Twitter or similar environments open to the general public will be regarded as "promotion to the general public" which is prohibited by our laws and regulations and that also those sharing this content may be held responsible.

USER GUIDE ON AIFD CODE OF PROMOTIONAL PRACTICE ARTICLE 20 AND DIGITAL COMMUNICATION
QUESTIONS AND ANSWERS

Question 1 - Is it appropriate for companies to contact physicians through social media channels?

Answer 1 - When using any medium for promotion, companies should act with the knowledge that they are bound by AIFD's Code of Practice. Companies can make corporate promotion on via social media. With regard to pharmaceutical promotion where promotion to the general public cannot be made, promotion can be conducted also on digital media which are accessed only by physicians, dentists and pharmacists and where they may clearly indicate the scientific references regarding the product promoted.

Question 2 -Is it appropriate for companies to contact patients directly or indirectly through social media?

Answer 2 - Any direct or indirect interaction of companies with patients and patients' relatives upon accessing their personal information is against laws and regulations. However, companies may open informative platforms intended to raise awareness on a disease to patients and patients' relatives on social media (Facebook, Twitter, Linkedin, YouTube, Google+, etc.). No pharmaceutical promotion or similar promotion can be conducted on these platforms. This rule applies for all digital environments including social media.

Question 3 - Is it appropriate for company employees to actively engage in social forums for disease and the use of drugs? At what point would their responsibility begin and end?

Answer 3 - Any such activity of company employees should be compliant with the codes of AIFD and the pharmaceutical sector. Companies should advise their employees that any communication through such forums should not breach the confines of common sense. A company employee calling a radio show, or promoting a product on a disease forum may cause the initiation of regulatory action against his/her company. It is essential that social forums are not used for promoting medicinal products; however, health information, the necessity of compliance with the treatment, the difficulties experienced when complying with treatment and solution proposals may be shared. Transparency and common sense are always the basis.

Question 4 - Is it appropriate for me to use video sharing sites, such as YouTube, to post comments on my Products and my company as a company employee using my true name, and is it appropriate if I share product videos using my true name?

Answer 4 - Since YouTube is a public platform, sharing any video or presentation therein that may be perceived as public promotion of a product will be in violation of AIFD Code of Practice. Any remarks shared concerning one's company should be free from any messages that risk being perceived as promoting a product. You can mention your company's social responsibility projects, or personnel policies, taking account of your company's internal rules.

Question 5 – Can a pharmaceutical company to open a Facebook account open to the general public, which does not comprise products and names of molecules but is intended to raise awareness only on a disease?

Answer 5 – Pharmaceutical companies may prepare pages for raising awareness on a disease, where the purpose of the page is clearly indicated, names of products and molecules are not included, no product promotion is made or any message, news and image that may be associated with product promotion is included. The company should clearly indicate that it has sponsored this page. Free text boxes (areas where comments are made) should be regularly followed by the pharmacovigilance officer of the sponsoring company. Any debate on drugs on Facebook shall be against the AIFD Code of Promotional Practice and will be regarded as "promotion to the general public." In case of adverse event report on the page, information should be duly compiled in line with relevant laws and regulations and company rules and the report should be submitted to relevant authorities.

Question 6 – Can a company prepare and disseminate a video not promoting a product or therapy, upon using viral marketing elements for the purpose of increasing the promotion or the number of clicks of an internet platform for raising awareness on a disease, which it has opened itself or has sponsored?

Answer 6 - Such an activity may be conducted, provided that the video prepared does not generate anxiety and fear about the disease or directs to a therapy and is compliant with the AIFD Code of Good Promotional Practice. Likewise, the relevant website should not direct to a specific therapy, it should aim to provide

information to patients and patients' relatives on symptoms, and be intended to direct the patient to a family doctor in case of a number of symptoms. Moreover, it should be ensured that the relevant website or video does not contain any hidden advertisement. Websites which lead to false hope and recommend a therapeutic method without receiving the opinion of a physician are regarded to be in breach of the ethical principles.

Question 7 -Is it possible to launch a website using a product name?

Answer 7 - Although there is no regulatory restriction, AIFD advises against launching websites using trademarks. On the other hand, owners of trademarks are recommended to acquire rights to websites carrying their brand names, to prevent others from acquiring rights to such domains.

Question 8 - Would that be a problem if product colors are replicated without using the product name at a website aimed at patients?

Answer 8 - The rule is to not promote drugs to the general public. Use of colors or compositions should not be a problem, as long as the rule is respected. When colors (or a logo or visual) is matched by patients with a product brand, then it may be characterized as a violation of the prohibition to promote to the general public.

Question 9 – What are the rules applied on the inclusion of a video, presentation and similar documents submitted by physicians to the company for being posted on websites prepared or sponsored by the company? Is the company responsible for the content of these messages?

Answer 9 – The site administrator and in some cases the company sponsoring the site (which is not owner by the pharmaceutical company but by 3rd parties under the direct or indirect sponsorship of the company) shall be responsible for the compliance of the content with laws and the code of promotional practice.

Question 10 – Can the presentation of a speaker be shared live with his/her colleagues not in the same environment but in remote clinics and cities via the internet along with the image and the content of the presentation, under the sponsorship of a pharmaceutical company? (Webinar, Live Broadcasting, webcasting)

Answer 10 – A pharmaceutical company may sponsor sharing of the presentation of a physician with his/her colleagues over the internet, simultaneously or upon being recorded so as to be viewed later. The promotion of this meeting can be made to relevant physicians by printed materials. Sharing should comply with the code of promotional practice.

Question 11 - Is it appropriate to start a page on Facebook, inviting physicians to exchange views on, for example, "Safety of Contrast Agents," creating a platform for sharing and discussing views?

Answer 11 - It may be possible if the platform is accessible solely to physicians, none other than invited physicians can access the page, in particular groups to whom promoting is prohibited, and the same rules that apply to holding physical meetings are respected. When the discussions made at the platform are shared with others, it becomes a promotional event and hence become subject to promotional rules (referencing, providing evidence, etc.).

Question 12 – Can companies organize virtual congresses, or sponsor virtual meetings and congresses?

Answer 12 - Virtual congresses may be held or sponsored, subject to the restrictions laid down in the relevant articles (i.e. Article 15) of AIFD Code of Promotional Practice. In such meetings, the type and scope of sponsorship should be clearly disclosed. When compiling and releasing speeches or correspondence from the meeting, the sponsor should take care to ensure that Code of Promotional Practice is respected, and that references are included etc.

Question 13 – Can the product promotion representative conduct a product promotion over the internet by appointment to a physician, dentist or pharmacist, instead of making a face-to-face call? (Distant promotion)

Answer 13 – Distant promotion can be made, if the person conducting the promotion avails of the qualities of a product promotion representative and acts in line with the rules that need to be complied with in face-to-face promotion.

Question 14 – The fact that only invited persons may join the group in closed Facebook groups, that the members cannot invite another member, that the correspondence of the members about this group does not appear on their homepage, enables the protection of information and prevent it from being shared. Can we create such closed groups for a specific target audience, both internally in the company and with a closed Facebook group of physicians?

Answer 14 – Provided that they comply with the AIFD Code of Promotional Practice, closed groups and discussion groups can be opened and sponsored. Groups comprising presentations or discussions with product promotion can only include physicians, dentists and pharmacists. The sponsoring company shall be kept responsible for ensuring that the comments made by colleagues within the group remain within the boundaries of the code of promotional practice and the Regulation. It may not be possible to delete the messages written by others in environments such as Facebook and the company which has opened or sponsored the site shall be responsible for the outcomes. In case of mention of an adverse effect within a closed group that needs to be followed in terms of pharmacovigilance, the sponsor or the founding pharmaceutical company shall be responsible for submitting the reports to the relevant authorities within the timeframe designated in the provisions of the Pharmacovigilance Regulation.

Question 15 – If a company provides unconditional sponsorship to a networking site established by patient groups or physicians, and the content of the forum/site is determined completely by the patient/physician group, what would be the responsibility of the company?

Answer 15 – First of all, it is advised to sign a written and detailed contract with the association or groups that will establish such type of sites. Considering that when the idea of establishing a website is proposed by the employees of the company, probably the articles of those whom fees are paid by the company will be included into the website, the site will mostly comprise discussions on the drugs of the sponsoring company and such discussions will inevitably result in messages favoring the company, it will be understood that such type of sponsorships should be provided carefully. It is advised to clearly indicate the contribution of the sponsor and its responsibilities also in the terms of use of the website.

Question 16 - According to AIFD rules, the sponsor should be disclosed on websites intended for patients. Can the company, being not the owner but sponsor of the website, be held responsible for the information and inconsistencies of such website?

Answer: These issues should be set forth in the sponsorship agreement. When it is discovered that a website intended for patients is using a product or a therapeutic modality for competitive purposes, a warning should be issued to the website administrator/owner. Please refer to the answers given to other questions on sponsor's responsibility.

Question 17 - Is it appropriate to link to other websites?

Answer 17 - This has been addressed also in the body of the Guide. Reliability and content of linked websites should be given consideration. Care should be taken when linking to patient forums and websites for patient discussion, remembering that linking to websites unaffiliated with the company where favorable views are discussed concerning the company's products will raise questions.

Question 18 - Is it appropriate for companies to correct erroneous entries at Wikipedia, Sourtimes, or Facebook walls?

Answer 18 – Debatable policies varying between companies are applied regarding this topic. It may be acceptable to make corrective entries at above mentioned sites, or similar websites, as long as the source of the data is referenced. However, such actions may be perceived as being promotionally motivated, and be subject of complaints. Providing the Patient Information Leaflet information will be an acceptable contribution, since it is public information. The latest approach in the European Union is to make such information passively available at the company's website, rather than actively disseminating product information. Another point that needs to be taken into consideration is that when a company corrects "certain information" at a social networking site, but omits to correct other information, e.g. of competitors, such behavior may be perceived by some as promotionally motivated, and the company is responsible for all information provided (similarly, when a promotional brochure or publication disseminated by a company contains erroneous information concerning competitors and when it is possible to detect the errors in such information by checking accessible sources, AIFD Code of Practice Panel (CPP) holds the view that the company disseminating the information has responsibility, even if the information is from a peer-reviewed journal).

Question 19 – Can blogs and social networking platforms be sponsored by companies?

Answer 19 - Article [8.8] of the Code of Promotional Practice calls for the clear indication of company sponsorship in all sponsored activities and materials. This rule applies also for the internet. If a company sponsors a pharmaceutical or therapeutic website, it should ensure that the information therein complies with laws and regulations and the Code of Promotional Practice. It is not acceptable for add links, information or material about an unregistered indication of a drug of the company in a blog sponsored by that company and it may be deduced that the company is making an off-label promotion of the product or is acting as an intermediary for the dissemination of such information. By definition, everyone may contribute as they wish on blogs (and social media "walls") and express their views and proposals freely. If a blog intends the discussion of drugs or in case the therapeutic views about a drug is expected to be expressed in the blog, pharmaceutical companies are advised not to sponsor such sites as they may not guarantee the conformity of their content with the Code of Promotional Practice.

Question 20 – As a pharmaceutical company of company employee on Twitter, can we retweet the tweet posted by a newspaper abroad about a drug we promote in Turkey or whose registration is expected to be granted from our business or personal accounts?

Answer 20 - As there may be persons other than physicians, dentists and pharmacists among the followers of business or personal accounts, retweeting a tweet comprising a pharmaceutical brand or name of a molecule, regardless of who or what its sources is considered as promotion to the general public in Turkey and thus should not be retweeted.

Question 21 – If a physician requests information about a product not registered in Turkey or a yet unregistered indication in Turkey of a product registered in Turkey which he has seen, heard or read about in a foreign publication or in a congress, can we share such information with him/her?

Answer 21 – If the physician indicates his/her request in the electronic environment or in writing, the company's Scientific Service may provide in printed form or via the electronic environment the information he/she has requested. In both cases, it should be clearly indicated that such information is sent to him/her personally and that its sharing with others would violate laws and regulations as well as copyrights.

Question 22- Are companies responsibly for collecting the adverse effects indicated on the pages which belong to them or which have sponsored?

Answer 22 – Yes, the responsibilities of companies include both the collecting of information and reporting them to relevant institutions and authorities.

Question 23 – What is the path to be pursued for answering inquiries from the general public or l professionals? Can physicians submit a literature request via the internet or mobile platforms?

Answer 23 – The responses provided to the questions raised by healthcare professionals via other media may be provided also in the electronic environment upon complying with the same rules. The person providing the answer shall be responsible for conveying the answer to the person raising the question. In answers to the inquiries raised by patients, these should be provided as indicated in Articles 19.8 and 19.9 of the AIFD Code of Promotional Practice.

Question 24 – What are the binding rules for my company when I make comments in relation with the competitors of my products, even if under a nickname?

Answer 24 – AIFD Code of Promotional Practice and the Promotion Regulation clearly describe the way in which comments can be made about competing products. The responsibility of the commitment to the code of ethical promotion does not depend on the media used. The responsibility of the company remains no matter what the environment is.

Question 25 – Where can I forward misleading information on the web and acts in violation of the Code of Promotional Practice and how can I file a complaint about these?

Answer 25 – You may contact in writing and by e-mail the AIFD General Secretariat where other complaints are reported. The documents and information to be filed in all complaints are indicated in the Code of Promotional Practice.

Question 26 – If a company promotes the contents of a website solely designed for HCPs with Twitter messages, would that be in breach of the AIFD Code of Practice or the Digital Guideline which is an integral part of the AIFD Code?

Answer 26 – It is acceptable to share information using Twitter about websites designed solely for the HCPs, as long as the tweets themselves are conform to the rules of the Code. From a Twitter account, information of the name or content of new additions to the website could be shared. Tweets should direct to the entrance page of the site where the user name and password is necessary to reach the said website; it should be assured that only HCPs could login in the website. It should be remembered that all "tweets" are in public domain and that the HCPs who receive the company tweet may re-tweet them to all their followers who are not necessarily all HCPs. ABPI (UK) considers and sanctions tweets containing the tradename or active substance name as promotion to the public, as the HCP, when RT and when his followers RT, the message reach non-HCPs. Such a behavior is not compatible with AIFD Code of Practice. Please refer to the sections and related Q&A about the constraints of using Tweets and blogs in pharmaceutical industry.

Question 27 – Would the services provided from company sponsored websites be considered as gifts as defined in the Code?

Answer 27 – Medical services (such as atlases, calculators) or content (such as online journals, downloading medical textbooks) or news (such as congress proceedings, presentations) are not classified as gifts as long as they are commons, available to every HCP reaching the website. In case textbooks and periodicals are made available to every visitor upon payment of a block fee to the editor or publisher, this is not considered a gift to HCPs. However, in case the company pays an additional access fee for every HCP for reaching the editor's site, this is considered as personalized gift and not acceptable under AIFD Code of Practice.

Question 28 – Is it possible to offer a modest gift to HCPs to attract them to the company websites?

Answer 28 – AIFD members will stop providing gift items to HCPs starting 2014, in line with the relevant EFPIA guidance. Companies shall not provide "gifts" to HCPs as gifts are prohibited by the Regulation on Ethical Behaviour of Public Officials article 15 and AIFD Code of Practice. Reminder items provided to HCPs during visits until 2014 and items distributed from congress stands cannot exceed 20TL threshold. Items to be offered to those who visit a website or answer a battery of questions or re-tweet a message, etc. are not considered as reminder items as described in the AIFD Code or the Regulation.

APPENDIX V

GUIDE ON THE HARMONIZATION OF COMPANY PROCEDURES WITH THE CODE OF PROMOTIONAL PRACTICE

Articles 14 and 15 of the Regulation on the Promotional Activities for Medicinal Products for Human Use necessitate the revision of implementation methods of companies.

The titles in the following guide prepared upon considering the applicable good practices and the Regulation, should be regarded as minimum requirements and implemented as part of the rules applied within the company itself.

1) Certification of Promotional Materials

The procedures to be applied should always ensure the following:

- Promotional materials are not issued until their final form is approved in accordance with Article 11 of this Code.
- The names of company authorities responsible for approval are reported to AIFD's Secretary General.
- The approval form should comprise at the least the requirements stipulated in Article 11.
- Revision and re-approval is required for materials still in use at maximum two-year intervals or in major changes necessitating re-approval about the product.
- Certificates of approval, a sample of the material approved with such certificates, information on the target group to whom distribution is made, method of distribution, documents relating to the first date of announcement should be preserved for at least two years following the last date of use.

The certificate of approval should bear a reference code and the same reference code should appear also on the referred promotional materials, so that there can be no doubt as to what has been certified. Each reference code should relate to only one promotional material.

Different size and different layouts of a piece of promotional material should be separately certified and each should have its own unique reference code.

2) Briefing and Training Materials of Product Promotion Representatives (PPR)

The certification requirements of Article 11 of the Code, which are covered above, apply also to briefing materials prepared for product promotion representatives in accordance with Article 12. Brief materials include the training materials used to instruct medical representatives about a drug and the instructions given to them as to how the product should be promoted.

Company procedures should ensure that no such material is used or issued prior to certification.

3) Expenses of Product Promotion Representatives

There should be procedure in place for approval and payment of the costs and expenses of PPRs in meetings and hospitality and the like. A system should be in place for an internal and external audit to check the nature of the expenditure made and assess the conformity of this expenditure with the Code.

4) Training of Product Promotion Representatives

Methods applied should ensure that:

- PPRs are adequately trained in relation to every product to be promoted (Article 12).
- Uncertified product promotion representatives should not be employed in the field unless they have passed a qualification exam in the company or previously in another institution or are qualified enough not to need basic training.
- Contract representatives are only employed if they comply with the requirements of the Code and the company's own employment criteria.

Even if promotional representatives are provided with a copy of the Code, they should also be given, against signature, written instructions about the application of the Code on their work. The instructions should cover matters such as the company's policies on meetings and hospitality and the associated expenditure and the specific requirements for product promotion representatives in Article 12 of the Code. It should be made clear how reporting to the "Scientific Service" of the company is to be carried out in relation to information received about the drugs which they promote when it comes to their notice, particularly the side effects and adverse reactions (Article 12.9).

It should be made clear to product promotion representatives as to whether they can themselves write letters or documents which are related with products and may thus be considered as promotional materials and the conditions under which they are authorized to write letters as well the type of letters.

5) Training and Quality Assurance in General Terms

It should be ensured that all company personnel concerned in any way with the preparation or approval or utilization of information and promotional materials or to be provided to physicians, pharmacists or the general public are fully conversant within the requirements of the Regulation and the Code.

Appropriate arrangements should be in place for providing training to relevant personnel on the Code and requirements. It should be possible to have internal trainings or external trainings to be arranged by AIFD.

There should be a method in place to ensure the prompt announcement of amendments in the Regulation and the Code to all relevant personnel when such an amendment takes place.

6) Provision of Drugs and Samples

Internal company procedures should ensure that the requirements of Article 13 are complied with.

Article 13 of the Code requires companies to have adequate systems of control and accountability for samples and for all products and samples distributed by company's sales representatives. There should be an adequate tracking system indicating which product has been distributed at what quantity and for how long to a healthcare professional.

7) Reminder Items and Inducements

Internal procedures should ensure that Article 14 relating to gifts and inducements are complied with and that promotional items are prepared in compliance with Article 14.

8) Meetings and Hospitality

Each company should have written internal processes that set out its policies on meetings, hospitality and the associated allowable expenditure and should ensure that all meetings that it plans are verified to see that they comply with Article 15.

Conformity of the meetings to be organized outside Turkey with Articles 11 and 15 should also be approved.

9) Breaches of the Code

In the event a company is found to be in breach of the Code, internal procedures should comprise steps that enable the relevant information about it is forthwith communicated internally to relevant members of staff.

Procedures should be in place to ensure that the use of the promotional material found to be in breach of the Code is stopped immediately. Internal control methods should enable the elimination of the possibility of having the claims or conditions giving rise to the breach to appear also in other materials, and to stop them from being used if there are any.

Companies are advised to keep written records of the action taken to recall materials.

10) Co-promotion

Adequate measures should be adopted in co-promotion agreements and the like to ensure that the Code is complied with. As companies will be kept jointly responsible within the Code if they co-promote a product and promotional materials are prepared in the name of both companies, each company should certify the promotional material separately according to Article 11 (with their own code numbers).

11) Non-Promotional Materials and Activities

Internal procedures should ensure that any material or activity regarded as non-promotional in nature is thoroughly examined by an appropriate member of the staff familiar with the Code with a view to determining whether it is indeed non-promotional (Article 11).

Account should be taken of the fact that a non-promotional material can be used for promotional purposes and therefore falls under the scope of the Code.

APPENDIX VI

EXAMPLES OF BREACH OF THE CODE AND LEVELS OF SEVERITY

No.	Type of Breach of Code (Level of Severity: 1: Mild; 2: Serious 3: Severe)	Corresponding Code Article	Severity Level
1	Activity or promotional material of the company may discredit the reputation of the pharmaceutical industry; it is in violation of eight principles stipulated at the beginning of the AIFD Code	Preface; 2	3
2	Promotion material is not designed according to updated SmPCs; missing or misleading or erroneous data	4.3; 4.5	1-3
3	Promotion is initiated before issuance of registration	4.2.	3
4	Unapproved products or indications have been announced in non-permitted platforms	4.5	2-3
5	There is excessiveness in format and costs	4.7; 8.5	1-2
6	Promotional material may cause over-consumption	4.6	1-3
7	Abbreviated SmPCs not included in the material or is incomplete	5	1-2
8	Tracking code of the material is missing	5.2	1
9	Material is not legible; key information is missing; it is presented in an illegible size/form	5.2	1-2
10	Advertisement placed in periodicals is not in conformity with the Code	6.3	1-3
11	Results of in vitro or animal experiments have been presented in a misleading manner	7.3	1-2
12	Comparisons are misleading	7.3	1-3
13	Comparisons with competing products are misleading	7.3	1-3
14	Disparaging references have been made to the products of other companies, competitors evaluated incorrectly	7.13	1-3
15	References have not been interpreted correctly, comparisons are misleading, statistics are incomplete or inaccurate	7.3	1-3
16	Graphs, illustrations and tables, presenting information in a misleading manner, are used	7.9	1-3
17	Incomparable doses have been compared, resulting in claims of superiority	7.12	1-2
18	“New”, “safe”, “effective”, “unique, “only”, “exceptional” have been used improperly	7.10;7.11	1-2
19	It is not indicated whether tables and graphs have been adapted	7.9	2-3
20	Indirect product promotion is made	7.12	2-3
21	IMS data have been used in promotion	8.11	1-2
22	Medical representatives have contacted patients	12.16	3
23	Medical representatives have not been trained adequately	12.3	1-3
24	Sample distribution has violated the Code	13	2-3
25	Reminder items distributed have been designed to suit use in public places	14.3	1-2
26	Entertainment tickets have been provided to physicians	15.12	2
28	Donations are in breach of the Code	14.8	1-3
29	The duration of training is not balanced with the period of hospitality	15.8	1-2
30	Promotion is made to physicians, involving use of entertainment	15.12	2-3
31	Promotional or launch meeting have been conducted in an improper venue, facility, establishment or time	15.4	2-3
32	Meetings conducted abroad have breached the Code	15.16	2-3
33	Hospitality and events breaching the rules have been provided in the congress setting	15.4	1-3
34	Payments in breach of the Code have been made to meeting participants	15.8	2-3
35	Excessive hospitality is provided	15.12	2-3
36	Expenses of accompanying persons have been paid in breach of the Code	15.10	3
37	Hospitality is based on the volume of prescriptions or another interest	15.11	2-3
38	The Code is breached in the use of consultants	16	1-3
39	Non-interventional studies have been used for promotional purposes	18	2-3
40	Prescription drugs have been promoted to the general public via direct or hidden promotion	19	2-3
41	Pharmacy windows have been decorated with prescription drugs	19	1-2
42	Pharmaceutical promotion has been made pursuant to the press conference relating to that drug	19	1-2
43	Prescription drugs have been promoted to the general public via hot lines and the internet	19.8	2-3
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APPENDIX VII

Official Gazette of the Republic of Turkey

Issued by the General Directorate of Legislation Development and Publication of the Prime Ministry

Official Gazette Where the Regulation Has Been Published	
Date	**No.**
26/8/2011	28037
Official Gazettes Where the Regulation Amendments Have Been Published	
Date	**No.**
9/2012	28427
14/10/2012	28441

By the Ministry of Health:

REGULATION ON THE PROMOTIONAL ACTIVITIES FOR MEDICINAL PRODUCTS FOR HUMAN USE

SECTION ONE
Purpose, Scope, Basis and Definitions

Purpose
ARTICLE 1 – (1) The purpose of this Regulation is to lay down the rules to be complied with in the promotional activities of medicinal products for human use to be conducted so as to ensure their rational use.
Scope
ARTICLE 2 – (1) This Regulation encompasses promotional activities of medicinal products for human use.

Basis
ARTICLE 3 – (1) This Regulation has been prepared;
a) On the basis of Decree Law No. 663 of 11/10/2011on the Organization and Mandate of the Ministry of Health and its Affiliate Bodies **(Amended by OG of 14/10/2012, with No. 28441)** and Law No. 1262 of 14/05/1928 on Pharmaceutical and Medicinal Products, and
b) In line with European Union Directive 2001/83/EC.

Definitions
ARTICLE 4 – (1) For the purposes of this Regulation, the following terms shall apply;
a) Ministry: Ministry of Health,
b) Product/Medicinal product for human use: Any natural and/or synthetically derived active substance or combination of substances, including biological products, enteral nutritional products, medical foods, traditional herbal medicinal products and immunological products, administered to humans with a view to curing, preventing and/or diagnosing a disease, or restoring, correcting or modifying a physiological function,
c) Summary of Product Characteristics (SmPCs): A document aimed at healthcare professionals, containing minimal information on a product,
ç) Patient Information Leaflet (PIL): An instructional document which should be inserted in the product packaging to inform patients on the product,
d) Registration/Permit: A marketing authorization granted by the Ministry for a medicinal product for human use, a biological product, a vaccine, or a traditional herbal medicinal product, or a registration granted for an enteral nutritional product or medical food,
e) Registration/Permit Holder: Any real person legal entity in whose name a registration/permit has been issued by the Ministry for its products,
f) Healthcare Professionals **(Amended by OG of 14/10/2012, with No. 28441)**: Any physician, dentist, pharmacist, nurse, midwife or a member of other professions listed in Supplemental Article 13 of Law No. 1219 of 11/04/1928 on the Practice of Medicine and Branches of Medicine,
g) Promotion (Amended by OG of 14/10/2012, with No. 28441): All informative activities organized by registration/permit holders or in the name or with the name, upon the request, with the contribution or support of registration/permit holders on the medical-scientific characteristics of medicinal products for human use covered

by this Regulation, as well as the activities of product promotion representatives within this framework, advertisements published in medical or professional books or journals, announcements made through direct mailing or the press, or other means of communication, and scientific/educational activities, meetings and similar events,

ğ) Promotional Materials **(Amended by OG-14/10/2012-28441):** Any printed materials that provide sufficient and relevant information on a product such as books, booklets or leaflets, or audiovisual materials such as films, slides or those presented with storage media such as CDs/DVDs; any publications and materials that may be used as a source of information/data/reference by relevant parties; free samples; patient training programs and materials; or reminder items of modest monetary value that does not surpass 2.5% of the applicable minimum monthly wage, such as pens, pen holders or calendars,

h) Product Promotion Representative **(Amended by of 14/10/2012, with No.28441):** Any person holding a certificate of qualification who promotes products to physicians, dentists or pharmacists through direct calls.

ı) Certificate of Qualification **(Supplement by OG of 14/10/2012, with No. 28441):** A certificate issued by the Ministry to graduates of Medical Promotion and Marketing Programs at universities directly, or to anyone who successfully passes an examination given, or commissioned to be given, after Ministry-approved in-service training.

SECTION TWO

Scope and Principles of the Promotional Activities of Medicinal Products for Human Use

Scope of promotion

ARTICLE 5 – (1) Promotional activities encompass promoting of medicinal products for human use covered in this Regulation to physicians, dentists and pharmacists, and informing of other healthcare professionals on matters such as the administration and side effects of products.

(2) Promotion towards healthcare professionals occurs through:

a) Publications disseminated / sold to healthcare professionals, or through publication in medical/professional journals with a scientific content,

b) Sponsoring or holding of scientific meetings,

c) **(Amended by OG of 14/10/2012, with No. 28441)** Calls by product promotion representatives to physicians, dentists and pharmacists and to other healthcare professionals to inform them on matters such as administration or side effects of product.

(3) Any promotion of medicinal products for human use to the general public through any public media or communication channels, including the internet, is prohibited, whether directly or indirectly, or whether through placement in programs, movies, TV series, news reports or similar media. This excludes Ministry-approved advertisements placed in newspapers/journals, announcing the market launch of a product to healthcare professionals.

(4) No healthcare professional may have a role as an actor or actress in promotional activities of such products without the permission of the Ministry. Likewise, legal entities, such as associations or foundations, are prohibited from taking part in promotional activities of such products, unless permission is obtained from the Ministry

Fundamentals and principles of promotion

ARTICLE 6 – (1) Information to the general public may be provided on occasions such as vaccination campaigns and combat with epidemics which are important to safeguard public health or other campaigns run by the Ministry to promote health upon permission of the Ministry and within the confines of principles and procedures set by the Ministry for such products.

(2) Except for promotions to be conducted in international congresses held in Turkey and informative activities conducted directly by the scientific service officer of the registration/permit holder upon the written request of a healthcare professional;

a) Medicinal products for human use not registered or permitted in accordance with applicable regulations,

b) Off-label use falling outside the fields defined in the Ministry-approved SmPCs of medicinal products for human use registered or permitted in accordance with applicable regulations,

shall not be promoted to healthcare professionals.

(3) Promotion of a product should be consistent with the information and data contained in such product's current SmPCs.

(4) Promotion should incorporate informative and factual medical data on a product's characteristics that will help healthcare professionals establish their own opinion on a product's therapeutic value.

(5) Where the promotion involves using citations, tables or other visual materials from medical journals or other scientific publications, the material should be authentically reproduced, providing full reference to relevant sources.

(6) Promotion should not be made through use of misleading, exaggerated or unproven information, or alluring visuals not directly related to the product, which can lead to unexpected risks or encourage unnecessary use of a human medicinal product.

(7) Promotion may not involve sweepstakes, lottery or similar tools.

(8) No benefits, whether cash or in kind, may be provided, offered or promised during promotion of human medicinal products to physicians, dentists or pharmacists. Likewise, the aforesaid healthcare professionals are prohibited from accepting or requesting any inducement during the course of such promotional activities aimed at them.

(9) Healthcare professionals should disclose any sponsorship received from registration/permit holders:
a) At the end of every article they author,
b) At the beginning of every speech/presentation they deliver.

(10) Registration/permit holders may donate to healthcare institutions or organizations, if the following conditions are met:
a) Prior permission is received from the administrative authority supervising the recipient organization, institution or family health center,
b) Tender award decisions for products covered in this Regulation are not influenced by the donation,
c) The donation does not lead to any unethical conduct which may be associated with product purchase,
ç) The donation does not encourage prescribing a specific human medicinal product,
d) The underlying intention is to promote either of research, training, patient wellbeing or care provided to patients,
e) The donation will be utilized by not any individual person, but the entire organization or institution,
f) Only the name of the registration/permit holder, and not of the product, may appear on the donated materials,
g) The donation is entered in the official books of the registration/permit holder,
ğ) Any donation of medicinal products, laboratory kits or similar items for use in clinical research is made directly to the principal investigator.

Scientific and Educational Activities

ARTICLE 7 – (1) **(Amended by OG of 14/10/2012, with No. 28441)** No scientific or educational activities related to promotion of a human medicinal product shall be used for any purpose other than communicating existing medical data and/or presenting new information. Registration/permit holders may not cover, whether directly or indirectly, transportation or accommodation expenses of participants taking part in these activities.

(2) Registration/permit holders may sponsor healthcare professionals for participating in scientific meetings such as congresses or symposia taking place in or outside the country on the following conditions:
a) **(Amended by OG of 14/10/2012, with No. 28441)** The meeting should be related to the area of specialty/role of the healthcare professional.
b) **(Amended by OG of 14/10/2012, with No. 28441)** A healthcare professional may benefit from the sponsorship of companies for three times in total within the same calendar year; not more than two of such sponsorships may be provided by the same registration/permit holder; only one of such three sponsorships may be used for a meeting abroad. This excludes meetings which healthcare professionals are attending as speaker, or as an investigator presenting a paper, sponsored by a marketing registration/permit holder.
c) Sponsorship will be provided to the organization holding the meeting, and not directly to individual participants.

(3) Registration/permit holders are obligated to notify the Ministry of particulars of sponsored healthcare professionals according to the Guidelines that will be subsequently issued to regulate these issues. The Ministry will collect this information in a database.

(4) Meetings of investigators, sponsored by the registration/permit holder, held in Turkey or abroad in connection with a national or international multicenter clinical trial, will not be considered attendance to a congress or symposium. Any application submitted to the Ministry for such meetings will include a clear description of the meeting's nature and it will be indicated that the meeting being held is for the aforesaid purpose.

(5) Except international meetings that are held each time in a different country, no meeting can be held or sponsored by registration/permit holders at seaside resorts or skiing resorts during the high season. The high season periods will be announced on the Ministry's website.

(6) Non-healthcare professionals may not be invited to the meetings, nor may their expenses be covered; however, guests of honor are excluded from this provision.

(7) **(Amended by OG of 14/10/2012, with No. 28441)** At least 60% of all meetings lasting more than 6 hours, organized or contributed to by registration/permit holders within a calendar year, will include a session on the rational use of drugs, relevant to the topic of the meeting. The content of presentations given during such sessions will be aligned with Ministry-approved educational materials and diagnostic and therapeutic guidelines, and submitted to the Ministry for review, as described in the guidelines.

(8) Persons appointed by the Ministry may, with or without prior notice, attend these meeting for inspection purposes.

Promotional Materials

ARTICLE 8 – (1) Promotional materials shall comprise materials and tools that are compliant with this Regulation.

(2) **(Amended by OG of 14/10/2012, with No. 28441)** The monetary value of reminder items used for calls may not exceed 2.5% of the applicable monthly gross minimum wage.

(3) Administrative supervisors will take the necessary precautions at health institutions to ensure that promotional materials are not exhibited where they can be seen by patients.

Free Samples

ARTICLE 9 – (1) Free samples may distributed only to physicians, dentists or pharmacists, to the extent) **(Amended by OG of 14/10/2012, with No. 28441)** that the following conditions are fulfilled:

a) Registration/permit holders shall set up and appoint qualified persons for an adequate system of records and control, for the production, importation and distribution of free promotional samples. Upon demand, these records shall be submitted to Ministry officials in the format – electronic or hardcopy – determined by the Ministry.

b) Free samples contain a quantity reduced in size. However, this requirement shall not be applied to enteral nutritional products and promotional samples of products which, for technical reasons, cannot be reduced.

c) The statement, "Free promotional sample – not for sale," will discernibly appear on the outer packaging of promotional samples on at least one surface. The same statement shall be printed also on the inner package, where this is possible.

ç) A copy of the SmPCs and the PIL, where available, shall be provided with the promotional sample.

d) Samples may not be provided or distributed of products containing psychotropic or narcotic substances, covered under the Single Convention on Narcotic Drugs of 1961 and the Convention on Psychotropic Substances of 1971.

e) In principle, there shall be no barcode/datamatrix on the packaging of promotional samples. If their inclusion is mandatory, permission will be requested from the Ministry, offering sufficient justification, and their sale shall be blocked in the Ministry's Drug Tracking System. Registration/marketing holders shall establish a system to enable safe withdrawal of free samples where necessary.

f) (Amended by OG of 14/10/2012, with No. 28441) Free samples of medicinal products for human use may be distributed up to 5% of the total annual sales upon monitoring the monthly sales in the first calendar year as of the introduction date, and in the second calendar year up to 5% of total annual sales generated the preceding year, and in the third, fourth and fifth calendar years up to 3% of total sales generated the preceding year, and after the fifth calendar year, up to 1% of total sales generated the preceding year.

g) Promotional samples may not be used as an investigational product during a clinical trial.

SECTION THREE
Product Promotion Representatives
Product Promotion Representatives

ARTICLE 10 – (1) A product promotion representative:

a) Should be equipped with full and adequate scientific data and knowledge necessary on the products promoted.

b) Should be provided with basic and essential Ministry-approved in-service training, either directly by their employer or through outsourcing by their employer, which will cover legal and ethical aspects of this service, and hold a qualification certificate issued by the Ministry. Qualification certificates shall be valid through the end of the fourth calendar year and product promotion representatives should renew their certification before expiry. Qualification certificates issued to graduates of universities' "Medical Promotion and Marketing Programs" need not renew their certification under this provision.

c) Persons holding at least a high school degree who were employed as a product promotion representative after 01/01/2015, are eligible to apply for a qualification certificate by presenting documentation of their having successfully passed an examination to be held for this purpose.

ç) For university graduates holding a "Medical Promotion and Marketing" degree, a qualification certificate shall be issued upon submission of their diploma, without further examination.

d) These persons will be registered in the Ministry's electronic registration database by their employer. Product promotion representatives holding a qualification certificate and registered in the system will be issued a Product Promotion Representative Identification Card by their employer, in a format prescribed by the Ministry.

e) Persons lacking a Product Promotion Representative Identification Card may not be hired by companies as a product promotion representative.

f) Companies should notify the Ministry within twenty days after a Product Promotion Representative stops working for them for any reason.

g) May serve more than one registration/permit holders. The responsibility rests with the registration/permit holder, reserving any corporate contractual rights of registration/permit holders.

ğ) May not promote any product or analogues to any healthcare professional, other than a physician, dentist or pharmacist; they may, however, provide healthcare professionals other than physicians, dentists and pharmacists with information on matters involving the administration or side effects of a product, subject to knowledge and permission of the relevant unit supervisor/physician-in-charge.

h) Should communicate promotional information to physicians, dentists or pharmacists, giving any favorable and unfavorable data that should be known about the product in a complete and accurate manner, when necessary, using promotional aids.

ı) Forward any adverse events/reactions, reported to them during product promotion, to the relevant scientific function in their companies.

i) Should not give product promotional materials to anyone other than a physician, dentist or pharmacist.

(2) Registration/permit holders and product promotion representatives are jointly responsible for the promotional activities carried out by product promotion representatives.

(3) Product promotion representatives may promote human medicinal products at public health institutions during working hours subject to the following rules:

a) At the beginning of a call, the product promotion representative will show his/her her product promotion representative identification card and disclose which marketing registration holder he/she is representing.

b) Relevant administrative supervisors at every public health institution will designate the most suitable time period to enable meetings between product promotion representatives and healthcare professionals for product promotion, taking account of the work schedules. Such designation should not disrupt educational functions or provision of health services to patients.

c) Product promotion is prohibited at emergency rooms or at outpatient clinics during patient-seeing hours.

(4) Product promotion representatives visiting healthcare institutions to perform their promotional functions may not be charged any fee, pecuniary or otherwise, under any designation whatsoever (e.g., donations or others) for gaining access to the institution.

(5) No poster or similar promotional material, which may be perceived as promoting a product, may be exhibited, placed, posted and/or affixed at state-owned healthcare institutions. However, this excludes posters and similar promotional materials used for purposes of campaigns run by the Ministry to promote health, including vaccination campaigns, outbreak alerts and anti-smoking or anti-obesity campaigns.

SECTION FOUR
Responsibility of Registration/Permit Holders
Responsibility of Registration/Permit Holders

ARTICLE 11 – (1) Registration/permit holders shall internally establish a scientific function, responsible for managing information pertinent to their marketed products, to operate according to the below guidelines, led by a qualified person who will be in charge of the operation.

(2) If a registration/permit holder wishes to announce the launch of a product to healthcare professionals through a press release, a genuine copy of the announcement will be sent to the Ministry for approval. A press release may be published only once. The size of a press release published in a newspaper may not exceed 1/8 of a full page. This activity will not be considered as promotion of a medicinal product for human use.

(3) **(Amended by OG of 14/10/2012, with No. 28441)** Congresses, symposia, seminars and similar meetings which a registration/permit holder intends to hold or partially sponsor will be submitted to the Ministry; and at least fifteen working days before each meeting, the content, a list of potential participants, projected expense items and the events should be notified to the Ministry. A response will be given to the applicant within ten working days after a submission is officially received, or the request will be deemed approved if no response is given.

(4) Following the completion of a sponsored meeting, the registration/permit holder will submit to the Ministry latest within one month, digitally and in the prescribed format, a list of participants, expense items and the activities conducted; the registration/permit holder concerned should retain examples of information and documents provided to participants for a period of two years, to be submitted to the Ministry upon request.

(5) Registration/permit holders are obligated to:

a) Ensure that promotion of the products for which they hold a registration/permit is in line with the requirements prescribed in this Regulation,

b) Submit any information and document required by the Ministry, pertinent to promotional activities,

c) Retain for two years a copy each of all the promotional materials used, to submit them to the Ministry upon request,

ç) Ensure that any decisions adopted by the Ministry with respect to promotion of products are fully implemented.

SECTION FIVE
Miscellaneous and Final Provisions
Inspections

ARTICLE 12 – (1) The Ministry will inspect, ex officio or upon receipt of a complaint, the promotional activities and any materials and methods employed during such activities. The Ministry will require the registration/permit holder to cease, terminate or correct the information provided during promotion which are found to be noncompliant with the guidelines in this Regulation or deemed inappropriate for public health. Any request by the Ministry to that effect should be complied with without delay.

Administrative sanctions

ARTICLE 13 – (1) Whoever acts or operates in violation of the provisions in this Regulation shall be subjected to, depending on the nature of the violation, the applicable provisions of Turkish Penal Code No. 5237 of 26/09/2004, Law No. 4077 of 23/02/1995 on Protection of Consumers, Law No. 4054 of 07/12/1994 on Protection of Competition, Law No. 6112 of 15/02/2011 on the Establishment of Radio and Television Enterprises and Their Broadcasts, and other applicable regulatory provisions. Disciplinary action shall be brought against healthcare professionals by their institutions and professional organizations.

(2) In the event of a breach of any provision made in Article 7, the registration/permit holder will be issued a warning by the Ministry, and in the event of a recurring breach, banned for one year from taking part in or supporting any congress or symposium activity.

(3) **(Amended by OG of 14/10/2012, with No. 28441)** In the event a human medicinal product is promoted in a manner that breaches this Regulation, the registration/permit holder will be issued a warning, and in the event of recurrence, banned from engaging in promotional activities for three months. If the breach continues, promotional activities of the registration/permit holder will be suspended for one year.

(4) **(Amended by OG of 14/10/2012, with No. 28441)** In the event of a promotional breach by a product promotion representative during the validity term of his/her Ministry-issued qualification certificate, such product promotion representative will be first issued a warning by the Ministry; the first repeat-breach will result in a 3-month suspension, and any subsequent breaches, a 1-year suspension of the qualification certificate. Product promotion representatives whose qualification certification is thereby suspended may not serve in this capacity for the duration of said timeframe and should turn in their Product Promotion Representative Identification Card to their employer.

Guidelines

ARTICLE 14 – (1) The Ministry shall issue relevant guidelines to provide guidance on the implementation of this Regulation.

Repealed Regulation

ARTICLE 15 – (1) The Regulation on the Promotional Activities for Medicinal Products for Human Use, published in Official Gazette No. 25268 of 23/10/2003, is herewith repealed.

Enforcement schedule

PROVISION ARTICLE 1 – (Supplement by OG of 14/10/2012, with No. 28441)

(1) The time schedule and principles and procedures governing enforcement of Article 10 shall be prepared by the Ministry and posted on the Ministry's official website by 30/06/2013**.**

Entry into force

ARTICLE 16 – (Amended by OG of 14/10/2012, with No. 28441)

(1) In this Regulation:

a) Article 7, paragraph 2, subparagraph (b) will enter into force on 01/01/2013 and paragraph 3 on 01/01/2012;

b) Article 9, paragraph 1, subparagraph (e) and (f) will enter into force on 01/01/2013;

c) Article 10, paragraph 1, subparagraphs (b), (e) and (f) and paragraph 3, subparagraph (a) will enter into force on 01/01/2015;

ç) All other provisions will enter into force on 31/12/2011.

Enforcement

ARTICLE 17 – (Amended by OG of 14/10/2012, with No. 28441)

(1) These Regulatory provisions shall be enforced by the Chairman of the Medicines and Medical Devices Agency of Turkey.

APPENDIX VIII

LAW ON PHARMACEUTICAL AND MEDICINAL PREPARATIONS

Law No. 1262 **Date of Enactment:** 14/05/1928

Date published in the Official Gazette: 26/05/1928 **No. of Official Gazette where it was published:** 898

Published in the Official Gazette No: 898

Article 1 – A pharmaceutical and medicinal preparation is any simple or formulized curative preparation commercialized under the manufacturer's name or under a private name in a fixed form compliant with scientific rules, except in a form and formulation described in the codex.

Those whose dispensation is conditional on a physician's prescription will be dispensed on prescription and others without a prescription, exclusively at pharmacies and pharmaceutical enterprises in line with the applicable law. **(Final sentence repealed: 23/02/1994 – Law No. 3977/Art. 4)**

Article 2 - (Amended: 04/01/1943 – Law No. 4348/Art. 1)

A) Curative soaps and medical foods not containing chemical substances and (…) which are not classified as a drug and toilet supplies not containing potent or toxic substances are not considered a medicinal preparation.

B) The preparations listed below are not subject to the mandatory permission which should be obtained according to the third article of this law:

I – Parenteral liquids and vaccines and similar protective and therapeutic substances which are not mixed with other substances or manufactured under a private name;

II – Extracts, amboceptors and similar substances for vital practices;

III – Simple tablets, vials, liquids and extracts and similar galenic preparations whose forms have been described in the codex which are unfit for direct sale to the general public and which are manufactured under a private name or under common chemical name of its active ingredient without reference to the manufacturer's name;

IV – Generics which bear only the chemical name of preparations registered under a private name.

The Ministry of Health has mandate to restrict or forbid import of all or some of the substances described in Paragraph B, Subparagraph I, and to set and supervise compliance with the qualities and conditions of those which will be imported from third countries. Such substances which, although banned, are detected to have been imported into Turkey or manufactured contrary to Article 95 of the Public Health Law, will be confiscated and destroyed by the Ministry of Health. Those who import such substances without registration will be prosecuted according to general provisions.

Substances listed in Subparagraph III of the same paragraph should have been manufactured at a laboratory of medicinal preparations holding a valid registration issued by the Ministry of Health according to Article 26 of the Law on Pharmacists and Pharmacies. Sale of such preparations to any party other than a pharmacy or a pharmaceutical wholesaler is prohibited.

Article 3 – Permission from the Ministry of Health should be obtained before commercializing pharmaceutical or medicinal preparations manufactured locally, or before importing those manufactured abroad.

Article 4 – Official permission of the Ministry of Health should be obtained also for importing chemical or medicinal substances containing a single chemical substance which, although not included in the codex, lacks the qualities of a pharmaceutical or medicinal preparation described in the first article herein and are re-commercialized by industrial chemical manufacturers for use in the treatment of disease.

Article 5 - (Amended: 08/02/1954 – Law No. 6243/Art. 1)

The authorization to manufacture pharmaceutical or medicinal substances or preparations and to open laboratories or factories in Turkey for that purpose rests with real persons or legal entities employing a qualified person who is a Turkish physician, pharmacist or chemist, or for substances and preparations falling within their area of expertise, a Turkish veterinarian or dental practitioner.

Pharmaceutical and medicinal preparations and substances should be manufactured at laboratories or factories which meet all scientific requirements and are equipped with adequate facilities.

Laboratories and factories of pharmaceutical and medicinal preparations and substances are subject to inspection by the Ministry of Health.

Article 6 - (Amended: 04/01/1943 – Law No. 4348/Art. 1)

To obtain permission for manufacturing preparations in line with the conditions prescribed in Article 5 above, an official application should be made with the Ministry of Health. Such application should be enclosed with five samples each from the preparations concerned, a certified formulation describing the composition of the preparation with a clear indication of the types and quantities of its constituents and the container closure making up the preparation's packaging, together with a description, samples and mockups, including an indication of the wholesale and retail selling price of the preparation.

Article 7 - (Amended: 04/01/1943 – Law No. 4348/Art. 1)

After examining and analyzing the official application and samples mentioned in Article 6 above, the Ministry of Health shall, if the following conditions are met, initiate the procedure for granting permission:

A) Applicant has the competencies set forth in this Law;

B) There is public interest in commercializing the proposed formulation in a preparation form;

C) There is no health concern associated with using the preparation;

D) The preparation is manufactured using appropriate craftsmanship, and is not disposed to degradation after extended storage;

E) The preparation has been shown by examinations and analyses to be compliant with the proposed formulation and to posses the claimed curative properties;

F) The preparation has an acceptable price and name.

The Ministry will determine and specify on the registration certificate whether the preparation's use is subject to a physician's prescription. Names of preparations granted manufacturing permission according to this Law will be published in the Official Gazette. The cost of analyses and the registration fee will be covered by the applicant.

The Ministry of Health may, taking account of market conditions, require adjustment of the prices of preparations.

Article 8 - (Amended: 04/01/1943 – Law No. 4348/Art. 1)

Requests for permission to import a medicinal preparation manufactured in a foreign country will be granted only when the applicant making the request is the owner of a pharmacy or pharmaceutical enterprise authorized to practice in Turkey, or representatives of factories or laboratories manufacturing such preparations, who reside in Turkey. Like preparations manufactured locally, an official application should be made with the Ministry of Health to obtain permission for such preparations.

The application should be enclosed with information on the preparation's manufacturing site, formulas, description of manufacturing process and an authenticated copy of the certificate of permission, if sale of the preparation is permitted in the country of origin – whether on prescription or otherwise. All documents should be legalized by a Turkish Consulate, and the submission should be attached with five samples. Cost of analyses and the registration fee will be borne by the applicant. The application herein will be processed according to the procedure described in Article 7 above, and preparations permitted will be imported through customs and their names published in the Official Gazette.

Where the representative of a medicinal preparation factory or laboratory is not a pharmacist or the owner of a pharmaceutical enterprise duly authorized according to the applicable law, such persons may not maintain a stock of preparations of factories or laboratories they represent in a quantity greater than that which is appropriate to exhibit or distribute them for use as a sample. Those who wish to maintain a larger stock should employ a pharmacist as qualified person according to applicable provisions of Law No. 984 on pharmaceutical enterprises.

Article 9 - (Amended: 04/01/1943 – Law No. 4348/Art. 1)

The procedure for processing applications submitted for a preparation to be manufactured locally or imported from a third country will be completed by the Ministry of Health within two months of their receipt and a response given to the applicant, to the extent that such timeframe may be extended as necessary for performing scientific analyses on the preparation, or for verifying its curative claims.

Article 10 – The responsibility to ensure purity and formulary compliance of preparations commercialized after obtaining authorization rests with their manufacturers and owners and for imported preparations their representatives who submitted the application for an import license. The Ministry of Health, where necessary, maintains ongoing oversight of such preparations by analyzing samples removed randomly, settling the cost of samples.

Article 11 – Any changes in a preparation's composition or its physical form, manufacturing process or name are subject to approval and permission of the Ministry of Health.

Article 12 - (Amended: 04/01/1943 – Law No. 4348/Art. 1)

The registration holder's name, the name and address of the laboratory where the preparation has been manufactured, registration number, instructions on the use of the preparation and its price should be clearly specified in Turkish on the preparation's outer packaging and a discernible warning and statement should be placed thereon, specifying the type and quantity of potent or toxic materials, if any, that the preparation contains, together with the date of manufacture where deemed necessary by the Ministry. Also, whether the preparation is prescription only should be clearly stated.

Article 13 - (Amended: 04/01/1943 – Law No. 4348/Art. 1)

Use of advertising through cinema films, signs, illuminated or otherwise, radio or any other media, praising a medicinal preparation and attributing them curative properties which they lack or exaggerating their existing properties is prohibited, to the extent that advertising messages such as "useful against X disease" in patient instructions and newspapers may be permissible. However, prescription only drugs may not be advertised anywhere except in medical journals. Mockups of advertising should be approved in advance by the Ministry of Health.

Films on scientific properties of a medicinal preparation may be shown upon Ministry of Health approval at Ministry-approved locations.

Article 14 – The Ministry of Health may permit by manufacturers and owners without submitting an application importing of cures which, although not included in the codex and lacking the characteristics of a medicinal preparation, have benefits that are commonly recognized in the medical community, and vital preparations and chemicals used in scientific research whose import is deemed beneficial.

Article 15 – The analysis fee and the registration fee mentioned in article seven and eight above are twenty five liras each. The analysis fee is prepaid at application, and the registration fee at issuance of the authorization certificate.

Article 16 - (Repealed: 25/05/1938 – Law No. 3402/Art. 1)

Article 17 - (Repealed: 25/05/1938 - Law No. 3402/Art. 2)

Article 18 - (Amended: 04/01/1943 – Law No. 4348/ Art. 1; Amended: 23/01/2008-Law No. 5728/Art. 42)

If, after analyses described in article 10 above, it is detected that the preparation's constituents are not pure or are incompliant with the approved formulation or the preparation has been manufactured in a manner to derogate from or eliminate its curative properties, and if such act does not constitute a criminal offense, the registration holder and whoever sells, supplies or causes selling of the preparation knowing that it was manufactured in such state will be fined not less than one thousand Turkish Liras and not more than twenty five thousand Turkish Liras, and the preparation's registration will be revoked.

Article 19 - (Amended: 04/01/1943 – Law No. 4348/Art. 1; Amended: 23/01/2008- Law No. 5728/Art. 43)

Whoever manufactures a medicinal preparation without registration or knowingly sells, supplies or causes selling of such preparations will be fined not less than five hundred Turkish Liras and not more than ten thousand Turkish Liras if they are registered to manufacture medicinal preparations, or not less than fifteen hundred Turkish Liras and not more than twenty thousand Turkish Liras if they lack register to manufacture

medicinal preparations. If it is detected that such preparations lack the curative properties attributed to them or are found to have been manufactured using impure ingredients which reduce or negate their properties, the penalty described in Article 18 is applied.

Importing medicinal preparations of foreign manufacture without registration for commercial purposes or knowingly selling, supplying or causing selling of such preparations is considered smuggling. Whoever commits the offense described in this paragraph will be prosecuted according to the Anti-Contraband Law.

Article 20- (Amended: 23/01/2008-Law No. 5728/Art. 44)

Whoever violates this Law, except circumstances described in Article 18 and 19 above, will be fined two hundred and fifty Turkish Liras.

The decision on the administrative fines and other regulatory sanctions laid down in this Law rests with the local authority.

Article 21 – The implementation procedure of this Law will be laid down in a regulation.

Article 22 – This Law enters into force on the date it is published. However, for preparations currently holding a manufacturing or import license from the Ministry of Health may continue to be manufactured and imported for six months as before, on the condition that an application for re-registration should be made within three months. Also, Articles 16, 17, 18, and 19 herein will enter into force six months after publication hereof. The quantity of preparations currently available in the country will be determined on the basis of individual representatives and documented on a list by the Ministry of Health, which will provide basis for permitting their sale in Turkey for six more months, after assessing a tax on them.

Article 23 – This Law will be enforced by the Ministry of Justice, Ministry of Finance, and Ministry of Health.

Supplemental Article 1 – The registration certificate granted will be void when the manufacturer or qualified person of a locally manufactured preparation or Turkish representative of a preparation manufactured abroad and imported into Turkey dies. If inheritors of a local manufacturer or qualified persons are competent to manufacture medicinal preparations, a new registration may be issued directly to their name, or if they lack such competency, to the name of a qualified person employed by them who is competent for such undertaking. New representatives appointed by foreign factories or laboratories are also subject to the same requirements. In either case, the preparations will be exempted from re-analysis and the analysis fee, if no change has been made in its formulation.

(Repealed: 11/06/2010 – Law No. 5996/Art. 47)

(Repealed: 11/06/2010 – Law No. 5996/Art. 47)

Supplemental Article 4- (Amended: 23/01/2008-Law No. 5728/Art. 45)

Whoever counterfeits medicinal preparations, manufacturing them in a manner that reduces or negates their curative properties and causing small or great harm to users of such preparations, and whoever knowingly sells, supplies or causes selling of such preparations will be punished according to the Turkish Penal Code and other applicable legislation.

Supplemental Article 5 - (Repealed: 23/01/2008-Law No. 5728/Art. 578)

Supplemental Article 6- (Amended: 23/01/2008-Law No. 5728/Art. 46)

Preparations becoming the subject of misdemeanor acts described in Articles 18 and 19 of this Law will be confiscated, and the title thereon will pass to the State.

Supplemental Article 7 – The Ministry of Health may permit import of unregistered preparations for purposes of analyses or experimentation or named patient use, and preparations imported in the name of public charity organizations or official institutions in a quantity up to that which is acceptable to the Ministry of Health, on the condition that such preparations are not re-commercialized.

APPENDIX IX

SUPPLEMENTAL ARTICLE 13 TO LAW NO. 1219 OF 11/04/1928

ON THE PRACTICE OF MEDICINE AND BRANCHES OF MEDICINE

Supplemental Article 13 - (Supplemental Article: 06/04/2011-Law No. 6225, Art. 9)

a) **Clinical psychologist**: A healthcare professional who holds a master's degree in psychology covering practice in a clinical setting over a bachelor's degree in psychology or psychological counseling and guidance, or a doctoral degree in psychology plus a master's degree in clinical psychology over a bachelor's degree in other programs. ...

b) **Physiotherapist:** A healthcare professional who holds a degree in physiotherapy from a college or school offering bachelor's degree programs. …

c) **Audiologist:** A healthcare professional holding a bachelor's degree in audiology from a college or school or holding a master's or a doctoral degree in audiology over a bachelor's degree in another field, who works in the field of hearing and balance control and to prevent hearing disorders in healthy individuals and identifies, rehabilitates and determines the devices used for correcting hearing and balance disorders in line with the diagnosis and therapeutic instructions of the specialist physician concerned.

ç) **Dietitian**: A healthcare professional holding a bachelor's degree in nutrition and dietetics from a college or school offering such programs, who determines healthy nutrition programs for healthy individuals, regulates nutrition programs for patients as instructed by a physician, develops nutrition programs for places where people eat in large groups, and ensures safety of foods.

d) **Speech and language therapist:** A healthcare professional holding a bachelor's degree in speech and language therapy from a college or school offering such programs, or a master's or a doctoral degree in speech and language therapy over a bachelor's degree in another branch, who works to prevent voice, speech and language dysfunction in individuals, and provides rehabilitation of swallowing, language and speech disorders diagnosed by a specialist physician.

e) Podologist**:** A health technician holding a degree in podology from a vocational college, who serves to protect and care for individuals' foot health, and performs foot therapy in line with diagnosis and instructions of the specialty physician concerned.

f) **Health physicist:** A healthcare professional holding a master's degree in radiotherapy physics, physics of diagnostic radiology or physics of nuclear medicine, over a degree in physics, physical engineering or nuclear power engineering, who – under the supervision or instructions of the specialist physician concerned – is responsible for use, application and purification of sources of ionizing radiation and radio isotope substances during and after diagnosis, imaging or therapy procedures, as applicable, performed using irradiation.

g) Anesthesia operator/technician: A health operator/technician holding a degree in anesthesia from a vocational high school or a vocational collage, who ensures safe initiation, execution and termination of anesthesia procedures under the instructions and responsibility of an anesthesiology and reanimation specialist.

ğ) Medical laboratory and pathology technician: A health technician holding a degree in medical laboratory and pathology procedures from a vocational college, who makes the preparations before medical analysis and performs medical testing of samples and blood center procedures using laboratory tools and devices to understand an individual's health condition or cause of death.

Medical laboratory technician: A health technician holding a degree in medical laboratory procedures from a vocational high school for health, who makes the preparations before medical analysis and performs medical testing of samples and blood center procedures using laboratory tools and devices.

h) Medical imaging operator/technician: A health technician/operator holding a degree in medical imaging procedures from a vocational high school for health or a vocational college, who obtains and develops images using medical imaging techniques.

ı) Oral and dental health technician: A health technician holding a degree in oral and dental health from a vocational college, who assists a dental practitioner during examination of patients, and prepares and maintains therapy materials in a ready-to-use state.

i) Dental prosthesis technician: A health technician holding a degree in dental prosthesis procedures from a vocational college, who constructs and repairs a jaw or facial prosthesis or orthodontic devices based on measurements taken by a dental practitioner.

j) Medical prosthesis and orthosis operator/technician: A health technician/operator holding a degree in medical prosthesis and orthosis procedures from a vocational high school for health or a vocational college, who designs, prepares for use, repairs and applies to patients under supervision of a specialist physician assistive devices and tools to be applied to parts of the body which need supporting, protecting or correcting with artificial organs that perform – albeit partially – the function of lost organs.

k) Operating room technician: A health technician holding a degree in operating room procedures from a vocational college, who supports the surgical team and performs the procedures and processes to prepare tools and instruments used in the operating room ready for surgery, provide the surgical team with the necessary materials, and ensure the environment of the operating room is optimal for the intended type of surgery.

l) Coroner technician: A health technician holding a degree in forensic medicine from a vocational college, who assists the coroner during forensic examination, removal of samples from the human body, autopsy and writing of a forensic examination report.

m) Audiometric technician: A health technician holding a degree in audiometry from a vocational college, who performs tests using appropriate equipment on patients whose indications have been defined.

n) Dialysis technician: A health technician holding a degree in dialysis procedures from a vocational college, who performs dialysis procedures on patients under the instruction of a physician.

o) Physiotherapy technician: A health technician holding a degree in physiotherapy from a vocational college, who assists physical therapy and exercise procedures under supervision of a physical medicine and rehabilitation specialist or physiotherapist.

ö) **Perfusionist:** A healthcare professional holding a bachelor's degree in perfusion from a college or school, or a master's degree in perfusion over a bachelor's degree in another branch, who operates the heart-lung machine to manage external blood circulation under supervision of the specialist physician during operations in the heart and/or major arteries.

p) Radiotherapy technician: A health technician holding a degree in radiotherapy from a vocational college, who administers the patient with the radiation therapy program prepared by a physician.

r) Pharmacy technician: A health technician holding a degree in pharmacy services from a vocational college, who supports pharmacy procedures and fills prescriptions under pharmacist supervision.

s) **Occupational therapist (Ergotherapist):** A healthcare professional holding a bachelor's degree in occupational therapy from a college or school, who plans and implements protective and rehabilitative programs relating to his or her profession by performing appropriate tests and measurements in healthy individuals; in ill persons the ergotherapist applies appropriate occupational therapy procedures – in line with the specialist physician's diagnosis – to improve patients' involvement in daily life, work, productivity and leisure activities, and to improve their health condition, prevent incapacitation, and enhance involvement by managing the environment.

ş) Occupational therapy technician (Ergotherapy technician): A health technician holding a degree in occupational therapy from a vocational college, who, in line with the specialist physician's therapy plan, applies the occupational therapy program under supervision of a specialist physician or ergotherapist.

t) Electroneurophysiology technician: A health technician holding a degree in electroneurophysiology from a vocational college, who operates under supervision of a specialist physician and assists him or her in the use of electroneurophysiological methods.

u) Mammography technician: A health technician holding a degree in mammography technology from a vocational college, who, when necessary, performs mammography and examines mammograms for positive or negative results for cancer, making them ready for assessment to support decision making of the radiologist.

No healthcare professional other than a physician or a dental practitioner may directly diagnose a disease, or plan and prescribe therapy for treatment. Job and duty details of healthcare professionals, and work conditions, jobs, and job descriptions of other healthcare professionals having a role in health services, and principles and procedures governing certified training, will be set forth in a regulation to be issued by the Ministry of Health.

The scope, definition, conditions and execution principles and procedures of traditional/complementary therapeutic procedures used in human beings will be set forth in a regulation to be issued by the Ministry of Health, provided said procedures may only be administered by or under supervision of a physician.

APPENDIX X

TURKISH MEDICAL ASSOCIATION'S DECLARATION ON PHYSICIAN-PHARMACEUTICAL INDUSTRY INTERACTIONS

Adopted during the "Ethical Declarations Workshop of the Turkish Medical Association", April 4-5, 2008, Ankara
Updated during the "2nd Ethical Declarations Workshop of the Turkish Medical Association", June 20, 2009, Ankara

It is recognized that ensuring physician-industry (pharmaceutical and medical technology) interactions occur in an ethical premise benefits robust development of health services and is particularly beneficial to promoting rational use of drugs. Due to its commercial aspects, however, physician-industry interactions may involve certain objectionable elements with potential untoward implications for good medical practice. Evidence-based medical practice should set the confines in which indications and limits of good medical practice are defined. Any behavior or obligation containing an element of "reciprocity" between physician and industry representatives should be strictly avoided. Prescribing patterns of physicians and their diagnostic/therapeutic practices should be guided by current scientific data, and physicians should follow the guidelines for rational use of drugs and good medical practice.

Meticulous scientific and ethical norms should be set for industry contributions to training and educational activities conducted in the context of continuing medical education (CME) and continuing professional development (CPD). Transparency and absence of any conflict of interest and full disclosure are essential characteristics of any interaction between physicians and the industry. To provide a robust framework in which to conduct physician-industry relations, a financing model needs to be developed for covering cost of participation in CME/CPD activities from public resources.

Turkish Medical Association has set the following core guidelines which all physicians should follow in their interactions with the industry: *[NB: Numbering not included in the original text.]*

i. During CME/CPD activities, awareness of the drawbacks inherent in interactions with industry representatives should be raised among physicians, both during and after medical school.
ii. Adequate and continual information should be provided to physicians on the guidelines for rational use of drugs and appropriate use of technology.
iii. Availability of independent sources should be ensured for scientific research.
iv. Promotional activities should be designed to contribute favorably to physicians' education and the care provided to patients and conducted openly, without any elements which may potentially give rise to a feeling of obligation on the part of physician toward the industry and their representative.
v. Use of institutional intermediaries should be encouraged for industry sponsorship to support scientific/educational activities.
vi. Industry sponsorship of scientific or educational activities should be transparent, and it should be clearly stated that the sponsorship has been provided without expecting anything in return.
vii. Such contributions should be routed through and supervised by non-profit entities, such as professional societies, specialty associations, or relevant academic segments. Transparency at all stages is essential. Strong emphasis should be placed on ethical responsibilities of the intermediary.
viii. Promotional materials, invitations to a scientific meeting and any associated accommodation acceptable to physicians should be of an educational character, have scientific functionality, and bear relevance to the practice, and their value should not exceed reasonable limits. Physicians should never permit provision, proposal or implication of any contribution of equipment or pecuniary benefit to them during promotion. Physicians should reject and never request any inducement or gift contrary to above provisions.
ix. No studies – including those for theses – should be conducted with solely commercial intentions which serve no scientific purpose and which are intended to direct physicians toward using a specific product to treat their patients with or to encourage adding of such product in a hospital's procurement list.
x. During the relevant activity, physicians should disclose any funding provided to them by the industry for scientific research or any honoraries they received in capacity of an advisor, instructor, speaker or stakeholder.
xi. Promotional activities should be conducted according to a set of rules. The frequency and duration of industry representatives' calls should be standardized by the physician's health institution to prevent any untoward impact on the time the physician allocates to his or her patients or other activities.
xii. The venue selected for a congress or scientific meeting should highlight the meeting's scientific character, and care should be taken to ensure the purpose of the event does transform to a touristic one

and the venue is selected taking account of participants' overall financial power. Holding of these events at academic or public institutions should be encouraged.

xiii. No promotional materials of the industry should be displayed at locations where CME/CPD activities are taking place.

xiv. The upper limit of congress participation fees should be periodically set by physician organizations, and congresses exceeding such limits should be considered for crediting.

xv. Accommodation offered by the industry during scientific events should be reasonable, secondary to the actual purpose of the meeting, and should not be extravagant. Industry sponsorship should be limited to covering the cost of travel, meals, accommodation, and registration fees. Physicians should never request industry to cover participation costs of their companions, including spouses, children or other relatives; and physicians should reject and report to their professional organization any proposals they receive to that effect.

xvi. Any disbursements to investigators in industry-sponsored research should be transparent and compliant with institutional guidelines.

APPENDIX XI

PHYSICIAN - PHARMACEUTICAL INDUSTRY GUIDELINES*
TTB-UDEK- Ethics Working Group
October 31, 2009

I – GENERAL PRINCIPLES

1. The main ethical concerns surrounding interactions between physicians and pharmaceutical and medical technology manufacturers (hereinafter referred to as "companies") are practices that undermine the care provided to patients, the reputation of medical practice in the public eye, the mutual respect among colleagues and the rule of maintaining an equal distance to all companies.

2. Physicians should be aware of the ethical concerns implicated in proceeds or material gains derived by virtue of their professional position from sources other than their practice, patients or publishers, except fees which they earn from practicing their profession or publishing their work.

3. Physicians should be aware that having close ties with companies in conducting their professional practice may influence their choices, jeopardizing the principle of always acting in patients' best interest. Physicians should avoid engagements which may undermine their ability to form their independent opinion in the best interest of patients.

4. If they are engaged in a business, advisory or similar contract role with companies or when they are the recipient of a scholarship, research grant or similar financial assistance, physicians should disclose the nature of their affiliation to the audience, when they are fulfilling a speaker role or a representative function for them.

5. Physicians should not accept any gift of high material value from companies, except those having a medical nature or an educational purpose.

6. Physicians responsible for pre-graduation medical education should take steps to protect medical students – who are in the process of developing their proficiency in the practice – from exposure to any encounters involving interactions between physicians and pharmaceutical and medical technology companies.

7. Physicians responsible for post-graduation medical education should organize training sessions on communication skills, clinical ethics, research ethics, etc. to raise awareness of ethical rules among junior physicians undergoing residency training and to prepare them for encounters involving interactions between physicians and pharmaceutical and medical technology companies.

II - PROMOTION

8. Physicians should reject promotion of products whose manufacture or sale has not been authorized by the Ministry of Health.

9. Physicians should be aware that promotional information should be accurate, provable and adequate to enable physicians to form their own opinion of the therapeutic value of the medicinal product in question and information used for promoting a medicinal product should be free from any misleading or unproven information which may lead to unnecessary use and unexpected risks.

10. Physicians should take care that citations, tabulations and other visual depictions of information used in promotional aids are properly sourced with references and faithfully reproduced, and a full disclosure statement by authors is included to highlight any conflicts of interest with an indication of whether the findings were based on data from a company-sponsored study and whether any honorarium is involved. Any deficiencies or inaccuracies identified should be brought to the attention of company representative or company head office, and any gross inaccuracies should be exposed to the professional community.

11. Physicians should reject any gifts offered to them, other than audio/visual aids such as books, booklets, brochures, films, slide decks, or electronic media containing information on a medicinal product or medical technology, or educational items such as national or international professional publications. Similarly, they should refrain from intermediating for provision of any non-educational items to health or auxiliary health professionals whom they work with, or from being involved in promotional activities in the form of sweepstakes.

12. Physicians should not demand any assistance, whether in cash or in kind, from companies in return for using their medicinal products or medical technologies in their practice, or at institutions where they hold an administrative post. This rule is not applicable to legitimate in-kind grants provided in line with the applicable legislation for purposes of supporting the development of educational capabilities of institutions.

13. Physicians should participate alone in promotional activities with a dominant educational element, and avoid those in which the accommodation, entertainment, or excursion components weigh heavier.

14. Physicians should avoid taking part in promotional activities which are unethical and which may restrict their independent judgment.

III – SPEAKING AT COMPANY PRESENTATIONS, EDUCATIONAL PROGRAMS AND PROMOTIONAL ACTIVITIES

15. Physicians should decline offers to speak at meetings organized by pharmaceutical manufacturers on topics in which they lack instructor-level expertise. They should refuse any fees beyond travel and accommodation costs, and an honorarium for their time and service.

16. Physicians should decline any offers to speak at company promotional events aimed at promoting prescribing of certain medicinal products or the sale of a medical technology.

17. Physicians should decline offers to speak at company promotional meetings, if they detect that the luxury level of the non-speaking-related accommodation provided goes beyond a modest meal, to encourage participation.

IV – ACCOMMODATION AND ENTERTAINMENT

18. Physicians should decline any offer of tickets for recreational events, such as movies, theater plays, sport events, or concerts.

19. Physicians should avoid events organized or sponsored by companies such as trips, parties, meals, or birthday parties, and should not ask companies to sponsor their personal events.

V – SPONSORSHIP OF CONTINUING MEDICAL EDUCATION AND SCIENTIFIC MEETINGS

20. Physicians should not accept company sponsorship of long-term educational programs, such as residency, fellowship, and postgraduate or postdoctoral programs, except short-term education and research, congresses or courses.

21. Physicians should avoid demanding company sponsorship of travel, accommodation and personal expenses, except registration fees, in connection with participation in continuing medical education programs organized by profit-oriented entities. No fee should be demanded, or accepted, to cover their time, or loss of potential earnings, for the duration of their participation in the educational program. Sponsorship of only lunches may be acceptable in these types of educational events.

22. Physicians should ensure that when they organize a scientific meeting, the organization committee includes no company representatives, the meeting venue is conducive to facilitating attendance, the meeting content is decided by the organization committee exclusively on the basis of scientific and objective criteria, the educational aids used during the meeting are developed by the organization committee, and the educational

environment is free from any company promotional materials. It should be ensured that drugs are referenced always using their common name, and never the brand, in the congress scientific schedule and in company-sponsored symposia.

23. Any sponsorship provided by manufacturers to physicians for participation in scientific meetings should be provided through meeting organizers and never to the participants directly.

24. When physicians attend a scientific meeting in the audience, their main purpose should be to advance their professional knowledge. And when they attend as speaker, they should ensure full disclosure of any conflict of interest.

25. Physicians should ensure disclosure of the funding sources and the expenses incurred for scientific meetings where they have an organizational role and be accountable and responsible to ensure full compliance of meeting practices with this guideline and the TTB Code of Medical Ethics.

VI – ADVISORY ROLES WITH COMPANIES

26. Physicians should be aware that their engagement with companies in advisory roles should be compliant with code of medical ethics.

27. When they are offered an advisory post, physicians should sign a written contract laying down their fee and the terms of service, and ensure any disbursements are made against invoice.

28. Also when they are in an advisory role, physicians should ensure that a moderate level of comfort is not exceeded in the accommodation and hospitality provided beyond that which is warranted by the meeting content and requirements.

VII – CONFLICT OF INTEREST WITH COMPANIES FOR ORGANIZATION OFFICIALS

29. When they are nominated for a post with a central or local executive board, an honor board, an ethics boards, a branch audit board, or a scientific working party of a specialty association, or with a subcommittee within a society developing guidelines for clinical practice, physicians are under obligation to disclose whether they are engaged with a company as an employee, as an advisor or in a similar business capacity or are otherwise receiving scholarship, research grant, or other semi-academic assistance.

30. In the event that while holding a post with any of the above organs or sub-organs of an association, a physician subsequently engages with a company in a contract or otherwise receives sponsorship from them giving rise to a conflict of interest with such company, he/she should notify the association's Executive Board. If they find it necessary, the Executive Board may commission the Ethics Board for an inquiry into the situation, or, if they identify a conflict of interest between the physician's role with the association and his/her relationship with the company, they may ask the physician to choose between his/her post with the association or his/her sponsor relationship with the company.

VIII – COMPLIANCE WITH THE RULES

31. Physicians should be mindful of ethical compliance of companies and their promotion and sales activities. They should warn medical representatives who make unethical proposals, and report them to the authorities.

32. Physicians should warn their peers who engage in unethical conduct with pharmaceutical manufacturers, and report them to their specialty association.

APPENDIX XII

GUIDELINES AND DIRECTIVES ISSUED IN RELATION WITH THE REGULATION

(*Check the website of the Turkish Medicines and Medical Devices Agency for Updated Texts.)*

GUIDELINES ON APPLICATIONS FOR THE DISTRIBUTION OF FREE PROMOTIONAL SAMPLES AND PRESS RELEASES WITHIN THE SCOPE OF PROMOTIONAL ACTIVITIES OF HUMAN MEDICINAL PRODUCTS

ARTICLE 1- These Guidelines lay down the rules for applications for issuing free promotional product samples and press releases, in line with Article 9 and Article 11, Paragraph 2 of the Regulation on Promotional Activities for Human Medicinal Products, issued in Official Gazette No. 28037, of 26/08/2011.

ARTICLE 2- The following principles shall apply for distributing free promotional product samples:

1) Applications missing any of the requisite documents will be disregarded.

2) To ensure safe recall of products when necessary, registration/permit holders will establish, and designate responsible roles for, an adequate record and control system for the production, importation and distribution of free promotional product samples. Upon request, the records will be reported to ministry officials, electronically or in writing, in the format determined by the Ministry.

3) Free samples may be distributed without specific permission by the Ministry, solely to physicians, dental practitioners and pharmacists, after satisfying the requirements laid down in Article 9 of the regulation.

4) As required under Regulation Article 9, paragraph 1, subparagraph (e), it is essential that no barcode/datamatrix is printed on the packaging of promotional samples. If barcodes/datamatrixes do appear on the packaging of free promotional samples proposed for distribution, permission of the Ministry should be sought in writing with valid justification.

ARTICLE 3- The following documents should be submitted when applying **for a permission to distribute free promotional samples**:

1) A specimen of the product samples (2 each),

2) Photocopy of the registration,

3) Last approved selling permission and the packaging mockup enclosed with it,

4) Last approved patient information leaflet, with a copy of the approval letter,

5) For applications involving a co-marketed product, a copy of the co-marketing approval letter issued to the registration holder by our Agency.

ARTICLE 4- The following general guidelines will apply when applying for a press release:

1) Applications missing any of the requisite documents will be disregarded.

2) Registration/marketing holders wishing to announce launch of a product to healthcare professionals via a press release will make an application to Turkish Medicines and Medical Devices Agency with an identical copy of the proposed announcement text. A press release may be run only once on the same day on all print daily publications. For print periodicals, a press release may be run once within 30 days after the permission date.

3) A press release should satisfy the following criteria:

a) The announcement should be without color,

b) It should not exceed one eighth of a full newspaper page (i.e. A5-size paper),

c) It should use the identical typeface as that used for the Agency-approved packaging,

d) It should not include any information/wording that is not included in the Agency-approved packaging.

ARTICLE 5- The following documents should be submitted when applying for a press release:

1) An identical copy of the announcement text,

2) Photocopy of the registration,

3) Last approved selling permission and the packaging mockup enclosed with it,

4) For applications involving a co-marketed product, a copy of the co-marketing approval letter issued to the registration holder by our Agency.

ARTICLE 6- Article 9, paragraph 1, subparagraph (f) of the Regulation concerning free samples will be implemented as follows:

1) First Calendar Year:

A. If the launch date (initial entry in the DTS) is within the first six months of the first calendar year, samples in a quantity up to 5% of total annual domestic unit sales occurring during the same year may be distributed, based on a monthly monitoring of sales.

B. If the launch date is within the second six months of the first calendar year, the period until the end of the next calendar year will be considered the 'first calendar year' and samples in a quantity up to 5% of total annual domestic unit sales may be distributed, based on the monthly monitoring of sales.

Example A: For a product that was launched on 30/06/2012, the first calendar year is year 2012.

Example B: For a product that was launched on 01/07/2012, the first calendar year is year 2013. For the purposes of this example, monthly sales over the 'first calendar year' of 18 months will be monitored, and free promotional samples in a quantity up to 5% of total sales over such 18 months may be distributed.

2) Second Calendar Year:

A. If a product was launched during the first six months of the preceding year, samples in a quantity up to 5% of total annual domestic unit sales may be distributed, based on linear interpolation of the total domestic sales over one year.

B. If the product was on the market the preceding year for one full calendar year, samples may be distributed in a quantity up to 5% of total annual domestic unit sales.

Example A: For a product that was launched on 30/06/2012, the limit is 5% of the 1-year sales figure, calculated by linear interpolation of a total of six months and one day, occurring during the product's first calendar year of 2012.

1-year sales is calculated as follows:

[(daily unit sales quantity over 6 months) / 6,033] X 12 = "Interpolation of total sales during the first calendar year."

Example B: For a product launched on 01/07/2012, the first calendar year is 2013. The number of samples that may be distributed in 2014 corresponds to 5% of total unit sales during calendar year 2013.

3) Third, fourth and fifth calendar years:

Samples may be distributed up to 3% of total annual domestic unit sales during the previous year.

4) Sixth, seventh, and subsequent calendar years:

Samples may be distributed up to 1% of the annual total domestic unit sales during the previous year.

ARTICLE 7- This guideline enters into force on 01/01/2013.

GUIDELINES ON SESSIONS ABOUT THE RATIONAL USE OF DRUGS (14/05/2012)

Purpose and Basis

The Rational Use of Drugs is defined as patients' receiving drugs appropriate to their clinical findings and individual characteristics, in appropriate doses, for an appropriate period of time, conveniently, and at an affordable cost. It is a Ministry policy to promote and create public awareness of this issue, and educational and promotional activities are essential to raising awareness.

Article 7, paragraph 7 of the Regulation on the Promotional Activities for Human Medicinal Products, published in Official Gazette No. 28037 of 26/08/2011, requires that "Any meetings sponsored by a registration/permit holder will include a session on rational use of drugs, relevant to the topic of the meeting. The content of presentations to be given during such sessions will be aligned with Ministry-approved educational materials and diagnostic/therapeutic guidelines and submitted to the Ministry with the application for permission," and Article 14 therein provides that "The Ministry will issue guidelines to clarify the implementation of this Regulation," which provide the basis for issuing these guidelines.

A description of meetings which should include a session on the Rational Use of Drugs and the characteristics of such sessions are given below.

Meetings That Should Include a Session on the Rational Use of Drugs

A session on the Rational Use of Drugs, relevant to the subject matter of the meeting will be included in any national meetings sponsored by registration/permit holders, including congresses, symposia, seminars, workshops or meetings held under any other designation, where the duration of meeting exceeds 6 hours in total and where medicinal products are promoted as part of the meeting program or through placement of promotional materials at locations where they can be seen by participants (e.g. booths, banners, brochures or other promotional activities).

Registration/permit holders sponsoring such meetings during a year should ensure that at least 60% of meetings sponsored by them during that year include a "Session on the Rational Use of Drugs."

Session on the Rational Use of Drugs

The content of presentations given during a Rational Drug Use Session will be aligned with the principles of Rational Drug Use, in the premise of Ministry-approved educational materials and diagnostic/therapeutic guidelines.

Presentations used for the session on the Rational Use of Drugs should at a minimum include the content of the "Presentation template for use during the sessions on the Rational Use of Drugs," available from the official website for Rational Use of Drugs at www.akilciilac.gov.tr. In addition to the standard template, the presentation content should be enriched with various aspects of rational use of drugs and/or by associating rational use of drugs with one or more of the topics covered in the meeting.

The session length should not be shorter than 30 minutes.

The session on the Rational Use of Drugs should be free from any promotional elements or references to a specific product or a registration/permit holder.

Reporting Procedure

The reports which registration/permit holders are required to make to the Ministry according to Article 11, paragraph 3 of the Regulation on the Promotional Activities for Human Medicinal Products should be submitted within the deadlines prescribed in the Regulation. The report should also include a statement that a "Session on the Rational Use of Drugs" will be included. The declared meeting program should include the following wording: "This meeting includes a session on the Rational Use of Drugs, according to Ministry of Health regulations governing promotional activities of human medicinal products.".

When making an application for a meeting according to the "Regulation on the Promotional Activities for Human Medicinal Products," registration/permit holders should remember to upload to the official website of the Medicines and Medical Devices Agency of Turkey a copy of the presentation which they will use for the session on the Rational Use of Drugs.

Presentations used during thee sessions will be pooled in a portfolio of educational aids on the Rational Use of Drugs. The content of a presentation may be disclosed – using proper citing of the sources – for use during other meetings aimed at promoting the Rational Use of Drugs.

GUIDANCE FOR APPLICATIONS FOR SCIENTIFIC MEETINGS AND EDUCATIONAL ACTIVITIES (14.05.2013)

Scope

ARTICLE 1 - (1) This Guidance set forth rules for applications submitted by marketing authorization or license holders for holding a scientific meeting or an educational event, in line with the "Regulation on Promotional Activities for Human Medicinal Products," published in Official Gazette #28037 of 26.08.2011.

Basis

ARTICLE 2 - (1) This Guidance is issued based on Articles 27 and 40 of Decree Law #663 of 11.10.2011 on the Organization and Mandate of the Ministry of Health and Its Subordinate Agencies, and the Regulation on Promotional Activities for Human Medicinal Products," published in Official Gazette #28037 of 26.08.2011.

Definitions

ARTICLE 3 - (1) For the purposes of this Guidance, the following terms will have the meaning provided next to each:

a) Scientific Meeting: Any national or international meetings, congresses, workshops, symposia, etc. held by national or international specialty associations of healthcare professionals, pharmacists'/physicians' associations, or marketing authorization or license holders.

b) The Unit: Rational Drug Use, Drug Supply Management and Promotion Office within the Office of the Vice-President for Economic Studies and Information Management, within Turkish Medicines and Medical Devices Agency.

c) Educational Activity: Any meetings for education or information exchange held or sponsored by marketing authorization or license holders, which may involve promotion of a human medicinal products.

ç) Agency: Turkish Medicines and Medical Devices Agency.

d) Official website of the Agency: The official website of Turkish Medicines and Medical Devices Agency.

e) Regulation: Regulation on Promotional Activities for Human Medicinal Products, published in Official Gazette #28037 of 26.08.2011.

General guidelines

ARTICLE 4 – (1) Meeting applications will be uploaded to the database using T.R. identification number and password of personnel authorized by marketing authorization / license holders for this purpose.

(2) The 'speaker' referenced in the provision, *"*This excludes meetings which healthcare professionals are attending as a speaker, or as an investigator presenting a paper, sponsored by a marketing authorization/license holder*,"* appearing in Article 7, Paragraph 2, Subparagraph (b) of the Regulation, may be a session chair, panelist, or instructor; if it is an investigator presenting a paper orally or in writing (e.g. oral presentation or posting of a poster, oral presentation of the study, etc.) for a scientific study involving multiple investigators, it may be only one of the investigators involved. In cases where, at the time of application to our Agency, the meeting participant is a speaker or an investigator presenting a paper, an "Admission Letter (Invitation Letter)" specifying the name of the meeting, issued to the person's name by the meeting organizer, must be appended to the application documents.

(3) Marketing authorization or license holders may not hold or sponsor, whether directly or indirectly, any meetings at ski resorts between December 01 and March 01, or at seaside resorts between June 01 and September 01. This excludes educational meetings organized within the above timeframes for physicians actively working in such regions.

(4) Because they are providing a public service, healthcare professional working at private healthcare institutions or organizations are also subject to the regulation and guidance.

(5) According to Article 11, Paragraph 3 of the Regulation, meeting applications submitted electronically or in writing by marketing authorization or license holders will be answered by the Unit only electronically within ten working days. For applications answered by the Unit, with deficiencies raised and indicated in the response, the applicant will rectify the deficiencies, submitting them electronically only, within five working days. On the third and fourth working days after the sending date of the deficiency notification, reminder

messages will be e-mailed by the system to the person submitting the application and their supervisor, informing them of how much time they have left to rectify the deficiencies. If new deficiencies emerge during the rectification phase of deficiencies, an extension will not be granted to rectify the new deficiencies, and the date the application was originally marked as containing deficiencies will be regarded. Any applications for which the applicant has failed to meet the deficiencies within the deadline will be marked as "REJECTED" by the system.

(6) The system will automatically reject any new application made by the same marketing authorization or license holder for a rejected meeting.

(7) As provided in Article 11, Paragraph 4 of the Regulation, a marketing authorization or license holder must provide "Feedback" at the latest within one month (30 days) after the meeting's ending date. The "Feedback" will be submitted – electronically only – by marketing authorization or license holders, and approved electronically only by the Unit.

(8) Where a marketing authorization or license holder had made a donation to an association/foundation etc. to enable the meeting, a statement typed and undersigned on company letterhead, describing the nature of the donation and how it was used by the association/foundation etc., will be uploaded to the system in PDF format, and an indication will be provided in the "Other Costs" section that the document has been attached. If participants were declared, recipients of sponsorships should be reported by the marketing authorization or license holder in the system as participants, as they are indirectly supported.

Notification procedures for scientific meetings

ARTICLE 5 – (1) The following considerations apply during application for scientific meetings or educational activities to be organized or sponsored by marketing authorization or license holders:

a) **Logging on to the system**:

Visit https://***e-islemler.titck.gov.tr*** ***(***https://***e-islemler.iegm.gov.tr)***,

Enter your TRID# in the field ***"TRID#,"***

Enter your password in the field "***Password,"***

Type the displayed letters/numbers in the field "***Image,"***

Click once on the button "**Enter."**

If you have accurately provided your TRID#, password and the verification letters/numbers, the system will give you access permission. If you mistyped your username or password, a warning message will be displayed "Login failed. Please try again." Your password will be blocked after five failed attempts. If your password has been blocked, you need to contact your supervisor for a new password, who is authorized to issue a password for the marketing authorization or license holder.

b) **Meeting Notification:** After logging on to the system, click "Meeting Applications" under the menu "Processes" to display the "Meeting Registration Screen."

Click on the tab **"Submit an Application."**

Enter data in the "Meeting Registration Screen" as follows:

c) Application Date: The system will automatically assign an application date for the meeting.

- Electronic or written applications for meetings must be submitted at least 15 working days before the meeting's starting date. The system will not allow submission of an electronic application, and written applications will not be assigned an incoming document reference number, when there is less than 15 working days to the meeting's starting date.
- The Unit will disregard any written application for a meeting that receives an incoming document reference number without making an electronic application.
- Applications submitted electronically within deadline, but **not submitted** in writing to the Agency's incoming documents service **on time** (i.e. at least 15 working days before the meeting's starting date) will be **disregarded.**
- **Meeting Application Cover Letter:** On the line "Cover Letter" in the section "**Attachments,"** click on the button "**Browse"** to select the document to attach [PortableDocument Format (PDF)] and click on "**Open"** to complete cover letter selection. Press the button "**Save Meeting**" to immediately attach the document to the application.

Note: An application cannot be submitted unless attached with a cover letter. The tracking number issued by the system after the application has been submitted will be sent (physically delivered) to the Branch Directorate for Incoming Documents and **always written on the cover letter.**

d) In the section **"Meeting Type,"** select either "Scientific Meeting" or "Educational Activity."

a. After selecting "Scientific Meeting":

- Click on the tab "Select a Scientific Meeting," and look up the meeting in the displayed list (use column headers to sort meetings registered in the system). If the meeting is listed, click on the button "Submit Application" on the right end of the line containing the meeting record. The system will return you to the "Application" page, with the form automatically populated with the meeting details. Complete the necessary fields to proceed with the application process.
- If the meeting is not listed, click on the tab **"Scientific Meeting Initial Registration"** on the top of the page. Complete meeting details in the displayed form and click "**Register."** The application proceeds, with the meeting name temporarily accepted.
- To enable verification of the "Meeting Name" by the Unit, be sure to attach the application with the "original announcement text," indicating the meeting's full title.

Note: For meetings notified as a Scientific Meeting, a healthcare professional may accept not more than a total of three instances of sponsorship within a given year, and not more than two of such instances of sponsorship may be provided by the same marketing authorization or license holder, and only one of such three instances of sponsorship may be used for a meeting abroad, according to Article 7, Paragraph (2), Subparagraph (b) (For domestic meetings, all three instances of sponsorship may be used). For meetings notified as an "**Educational Activity**" no limitation is applied on the number of meeting participants.

b. After selecting "Educational Activity," enter meeting details as follows:

For scientific meetings, applied for by selecting the tab **"Scientific Meeting Initial Registration,"** and for educational activities, the data entry procedure is as follows:

- **Country**: Select a meeting country from the list. (Only Turkey is selectable for educational activities)
- **City:** Select a meeting city from the list, or a state for the USA or India.
- **District**: After selecting a province in Turkey, select a district.
- **General Title of the Meeting**:
  - Scientific Meeting Title: Provide the meeting title indicated in the original meeting announcement.
  - Educational Activity Title: Provide the educational activity's title.
- **Association/Organization Organizing the Meeting:** From the list, select the association/organization holding the meeting. To add an unlisted association/organization, select the option "Other." Associations/organizations added using the option "Other" will be added in the system only after they have been verified by the Unit. If the meeting is organized by the marketing authorization or license holder, the checkbox "Own Meeting" should be marked.
- **Agency/Agent Undertaking the Organization:** Provide the name of the agency/agent who is undertaking the organization. (For international meetings held abroad, provide the name of the agency/agent from whom the marketing authorization or license holder making the application is directly receiving this service).
- **Meeting Starting Date:** Provide the meeting's starting date.
- **Meeting Ending Date:** Provide the meeting's ending date.
- **Meeting Venue (name of hotel, congress center, facility, etc.):** Provide the full name of the meeting venue.
  - Select the checkbox "I do hereby attest that the meeting is compliant with the requirements set forth in Article 7, Paragraph 5 of the Regulation." The system will not process the application unless this checkbox is selected.
- Meeting Program: Attach the meeting program in PDF format. The application may not be submitted unless it is attached with this document. The date and time at which the person declared as a speaker or a paper presenter will be giving a speech/presentation should be marked on the program, and the document should be scanned and attached in PDF format.

(2) Sponsorship provided for an organization: In the section for sponsorships provided for an organization, check the box Booth / Satellite Symposium / Total Honorarium Paid to Speakers / Total

Disbursements Paid to Participants / Other Costs, as appropriate. After checking a box, a text field will appear wherein a VAT-inclusive cost figure should be entered in "TL."

Important:

- In the text field that appears after checking the box for "Total Disbursements Paid to Participants," the total cost is entered in TL (travel, lodging, registration fee, etc.). This is the total cost amount for all participants.
- After selecting the checkbox "Educational Activities," check the box next to the statement **"I do hereby attest that participants' travel, lodging and similar expenses are not covered by our company,"** appearing in the popup window and confirming that the participants' travel and lodging expenses are not covered. The system will not allow submitting the application unless this warranty checkbox is selected.
- If no participant is sponsored, select the checkbox "There are no sponsored participants."
- **Other Costs**: The nature of the sponsorship (e.g. rental, meals, communications, stationeries, personnel costs, etc.) should be clearly described in the description section.

(3) "Rational Drug Use Session" section**:** According to Article 7, Paragraph 7 of the Regulation, any meetings sponsored by a marketing authorization or license holder must include a session themed "**Rational Drug Use (RDU)," relevant to the subject matter of the meeting**.

Check "Yes" or "No," as appropriate, in the section "Is there a Rational Drug Use Session?"

- The application process may continue when the checkbox "Yes" is selected. During the **feedback** submission for the meeting, the original copy of the RDU session presentation must be uploaded to the system. If the RDU session presentation is not uploaded during **feedback** submission, the system will treat it as RDU session being **"Unavailable."** If an RDU session relevant to the meeting's topic was included in the meeting although **"No"** was checked during application, the status of the RDU meeting will be treated as being "**Available**," if its documentation is uploaded during feedback submission.
- Select one of the three options (There is no rational drug use session / Meeting duration is less than six hours / It is an international meeting) that pops up when the checkbox "**No**" is selected. The application may not proceed unless one of the options is checked.

(4) "Attachments" section**: a)** All documents to be uploaded to the system during application must be attached as follows:

a. Attach Files: Attached files should meet the following requirements:

- Electronic files should be created in PDF format. The system will reject electronic documents created in any other format.
- Files should be converted from text to PDF as far as possible. Files which cannot be converted from text format, such as images or signatures, should be converted from TIFF to PDF. Files should be text-searchable. Regardless of whether the source material is text or image, the average page size of any PDF file **must not exceed** 100 KB.
- Excluding the "Rational Drug Use" presentation file, the total size of attachments may not exceed 20 MB.
- Where providing documents in text format is not possible (e.g. files containing signatures, etc.), it is advised to scan these documents in black and white at a maximum of 300 dpi resolution.
- Before submission, the documents should be always tested for readability. This responsibility rests with the marketing authorization or license holder.
- All documents attached in the "Attachments" section appear below the "Attachments" section, after the button "Save Meeting" is clicked. The responsibility to verify whether documents were properly uploaded rests with the marketing authorization or license holder.

b. Save Meeting: After all data have been entered in the meeting registration screen, click on "**Save Meeting."** Which sets the status of the notification to "New Electronic." Applications having this status may be updated.

- The buttons that appear at the bottom of the page upon clicking the **"Save Meeting"** button and their functions are described below:

- **"Update"**: Press the "**Update**" button to save any modifications after making changes in any field of the application form.
- "**Participants**": Press this button to add participants, as described below.
- "**Print**": Press this button to take a printout of your application.
- "**Submit Application**": Press this button to complete your application and request a tracking number. Before pressing **"Submit Application,"** all documents and information (participants) related to the application must have been uploaded to the system. After "**Submit Application**" has been pressed, no modifications can be made, nor any additional documents uploaded until the Unit processes the application.
- "**New Registration**": Press "New Registration" to make a new meeting application.

- **Procedure for Adding Participants:**

- Before sending in the "Meeting Application," press "**Participants**" and enter the TRID# in the "T.R. Identification Number" field and press "**Query."** After the query automatically retrieves participant details, verify the information and use the correct button to correct any inaccuracies or inconsistencies with the participant's current information.
- If the query returns no results for the participant, a warning is displayed: "**No Record Found**." Click on "**OK**" below the warning window. Check the box "Enter information manually," next to "Query," to enter the participant's details manually.
- Participants who are nationals of the Republic of Turkey may not be added to the meeting unless their "T.R. Identification Number" is entered.
- For participants without a "T.R. Identification Number," select the checkbox "Not a citizen of Turkey." Then, select the participant's country from the list and manually enter/select other details. When manually entering data:
  - Put only the participant's first name in the "name" field, and surname in the "surname" field. **No prefix or suffix should be provided** with the participant's name or surname.
  - If the participant is currently working at an institution/organization (e.g. hospital, family medical center, university, etc.), this should be entered in the relevant field in a complete, current, and accurate manner.
- For the participant to be added to the meeting, select the appropriate option ("**Participant," "Speaker"** or **"Investigator Presenting a Paper")** in the section "**Nature of Participant."** For persons marked as "Speaker and person presenting a paper," the date and time on which they would be giving their speech/presentation should be **marked/indicated on the meeting program,** and uploaded in PDF format. When the checkbox "Investigator Presenting a Paper" is selected, the title of the paper should be entered in the popup field.
- After entering participant details in an accurate, complete and current manner, select the checkbox next to the statement: "I hereby attest that the participant details I have provided herein are complete and accurate, and the entire legal responsibility that may arise due to submission of erroneous information rests with our company."

  Note: The Unit will check the accuracy of the participant's name against the "T.R. Identification Number" provided.
- The buttons below the "Add Participant Screen" and their functions are described below:
  - **"Add Participant"** button: Use this button to add a participant to the system.
  - **"Update"** button: Press this button to save the final version of a record, after correcting any erroneous entries.
  - **"View Participants"** button: Press this button to view participants you have defined for this meeting.
  - **"Clear"** button: Press this button to clear the form before entering a new record.
  - **"Return to Meeting"** button: Press this button to return to the meeting page.

  Important:
- For all meetings organized or sponsored, the marketing authorization or license holder must enter all data required by the system as described above. If there are no sponsored participants,

be sure to select the checkbox "**There are not sponsored participants,"** at the bottom of the section "Submit Application."

- For "**Educational Activities**" organized or sponsored by marketing authorization or license holders, participants' names and T.R. Identification Numbers must be entered in the system during "Feedback" submission, as described above. For applications for Educational Activities, the marketing authorization or license holder must detail in the description field the total number of persons to attend the event, and where they would be attending (province, district, practice name).
- To ensure participant records or up to date, participants may be added/removed and the form may be updated after a tracking number has been assigned, as long as the electronic status of the meeting is "**New**" or **"Incomplete**." After **"Preapproval"** is given to the meeting by the relevant unit, no modifications may be made in an electronic application until the meeting's ending date. All modifications relevant to the application should be reported during the "**Feedback**" process.
- If important changes relevant to the meeting occur (i.e. change of meeting title, meeting venue, meeting type) after a "**Preapproval**" has been given, an application needs to be made reflecting the new situation. In that case, any previous applications for the meeting must be cancelled. The marketing authorization or license holder making the application must make **a written** cancellation request to the relevant unit.
- If it is desired to add a "new participant" to a "Preapproved" participant list before the meeting, meeting participation may be sponsored after checking the system for the total number of sponsored participation instances of this participant in (in the Search for Participants tab). The entire responsibility rests with the applicant for checking in the system the previous participation status of these participants (i.e. the number of sponsored participations in meetings).

Feedback

ARTICLE 6- (1) Feedback for completed meetings whose status is "**Preapproval"** will be made electronically within 1 month (30 days) after the meeting's ending date.

(2) To give Feedback, press the button "**My Applications.**" In the page that opens, enter the tracking number that was assigned during the initial meeting application in the field "**Tracking Number"** and press **"Search."** Click on the **"View**" link that appears on the entry line. After making the necessary modifications (e.g. participants, cost, etc.) in the page (documentation for these changes should be uploaded to the system), press the "**Update**" button. After checking and confirming the accuracy of all information, press **"Feedback."** A message, "**Your feedback has been received,"** is displayed, and from this point onward no changes are possible.

(3) On the 23rd and 28th day after the meeting's ending date, the system will e-mail reminder notices to the person who submitted the application and his or her supervisor, reminding them to submit feedback.

- After 1 month (30 days), the status of applications for which a "Feedback" has not been received will be automatically changed to "Feedback."
- For meetings for which "Yes" was checked on the line "Is there a Rational Drug Use Session?" the RDU presentation file must be submitted with the feedback (the original Power Point presentation used during the meeting, with panelist credentials for citation purposes). If the presentation file is not uploaded, the system will consider the RDU presentation as "Unavailable."

Effectiveness

ARTICLE 7- (1) This Guidance will enter into force on its approval date. (14.05.2013)

Enforcement

ARTICLE 8- (1) This Guidance will be enforced by the President of Turkish Medicines and Medical Devices Agency.

Principles and Procedures and the Implementation Timeline for Training of Product Promotion Representatives for Promotion of Human Medicinal Products (29.06.2013)

Purpose

Article 1 – This Guideline sets forth the implementation timeline, and principles and procedures for training of product promotion representatives in accordance with the Regulation on Promotional Activities for Human Medicinal Products, Article 10, published in Official Gazette #28037 of 26.08.2011.

Basis

Article 2 – (1) This Guideline is issued based on the Regulation on Promotional Activities for Human Medicinal Products, published in Official Gazette #28037 of 26.08.2011, and Decree Law #663, dated 11.10.2011, on the Organization and Mandate of the Ministry of Health and Its Subordinate Agencies, Articles 27 and 40.

Definitions

Article 3 – (1) For the purposes of this Guideline, the following terms and definitions apply:

a) Unit: Rational Drug Use, Drug Procurement Management and Promotion Department, Office of the Vice-President for Economic Research and Information Management, Turkish Medicines and Medical Devices Agency;

b) Training: A distance learning program whose curriculum is determined by the Agency and offered to any product promotion representative candidate who wish to receive a qualification certificate;

c) Agency: Turkish Medicines and Medical Devices Agency;

ç) Agency's official website: The official website of Turkish Medicines and Medical Devices Agency;

d) Product Promotion Representative (PPR): A qualification certificate holder who promotes products directly to physicians, dental practitioners and pharmacists;

e) PPR Databank: A properly secured electronic database of PPRs issued a qualification certificate, containing their information and records;

f) Qualification Certificate: A certificate issued to graduates of Medical Promotion and Marketing Programs of universities, or to persons who successfully pass an examination organized by the Agency after in-service training;

g) Qualification Examination: An examination that every PPR who completes training must take.

h) Authorized Institution: Universities authorized by Turkish Medicines and Medical Devices Agency to give education and examination to product promotion representatives.

ı) Regulation: The Regulation on Promotional Activities for Human Medicinal Products, published in Official Gazette #28037 of 26.08.2011.

Product promotion representative training and examination

Article 4 – (1) The application procedure:

a) Candidates seeking to attend PPR training courses make an application with an authorized institution, posted on the Agency's official website.

b) Training application requirements, the content of training, and any arrangements regarding examinations will be announced by authorized institutions.

(2) The training procedure:

a) Training is provided using distance learning methodology, based on the curriculum determined by the Agency.

b) Training will be provided 4 (four) times in three monthly periods during year 2014, and only twice in any other years. Applicants whose applications have been accepted will be provided access to distance learning by the authorized institution. A candidate must complete training to be eligible to take the required examination at the end of the training course.

(3) The examination procedure:

a) At the end of the training course, candidates must take the examination. Trainees who fail the examination can take a make-up examination, the timeline for which will be posted by the authorized institution.

b) Examinations will be given under supervisor oversight at the location and on the date to be announced by the authorized institution.

c) There will be 4 (four) qualification examinations in year 2014, and at least 2 (two) in year 2015 and any subsequent years.

ç) A candidate must score 70 (seventy) points or higher to pass the examination.

d) Examination results will be posted by authorized institutions.

Issuing of a qualification certificate and identification card

Article 5 – (1) The issuing procedure of qualification certificates:

a) After the examination, the authorized institution will forward to the Agency identification details and scores of candidates who are considered to have passed the examination.

- Candidates who are eligible to receive a qualification certificate must make a written application to the Agency, attached with the following documents:
  - Diploma or graduation certificate
  - Photocopy of identification card
  - 2 x passport photos
  - Bank deposit slip, showing that the Qualification Certificate fee has been deposited in the Agency's bank account.

b) Graduates of universities' "Medical Promotion and Marketing Programs" must also obtain a qualification certificate if they wish to work as a PPR.

- Graduates of Medical Promotion and Marketing programs must make a written application to the Agency, attached with the following documents:
  - Diploma or graduation certificate
  - Photocopy of identification card
  - 2 x passport photos
  - Bank deposit slip, showing that the Qualification Certificate fee has been deposited in the Agency's bank account.

c) The qualification certificate fee will be announced in the Agency's annual tariff of fees.

ç) Qualification certificate recipients will be recorded in the Agency's PPR Database.

d) A qualification certificate will be valid through four calendar years from the issuance date. A PPR must obtain recertification before expiration of their existing certificates. (Example: A qualification certificate issued in year 2015 will be valid until 31.12.2018). This excludes qualification certificates issued to graduates of universities' "Medical Promotion and Marketing Programs."

(2) The issuing procedure of PPR Identification Cards:

a) After being registered in the system, a PPR holding a qualification certificate will be issued a PPR Identification Card by their employers, in a format to be determined by the Agency by the end of 2014.

b) Graduates of "Medical Promotion and Marketing Programs" who wish to work as a PPR must also obtain a PPR Identification Card.

Miscellaneous Provisions

Article 6 – (1) The Agency may revise the number of courses and examinations in a year to reflect demand.

(2) To allow PPR candidates an opportunity to apply, a sufficient timeframe will be set before each training term, which will be announced by authorized institutions.

Effectiveness

Article 7 – (1) This Guideline will enter into force on the date it is published. (29.06.2013)

Enforcement

Article 8 - (1) The provisions of this Guideline will be enforced by the President of Turkish Medicines and Medical Devices Agency

APPENDIX XIII:

Regulation on the Principles of Ethical Behavior of the Public Officials and Application Procedures and Essentials (Entered into effect as published in Official Gazette dated 04/13/2005 and numbered 25785)
Selected Clauses (translation taken from Council of Ethics for Public Service website, reached on 15 July 2013)

Objective

Article 1 – The objective of this Regulation is to establish ethical culture in public, to determine the principles of ethical behavior of the public officials who have to abide while executing their duties, to assist them in order to display behaviors in accordance with these principles and to raise the confidence of community to the public administration by eliminating the situations which create distrust in the society and which impairs the principles of justice, integrity, transparency and impartiality in carrying out the duties, to inform the community about the behaviors they are entitled to expect from the public officials and to arrange the procedures and essentials of application to the Council

Scope

Article 2 – This Regulation comprises the administration and auditing committee, the whole staff including the supreme committee and committee chairman and members working in the offices which are contained in the general budget, annexed budget administrations, public economic enterprises, institutions using own capitals, local administrations and their alliances, all public institutions and organizations established under the names of committee, supreme committee, association, institute, enterprise, organization, fund and others possessing the public legal entities.

The provisions of this Regulation are not (applicable) for the President, the members of the Grand National Assembly of Turkey (Parliament), members of Council of Ministers, Turkish Armed Forces, members of judiciary, and universities.

...

Avoiding conflict of interest

Article 13 – Conflict of interest means all sorts of interests, financial or other liabilities and the situation of having such personal interests provided for the public officials, their relatives, friends or the person or organizations they deal with which affect or seem to affect their performance of the duty impartially and objectively.

Public officials have personal responsibility in the conflict of interest and as they are the ones to personally know the situation in which conflict of interest may rise. They should proceed cautiously in any potential or real conflict of interest, take necessary steps to avoid conflict of interest, notify the situation to their seniors as soon as they realize conflict of interest and keep themselves away from benefits that are in the scope of conflict of interest.

Not using the duty and authorities to derive benefits

Article 14 – Public officials cannot derive benefit in favor of themselves, their relatives or of the third persons by using their duty, title and authority and cannot intercede, favor their relatives, friends and fellow townsman, perform political nepotism, discrimination or nepotism of any kind.

Public officials cannot have their or others' book, periodical, cassette, compact disc and any other similar products sold or distributed; cannot derive benefits to any organization, foundation, association or sports club by donations, help or similar ways.

Public officials, when they are on duty or they leave the duty, cannot use the official or secret information they acquired during performance of their duty or as a result of these duties in order to derive economical, political or social benefits for themselves, for their relatives or for third persons directly or indirectly, cannot explain this information to any institution and organization except from the competent authorities.

Public officials cannot use the sources of the institution they work for in the election campaigns directly or indirectly or have those sources used.

Prohibition of receiving gifts and deriving benefits

Article 15 – All sorts of goods and benefits which are accepted directly or indirectly whether having economical value or not and which affect or have the possibility to affect the fulfillment of their duties, impartiality, performance and decisions are within the context of gift.

The basic principle for the public officials is not to receive or give gift and not to derive interest as a result of duty.

Public officials cannot receive any gift or derive benefit from natural or legal persons who have work, service or benefit relationships related to the duty they perform, for themselves, their relatives or third persons or organizations directly or through an interceder.

Public officials cannot give gifts by using the public sources, cannot send wreath or flowers to a natural or legal person except from official day, ceremony and festivals; they cannot give out a notice of commemoration, make an announcement or a celebration which are not related to the service.

Among the gifts given by the foreign persons and organizations according to the decency and protocol rules in the international affairs, saving for the provisions of article 3 of the Act numbered 3628, the ones that are below the limit of the said article are declared.

• Donations which mean contribution to the organization for which the public officials work, which will not affect the execution of the organization services in accordance with the law and which are received, provided that they are allocated for the public service, recorded in the fixed assets list of the organization and that they are declared to the public (except from the official car and other gifts received in order to allocate for the service of a specific public official) and the donations which are granted to the institution and organizations,
• Book, magazine, article, cassette, calendar, compact disc or such goods,
• Gifts or rewards acquired in publicly held competitions, campaigns and activities,
• Gifts having the value of souvenir which are given in publicly held conferences, symposium, forum, panel, meal, reception or similar activities,
• Advertisement and handicraft products which are distributed to everyone and which have symbolic value,
• Credits taken from financial organizations according to the market conditions,
are outside the scope of the prohibition of receiving gifts.

a) Gifts of greeting, farewell and celebration, scholarship, travel, cost-free accommodation and gift vouchers received from the people who have service or interest relations with the institution they work for,
b) Transactions which are made from unreasonable prices according to the market price when buying, selling or hiring movable or immovable goods or service,
c) All sorts of gifts including jewelry, clothes, food or any other goods given by those benefiting from the service,
d) Loans and credits taken from the people, who have work or service relations with the institution,
are within the scope of the prohibition of receiving gifts.

The officials within the scope of this Regulation who are at least general director, equal to or above general manager notify the list of the gifts they received in the previous year and which are stated in the 5 th paragraph of this article and (a) clause of the 6 th paragraph to the Council until the end of January without waiting for any warning.