AIFD Code of Good Promotional Practice and Good Communication

Edition 6.01

Effective as of April 1st, 2017.

AIFD Code of Good Promotion and Good Communication

Association of Research-Based Pharmaceutical Companies (AIFD) Code of Practice on Interactions 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

Edition 6.01

Effective as of April 1st, 2017

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Main differences in edition 6:

The text is reformulated in line with the TITCK Promotion Regulation dated 3rd July 2015 and related Guidelines.
The ranking and numbering of articles and the numbering of clauses are modified.
The modifications made on 10 April 2014 in the Law 1262 are included.

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 which have shaped the AIFD 2013 Code of Good Promotional Practice and Good Communication and constitute its philosophical and ethical infrastructure. The Code of Promotional Practice may not provide an answer for each situation and problem to arise. In case of a matter not comprised by 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 first priority of pharmaceutical companies shall be the health and well-being of patients.

2. Pharmaceutical companies shall comply with the high quality level, safety and activity standards designated by rule-making regulatory bodies and try to advance these even further.

3. The relations of pharmaceutical companies with their stakeholders shall always be conducted in an ethical, respectful and professional level at all times and under every condition. Nothing or no service offered or provided by pharmaceutical companies shall lead to inadequate impacts or be perceived as inadequate, due to its style, content or conditions.

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

5. Promotion shall be ethical, accurate, balanced and not 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 shall pay due respect to the privacy of patients and healthcare professionals to whom they provide service and the confidentiality of their personal details.

7. All pharmaceutical researches and scientific studies conducted or sponsored by pharmaceutical companies shall be performed for the purpose of contributing to the well-being of patients and the advancement of science and medicine. Pharmaceutical companies are determined to ensure the transparency of industry-sponsored clinical trials conducted on humans.

8. Pharmaceutical companies shall act in compliance with the letter and spirit of applicable codes of the industry. It is the responsibility of pharmaceutical companies to train all employees as required, in order to achieve this goal.

Sincerely,

Dr. Ümit Dereli

AIFD Secretary General and Chief Operating Officer

AIFD Code of Good Promotional Practice and Good Communication

Pharmaceutical promotion is among the key activities of 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.

2017, 6th 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, TITCK, published in the Official Gazette dated 03/07/2015, No. 24905, as well as the relevant 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, No. 2001/83/EC and 2004/27/EC, on Medicinal Products for Human Use;
- Amendments in **EFPIA** 2013 (**E**uropean **F**ederation of **P**harmaceutical **I**ndustries and **A**ssociations) "Code of Practice on the Promotion of Medicines", "Code of Practice on the Relationships with Patient Organizations" and "Code of Disclosure on Transfers of Value from Pharmaceutical Companies to Healthcare Professionals and Healthcare Organizations"; June 2014 and December 2014;
- **IFPMA** 2012 (**I**nternational **F**ederation of **P**harmaceutical **M**anufacturers & **A**ssociations) Code of Pharmaceutical Marketing Practices;
- 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 (TTB) Declaration on Physician-Pharmaceutical Industry Interactions (June 2009);
- TTB-UDEK (Council for Coordination of Medical Specialties) Ethics Task Force on Physician-Pharmaceutical Industry Interactions Guidance (October 2009)
- Law on the Protection of Personal Data, no. 6698 (7 April 2016)

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. The 6th Edition was approved by the AIFD General Assembly on 24 February 2017 and became effective as of 1st April 2017.

AIFD Code of Good Promotional Practice is intended to provide guidance to member companies in the interpretation of the Regulation and the associated Guidelines on the Promotional Activities for Medicinal Products for Human Use of the Ministry of Health, Turkish Medicines and Medical Devices Agency (TITCK); 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, TITCK and 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 (TITCK) of the Ministry of Health of the Republic of Turkey shall be sought.

AIFD Code of Practice Panel (CPP-TIDK) AIFD Code of Practice Appeal Board (CPAB-TITEK) 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. The articles, article clarifications and justifications constitute the set of rules of the Code.

Articles of the Regulations and Guidelines to which reference are 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-only 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 shall be to safeguard public health. However, this objective shall 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 shall 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 each update of the Code, abovementioned central theme of the EU Directive 2001/83/EC and the mission and vision statements of AIFD have been used for 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-only 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.(*Text approved during the 2010 AIFD General Assembly*)

According to the Scope of the EFPIA Code;
”Member Companies must comply with any applicable codes of the EFPIA member industry association in the country where they conduct activities – directly or via a company – in the market in Europe”; and
“Even if an EFPIA member Company is not a member of an EFPIA member industry association in any European country, they accept that they are bound by the rules of the EFPIA member association (and therefore any applicable sanctions that may be imposed thereunder) as they an EFPIA member.”

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 and the Law on the Protection of Personal Data. 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. When AIFD Code and the legislation differ, the most restrictive one shall be implemented. In case AIFD Rules and legislation are in contradiction, the legislation shall be followed.

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- Preservation of the Reputation of the Industry and the Confidence Towards the Industry

Confidence in the pharmaceutical industry is based on the perception of the behavior of companies by stakeholders and the public. Activities, methods applied or materials used in associated with promotion shall never reduce the reputation of the pharmaceutical industry and trade or the confidence towards the industry. Companies and AIFD shall be obliged to closely monitor promotional activities and adopt relevant measures.

Article Clarifications and Justifications

1. 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 shall 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 (text) and spirit of the Code.

The acceptability of any meeting or event in terms of this Code of Ethics may be evaluated with the responses to be provided to the following four questions composing the Ethics Screen®:

1) ***(Standards)*** Is this activity compliant with legislations and rules?
2) ***(Sense of justice)*** Is this activity balanced and fair? Would we have been annoyed if the competing company (someone else) had done this?
3) **(Emotions and Ethical Values)** Would our company and invitees be annoyed if the details of this activity were heard by the public?
4) To what degree will the "**perceived reality**" in this meeting or activity overlap with the "**objective reality**"?

Article 2- Purpose and Scope

Purpose

2.1. This Code is based on the Regulation defining the promotional rules aimed at ensuring the rational use of products (medicinal products for human use, enteral nutritional products and medical infant formulas) (Reg. Art.1.1).It is prepared for the purpose of providing guidance for compliance to the rules stipulated in this Regulation and relevant legislations in the marketing of medicinal products for human use by AIFD member companies and non-AIFD member companies which have agreed in written to comply with this Code; observing that the pharmaceutical industry does not deviate from internationally accepted high ethical standards stipulated in the IFPMA and EFPIA Codes and ensuring that such level is preserved.

Scope

2.2. This Code shall primarily comprise promotional activities for medicinal products for human use directed at physicians, dentists and pharmacists. (Reg. Art.5.1)

2.3. The Code also comprises the provision of information to other healthcare professionals, assistant healthcare personnel and administrative healthcare personnel (Meetings Guideline Art.6.1) with regard to the administration of products to patients, the aspects to be considered during the administration, adverse events and similar topics.

2.4. 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; clinical drug trials and ethically important aspects of non-interventional drug studies; relations with healthcare professionals to take part in the consultancy and advisory boards of companies.

2.5. 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. The disclosure to TITCK and to the public of the Transfers of Value to Healthcare Professionals, Medical Associations and Healthcare Organizations, in line with the EFPIA principles are also within the scope of the Code.

2.6. The Code also comprises the areas not directly associated with promotion: including but limited to, sponsorship declarations (Article 8), certain rules on the distribution of drugs and reduced samples (Article 13), provision of information to the general public and information provided directly or indirectly to the general public (Article 20) also fall under the scope of the Code.

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

2.8. This Code does not encompass *public promotion* in line with special legislations relating to medicinal products for human use which have received registration or permit to be sold without prescription and which are not reimbursed.

2.9. 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.

2.10. 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.

Article 3- Definitions

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

3.1. Promotion: All informative activities conducted towards healthcare professionals (HCPs) by registration/permit holders or in the name or with the name, upon the request or with the approval, 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 (PPRs) within this framework, advertisements placed on medical or professional publications, announcements made through direct mailing or the press, the Internet or via other means of communication, and scientific/educational activities, meetings and similar events. (Reg. Art.4.1.j)

The Code regulates the following activities, including but not limited to the following topics: (Reg. Art.4.1)

a) All promotional and informative activities intended for physicians, dentists and pharmacists, about the medical-scientific features of medicinal products for human use; promotional and informative activities towards the dietitians about the enteral and parenteral nutritional products and medical infant formulas;
b) Publications that can be used as information source, database and reference or providing access to their electronic versions;
c) 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;
d) All activities of Product Promotion Representatives, including the use of promotional materials and verbal promotion;
e) Advertisements to be placed on medical and professional books and journals;
f) Advertisements made via direct mailing or by using the electronic environment; announcements made through printed and visual media or via other communication media;
g) Company sponsored activities and company activities conducted by using digital environment and social media;
h) Distribution of free samples;
i) Reasonable sponsorships and hospitality provided for promotional purposes;
j) 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;
k) Promotions in international meetings held in Turkey;
l) Promotion and hospitality intended for HCPs executing their profession in Turkey in meetings held outside Turkey; however, the rules of the host country shall also be complied with in such type of meetings.
m) Participation in fairs and exhibitions,
n) 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;
o) Programs and materials intended for patient education (Reg. Art.4.1.k);
p) 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 restrictions 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 infant formulas;
c) Promotion of kits, *in vitro* diagnostic tests, medical devices, equipment and supplies which may sold directly to the public;
d) Promotion of lenses and lens solutions;
e) Promotion of health and wellness products and food;

as well as;

f) 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);
g) 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;
h) Trade practices comprising prices, discounts or sales conditions to distribution channels;
i) Summary of Product Characteristics (SmPC);
j) Labelling on drugs, Patient Information Leaflets (PIL);
k) 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;
l) 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);
m) Corporate promotions.

3.3. Medicinal Product for Human Use / Drug: Any active substance or combination of substances of natural and/or synthetic origin, administered to humans, 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; (Reg. Art. 4.1.b)

3.3.1. **Product:** Medicinal products for human use, enteral nutritional products and medical infant formulas; (Reg. Art. 4.1.l))

3.4. Prescription product: Medicinal product that requires a prescription to be sold at pharmacies, that should not be sold without prescription or needs to have prescribed for reimbursement;

3.5. Registration / Permit / Marketing Authorization: The certificate prepared by the Agency, showing that a product may be manufactured and marketed with a specific formulation, a specific pharmaceutical form and dosage, and in accordance with approved product characteristics, (Reg. Art. 4.1.ğ))

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 Regulation. Art.26),

3.7. Promotional Materials: (Reg. Art 4.1.k; 8.1) Promotional materials comprise materials and tools which comply with the Regulation as well as the AIFD Code*. Promotional materials refer to any material used in promotion or advertising, directly via product promotion representatives and distributed in the meetings directed at healthcare professionals, including but not exclusive of the following:

a) Printed materials such as booklets, medical journals, leaflets and advertisements, providing sufficient and necessary information about a product;
b) Printed materials such as booklets, medical journals, leaflets and advertisements, providing sufficient and necessary information about relevant diseases addressed by the product;
c) Audio-visual materials with an educational or informative purpose, presented in storage media such as flash disks and CDs/DVDs;
d) Audio-visual materials such as films, slides, video shoots, databanks and electronic media including the Internet;
e) Any type of publications and materials that may be used as a source of information/data/reference by relevant circles and the electronic access to such materials;
f) Free samples in reduced package quantity;
g) Promotional taste samples aimed at enabling the tasting of enteral nutritional products for prioritized oral use, by the patients before the initiation of treatment by healthcare professionals, for the purpose of supporting a rational use of drugs and compliance with treatment; (Reg. Art. 9.1.f)
h) Programs and materials intended for patient education; (Reg. Art 4.1.d,k)
i) Pens and notepads which may be distributed by companies only in the product promotional meetings they organize.

***Note:** Even though they are permitted by the Regulation, reminder promotional items within modest monetary limits (reminder materials which do not exceed 2.5% of the monthly gross minimum wage (Reg. Art 4.1.k) should not be used according to the AIFD Code.

3.8. Healthcare Professionals (HCPs)

3.8.a. Physicians, dentists, pharmacists executing their profession in Turkey, regardless of their nationality (According to EU and Turkish health legislations, promotion may only be directed at physicians, dentists and pharmacists.)
3.8.b. Dietitians,
3.8.c. Nurses and midwives,
3.8.d. Members of other professionals defined in supplemental Article 13 of Law No. 1219, of 11/04/1928, on the Practice of Medicine and Branches of Medicines; (See Annex X) (Reg. Art. 4.1.f)

3.9. Product Promotion Representative (PPR) / Product Promotion Officer / 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.m)

3.10. Certificate of Qualification: The certificate issued directly to graduates of the Medical Promotion and Marketing Program and Medical Representative and Marketing Department at universities or to anyone who successfully passes an examination held or commissioned to be held by the Agency following the education provided by authorized institutions, within the framework of the curriculum defined by the Agency; (Reg. Art. 4.1.o)

3.11. Summary of Product Characteristics (SmPC): The document prepared for healthcare professionals as part of the Registration Dossier, containing the registered/permitted indications of the product and minimum information relating to the product; (Reg. Art. 4.1.e)

3.12. Abbreviated SmPC: Succinct information relating to the drug which 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;

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

3.14. Scientific Service: The department organized by the registration/permit holder within its own organization to ensure the proper conduct of the promotion of products for which it holds registration/permit in compliance with relevant regulations, and where only physicians/dentists/pharmacists are employed (Reg. Art. 4.1.c; Art.11)

3.15. Transfers of Value: It refers to the transfers of value in cash, in kind or via other means performed directly or indirectly for pharmaceutical promotion or other purposes in association with the development of sales of medicinal products for human use provided with prescription. Direct transfers of value refer to the transfers performed directly to the benefit of a Recipient by a Member Company. Indirect transfers of value refer to the transfers of value

performed to the benefit of a Recipient, on behalf of a Member Company or via an intermediary, and where the Member Company knows or may define the HCP/HO to benefit from the Transfer of Value. (EFPIA Code; Reg.Art.11.7) **The processes of disclosures to TITCK and to the public in line with EFPIA principles are different.**

3.16. Registration Holder / Pharmaceutical Company / Company: Real persons or legal entities in the name of whom a registration/permit has been issued by the Ministry for their products; (Reg. Art. 4.1.h)

3.17. Regulation: Regulation on the Promotional Activities for Medicinal Products for Human Use, published in the Official Gazette No. 29405 of 03/07/2015, 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 Mandate 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-December 31;

3.20. Ministry: The Ministry of Health, the relevant bodies of the Ministry of Health and of the Turkish Medicines and Medical Devices Agency (TMMDA) (Turkish acronym: TITCK).

3.21. Scientific Meeting: Scientific Meeting: Congresses, symposia, workshops, seminars, courses and meetings organized in the country or abroad by the Ministry, national and international associations whose members are healthcare professionals, healthcare institutions and organizations, universities, physician/dentist/pharmacist professional associations or registration/permit holders, with the purpose of giving information on a scientific subject; (Reg.Art.4.1.ç)

3.22. Product Promotion Meeting: Meeting organized by the registration/permit holder for the promotion of its product. (Reg.Art.4.1n)

Article Clarifications and Justifications

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 applied to the advertising of drugs in professional publications printed in Turkey and/or intended for the readers in Turkey. Journals produced in Turkey as a sister publication of an international publication are also included into the scope of this Code. Journals, vade mecum 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.p. 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 shall be interpreted from this perspective. The activities defined in this sub-article are definitely incompatible with the Regulation and ethical norms.

3.2. 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 shall be carried out in accordance with the AIFD Code of Promotional Practice.

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

3.2.a. 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 Herbal Medicinal Products, Official Gazette, October 6, 2010, Article 4.f)

3.2.a. Traditional Drugs: Substances of herbal or natural origin without an indication, generally sold at herbalists, grocery stores and supermarkets, and which are not among medicinal products use registered or permitted by the Ministry of Health.

3.2.f. 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 shall not have the appearance of a promotional material.

3.2.h. 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 shall monitor trade practices closely in order to prevent misevaluations and unfair criticisms towards the pharmaceutical industry and trade.

3.3. 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, Art.4.e)

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

3.7.a. **Book, booklet**: "Books and booklets containing sufficient and necessary information on the product or the disease(s) related with the product may be distributed as a promotional material. Books qualified as a textbook are included into the restriction on the distribution of books.

3.8. Healthcare Professionals (Reg. Art. 4.1.f)**:** Supplemental Article 13 of Regulation No. 1219, of 11/04/1928, on the Practice of Medicine and Branches of Medicine stipulates that "Healthcare professionals other than physicians and dentists shall not plan any treatment or write prescription by diagnosing directly diseases." In line with the EU acquis communautaire, the Regulation restricts the "promotional" activities of pharmaceutical companies to those who are authorized to write a prescription (that is, physicians and dentists) and pharmacists.

3.8. Healthcare Professionals,: 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 of the relevant unit is informed thereof and has granted his/her approval. As an exception, to dietitians, the promotion of only enteral and parenteral nutritional products and of medical infant formulas can be made.

3.8. Nurses, Midwives, Health Operators, Health Technicians: The Regulation allows, under the condition of the approval by the clinic responsible, the dissemination of information on the proper use of the products and their side effects to the other healthcare professionals in line with the classification made in the Meetings Guideline (Guideline Art.6.1)

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. Promotion to healthcare professionals can be made:
a) Using materials for promotion to physicians, dentists and pharmacists
b) Sponsoring or holding scientific meetings and product promotion meetings,
c) Visits by product promotion representatives to physicians, dentists and pharmacists. (Reg. Art.5.2)

4.3. The promotion of products to the general public, directly or indirectly through any public media or communication channels including the Internet is prohibited, whether through programs, movies, TV series, news reports or similar media.
This excludes Agency-approved advertisements placed in newspapers/journals, announcing the market launch of a product to healthcare professionals. (Reg. Art.5.3)

4.4. The PIL/indications of products that have been approved by the Agency may only be published
a) in media defined by the Agency, and
b) in the own website of the registration/permit holder.
c) Apart from those enumerated, no activities may be conducted for public promotion or information of products, by using partially or completely the Agency approved SmPC/PL/indications. (Reg. Art.5.4)

4.5. Promotion bans:
a) Products that have not been registered or permitted in accordance with the relevant Regulation,
b) Indications other than those approved by the Agency for products registered or permitted in accordance with the Regulation,
c) Except the promotional activities for the purpose of pharmacovigilance of products that are procured through international suppliers and are purchased by the Social Security Institute within the scope of alternative reimbursement models and notified to the Agency; the products that are registered or permitted in line with the relevant Regulation, but for which the Agency gives permission to be imported against prescription as they are not available in the domestic market,
shall not be promoted to the healthcare professionals. (Reg. Art.6.2)

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

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

4.6. The promotion a medicinal product for human use shall be consistent with the information, data and details provided in the updated Summary of Product Characteristics (SmPC) approved by the Ministry. (Reg. Art.6.3)

4.7. Promotion shall 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, clear and balanced medical information about the characteristics of the product. (Reg. Art.6.4)

4.8. The promotion of drugs shall be conducted in an objective and unexaggerated manner and encourage the rational use of drugs. The referred promotion shall not only conform to legal requirements, but also to high ethical standards and be in good taste.

4.9. Promotion shall not be made through use of misleading, exaggerated or unproven information which can encourage unnecessary use of a product in humans or lead to unanticipated risks, or through use of alluring visuals not directly related with the product. (Reg. Art.6.6)

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

4.11. Healthcare professionals cannot take part in the promotion of medicinal products for human use unless permit is obtained from the Ministry. Likewise, also legal entities such as universities, professional associations, other associations or foundations active in healthcare sector cannot take part in the promotion of these products, unless permitted by the Ministry. (Reg. Art.5.5)

Article Clarifications and Justifications

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.

4.2.2. 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-only drugs.

4.2.3. 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 of the Regulation. This permit applies only for large-scale international congresses.

b) It shall 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 indications) is not yet 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.

c) It is possible for medicinal products for human use and/or their indications not registered or permitted in Turkey or registered under another name to be included into the promotional booths at international meetings or for their materials to be distributed in these congresses under the following conditions. (EFPIA HCP Code 10.3):

(i) The promotional materials, except for promotional brochures distributed, shall clearly indicate the countries in which the product or indication is registered and that it is not registered in Turkey;

(ii) If reference is made to the prescribing conditions in the countries where the product is registered, it shall be indicated that the registration and administration information such as utilization and warnings may differ from country to country.

4.2.4. 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.

4.2.5. Scope of prohibitions: In accordance with the current legislation, it is forbidden to promote products, galenic forms, packages not registered in Turkey or unapproved indications. Promotion shall not be initiated prior to the receipt of Registration or Permit.

4.2.6. Notification of Relevant Institutions on 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.

4.2.7. 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.

4.2.8. 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 in Europe, legitimate platforms have been defined by AIFD as follows:

a) Independent peer-reviewed medical 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.

4.2.10. Information shared in abovementioned 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. *Note: Satellite symposia, which were listed under legitimate sharing out of the scope of the Regulation, are no longer in the above list, following the TITCK Promotion Regulation publication on 3rd July 2015. Turkish Health Agency TITCK considers satellite symposia as product promotion meetings.*

4.2.11. Sharing of literature comprising also products and indications not yet registered/approved in Turkey is possible, as long as the referred information is provided upon **the written request of healthcare professional**, the information is conveyed personally by the Scientific Service personnel, 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** and that the non-registered product or indication is not promoted visually or verbally during this communication.

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

4.9. and 4.11. 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, recording 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 SmPC and Other Mandatory Information

5.1.1. Abbreviated summary of product characteristics listed in Article 5.2, shall 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 shall constitute a whole with the promotional materials.

5.2. Abbreviated summary of product characteristics shall 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 SmPC;
(vi) Dosage and method of use;
(vii) Major side effects and precautions to be adopted;
(viii) Major interactions, incompatibilities;
(ix) Contra-indications, warnings and conditions to be observed during the administration of the product (pregnancy, lactation, driving);
(x) 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;
(xi) Name and address of the manufacturer, importer or distributor;
(xii) Registration date and number;
(xiii) The statement reading, “Please contact our company for detailed information;
(xiv) Legal classification (prescription or non-prescription, red and green prescription categories, narcotics, controlled drugs);
(xv) Public sales price of commercial forms (including VAT) and the approval date of the price;
(xvi) Tracking code/number of the material and the printing date (or intended usage date) of the materials;
(xvii) The date of preparation and/or latest date of update of the SmPC taken as basis in the information of the materials.

5.3. The information specified above in relation with the dosage, mode of administration, side effects, precautions, “reverse black triangle” sign in drugs subject to additional monitoring, contra-indications and warnings shall be placed in such a position in the promotional material so that their association with the clams and indications relating to the product are easily seen by the reader. For products subject to additional monitoring, the reverse black triangle ▼ sign and the standard information for products on additional monitoring should appear in the PIL and SmPC of the products. In all materials given to HCPs and patients the additional monitoring status should appear and adverse reactions reporting should be encouraged.

5.4. Furthermore, the name of the active substance of the drug shall appear at a legible size on the promotional materials, 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 SmPC shall be provided in compliance with either one of the following routes:

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

5.5.2. When the abbreviated SmPC is included into an interactive data system, instructions for accessing it shall be clearly displayed.

5.6. In case the promotional material is presented over the Internet, there shall be a clear and prominent statement as to where to find the abbreviated SmPC.

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

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

Article Clarifications and Justifications

5.1.1. Abbreviated SmPC: Each promotional material related to a drug shall contain mandatory information. Abbreviated SmPC shall be consistent with the SmPC related with that drug.

5.1.2. Use of SmPC in Scientific Meetings and Congresses: Mandatory information about the products promoted on posters and exhibition panels at meetings shall be provided either directly on the posters or panels or at the company booth. If the abbreviated SmPC is available at the company booth, this shall be indicated on the posters or panels.

5.2.1. Abbreviated SmPC shall be compliant with the relevant Regulations (Regulation on Packaging and Labeling), Guidelines and Notifications issued by the Ministry of Health; applicable legislation shall be followed.

5.2.2. Legibility of Abbreviated SmPC: Abbreviated SmPC comprises the essential information that shall 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 shall be ensured.

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

a. The font size shall be such that a lower case "c" is no less than 1 mm in height.
b. Sufficient space shall be left between the lines to facility easy reading.
c. A legible font style shall be used.
d. There shall be adequate contrast between the color of the text and the background. Dark print on a light background (preferably white background) shall 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; in such cases, the use of the active substance name more commonly used in the European Union is recommended. In any case, the active substance name used in the updated and approved SmPC shall be used. Indicating the open or closed chemical names or formulation or omitting the name of the active substance even if it exists is considered as a breach of the Code. Using color and font that makes it difficult for the generic name to be read shall also be considered a breach of the code.

5.2.iii. Quantitative list related with the dosage: The dosage shall 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 shall 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 shall fully comply with the indications specified. Most frequently seen adverse events and relevant warnings associated with usage in these indications shall 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 shall 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 contraindications, 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 the 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 SmPC may the new material is prepared, it would be beneficial to provide an explanation such as "*to obtain the current sales price of the product, see:* www.ourcompanyfirmamiz.com.tr/companyfirma" 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 the intended date of usage, while others prefer to indicate the printing date. Both are acceptable, as long as the date of update of the latest SmPC taken as basis for the information used in the material indicated.

5.5. Abbreviated SmPC in 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 affiliated part of a professional publication, it shall bear the date on which it was drawn up or last updated.

Article 6- Full and Abbreviated Advertisements, Advertisements on Journals

6.1. A full advertisement is the one that includes promotional claims for the use of products. Full advertisements shall 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".
e)

6.3.1. Advertisements of prescription-only drugs may be published only in medical, scientific and commercial journals sent of distributed under subscription to physicians, dentists and pharmacists. They cannot appear in newspapers, magazines, television, radio and similar media open to the general public (Reg. Art.5.3

6.3.2. 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)

6.3.3. In case the registration/permit holder wishes to declare the market introduction of the product to healthcare professionals via a press release, permission shall 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 5.1) No artwork or illustration is allowed in such type of advertisements.

6.3.4. 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)

6.3.5. 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.11.2 ; Art.5.3)

6.4. 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. Corporate advertisements are not in the scope of this Code.

Article Clarifications and Justifications

6.1. Company address: Telephone and fax numbers and the website address may be included into the advertisements and on the promotional materials as updated address that will enable physicians and pharmacists to forthwith reach the company. The website or the full address may be provided in reminder advertisements and promotional materials.

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

It is recommended for the 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 shall 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-only drugs. Advertisements in such publications are considered by AIFD as a breach of the Regulation and the Code of Promotional Practice.

6.3.4.a. Press Releases; (Press Release Guidelines, Article 5.3.)

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

6.3.4.b. Documents to be Submitted in the Press Release Applications: (Press Release Guidelines, Article 6)

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 co-promotion 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 shall 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 shall 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 shall not be misleading directly or by implication; they shall not mislead healthcare professionals by distortion, exaggeration, undue emphasis or in any other way.
c) Any type of information appearing on the promotional material shall 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 shall comprise “comparative features”. Comparison can be made in a promotional material under the following conditions, without making any reference to trademarks.

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 shall be provable. Side effects and adverse events shall be supported with clinical experience. Additional reference is not required for the information and data included into the approved SmPC 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 shall be specified.

7.7. When the promotional materials refer to “*data on file*”, the section relating to the claim in this data shall 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 (*replacement or changing*) 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) in Promotion

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 shall 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 shall absolutely be necessary to specify in the promotional material that the citation, graph or table has been adapted, modified, shortened or adjusted. The adaptation made shall not disrupt or modify the meaning of the citation. (Reg. Art.6.5)

7.9.2. The texts, illustrations, tables, pictures and graphs shall conform to the Code. Graphs and tables shall be presented in such way as to give a clear, accurate and balanced view about the relevant topic.

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

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

7.9.5. The use of claims known to be no longer valid in promotion shall be regarded as breach of the Code.

7.9.6. All information and claims about side effects and adverse events shall 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”, reliable and “effective” shall be used only when substantiated with sufficient and valid medical evidences.

7.11. The word “new” shall not be used to describe any product or form or therapeutic indication which has been registered in Turkey for per a period longer than twelve months. It shall be clearly specified what is exactly meant by the word “new”. (molecule, indication, galenic form, dose type, commercial presentation, etc.)

7.12. Exaggerated or all-embracing claims (the most superior, the most reliable, the effective, perfect, unique), if not proven, shall not be used. What is defined in the comparison and its limits shall be clearly indicated.

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

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

7.15. Copyrights of reprints and citations: Copyrights of authors, publishers and investigators shall be observed.

Article Clarifications and Justifications

7. Information, Claims and Comparisons: Pharmaceutical promotion shall be compliant with Law No. 6502 on the Protection of Consumers and especially with Article 61, as much as with the relevant legislation of the Ministry of Health.

7.2. Misleading Information

The Scientific Service of companies shall 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 shall be used carefully, ensuring that the meaning is preserved and not disrupted.
iii. Economic evaluation drugs: Pharmacoeconomic findings shall be used carefully and shall not be exaggerated.
iv. A totally new clinical or scientific view: Until a clinical or scientific topic is generally accepted, particular care shall be displayed to ensure that this topic is treated in a balanced manner in promotion.
v. Unfounded comparisons: A drug shall not be described as “better” or “stronger” without openly identifying the compared product.
vi. As with any comparison, price and cost comparisons shall also be accurate, fair and balanced and comparison criteria such as similar duration of treatment, cost for patients and the social security institution and the comparison shall not be misleading.
vii. Statistics used shall be accurate. Statistical significance shall be watched for. The accuracy of statistics shall be evaluated before being used as 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 shall be presented in a balanced manner in the promotional material

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 shall be in line with the updated SmPC approved by the Ministry. Unregistered indications cannot be promoted even if they are included into a publication.

7.4.b. Claims shall be substantiated by literature from peer-reviewed journals. References shall always be provided for all promotional claims, on the front or back page or inside the material. Reference shall be provided also for the slogan appearing on the cover page of the promotional material, unless the text used in this slogan is not included into the SmPC 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 SmPC and are not older than two years (date of congress being day zero).

“Submitted papers” shall not be used as a reference in promotion.

7.6. Citation of References: All sources used as basis for promotional materials and which have been cited shall 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 shall be proven. In case the company does not want to reveal the data on file, this data shall not be used in promotion.

7.9.a. Graphs, Illustrations and Texts: The graphs or pictures used shall not be misleading; they shall not cause any warning or contra-indication to be overlooked. Titles and coordinates of tables and graphs shall be specified accurately and adequately.

7.9.b. Special attention shall be displayed so that the placement of 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 fairly.

7.9.c. It shall be taken into account that information not directly related with the product 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.d. Current Opinion of Authors: Nowadays when data interpretation and information are changing rapidly, companies shall 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.

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

7.15. Copyrights: Copyrights of the publications used shall be observed. The dissemination, duplication and processing rights of the publications to be used shall 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. Before translating, duplicating, distributing the literature used in promotion, it shall 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 shall be contacted. Third party service providers shall be warned against potential violations of copyrights.

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

8.1. It shall be aimed to maintain high standards at all times. (EFPIA, 5.01)

8.2. Promotional materials and activities,

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

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

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

8.6. Mailings, envelopes or wrappers shall 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 shall not be used for promotional purposes, except when requested or with prior permission of the recipient. When an individual requests that his/her name is removed from the records, this request shall be forthwith fulfilled.

8.8. Clear Declaration of Sponsorship: In case of any direct or indirect company sponsorship of activities and materials relating to drugs and their use, whether promotional in nature or not, this sponsorship shall 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 shall certainly be indicated that this research is conducted with the request or support of a pharmaceutical company.

8.10.1. Rule of Transparent Conduct of Promotion: Companies shall 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 shall not target disguised product promotion. The primary goal of such types of programs, assessments and studies shall be scientific and educational.

8.10.3. Promotional papers and articles published by the monetary support or other type of sponsorship of a company shall 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 shall not be promotional in nature. These studies shall 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 shall not be carried out as promotion under the appearance of a research and for influencing physicians.

8.13. Healthcare professionals shall disclose any sponsorship received from registration /permit holders:

a) At the beginning of every speech/presentation they deliver,

b) At the beginning of every speech/presentation they deliver. (Reg. Art.6.9)

Article Clarifications and Justifications

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

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 shall 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 and Disguised Promotion Under the Appearance of Editorials: Advertisements shall not be published under the appearance of editorials. Hidden or disguised pharmaceutical promotion under the appearance of a news or report shall not be performed. Sponsorships shall be described. Promotional purpose shall 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 shall 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 shall be separated from each other.

The use of IMS grid sales data in promotions does not conform to the Code.
It shall 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.

8.13. 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. Before sending promotional materials to physicians, dentists and pharmacists physically or via electronic mail, written permission shall be obtained from them for receiving such mail and for preserving their address and contact details and their requests for being removed from the mailing lists, other than those used for adverse effect notification and urgent warnings, shall be forthwith fulfilled.

9.2. Promotion shall only directed at physicians, dentists and pharmacists who are interested in the topic being promoted and who may benefit from it.

9.3. Respect for the Confidentiality of the Information Collected

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

Article 10- Scientific Service and Its Duties

10.1. Registration/permit holders shall 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 and the approval of non-interventional drug trials and will appoint the person(s) (physician or pharmacist) responsible for these activities. (Reg. Art.11.1) (EFPIA 15.02.g; 18.02.a) Companies shall inform AIFD about the scientific service officers of their company. Only physicians/dentists/pharmacists are employed in Scientific Services. (Reg.Art.4.1.c)

10.2. The Scientific Service shall ensure that the promotion of medicinal products, the registration/permit 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 shall monitor and document that the product promotion representatives employed by the company are adequately trained, regularly updated and fulfill the obligations expected from them.

10.4. Where requested by the Ministry, the Scientific Service officer shall supply all documents and information regarding promotional activities. Reg. Art.11.5.b)

10.5. The Scientific Service officer shall ensure 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 shall be kept for at least five years. (Reg. Art.11.5.c)

10.7. The names of the product promotion representatives promoting products registered by the company, the districts where they work, the names of healthcare professionals to whom they make promotion and of the products they promote, their dates of hiring and of exit from the company are kept by the Scientific Service to be submitted to the Agency (TITCK) upon request. (Reg. Art. 11.5.ç)

10.8. The provision of information directly by the Scientific Service Officer about a product or indication not registered in Turkey upon the written request of a physician, dentist or pharmacist, is possible. (Reg. Art.6.2)

10.9. Scientific Service keeps the documents related to any request made by a physician, dentist or pharmacist for unregistered products for five years. (Reg. Art.11.5.d)

10.10. The Scientific Service should regularly monitor the list of "products falling under additional monitoring", include the reverse black triangle ▼ sign and the text "This product is under additional monitoring" in the promotional materials of these products. (Reg. Art.11.5.e). This standard text the symbol should appear in the SmPC /PIL of the product and in all promotional materials made available to HCPs and patients and the recipients should be encouraged to report adverse reactions. (IFU Guideline 3.3.2)

Article Clarifications and Justifications

10. Scientific Service: AIFD member companies shall ensure that the AIFD General Secretariat has an up-to-date list of the names of the Scientific Science officers they have appointed (Medical Director, Medical Manager, Regulatory Affairs Manager, Compliance Officer or other officers deemed suitable by the company), their brief CVs, emergency phone numbers and e-mail addresses.

10.1. *The Agency (TITCK) had informed the industry that with a temporary Regulation article, it would allow those who were employed by the Scientific Service of a company prior to 3/7/2015 [publication of the most recent Promotion Regulation], even if they are not physician, dentist or pharmacist, would be able to continue their employment*. (The temporary Regulation article publication is pending.)

10.1.2.a. The Scientific Service Officer shall 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 conduct of relevant activities, as well their approval. Such person shall certify that he/she has examined the final version of the material, and that according to his/her opinion, the material or activity is compliant with the Code of Promotional Practice and other regulations, with the SmPC of the relevant product, and that the information provided about the product is presented in an accurate, balanced and realistic manner.

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

It shall be taken into account that the five-year preservation period begins as of the last wide-scale use of the material.

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

10.10. Additional Monitoring, reverse triangle: Reverse black triangle and explanatory standard text that aim to encourage health professionals and patients to report all suspicious adverse reactions should be included in promotional materials presented to healthcare professionals, in SmPC /PIL and in informative materials given to patients. in printed and electronic media.
Post-marketing spontaneous adverse reaction reports continue to be one of the cornerstones of pharmacovigilance activities. The data transmitted by the adverse reaction reports are an important source for signal detection activities. For this reason, awareness of health professional members and patients about the need to report suspicious adverse reactions and encouraging them to report is an important tool in monitoring the safety profiles of medicines.
Registration holder; (1) keeps a list of drugs subject to additional monitoring and includes a standard explanatory statement and the ▼sign in the SmPC / PIL of the drugs. (2) Healthcare professionals and patients will be informed of any additional monitoring status and encourage the reporting of adverse reactions. (3) When applicable, applies for a variation for the inclusion or elimination of the reverse black triangle mark and the standard explanatory statement to the SmPC / PIL of the related product.

Black icon ▼ and explanatory statement
The minimum length of each side of the inverted black triangle ▼ should be 5 mm and should correspond to the size of the standard text following the triangle.
At the top of the SmPC of the drugs on the list, the following declaration will be placed above the commercial name of the drug and the inverted black triangle symbol will be placed immediately before the declaration. "*This drug is subject to additional monitoring. This triangle will ensure that new safety information is quickly identified. Healthcare professionals are expected to report suspected adverse reactions to TÜFAM. See IFU Guideline Section 4.8 How to report adverse reaction*s? "
A similar statement will appear in the instruction for use for patients (PIL). The name of the medicinal product in the instructions for use, the indication of the active substance (s) and the auxiliary substances shall be as follows: "*This medication is subject to additional monitoring. This triangle will ensure that new safety information is quickly identified. You can help by reporting any side effects from the field. You can look at the end of Chapter 4 of the IFU Guide to learn how to report side effects*. "
When the drug is included or removed from the list, the registration holder shall update the SmPC and the patient instructions for use (PIL) by adding or subtracting the black symbol and the standard descriptive phrase.
If the addition or removal decision to the list [additional monitoring] is taken during the registration process (eg registration application, indication addition, extension of the license validity period ...) SmPC / PIL shall be updated accordingly before the end of the registration process.

Criteria for including medicines in the additional monitoring list:
Pursuant to the eighth paragraph of Article 8 of the "Regulation on the Safety of Drugs" published on 15 April 2014, it is obligatory to include in the list the following categories of medicines: (1) Products that are included in the additional monitoring list in international applications. (2)

Biosimilars that are already registered or in the registration process. (3) Drugs followed in Turkey by special monitoring systems (eg drug safety monitoring form, web based monitoring systems, drugs with limited distribution). (4) Medicines that applied for registration under special circumstances of the Regulation of Medicinal Products for Human Use. (5) Drugs licensed with the condition to carry post-registration safety study (6) Medicines containing a new active substance which is not included in any of the medicines previously licensed in Turkey, which were applied for after the date of 15.04.2014. (7) All biotechnological drugs for which a registration is sought after 15.04.2014. (8) All blood products licensed after 01.01.2011. (9) Drugs that the institution deems necessary.

The criteria for determining the first prescribed time to remain on the additional monitoring list
The Authority may remove a drug listed on the list five years after it has been licensed in Turkey or may extend this period. If new concerns about safety arise during the life cycle of the drug, the drug may be re-listed.

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 of the company. 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 conformity of all activities falling under the definition of “promotion”, including meetings and sponsorships, in addition to promotional materials, to the Code, shall be approved by the Scientific Service.

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

11.4. Companies shall 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; provision 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 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 (PPRs) is described in Art. 12.

Article Clarifications and Justifications

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.

11.1.a. The approval process is conducted for the purpose of ensuring full conformity of promotions to 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 shall be re-initiated.

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

11.2. Entry into the System and Approval of Meetings in Conformity with the Guidelines: Meeting and participant information that needs to be entered into the system of the Ministry of Health in accordance with the new Regulation and relevant Guidelines shall be carefully followed by the top management of the company in order to avoid being subjected to severe sanctions. Conformity to the restrictions stipulated in Article 16 is the responsibility of the Scientific Service on behalf of the registration/permit holder.

11.5. Certification of Trainings (Documentation and Approval): Trainings to be conducted on the Code of Promotional Practice shall be documented. The participation of company employees in trainings organized by AIFD or upon the approval of AIFD about the Code of Promotional Practice may also be regarded sufficient for the certification.

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

12.1. Member companies shall ensure that their employees 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 healthcare institutions (Product promotion representatives – PPRs) are adequately trained on applicable laws, Regulations, guidelines, health and advertisement regulations, AIFD Code of Promotional Practice and the relevant Regulation.

12.2. Product Promotion Representatives holding a Certificate of Qualification can work in companies with the title of PPR. (Reg. Art.10.2.a) (This article will be effective on 1/1/2019)

12.3. Graduates of university programs for "Medical Promotion and Marketing Program" will be issued the certificate of qualification upon submission of the diploma. Persons who hold at least a university degree and successfully pass an examination covering the curriculum posted on the Agency's official website will be issued a qualification certificate by the Agency. (Reg. Art.10.1)

12.4. Product promotion representatives must obtain a qualification certificate issued by the Agency by 01.01.2019. Those who are at least a high school graduate and who have successfully passed an examination and become eligible to obtain a qualification certificate prior to said deadline will be issued a qualification certificate by the Agency. The requirement of holding a high school diploma is not mandatory for persons who worked for two full years as a product promotion representative over a five year period before the publication date of the Regulation. (Guideline 5.3)

12.5. Upon receiving their qualification certificate, PPRs are registered by the Agency in its electronic register system. Registration/permit holder will issue a "Product Promotion Representative Identity Card", the format of which is defined by the Agency, to those product promotion representatives who are registered in the system and possessing the qualification certificate. They may not be employed as product promotion representatives if they do not possess the Identity Card. (Reg. Art.10.2.b) (This article will be effective on 1/1/2019)

12.6. PPRs are obliged to be equipped with full, sufficient and necessary scientific data and knowledge about the products they promote; their company shall monitor that they have received adequately basic and in-service continuous training to serve this purpose.

12.7. Companies shall be responsible for the activities of their PPRs.

12.8. When fulfilling their duties in a responsible manner, PPRs shall always act in line with high ethical standards and the Code of Promotional Practice.

12.9. Product promotion representatives may not promote any product or analogues or distribute promotional materials to any other healthcare professionals than the physicians, dentists or pharmacists. (Reg. Art.10.2.c). They may promote to dietitians only enteral and parenteral nutritional products and medical infant formulas.

12.10. PPRs shall not contact directly patients and patients' relatives.

12.11. PPRs must forward any adverse events/reactions reported to them during product promotion to the scientific service, product compliance departments in line with the procedures and without delay ((Reg. Art.10.2.ç).

12.12. PPRs 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. (Meeting Guideline 6.1)

12.13. PPRs 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) In order to achieve this, companies shall prepare training-guidance materials to PPRs on the technical aspects of each drug.

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

12.15. In line with applicable laws and regulations, the Summary of Product Characteristics of the relevant product shall be made available by the PPR to be presented upon request to the physicians, dentists or pharmacists.

12.16. The number, timing, duration and type of calls to physicians, dentists or pharmacists by PPRs in private surgeries, pharmacies and other healthcare institutions shall be organized in a manner so as to avoid disturbing the physicians, dentists, pharmacists and patients. Promotion of human medicinal products by the product promotion representatives at public health institutions during office hours are subject to the following rules: (Reg. Art.10.3)

a) Relevant administrative supervisor 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 time allocation must not disrupt educational functions, or provision of health services to patients.

b) Product promotion representatives will declare which registration/permit holder they represent at the beginning of the visit, and show their product promotion representative identity card.

12.17. Product promotion representatives may not be charged any fee, even as donation or otherwise, for access to healthcare institutions and organizations. (Reg. Art.10.4) PPRs shall not provide any monetary or similar incentives or

offers to physicians, dentists and pharmacists in order to be able to have the opportunity to visit them. No fees shall be offered or paid in return for the duration of the visit. (Reg. Art.6.8)

12.18. No poster or similar promotional material, which may be perceived as promoting a product, may be exhibited, placed, posted and/or affixed at healthcare institutions. However, 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, are excluded from this prohibition. (Reg. Art.10.5)

12.19. In case of breach in promotion by PPRs during the period of validity of the certificate of qualification issued by the Ministry;

a) the PPR shall be first warned by the Ministry
b) In case of any other breach of the Regulation during the following twelve months is detected, the certification of qualification shall be suspended for a period of three months
c) In case of any breach of the Regulation within twelve month after the previous suspension, the certificate shall be suspended for a period of one year.
d) The PPR whose certificate of qualification is suspended shall not work as PPR during this period and her/his PPR Identification Card shall be taken back by the employer company. (Reg. Art 13.4)
e) The sanctions mentioned in the Regulation are also taken for the employer of the sanctioned PPR.

12.20. The procedures and principles on the training, certification and records of PPRs shall be stipulated in a Guideline.

Article Clarifications and Justifications

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

12.8. High Ethical Standards: Companies shall highlight in their medical and sales & marketing trainings the characteristic of pharmaceutical promotion which has commercial purposes but which gives precedence to the provision of medical information and the rational use of drugs.

12.10. Product Promotion Representatives Shall Not Contact Patients Directly: Patient training programs need is approved by the Ministry. It is not appropriate that company employees (or those working on behalf of the company) assist patients in their transactions relating to their medical reports, prescriptions and other documents and contacting with patients and patients' relatives in similar situations. PPRs shall not be involved in activities such as finding patients for trials.

The roles of trainers of prescribed special application tools and PPRs shall be separated. Companies are advised to use separate teams for patient training. No material of promotional purpose or which may be perceived as such shall be present or no activity shall be performed during the period allocated for patient training. Training on the administration of the devices for the administration of drugs prescribed to patients (such as insulin pumps, etc.) shall be carried out by teams without sales responsibility and these teams shall preferably staffed with nurses.

12.11. Collection of Adverse Events Reports from Physicians, Dentists and Pharmacists: The collection process of adverse events (and side effects) notification reports shall be included into the basic training package of product promotion representatives and they should go through systematic re-training. According to the pharmacovigilance guideline, "Direct communication from members of the health profession, reports in the press, interviews with company representatives of health professionals, including product promotional staff, notifications made to members of patient associations, or reports made as a result of group actions should be accepted as spontaneous reports."

12.14. Training-Orientation Materials must be carefully prepared so as not to lead to misunderstandings and misinterpretations.

12.15. The SmPC information to be distributed to physicians should be current. This information can be printed or stored and distributed in other contemporary communication media (CD, flash disk, company web page). The promotional person must be presented in print as soon as he / she wishes.

12.16. Text compliant with the Regulation, EFPIA Code and TTB Declaration on Interactions between Physicians and the Industry.

12.20. Product Presentation Representative Exam; Proof of Proficiency Certificate and ID Card (The following text has been taken from the relevant guide, the item headings and item numbers in the guide are preserved; the guideline provisions will come into force in 2018 and 2019.)

Designation of examiners
ARTICLE 6 – (1) Examiners will be designated by the Agency for a four-year term, including 2018, among universities who express willingness to be an examiner and meet all of the requirements to be established by the Agency and communicated to universities in writing in 2017.
2) Examiners will be posted on the Agency's official website along with their commission term.
Examination application
ARTICLE 7 – (1) PPR candidates will personally make an application to an examiner.
2) PPRs candidates who fail the examination must personally apply again to retake the examination.
3) The examination fee will be payable to the examiner.
4) All arrangements pertinent to the examination will be announced by the examiner.
Examination

ARTICLE 8 – (1) The distribution of questions across courses and the total number of examination questions will be announced on the examiner's official website.
2) The examiner will make available on its official website a databank of test questions comprising not less than 500 questions, of which not more than 40% may appear in the examination.
3) Examinations questions:
a) will be prepared by a scientific board within the examiner, comprising faculty members for the courses concerned, in accordance with the curriculum announced by the Agency;
b) may not include "all of the above" or "none of the above" as choices;
c) may not contain any identical questions from the previous two examinations.
4) The examination schedule will be announced by the examiner.
5) The examination will be held at the locations and on the dates as announced by the examiner, as a supervised examination.
6) At least 2 (two) qualification examinations will be held every year.
7) The passing examination grade will be 60 (sixty) or above.
8) The number of questions correctly answered in the examination will be used as the number of correct answers providing basis for scoring.
9) Examination results will be announced by the examiner in the form of grades.

Issuing of a Qualification Certificate and Identification Card

Qualification certificate

ARTICLE 9 – (1) Candidates who successfully pass the PPR qualification certification examination, becoming eligible to receive a qualification certificate, and graduates of university programs for developing product promotion representatives will be issued a qualification certificate by the Agency, upon presenting the relevant unit of the Agency with the following documents:
a) Notarized duplicate of the diploma or graduation certificate, or a copy whose authenticity has been certified by the issuing institution with a wet signature.
b) For non-high-school graduates, a formal letter issued and submitted to the Agency by the registration/license holder, confirming that the person in question has actually worked for two full years as a product promotion representative over a five-year period before the publication date of the Regulation.
c) Photocopy of the national identification card.
d) 2 passport photographs.
e) Bank slip, showing deposit of the qualification certification fee into the Agency's bank account.
2) The qualification certification and renewal fees will be announced in the Agency's annual tariff of fees.
3) Holders of a qualification certificate will be recorded in the Agency's PPR database.
4) Aspects related to the use of the PPR database will be announced by the Agency in a guideline.

Issuing PPR identification cards

ARTICLE 10 – (1) PPRs holding a qualification certificate registered in the system will be issued a PPR identification card by their employer, in the format designated by the Agency.
2) The PPR identification card format will be announced by the Agency on the Agency's official website by 31.09.2018.

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 purpose of patient treatment.

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, to safely withdraw them where necessary. Upon demand, these records shall be submitted to Ministry officials electronically or in hardcopy in the format designated by the Ministry. (Reg. Art.9.1.a)

13.3. The recording system shall 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 commercial barcodes/datamatrixes or price tags are used on the packages of promotional samples. The outer package shall bear the relevant information on the production process, withdrawal and stock follow-up. In case of presence of a barcode/datamatrix on the packages of Free Promotional Samples planned 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 of product. 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 visible manner. Where it is 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 SmPC, shall always be provided, where available, along with the promotional sample. (Reg. Art.d.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. The samples of the products listed in the "Medicines Not to be Distributed" declared on the official website of the Agency (TITCK) shall not be distributed. (Reg. Art.9.1.e)

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

13.12. Sample Distribution Rules for AIFD Members:

13.12.1. Reduced sample of a product may be provided upon his/her first dated and signed written request of a healthcare professional authorized to prescribe a prescription (physician or dentist) at an amount not exceeding 4 (four) samples per year only for a period of 2 years (24 months) for the purpose of enabling his/her to get acquainted with that drug (4x2 years rule). The same rule shall apply also for new drugs*. (See Article 13.13.)

13.12.2. The total number of samples that may be distributed any year for a product shall not exceed the total amount for that product designated according to the previous year in line with the restrictions in the Regulation and “samples may be distributed to a physician who makes a request only in line with the rule of maximum 4 samples per year* throughout 2 years as of the first date of request of the physician”, as stipulated in Article 13.12.1 of the AIFD Code.

13.12.3. Sample Distribution Rule in the Regulation (Reg. Art.9.1.f)

13.12.3.1. Free product samples may be distributed at the amounts to be calculated as indicated below as of the market introduction date of each medicinal product for human use (the date on which the company records the drug on the Drug Tracking System)**:**

13.12.3.2. At an amount not exceeding 5% of the total sales, upon tracking the month sales realizations on the first calendar year;

13.12.3.3. At an amount not exceeding 5% of the sales amount of the previous [calendar] year on the second calendar year;

13.12.3.4. At an amount not exceeding 3% of the sales amount of the previous year on the third, fourth and fifth calendar years;

13.12.3.5. At an amount not exceeding 1% of the sales amount of the previous year, after the fifth calendar year.

13.12.4. The reduced sample distribution rules indicated above shall be applied by AIFD members as of July 1, 2012.

13.12.5. *A “new drug” is a product newly issued a registration for its market introduction in an indication following 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 forms registered in existing indications shall not be regarded as a new drug.

13.12.6. Taste samples of enteral nutritional products are not included in the scope of this article. Taste samples of enteral nutritional products are not included into the scope of AIFD’s 4x2 restriction and the regressing 5% rule of TITCK. The taste samples of enteral nutritional products may be distributed provided that they do not exceed 5% of the total annual sales amount of the product group being distributed, without any year restriction.

Article Clarifications and Justifications

13. Samples In accordance with EU directives and the EFPIA Code, distribution of free reduced samples of prescription-only drugs may only be allowed in special 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) shall 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 shall not be delivered in their original commercial packages; their packages shall not bear any price tags or commercial drug barcodes**.**

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

13.3.1. Companies shall avail of 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 shall include starter kits and the drugs used in trials.

13.5. Documents to be Submitted in the Application for Receiving a Distribution Permit for Free Samples

a) Sample specimen (2),
b) Photocopy of registration,
c) Latest approved sales permit and the package mockup enclosed with it,
d) Latest certified package 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. No Supply of Samples to Pharmacies: In line with EFPIA's interpretation of the EU Directive, AIFD does not regard suitable the supply of samples of prescription-only drugs to pharmacists**.**

13.12.1. Distribution of samples upon the written, dated and signed request of physicians: The EFPIA Code indicates that the samples are distributed upon the "unsolicited request of physicians". Therefore, the relevant physician shall submit his/her sample request in written and with a date and sign it.

13.12.2. 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 article. (5%-3%-1% and 4x2 rules shall apply.)

13.12.3. Designation of the amount of free samples that may be distributed (the 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 shall not exceed the amount to be calculated according to the following table as of the market introduction date of the relevant product, as of January 1, 2013. The enforcement of this provision shall be initiated as of the market introduction date of each medicinal product for human use. (Reg. Art.9.1.f, Guidelines on the Distribution of Free Samples)

The enforcement of Paragraph (f) in the 1st clause of Article 9 regarding free samples in the Regulation 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 first calendar year is 2012.
Example B: For a product introduced into the market on 01/07/2012, the first 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".
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 shall be calculated as follows:

[(1-day unit sales figure of 6 months) / 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, 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.

13.12.3.1. 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.

13.12.6. 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 samples 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 exceeded.

Article 14- Promotional Materials, Medical & Educational Materials

14.1. Promotion of medicinal products for human use shall only be directed at physicians, dentists and pharmacists. When promoting medicinal products for human use to physicians, dentists and pharmacists, no benefit, whether in cash of in kind, may be provided, or even offered or committed to these persons. The healthcare professionals shall not accept or request any inducement during the promotional activities directed at them. (Reg. Art. 6.8)

14.2. Prohibition of Gifts:

No gift or reminder material qualified as a gift or pecuniary advantage in cash or kind, which may be perceived as an inducement in relation with a promotion or for prescribing, procuring, administering, recommending the administration of or selling or buying a prescription drug shall be supplied, given or promised to healthcare professionals or those at an administrative position. (EFPIA 2013, Article 17.01) The materials defined in Article 14.3 which may be distributed to HCPs shall not comprise any material which may be perceived as designed to bypass the prohibition on gifts. (EFPIA 2013, Article 9.01)

14.3. Materials for Sharing Medical Information and Educational Materials

14.3.1. The transmission of materials for sharing medical information and educational materials to healthcare professionals is permitted provided that each material;

(i) has an inexpensive real or perceived cost;
(ii) is directly relevant to the practice of medicine or pharmacy services; and
(iii) is directly beneficial to the care of patients. (EFPIA 2013, Article 9.01)

Member companies shall act in line with the warnings stipulated in the guiding texts to be prepared within the framework of this article. (EFPIA 2013, Article 9.03)

14.3.2. Notepads and pens of reasonable value may be provided to the healthcare professionals and administrative staff attending, scientific meetings, satellite symposia; promotional and similar meetings and conferences organized by the company, for the purpose of being used in this meeting. These materials may bear the name and logo of the company hosting the meeting but shall not contain information on company drugs.

14.4. Medical Publications, Books and Journals

Companies are not allowed to provide professional and medical books, qualified as a textbook, in printed or electronic form, or subscriptions to journals, to healthcare professionals for their personal use. Books and journals may be provided only to a healthcare organization in accordance with the AIFD Code of Promotional Practice; a delivery certificate and/or certificate of appreciation or a fixture record document indicating that it has been delivered to the relevant organization shall be obtained and the cost will be disclosed under the name of the organization included into the scope of transfers of value indicated in Articles 22 and 23. The procurement of books and journals to organizations shall not be performed for the purpose of encouraging the prescription of a drug or a range of drugs of a company, shall not put physicians, dentists and pharmacists or the clinics and hospitals that have received the books or journals under any obligation and shall be complimentary.

14.5. No promotion or service shall be provided to healthcare professionals through **sweepstakes or 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 to healthcare professionals.

14.7. If a reminder printed material contains only the following, it is not necessary to include the mandatory information indicated in Article 4.2:

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

14.8. Company representatives shall adopt relevant measures to ensure that the promotional materials are not displayed in a manner that be seen by the patients in the healthcare organizations. (Reg. Art. 8.2)

14.9. Trade Conditions: Direct or indirect commercial agreements, monetary discounts or discounts in kind, installments granted shall not be included into the scope of transfers of value as long as they comply with commercial customs (Article 3.2.h)

Article Clarifications and Justifications

14. Promotional Materials

14.2. The enforcement of the Positive List effective between 2004-2011 in the AIFD Code of Promotional Practice has been rescinded. As all gifts have been banned, also the Negative List has been removed from the text. (All gifts are included into the Negative List.)

14.3. **Prohibition of the Distribution of Gifts: It shall become effective as of January 1, 2014. (**Companies may distribute the reminder materials in their stock until June 30, 2014.)

14.4. Restriction on the distribution of textbooks to physicians shall become effective as of January 1, 2015.

14.3. What is acceptable within the scope of Materials for Sharing Medical Information and Educational Materials?

14.3.1. EFPIA has recommended AIFD and its other member organizations to provide indicative examples and definitions to member companies. The distribution of Materials for Sharing Medical Information and Education Materials to HCPs shall not be used for bypassing the article on "prohibition of gifts", indicated in Article 14.3 or for violating the prohibition.

14.3.2. Notepads and pens: As of January 1, 2014, companies may provide pens and notepads at a modest cost, not bearing any product brand but veering the company logo and name only to the participants in the meetings they organize themselves.. Product promotion representatives may not provide a notepad, pen or stationary during their calls. The cost and the perceived value of the notepad and pen to be provided to the healthcare professionals who attend a meeting shall be modest.

14.3.3. Pens and notepads shall not be distributed at congress stands.

14.3.4. The pens and notepads placed inside the conference bags at congresses shall not bear the company logo or the product brand. (EFPIA)

14.3.5. DVDs and flash disks, containing information to be shared and educational materials, at a cost not exceeding a **modest value** and at the perceived value, may be provided to healthcare professionals**.** The expediency of their content shall be approved by the Scientific Service; the DVDs and flash disks shall have a capacity in proportion with the educational material they contain.

14.3.6. Materials with medical information and educational materials which may be distributed on a wide scale are the printed materials which may be distributed to healthcare professionals or to patients via healthcare professionals and the demo materials describing the administration of drugs to the patients. Such materials shall not be composed of materials which may be bypassing AIFD's prohibition of gifts.

The materials directed at **patients** are materials which have been approved by the Scientific Service of a company for the provision of direct benefit for the treatment of a patient, which are at a modest value and which may be delivered to patients or their relatives via physicians and pharmacists. Such type of materials may not be distributed at congress booths, but one sample of each material may be displayed at the booth. These materials may bear the name or logo of the company distributing them. The materials prepared for the purpose of being distributed to patients may bear the name of the drug only where this is mandatory for ensuring their expediency. No material directed at patients shall be intended for generating a request for a drug by the patients or their relatives.

14.3.7. Promotional materials, slogans and visual materials of prescription-only drugs, shall not appear on the materials (such as calendars, planners) distributed by other companies or organizations not allowed to be distributed by their companies.

14.3.8. For products required to be distributed via a cold chain, expedient isothermal bags, boxes and coolers (ice batteries) provided free of charge to pharmacies or wholesalers and utilized for ensuring the relevant drug to be delivered to patients or physicians under cold chain conditions shall not be included into the scope of this article.

14.3.9. 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.

14.3.10. 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 general public. Company logo may be printed to indicate a sponsorship.

14.4. **Medical Publications, Books and Journals:** It will be sufficient for the company to obtain a certificate of appreciation and/or delivery notice and/or fixture record document indicating that the books and journals have been received by the relevant organization.

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

14.5.2. Knowledge Contests: Companies may conduct knowledge contests in the corporate promotion meetings and congresses in order to measure the level of knowledge of the participants and increase interest in the event, as long as these remain secondary to the meeting; but they cannot give prizes at the end of the contest. It is not suitable to present gifts by sweepstakes, either. Companies may not organize prize contests directed at patients.

14.7. Company address: The advertisements and the promotional materials may bear the telephone numbers, mail box, mailing address or website as the contact address of the company.

15. Donations and Sponsorships

Donations performed in line with laws and regulations shall not be regarded as a gift under Article 14 of the AIFD Code.

15.1. Donations Directed at Public Healthcare Organizations:

Registration/permit holders may provide donations to public healthcare institutions or organizations provided that they fulfill the following conditions: (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 give rise to any unethical conduct which may be associated with product purchase,
d) The donation does not encourage prescribing of a specific medicinal product for human use,
e) The donation will fulfill one of the purposes of improving research, education, health and patient care,
f) The donation will be utilized not only by one individual but by the entire organization or institution, (Reg. Art.6.10.e)
g) Only the name of the registration/permit holder, and not of the product, may appear on the donated materials,
h) The donation is entered in the official books of the registration/permit holder,
i) Any donation of medicinal products for human use, laboratory kits or similar donations aimed to be used in a clinical trial are made directly to the principal investigator. (Reg. Art.6.10.g)

15.2. Sponsorships and Donations Directed at Health, Research & Development and Education

Donations and assistance may be provided to non-governmental organizations, associations, foundations and organizations established by physicians, dentists and pharmacists or involving them and/or providing healthcare services or conducting research and not falling under the scope of another section of the AIFD Code of Promotional Practice:

a) If it is performed for the purpose of sponsoring a research related with health or the provision of a specific public health service;
b) If it registered on the official records of the donator/sponsor;
c) If a written commitment is obtained from the organization receiving the sponsorship/donation that the sponsorship provided will be included into their records and that it will be disclosed to the public;
d) If the it is not directed at the recommendation, prescribing, purchase, sales, distribution, promotion or use of a drug or some drugs;
e) If the personal or scientific expenditures of persons designated by companies are not covered by making a "conditional donation".

It should be noted that health institutions and organisations are supposed to take prior permissions from their central organisations before accepting donations, therefore rules published in this respect should be taken into consideration. (Reg. Art. 6.11)

15.3. No personal donation shall be made directly or indirectly to healthcare professionals. (Reg. Art.6.10.e)

15.4. Sponsorship of healthcare professionals in their participation in national or international events fall under the scope of Article 16.

15.5. The donations and sponsorships to be made within each year shall be disclosed to the public in accordance with Articles 21 and 22 to the public and according to Article 23 to the Agency (TITCK)..

Article Clarifications and Justifications

As indicated in Article 21, donations to be made to patient organizations, payments made in return for the services to be received from patient organizations shall be disclosed to the public by AIFD members as of 2013.

As indicated in Article 22, all Transfers of Value made to physicians, physician and pharmacist organizations, associations, as well as to healthcare organizations and clinics shall be disclosed to the public by AIFD members as of 2016, in a manner so as to comprise the data of 2015.

Article 16- Scientific and Educational Meetings and Hospitality

16.1.1. Scientific and educational meetings such as congresses, seminars and symposia, including those organized by the financial contribution of the companies, are the most suitable settings for introducing a new medicinal product or a new indication of a product in use and also provide suitable platforms for promoting collegiality among colleagues.

16.1.2. 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, shall 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, shall comprise hospitality only when needed and if adequate, and conform with the entire letter and spirit of the Code of Promotional Practice.

Definitions:

16.2.1. Scientific Meetings: Scientific meetings refer to national and international meetings, congresses, symposia, workshops, seminars and similar meetings, organized by either the Ministry, national and international specialty

associations of healthcare professionals, physician/pharmacy organizations, healthcare organizations and institutions, universities or registration/permit holders, to convey a scientific message. (Reg.Art. 4.ç)

16.2.2. Product Promotion Meetings: Product promotion meetings refer to events organised by the registration/permit holder to promote its product for traning or knowledge sharing purposes. (Reg.Art. 4.n) Such meetings are organised to share the medical information about the product or new information. (Reg.Art.7.1)

Hospitaliy Conditions:

16.3. Companies may sponsor and host healthcare professionals in scientific meetings and educational activities, as much as allowed laws and regulations.

16.3.1. 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. 7.11) Hospitality and financial contribution shall 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.

16.3.2. Registration/permit holders may, depending on the content of the meetings, sponsor the participation only to the scientific meetings of students in healthcare related faculties and higher education institutions. (Reg.Art. 7.5)

16.3.3. Hospitality expenses related with the scientific companies sponsored or organized by companies must be restricted to travel the genuine registration fee of the scientific section of the meeting, reasonable accommodation and transportation expenses and meal expenses.

16.3.4. The participation or sponsoring the participation of a healthcare professional in a meeting cannot be associated with the commitment of prescribing specifically a drug or the products of a company or the achievement of a certain amount of sales. The level of accommodation shall not be associated with previous services of the healthcare professional as a prescriber.

Meetings, General Rules

16.4. Hospitality and hosting activities directed at promotion shall not make the purpose of the meeting secondary. Such meetings shall be held in a suitable venue, in a suitable manner and at a suitable level. Accommodation shall always be at reasonable level, remain secondary to the main purpose of the meeting, and shall not be at a level with is exaggerated for the environment, and which may be regarded as extreme by the participants or the public. As a general rule, accommodation costs shall not be higher than the amount that may be afforded by the invitees. . (IFPMA, EFPIA) The period allocated for accommodation shall not be longer than period allocated for the scientific activity.

16.4.1. Meetings and Hospitality Abroad

No company may organize or sponsor meetings abroad, barring the following exceptions: (EFPIA 10.05)

a) If the meeting is international, where it is more suitable to hold the meeting abroad for logistic reasons, as the 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.

16.5. Registration/permit holders can sponsor or organise scientific meetings abroad if the meetings are international in nature or if the majority of the participants are healthcare professionals not afiliated with Turkey. This condition will not apply for scientific meetings organised or sponsored by the Ministry. (Reg.Art.7.4)

Rules for Meals.

16.6. Upper threshold for meals: (EFPIA 10.05) **60€/person/meal.** Member companies shall not supply, provide or offer any meal (food and beverages) not compliant with the following condition to healthcare professionals: In each case/each meal; the cost of the meal (food and beverages) supplied, provided or offered to healthcare professionals shall not exceed the upper monetary level of 60€/person/meal, excluding VAT (AIFD Board decision). The upper limit for meals of the host country applies in meetings outside Turkey. (EFPIA 10.05.) The upper limit of AIFD shall apply in case no meal limit is specified in the host country.

16.7. Tea, soft drinks or meals may be offered before or after in association with a meeting, if it is at a reasonably acceptable level under local conditions and if offered only to the attendants of that meeting.

HCP Sponsorship Rules

16.8. Scientific Meetings: Registration/permit holders may sponsor healthcare professionals for participating in scientific meetings such as congresses or symposia taking place in Turkey or abroad under the following conditions (Reg.Art.7.2)

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

16.8.2. The meeting shall be related with the specialty/role of the healthcare professional. (Reg.Art.7.1).

16.8.3. A healthcare professional may benefit from the sponsorship of companies as participant four times in total within the same calendar year. (Reg.Art.7.2.a)

16.8.4. A registration/permit holder may provide to a healthcare professional participation sponsorship maximum for two out of these four sponsorships within a calendar year. (Reg.Art.7.2.a)

16.8.5. A healthcare professional during a calendar can benefit of only two sponsorships of the four for meetings abraod as participant. (Reg.Art.7.2.a)

16.8.6. In scientific meetings organised as modules over a time period, each module is evaluated as one scientific meeting.

16.8.7. Meetings where healthcare professionals attend a meeting as a) speaker, b) moderator), c) panelist, d) trainer or e) the only investigator presenting a scientific study (verbally or as a poster), with the support of registration/permit holders are not considered within the scope of the restriction indicated above. (Reg.Art. 7.2.a)

16.8.8. In scientific meetings organised or sponsored by the Ministry, participants are out of scope of the abovementioned restriction.(Reg.Art. 7.2.b) The meetings to be organised or sponsored by the Ministry are decided by the Undersecretary of the Ministry and such meetings are announced in the official website of the Agency (TITCK). (Meeting Guideline.5.1.b)

16.8.9. Meetings of investigators, sponsored by the registration/permit holder, held in Turkey or abroad, in connection with national or international multicenter clinical trials, are not considered attendance to a congress or symposium. Application should be submitted to the related Department for such meetings. (Reg.Art.7.7)

16.8.10. Sponsorship of registration, accommodation and travel shall be made to the organization(s) holding the meeting and not directly to the participants. (Reg.Art. 7.1.c.)

16.8.11. Registration/permit holders shall notify the Ministry about the information of healthcare professionals or of the students they will sponsor, as indicated in the relevant Guideline. The Ministry collects this information in its database. (Reg.Art.7.6)

16.9. Persons appointed by the Ministry may, with or without prior notice, attend these meeting for inspection purposes. (Reg.Art. 7.12)

Restrictions

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

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

16.10.3. 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

High Season

16.10.4. Except for 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 in skiing resorts are between 1 December- 1 March and at seaside resorts between 15 June – 15 September periods. These restrictions do not apply to scientific meetings organized or sponsored by the Ministry. (Reg.Art. 7.8)

16.11. Sponsored Meetings, Their Announcements and Abstracts: When a meeting is sponsored by pharmaceutical companies, this information shall 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 shall be printed in a manner to enable participants and readers to notice it immediately.

16.12. Support and Sponsorships to Associations and Clinics: The conditions of and restrictions about the support, donation and sponsorship to associations formed by healthcare professionals and to hospital clincs are detailed in Article 15 and 18 of the present Code.

16.12.1. Requirement of Including a Session on the Rational Use of Drugs in Sponsored Meetings:
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 within the scope of the post-meeting report, as indicated in the relevant Guidelines. (Reg. Art. 7.10)

16.12.2. Increasing awareness about Pharmacovigilance in meetings:

In events organised or sponsored by the registration/permit holder, inclusion in the program of a presentation or of a educational video prepared by the Agency is sought. Posters and leaflets prepared by the Agency for this purpose are also displayed in visible areas as well. (Reg.Art.7.9)

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

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

16.13.2. At least fifteen working days prior to each national meeting, and thirty working days prior to meetings abroad, it is mandatory to report to the Agency 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 are answered only electronically within ten working days. If no response is received from the Agency within the ten working days, this will be regarded as approved application. (Reg. Art. 11.3)

16.13.3. 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 Promotion Guidelines, the list of participants, expense items and the events performed, in the specified format and on digital media. (Reg. Art 11.4)

16.13.4. One day scientific meetings: In one-day meetings organised without the reimbursement of registration, accommodation and travel of participants the list of participants are not communicated to the Agency.

16.13.5. Copies of information and documents presented to participants and documents related to the sponsorships shall be preserved by the relevant registration/permit holder for a period of five years. (Reg.Art. 11.4)

16.13.6. Scientific Meetings and Product Promotion Meetings, General Principles (Meetings Guideline art.7 1-5)

16.13.6.1. The electronic applications of scientific and product promotion meetings are conducted according to the "Guideline for electronic application for scientific meeting and product promotion meeting".

16.13.6.2. The cancellations of scientific meetings and product promotion meetings are submitted to the Agency in a official letter before the reporting closure date.

16.13.6.3. The changes in venue (hotel, meeting location) of scientific and product promotion meetings are informed to the Agency at least three days prior of the meeting by an official letter by the registration/permit holder.

16.13.6.4. The scientific meetings date changes are informed by official letter to the Agency for meeting cancellation. A new application is necessary for the new meeting date.

16.13.6.5. Date changes of product promotion meetings are informed to the Agency at least five days prior of the meeting with an official letter.

16.13.7. In order to establish neutrality, meetings exceeding four hours of duration organised by healthcare organisations or institutions should get the support of at least two companies/group of companies with products related to the meeting objective. (Meeting Guideline.5.8)

16.13.8. Sponsorhip types for Scientific Meetings: Sponsorhips to scientific congresses can be as follows:

a) general sponsorhip of the meeting,
b) sponsorship of participants and of the speakers,
c) satellite symposia participation and
d) stand fees.

Sponsorship applications under such items as panel sponsorship, session sponsorship, opening cocktail, gala dinner, social program will not be accepted by the Agency. (Meeting Guideline.5.10)

16.13.9. During the initial application for the scientific meeting, the following information should be submitted to the Agency: the name of the meeting, the location (country and city) of the meeting, the beginning and end dates of the meeting, the name of the organisation / association organising the meeting, the venue of the meeting, and the web link to the meeting announcement from the meeting organisor association.

16.13.10. In the sponsorship applications for the meetings the scientific name of which has been approved by the Agency, it is mandatory to report the name of the agency undertaking the organization (in the international meetings held abroad, the registration/permit holder shall enter the name of the agency used in Turkey), the cost of the satellite symposium where applicable (the program, the name of the product to be promoted, the speaker and the fee paid to the speakers, where applicable, shall be disclosed), the payment made to the speakers where applicable, booth participation where applicable (the name of the product to be promoted) and the speaker(s) and the abstract presenter(s) where applicable, as well as the payments to these participants upon entering information in the relevant sections.

16.13.11. For meetings with interventional procedures, registration/permit holder should get the approval of the of the competent authority of the healthcare institution.

16.14. Product Promotion Meetings (Meeting Guideline.6.1-10)

16.14.1. Product promotion meetings may be organized by registration/permit holders for the promotion of their products to physicians, dentists, pharmacists and dietitians.
16.14.2. The meetings intended for other healthcare professionals, where the use and administration of the product is demonstrated, is considered in this scope.
16.14.3. Registration/permit holders may receive scientific support from specialized associations, medical academic staff, healthcare institutes and institutions and the institutions providing education in the fields associated with the product for product promotion meetings.
16.14.4. The transportation and accommodation expenses of the participants, except for the speakers, shall not be covered by the registration/permit holders in the product promotion meetings. (Reg.Art.7.3)
16.14.5. Registration/permit holders may sponsor manufacturing units visits in Turkey within the Scientific Meetings concept, as described in Article 16.8. (Reg.Art.7.3)
16.14.6. Product promotion meetings may only be organized by the registration/permit holders. The meetings falling into this scope may not be organized by a donation together with an association or other institutions.
16.14.7. Product promotion meetings may not be organized for the students studying at the faculties or colleges training healthcare professionals.

16.14.8. Application to the Agency for Product promotion meetings:
16.14.8.1. The following shall be reported to the Agency during the application in the sponsorship applications for product promotion meetings:
a) Name and topic of the meeting,
b) Beginning and ending dates of the meeting,
c) The agency undertaking the organization (the tourism agency or the organization company)
d) Venue of the meeting,
e) Where applicable, the total payment paid to the speaker and the other expenses.
f) The company and the name of the speakers in the program are entered in the system, except the foreign speakers and speakers that are not healthcare professionals.

16.14.8.2. In the reports submitted to the Agency, the province, institute or institution where the invited participants work, the profession and branch of the healthcare professionals, the product to be promoted, approximate number of participants and the commitment information indicating that the participants will be entered into the system in the feedback shall be included on the cover letter.
16.14.8.3. The program of the meeting shall comprise the topic, the name(s) of the speaker(s), the time and the dates.
16.14.8.4. The meeting name should reflect the subject of the organised meeting.

16.14.9. Web based product promotion meetings: In web-based product promotion meetings, the fees paid for all the participants listening to the meeting via remote access simultaneously and in the location where the speaker is speaking shall be reported as the total amount. The list of participants shall be reported to the Agency during feedback submission along with the details stipulated in clause 16.14.8.2.

16.15. Rules of Disclosure of sponsorships and donations to the Agency and the Public: All AIFD member companies shall report direct or indirect transfers of value made to all HCPs and HCOs to the Agency (TITCK) (Reg.Art. 11.7.a). Disclosure of Transfers of Value to the public are explained in Article 22, disclosure to TITCK in Article 23.

Article Clarifications and Justifications

6. Definitions:

a. "**Reasonable":** Accommodation and meeting facilities, at the market value of the region and not to be perceived as luxurious; coach services with accredited travel safety; train tickets; economy class plane tickets;
b. "**Appropriate" "Acceptable", "Logical**": Limits which are acceptable for the "common man";
c. "**Renowned**": persons who have become famous in the field of popular culture, for performers; TV presenters and DJs,
d. **"Grandiose", "exaggerated", "extravagant", "renowned with its activities":** Locations and accommodation facilities that describe themselves with these or similar adjectives for meeting locations and accommodation facilities, or those where accommodation facilities wherein or in the immediate vicinity of which games of luck are played or which are regarded as exaggerated according to EU standards (such as golf courses);
e. **"Modest":** Modest materials are defined as materials the cost of which does not exceed 2.5% of the effective monthly gross wage, excluding VAT. (Reg. Art 8.2) The value perceived by the healthcare professional and patient shall be the same.
f. **"Symbolic":** Materials such as plates and paper weights, with no market value but with a symbolic value.

16. 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 shall 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.

16. Inspection of the Meetings Held by the Scientific Service: Companies shall do what is necessary to ensure that all events planned to be held, supported or sponsored are compliant with the Code. The meetings planned, attended or sponsored outside Turkey fall under the scope of This Code.

16.3.1. 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"

16.3.1. 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.

16.4. 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 shall 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, shall be avoided. Even if it is appropriate to serve tea, coffee, fruit 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.

16.4.1. 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 shall 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 shall be taken into account in the educational programs.
b. As with any other scientific meeting, the aspect to attract the invitees shall 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 shall be appropriately reminded to invitees who are public officers that it shall obtain a permission from their institution for attending the meeting. It shall 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. Likewise, information shall be obtained about the rules in the relevant country where the meeting is held outside Turkey.

16.6. Meal threshold in meetings abroad, the meal threshold of the host country rule: In cases the meal limit is not declared in the host country, the AIFD threshold should be observed. To obtain the meal thresholds in host countries please visit their web sites of the EFPIA member industry associations..

16.8.3. Multiple sponsorship of a participant for the same event: The Agency TITCK does not accept multiple sponsorhips of one individual for one event. Even if each company only sponosr one item of the package, TITCK will count each sponsorship separately for the person.

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

16.10. Hospitaliy and sponsorships; Unsuitable Activities:

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 at healthcare professionals.

c) Pharmaceutical companies shall not organize social, sportive meetings or leisure programs for healthcare professionals. (Gala dinners and inaugural cocktails shall 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 shall not undertake, directly or indirectly, sponsorship of dinners, inaugural and closing cocktails and "gala dinners" in congresses and shall 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.

16.10.4. 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) 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 under this scope and are not deemed suitable .
c) International meetings documented to be organized each year (or at regular intervals) in different countries are outside the restriction mentioned above .

16.11. Meetings Sponsored, 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 shall pay attention to the fact that these reports may have the characteristics of a promotional material and that they shall comply with this Code. The names of sponsoring companies shall be clearly indicated and there shall not be the possibility or suspicion of a disguised promotion.

16.12.1. Session on the Rational Use of Drugs (AIKO-RUD): (RUD Guidelines)

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

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

16.12.1.b. 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.

16.12.1.c. The presentations to be included into the session on the Rational Use of Drugs shall 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.

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

16.12.1.e. 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 shall be added in electronic environment via the official website of the Turkish Medicine and Medical Device Agency.

16.12.1.f. The program of the meeting shall 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".

16.12.1.g. 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.

16.12.2. Increasing awareness about pharmacovigilance: videos shows can be shown from companies' stands in congresses or with the approval of congress organisers, they can be shown during the the first sessions each day. Pharmacovigilance should be included in the launch meetings of new products. During pharmacovigilance video shows excesses should be avoided.

16.13.7. Sponsorships types during scientific meetings:

16.13.7.a. General sponsorship of a congress is the support given to the meeting organising institution to organise the meeting. Meeting organisers should not use such support to pay for the registration, accommodation and travel expenses of the participants.

16.13.7.b. Participant and speaker sponsorship comprises payments of registration, accommodation and travel expenses of the participants and of the speakers and the honoraria paid to speakers in line with the Regulation.

16.13.7.c. Satellite symposium is the session during scientific congresses where productpromotion is carried. Meeting organisers should not use the support made for satellite symposia organisations to pay for the registration, accommodation and travel expenses of the participants.

16.13.7.d. Stand (booth) sponsorship, is the support made by the registration/permit holder by renting a stand from the meeting organiser to promote its product(s) or its company's activities and the expenses made in stand area for hospitality. Meeting organisers should not use such support to pay for the registration, accommodation and travel expenses of the participants.

Article 17- Interactions with Consultants

17.1. 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.

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

17.3. 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.

17.4. Payments to Speakers in Scientific Meetings and Educational Activities

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.

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

17.4.2. It is possible for a physician benefitting from revolving capital not to be receive an honorarium fee against consultancy/speech services only the approval of the relevant institution upon a signing of a contract.

17.4.3. If a healthcare professional does not benefit from a revolving capital or works at a private institution or his/her private practice, payment shall be made against a Self-Employment Invoice.

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

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

Article Clarifications and Justifications

17.2. Honorarium: The honoraria to be paid to speaker HCPs shall be designated upon making a benchmark with the fair market value.

The following factors shall be considered in the calculation of the "Fair Market Value": the salary or income of the speaker, whether the speech is based on their own original work; the reasonable time of research for the preparation of the speech; the qualification of the speaker as a reference person in his/her topic on a local, national and global scale and national and international reasonable honorarium payments for similar speakers.

17.4.5. Healthcare professionals who do not receive their speaker fee via the revolving capital shall not use their official title (Head of Department of XYZ at XYZ University, Clinic Chief at ABC Hospital), indicating their affiliation with their institution, in their speech and presentations. Acquired titles regarded a suitable by the Turkish Medical Society (TTB) (Dr., Assoc. Prof., Prof., etc.) may be used. Affiliated institutions may be indicated on publications. The Ethical Directives of TTB shall be taken into account with regard to this topic.

Article 18- Interactions with Associations and Societies of Healthcare Professionals and Congress Organizing Agencies

18.1. 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 shall be known also by professional associations of healthcare professionals and companies organizing meetings and be applied as strictly.

18.2. 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 shall be requested from organizing companies.

18.3. Requirement of a Session on the Rational Use of Drugs (See Article 16.5)

18.4. Satellite Symposia and Scientific Program

18.4.1. The main responsibility with regard to the conformity of the content of the satellite symposia with laws and regulations and the AIFD Code of Promotional Practices lies with the main organizing company. TITCK (The Agency) defines satellite symposium as "product promotion meetings conducted during scientific events". (Meetings Guideline 5.10.c)

18.4.2. The topics and speakers of the satellite symposia sponsored by companies are included into the scientific program of the congress upon being approved by the Scientific Board of the Congress. The Scientific Board of the Congress shall approve the scientific quality of the topics and speakers of satellite symposia as much as they do with all other sessions of the congress.

18.5. Exclusive Sponsorship

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

Article 19- Non-Interventional Studies Conducted with Marketed Products

19.1. 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 administering 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.

19.2.1. As a principle in non-interventional studies, the treatment of the patient shall have been initiated prior to the decision to be recruited into the study. (GNISCD, 4.1) Inclusion of the patient into a treatment strategy shall be decided according to the therapeutic need and according to the trial protocol.

19.2.2. Prescription of a drug and inclusion of a patient in a non-interventional study are two separate topics that shall 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, 4.5)

19.2.3. A drug shall not be prescribed for the purpose of including a patient in a non-interventional study. (GNISCD, 4.5)

19.3. 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.

19.4.1. 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. (GNISCD, 22.1)

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

Article Clarifications and Justifications

19. 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 applied in the past or are still ongoing. In any case, all these studies shall be conducted in line with Article 17.3 of this Code of Promotional Practice (Service Contracts).

19.3. 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 shall 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) The trial shall avail of a written study plan (protocol) and (ii) there shall 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) shall be clearly specified;
b) Any payment to made shall 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 shall be reported to the Ministry and the study shall not be initiated before obtaining the relevant permit; if non-interventional studies need to be examined by the ethical committee, relevant applications shall be submitted and permits shall 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 shall be complied with;
e) The sponsoring company shall not conduct a non-interventional study with a promotional objective or to be perceived as such. A study shall not constitute an inducement to recommend, prescribe, purchase, supply, sell or administer a particular drug;
f) The study protocol shall be approved and supervised by the Scientific Service;
g) An outcome report shall be prepared on the conduct of the non-interventional study and its results: the study results shall be analyzed by or on behalf of the sponsoring company and summaries thereof shall be made available within a reasonable period of time to the company's Scientific Service. All documents of the non-interventional study shall be preserved for a period of at least 5 (five) years for later access and further evaluation;
h) The company shall 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 shall be submitted to the Ministry;
j) In case an approved study cannot be started for any reason or terminated before completion, this shall be reported to the Ministry along with its justifications.

19.3.h. Sharing the results of non-interventional studies with physicians, dentists and pharmacists

Companies shall 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 20- Relations with the General Public and Media

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

20.1.1. 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) No prescription drug or its reduced sample may be distributed to the general public directly or via indirect means.

20.1.2. As indicated in Article 6.5, This excludes Ministry-approved advertisements placed in newspapers/journals, announcing the market launch of a product to healthcare professionals. (Reg. Art.5.3)

20.1.3. 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. (Reg. Art.6.1) Where regarded suitable by the Ministry, the (INN) names of products, company name and logo may be indicated.

20.3. 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. (Meetings Guideline 6.1)

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

20.5. Relations with Pharmacies

Promotion of prescription only drugs to the general public shall not be conducted in pharmacies**.** (Regulation on Pharmacies and the Practice of Pharmacy, Article 25.3) Prescription only drugs shall not be used in the window decorations of pharmacies. Commercial relations with pharmacies remain outside the scope of this Code.

20.6. Relations with Wholesalers and Their Personnel

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

20.7. Relations with Medical Reporters

Meetings with medical reporters shall be conducted in such a manner so as to avoid breaching this Code of Promotional Practice.

Corporate press conferences remain outside the scope of this Code.

20.8. 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 the calls.

20.9. Not Providing Any Advice on Personal Medical Matters

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

Article Clarifications and Justifications

20.7.1. Relations with Medical Reporters: Press conferences may be organized in line with laws and regulations for announcements to be made to the general public (adverse events, warnings on the use of drugs, statements about withdrawal, etc.); it shall be ensured that the information and images to be provided in press conferences do not contain a content that may be perceived as pharmaceutical promotion and are not reflected on the press as such.

20.7.2. Path to be Pursued in the Invitation of Press Members: Pharmaceutical companies may invite a press member to any educational, informative meeting or meeting on the assessment of a research or manufacturing site. In order to avoid that articles and pictures which may be perceived as promotion in public communication media (press, TV, social media, etc.) beyond the control of the company, the relevant company shall make a statement to the invited press members, reminding the restrictive laws and regulations and national and international codes of ethics of the pharmaceutical industry.

Article 21- Interactions Between Pharmaceutical Companies and Patient Organizations

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. If they will be maintained in Turkey or will cover patients and/or their caregivers stationed in Turkey, relationships with international patient organizations 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 shall have in place a written agreement. This shall state the amount of funding and also the purpose (e.g. unconditional support, specific meeting or publication, etc.). It shall 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 shall have an approval process in place for these agreements.

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

21.5. Use of Logos and Proprietary Materials

Pharmaceutical companies shall 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 shall be clearly indicated.

21.6. Editorial Control

Pharmaceutical companies shall 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 shall 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 shall be sufficiently comprehensive and clear to enable an ordinary reader perceive the nature and dimension of the support provided to the company. The description shall 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 shall 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 shall 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 shall publicize the list of patient organizations to which it provides significant service under contract. This description shall 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 shall 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) 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 shall be clearly identified before contacting the consultant, requesting the service and initiating talks with potential consultants.
c) The criteria used for selecting a consultant shall fulfill the need which has been identified. Persons appointed for selecting consultants shall 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 shall 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 shall keep records demonstrating that they have received services offered by consultants and used these in line with their needs.
f) The company shall not expect the Patient Association to support a drug in return for having requested a service.
g) The payment made for consultancy or services shall 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 shall 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 shall 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 shall 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 shall be held in proper venues, the style and level and hospitality and hosting activities shall be aimed at achieving the main objective of the meeting and these shall 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 shall always be at a reasonable level and shall 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 shall be restricted to travel costs, meals, accommodation and the genuine registration fee of the meeting.
d) Hospitality shall 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 shall 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. I shall be applied about companies violating this Code.

Article Clarifications and Justifications

21: Guidelines on the Interactions Between Pharmaceutical Companies and Patient Organizations

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. V shall be observed with regard to Enforcement and Sanctions.

This Code builds upon the following principles that EFPIA, together with pan-European patient organizations, subscribes 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 shall 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. IV 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 shall 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 contribution as well as the contracted services provided to sponsored patient organizations shall 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 5, entitled "Transparency" in the EFPIA Code on Interactions with Patient Organizations, updated in 2011:

> Each company shall make publicly available a list of patient organizations to which it provides financial support and/or significant indirect/non-financial support. This shall 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 shall 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 shall specify clearly the non-monetary benefit that the patient organization receives. This information may be provided on a national or European level and shall be updated at least once a year. (The requirement to include the monetary value of support shall be fulfilled 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).
> Companies shall ensure that their sponsorship is always clearly acknowledged and apparent from the outset.
> Each company shall make publicly available a list of patient organizations that it has engaged to provide significant contracted services. This shall 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 shall also make public the total amount paid per patient organization over the reporting period. (The requirement to include details of contracted services shall be fulfilled 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- Disclosure of Transfers of Value from Pharmaceutical Companies to Healthcare Professionals and Healthcare Organizations (HOs) to the Public

(Text compliant with the EFPIA Code on Disclosure. Note: Following the letter from TITCK dated 30.03.2016 and with the approval of EFPIA, disclosures of 2015,2016,2017 shall not be publicly disclosed by AIFD member companies.)

22.1.01. *General Obligation.* Subject to the terms of this Code, each Member Company shall document and disclose Transfers of Value it makes, directly or indirectly, to or for the benefit of a Recipient (a HCP or HO), as described in more detail in Article 22.3.

22.1.02. *Excluded Disclosures.* Without limitation, it shall not be mandatory to disclose the following Transfers of Value:

i. Transfers of value that are solely related to over-the-counter drugs;
ii. Promotional materials, reduced samples, values of food and beverages not exceeding the ceiling value indicated in the AIFD Code of Promotional Practice and values that are not listed in Article 22.3;
iii. Transfers of value that are part of the definition of commercial purchase and sales between a Member Company and a pharmacy, healthcare organization or pharmacy wholesaler (discounts, payment terms, etc.).

22.1.03. *Schedules.* The attached Schedules form part of this Code. Definitions of capitalized terms are included in the "Clarifications" section of this article to ensure consistent understanding of such terms.

22.1.04. The Transfers of Value to be disclosed are as follows:

i. Donations, supports, sponsorships and support in kind provided in accordance with Article 15 to healthcare organizations and associations of physicians;
ii. Contracts signed in accordance with Articles 17 and 18, between healthcare organizations, associations and companies;
iii. Sponsorships provided in accordance with Article 16, to enable the participation of physicians in congresses and scientific events;

iv. Payments made to healthcare organizations for registration, room rental and similar expenses to enable healthcare professionals participate in educational meetings and congresses;
v. Sponsorships of Clinical Research & Development Activities

22.1.05. The transfers of value to Patient Associations have been covered in Article 21 and remain outside the scope of this article.

22.1.06. The rule of "No Consent, no Transfer of Value" according to TITCK: (Reg.Art.11.7) The Registration/permit holder may transfer any values exceeding 10% of current gross monthly minimum wage to healthcare institutions and organizations, universities, to healthcare professionals and professional organizations, unions, associations and foundations with activities in the healthcare industry of which they are members; and non-governmental organizations founded to preserve and improve health, only upon the condition of abiding by the following rules:

22.1.06.a. The Registration/permit holder notifies the Agency of all value transfers made within one calendar year, in a format and detail defined by the Agency; within the first six months of the following year.

22.1.06.b. For any value transfer to be made within this scope, the Registration/permit holder shall collect written consent from the healthcare professional, and in the institutions and organizations, of the authorized supervisor, for the acceptance of the value transfer and for the transmission of the value transfer to the Agency. **The Registration/permit holder shall not make any value transfer if the written consent is not obtained.**

22.1.06.c. All data and documents pertaining to the value transfer should be retained by the registration/permit holder for five years.

22.2.01. *Annual Disclosure Period.* Disclosures shall be made annually and each reporting period will cover a full calendar year ("**Reporting Period**").

22.2.02. *Time of Disclosure.* Disclosures shall be made by each Member Company within 6 months after the end of the relevant Reporting Period. The information disclosed shall be required to remain in the public domain for a minimum period of 3 years after the time such information is first disclosed in accordance with Article 22.2.04, unless, in each case, (i) a shorter period is required under applicable national data privacy or other laws or regulations, or ii) the Recipient's consent relating to a specific disclosure, if required by applicable national law or regulation, has been revoked.

22.2.03. *Template.* For consistency purposes, disclosures pursuant to this Code shall be made using a structure set forth in Schedule 2 in APP. III in accordance with Article 22.2.04 (ii). Deviation from this schedules may only be accepted in case of legal obligation; therefore a single standard schedule shall be used in each country. (AIFD members in Turkey shall make their disclosures in line with the standard of Schedule 2 in APP. III.)

22.2.04. *Platform of Disclosure.* Disclosures can be made in either of the following ways, provided that they are unrestricted and publicly available:
i. On the relevant Member Company's website in accordance with Article 22.2.05; or
ii. On a central platform, developed upon the initiative of AIFD or with its approval; or a platform developed by the health authority or a umbrella health association (provided that disclosures are made, so far as possible, using Schedule 2)

22.2.05. *Applicable National Code.* Disclosures shall be made pursuant to the national code of the country where the Recipient has its physical address. If a Member Company is not resident or does not have a subsidiary or an affiliate in the country where the Recipient has its physical address, the Member Company shall disclose such Transfer of Value in a manner consistent with the national code applicable for the Recipient.

22.2.06. Disclosures shall be made in Turkish. Member Companies are encouraged to make disclosures also in English.

22.2.07. *Documentation and Retention of Records*. Each Member Company shall document all Transfers of Value required to be disclosed pursuant to Article 22.1.01 and maintain the relevant records of the disclosures made under this Code for a minimum of 5 years after the end of the relevant Reporting Period, unless a shorter period is required under applicable national data privacy or other laws or regulations.

22.3.01. *Individual Disclosures.* Except as expressly provided by this Code, Transfers of Value shall be disclosed on an individual basis. Each Member Company shall disclose on an individual basis for each clearly identifiable Recipient, the amounts attributable to Transfers of Value to such Recipient in each Reporting Period which can be reasonably allocated to one of the categories set out below. Such Transfers of Value may be aggregated on a category-by-category basis, provided that itemized disclosure shall be made available upon request to (i) the relevant Recipient, and/or (ii) the relevant authorities.

22.3.01.1. *For Transfers of Value to an HCO, an amount related to any of the categories set forth below:*

22.3.01.1.a. Donations and Grants: Donations and Grants to HCOs that support healthcare, including donations and grants (either in cash or benefits in kind) to institutions, organizations or associations that are comprised of HCPs and/or that provide healthcare

22.3.01.1.b. Contribution to costs related to Events: Contribution to costs related to Events, through HCOs or third parties, including sponsorship to HCPs to attend Events, such as:

i. Registration fees;
ii. Sponsorship agreements with HCOs or third parties appointed by an HCO to manage and Event; and
iii. Travel and accommodation expenses.

22.3.01.1.c. Fees for Service and Consultancy. Transfers of Value resulting from or related to contracts between Member Companies and institutions, organizations or associations of HCPs under which such institutions, organizations or associations provide any type of service to a Member Company or any other type of funding not covered in the previous categories. Fees, on the one hand, and on the other hand Transfers of Value relating to expenses agreed in the written agreement covering the activity will be disclosed as two separate amounts.

22.3.01.2. *For Transfers of Value to an HCP*:

22.3.01.2.a. Contribution to costs related to Events. Contribution to costs related to Events, such as:

i. Registration fees and
ii. Travel and accommodation expenses.

22.3.01.2.b. Fees for Service and Consultancy: Transfer of Value resulting from or related to contracts between Member Companies and HCPs under which HCPs provide any type of services to a Member Company (or any type of funding not covered in the previous categories). Fees, on the one hand, and on the other hand Transfers of Value relating to expenses in the written agreement covering the activity will be disclosed as two separate amounts.

22.3.02. *Aggregate Disclosure.* For Transfers of Value where certain information, which can be otherwise reasonably allocated to one of the categories set forth in Article 22.3.01 cannot be disclosed on an individual basis for legal reasons, a Member Company shall disclose the amounts attributable to such Transfers of Value in each Reporting Period on an aggregate basis. Such aggregate disclosure shall identify, for each category, (i) the number of Recipients covered by such disclosure, on an absolute basis and as a percentage of all Recipients, and (ii) the aggregate amount attributable to Transfers of Value to such Recipients.

22.3.03. *Non Duplication.* Where a Transfer of Value required to be disclosed pursuant to Article 22.3.01 or 22.3.02 is made to an individual HCP indirectly via an HCP, such Transfer of Value shall only be required to be disclosed once. To the extent possible, such disclosure shall be made on an individual HCP named basis pursuant to Article 22.3.01.2.

22.3.04. *Research and Development Transfers of Value.* Research and Development Transfers of Value in each Reporting Period shall be disclosed by each Member Company on an aggregate basis. Costs related to events that are clearly related to activities covered in this section can be included in the aggregate amount under the "Research and Development Transfers of Value" category.

22.3.05. *Methodology.* Each Member Company shall publish a note summarizing the methodologies used by it in preparing the disclosures and identifying Transfers of Value for each category described in Article 22.3.01. The note, including a general summary and/or country specific considerations, shall describe the recognition methodologies applied, and shall include the treatment of multi-year contracts, VAT and other tax aspects, currency aspects and other issues related to the timing and amount of Transfers of Value for purposes of this Code, as applicable.

22.4.01. *Reporting*. AIFD shall produce at least annually the following reports: *(EFPIA 4.05)*

i. The enforcement of this Code by AIFD Member Companies; and
ii. The follow-up report on the activities relating to this Code, following the first issuance of national disclosures (the first report about this topic to be produced in September 2019).

22.4.02. *Code Compliance*. AIFD Good Promotional Practice Committee (ITUK-GPP) shall assist Member Associations to comply with their obligations under this Code. *(EFPIA 5.01*)

22.4.03. *Amendments to the Code*. AIFD Good Promotional Practice Committee (ITUK-GPP) shall regularly review this Code and any guidance issuance regarding compliance with this Code. Proposed amendments to this Code shall be submitted for approval to the AIFD Board of Directors and the AIFD General Assembly following consultation with AIFD members. *(EFPIA 5.02)*

22.4.04. Sanctions: The sanctions stipulated in Appendix I shall apply also in the enforcement of this article. *(EFPIA 4.04)*

Article Clarifications and Justifications

Definitions Related with Article 22

Recipient
Any HCP, or HCO as applicable, in each case, whose primary practice, principal professional address or place of incorporation is in Turkey.

Donations and Grants
Collectively, those donations and grants (either cash or benefits in kind) within the scope of Article 15 of the AIFD Code.

Transfer of Value
They refer to direct or indirect transfers of value, whether in cash, in kind or otherwise, made, whether for pharmaceutical promotion or for other purposes, in connection with the development or sale of prescription-only medicinal products for human use. Direct transfers of value are those made directly by a Member Company for the benefit of a Recipient. Indirect transfers of value are those made on behalf of a Member Company for the benefit of a Recipient, or transfers of value made through an intermediate and where the Member Company knows or can identify the HCP/HCO that will benefit from the Transfer of Value.

Research and Development Transfers of Value

Transfers of Value to HCPs or HCOs related to the planning or conduct of (i) non-clinical studies (as defined in OECD Principles of Good Laboratory Practice); (ii) clinical trials (as defined in Directive 2001/20/EC); or (iii) non-interventional studies that are prospective in nature and that involve the collection of data from or on behalf of individual, or groups of, HCPs specifically for the study.

Events
All promotional, scientific or professional meetings, congresses, conferences, symposia, and other similar events (including, but not limited to, advisory board meetings, visits to research and manufacturing facilities, and planning, training or investigator meetings for clinical trials and non-interventional studies) (each, an "Event") organized or sponsored by or on behalf of a company.

POs (Patient Organizations)
Patient Associations or other Patient Platforms or other organizations defined in Article 21 of the AIFD Code of Promotional Practice focusing on the interactions with Patient Organizations.

HCOs (Healthcare Organizations or Associations Established By Healthcare Professionals)
Any legal person (i) that is a healthcare, medical or scientific or organization – irrespective of the legal or organizational form – such as a hospital, clinic, foundation, university or other teaching institution or learned society (except for patient organizations within the scope of PO Code) whose business address, place of incorporation or primary place of operation is in Europe or in Turkey or (ii) through which one or more HCPs provide services.

HCP (Healthcare Professional)
Any natural person that is a member of the medical, dental, pharmacy or nursing professions or any other person who, in the course of his/her professional activities, may prescribe, purchase, supply, recommend or administer a medicinal product and whose primary practice, principal professional address or place of incorporation is in Turkey. *Also the following fall under the scope of HCP defined in this article:*
(i) any official or employee of a government agency or other organization (whether in the public or private sector) that may prescribe, purchase, supply or administer medicinal products and (ii) any employee of a Member Company whose primary occupation is that of a practicing HCP. However, the following are not included into this definition: (a) All other employees of a Member Company and (b) a wholesaler or distributor of medicinal products

HCP Code: AIFD Code of Promotional Practice

In APP VI are presented templates for collection of consent forms for disclosure to the public for HCPs and HCOs.

Article 23- Disclosure of Transfers of Value from Pharmaceutical Companies to Healthcare Professionals and Healthcare Organizations (HOs) to the TITCK (Turkish Agency of Medicines and Medical Devices) (Reg. Art. 11.7; Transfer of Value Guideline)

23.1. *General Obligation:* The Registration/permit holder may transfer any values exceeding 10% of current gross monthly minimum wage to healthcare institutions and organizations, universities, to healthcare professionals and professional organizations, unions, associations and foundations with activities in the healthcare industry of which they are members; and non-governmental organizations founded to preserve and improve health, only upon the condition of abiding by the following rules:

23.1.1. For any value transfer to be made within this scope, the Registration/permit holder shall collect written consent (Consent Form) from the healthcare professional, and in the institutions and organizations, of the authorized supervisor, for the acceptance of the value transfer and for the transmission of the value transfer to the Agency.

23.1.2. The Registration/permit holder **shall not make any value transfer if the written consent is not obtained.**

23.1.3. The Registration/permit holder notifies the Agency of all value transfers made within one calendar year, in a format defined by the Agency and in detail; within the first six months of the following year.

23.1.4. *Template:* The template sheets given in APP IV are integral part of the Agency data submission process.

23.2.1. Reporting Threshold: Any Transfer of Value, inclusive of VAT, whose monetary value exceeding 10% of the current monthly minimum wage shall be reported to the Agency.

23.2.2. Calculation Method of the Reporting Threshold: When calculating individual share of value per participant for an event, the basis will be the amount found by dividing the total expenditure incurred by the registration/license holder for holding the event to the number of participants.

23.3. Transfers of Value to Healthcare Organisations (HCO):

For transfers of value made directly or indirectly by registration/license holders where the value per healthcare organization or institution exceeds the VAT-inclusive monetary equivalent of 10% of the monthly gross minimum wage,

i- i- the name of the recipient organization or institution,
ii- ii- tax number
iii- iii- the province of registration

will be reported to the Agency, along with particulars based on the examples of scope listed below:

a) Donation.
b) Contribution to covering event-related costs.
c) Sponsorship agreement.
d) Honorarium or Consultancy Fee.
e) Any other transfers of value.

23.4. Transfers of Value made directly or indirecly to Healthcare Professionals (HCP):

For transfers of value made directly or indirectly by registration/license holders to healthcare professionals, where the value exceeds the VAT-inclusive monetary equivalent of 10% of the monthly gross minimum wage,

iv- the name and surname of the healthcare professional,
v- her/his TC national identification number,
vi- work address,
vii- name of the province of work address,

will be reported to the Agency, along with particulars based on the examples of scope listed below:

a) Contribution to covering event-related costs, i.e. registration fee, travel, lodging and meals.
b) Honorarium or Consultancy Fee.
c) Any other transfers of value.

23.5. Off scope Transfers of Value: Transfers of value which are considered off-scope for disclosure include the following:

a) Free promotional samples.
b) Transfers of value not exceeding 10% of the currently applicable monthly gross minimum wage (e.g. meals or beverages).
c) Transfers of value having the nature of a qualified investment for Research and Development (R&D).
d) Commercial transfers of value to pharmacies, institutions, wholesalers (discounts, sales terms, etc.)
e) Promotional materials.

23.5. Reporting Period and Format

23.5.1. Registration/license holders will report particulars of transfers of value during the calendar year using the dedicated system established by the Agency for this purpose, in the format provided in Appendix IV.

23.5.2. The registration/license holder must personally file all applicable reports with the Agency concerning any actions or transactions involving a transfer of value through a contract company

23.5.3. All reports under these Guidelines must be exclusively made electronically by the registration/license holder, using the dedicated system established by the Agency for transfers of value.

23.5.4. Collection of data under these Guidelines will commence from 01.01.2016, and the first report to the Agency will be submitted by 30.06.2017.

23.5.5. A separate guidance regarding the use of the system for transfers of value will be issued by the Agency and published by the end of 2016.

23.6 Requirement to Obtain Written Consent of Healthcare Professionals or Healthcare Organizations or Institutions

23.6.1. Before performing a transfer of value, the party performing the transfer of value, whether directly or indirectly, must obtain written consent of the healthcare professional or the authorized supervisor of the healthcare organization or institution concerned, for accepting and reporting the transfer of value to the Agency. **A transfer of value may not be made unless such written consent is received**.

23.6.2. The written consent may be obtained on a case-by-case basis, or on a time-limited basis covering a period of time: Consent declaration can be withdrawn by the institution or the individual before the transfer of value takes place, except in instances mentioned in the Guideline.

23.6.3. The consent given to the reporting of a transfer of value to the Agency may not be withdrawn after the transfer of value is completed based on the written consent of a consenting individual or authorized official.

23.6.4. Authorized supervisor (*yetkili amir)* in healthcare organisations and institutions;; At healthcare organizations or institutions, the authorized supervisor is the office of the chief physician, office of the dean, association president/authorized signatory or, without limitation, the authorized signatory of any organization or institution covered by the Regulation and these Guidelines.

23.6.5. Obligation to obtain consent from each institution in case of multiple organisators: Where an event is jointly held by multiple healthcare organizations or institutions, each individual organization or institution to which a value will have been transferred is subject to reporting, and the written consent of each of the organizations or institutions involved must be obtained for the sponsorship request and reporting to the Agency.

23.7. Procedural Note: The following rules apply to documenting payments:

23.7.1. For service agreement fees, donations, grants and sponsorships, the value for the calendar year in which the transfer of value was recognized will be disclosed, including agreements covering more than one year.

23.7.2. Transfers of value for travel (e.g. flight, coach, bus tickets), accommodation (e.g. lodging costs) and registration fees related with events, e.g. congresses or meetings, will be disclosed in the calendar year in which the event occurred.

23.7.3. In other transfers of value, payment date should be taken into account.

23.8. Reporting in case of non-participation or partial participation

23.8.1. Where a healthcare professional is unable to attend an event or a part of an event for any reason, only that portion of such expenditures which was transferred to the healthcare professional will be included in the disclosure of the transfer of value.

23.8.2. If the attendance of a participant was cancelled prior to the event for which payments were made, but the transfer of value in the name of the person could not be cancelled, the total value of such transfers must be reported to the Agency all the same, if it exceeds the VAT-inclusive monetary equivalent of 10% of the monthly gross minimum wage applicable on that date.

23.9. Transfers of Value to an individual through a healthcare institution: Where a contract is signed with a healthcare professional through a healthcare organization or institution which they work for, and the payments are made to the healthcare organization or institution (or to the revolving fund of the institution),

a. the transfer of value will be reported under the name of the healthcare organization or institution, stating the name of the healthcare professional concerned.

b. Any other expenses related to the individual, such as travel, registration and accommodation, will be separately reported under the name of the healthcare professional.

23.10. Documentation and safekeeping of the documents and data: All data and documents pertaining to the value transfer will be retained by the registration/permit holder for a period of five years.

Article Clarifications and Justifications

23.5. Value Transfers for R&D purposes with investment characteristics

23.6. Members companies may use of the templates given in App VI (Consent Form for Transfers of Value) to collect consents from HCPs and HCOs.

Article 24- 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.)

24.1. Introduction:

A major responsibility of the pharmaceutical industry is not only to ensure that the general public 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.

24.2. Principle of Transparency and General Rules

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

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

24.2.3. **Protection of Visitor Information:** Personal information collected from visitors in the websites established by companies or on their behalf shall be kept confidential. The website shall 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 shall be clearly indicated.

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

24.2.5. Each website shall have a homepage; discernibly containing the following information:

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

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

24.2.5.3. 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.

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

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

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

24.2.7.2. Website names shall 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.

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

24.2.9. Information intended for physicians, dentists and pharmacists on the website and information for the general public shall 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 shall be prepared under the supervision of the Scientific Service.

24.2.10. Links from this website to other sites on the internet shall 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.

24.2.11. 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 shall be regularly verified.

24.2.12. 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.

24.2.13. Users shall 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.

24.2.14. The following recommendation shall 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"**.

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

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

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

24.2.18. 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, each member company shall take prompt legal action to cease activity of such website. Such applications shall be documented at a level that may provide proof of action to AIFD or other relevant authorities upon request.

24.2.19. AIFD User Guide on Digital Communications in the Pharmaceutical Industry: "AIFD User Guide on Digital Communication Applications in the Pharmaceutical Industry", presented in APP. X of the Code of Promotional Practice has been prepared for the purpose of describing in detail Article 24 for company employees responsible for digital communication and marketing applications as well as third parties appointed by the company and constitute an integral part of the AIFD Code of Promotional Practice.

Content of Websites

24.3. 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 the Code of Good Promotional Practice. 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.

24.4. 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 shall 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.

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

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

24.4.3. Content of information provided shall be suitable for the target audience.

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

24.5.1. 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 this Code of Promotional Practice. The promotion of these products shall be compliant with current laws and regulations.

24.5.2. 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.

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

24.5.4. Pages intended for patients shall 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*" shall be included, at all times, on each relevant page.

24.5.5. The brand names shall 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) shall always be specified.

24.6. Web Pages Intended for Healthcare Professionals and Containing Also Product Promotion

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

24.6.2. Access to promotional materials of prescription medicines and medicinal products for human use the public promotion of which is legally allowed, shall only be allowed for physicians, dentists and pharmacists. It shall 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) shall 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.

24.7. Applications via Electronic Mails

24.7.1. 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 shall 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.

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

24.7.3. 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 shall be avoided and these individuals shall be advised to consult a physician or a pharmacist.

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

24.8. Links to Other Websites

24.8.1. 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.

24.8.2. 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.

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

24.8.4. When providing links to other websites, there shall 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.

24.9. 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.

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

24.11. Digital-Based Promotional Methods

24.11.1. 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.

24.11.2. 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.

24.11.3. Content shall 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.

24.11.4. 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 shall be clearly disclosed. When compiling and releasing speeches or correspondences from the meeting, the sponsoring company shall care that the Code of Promotional Practice is respected and that scientifically accepted references etc. are included.

24.12. Sharing Information via Digital Communication Means

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

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

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

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

24.12.4.1. Use of "Share" or "Like" in promotional messages: Physicians and pharmacists shall not 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 shall not be mentioned. The content intended for production promotion, prepared for Healthcare Professionals shall only be shared in social media upon making entry with a username and password.

24.12.4.2. 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.

Article Clarifications and Justifications

24. Internet, Digital Platforms, Social Media

24.2.2. 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 shall 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.

24.2.6. 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.

24.2.12a. Links provided from the website to other websites shall 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..

24.2.12b. 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 shall be regularly verified.

24.2.19. 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 shall resort to legal means in order to stop the activity of this website.

24.6.2. 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-only 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." shall 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 25- Promotional and Sales Activities Commissioned to Third Parties

25.1. 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.

25.2. Contracted Company: Legal person which is authorized by the registration/permit holder by contract to conduct the processes and procedures concerning promotional activities on its name or together with it, provided that all legal liability shall rest on the registration/permit holder; and whose name the registration/permit holder is

obliged to notify to the Agency. (Reg.Art.4.i)

25.3. The Registration/permit holder may conduct promotional activities through contracted companies. (Reg.Art.11.6) The Registration/permit holder is severally liable for all processes and procedures to be conducted within this scope. In promotional activities conducted through a contracted company, the Registration/permit holder shall;

a) Submit the contract or any amendments to the Agency within thirty days after these are enacted,

b) Notify the Agency personally all promotional processes and procedures conducted through the contracted company,

c) record the names of the product promotion representatives promoting products in their name, the districts where they work, the names of healthcare professionals they promote to and of the products they promote, dates of their hiring and exit from the company for all processes and procedures to be conducted, and to submit these to the Agency upon request,

d) Retain for five years any data and documents pertaining to this paragraph. (Reg.Art.11.6)

25.4. 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.

25.5. Co-promotion

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

Article Clarifications and Justifications

25.4.1. To avoid misunderstandings, the projects shall be assigned with clearly defining contracts.

25.4.2. 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 26- Training on Raising Awareness and Good Promotional Practice

26.1. Within the framework of applicable laws and regulations, AIFD shall adopt 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 shall make 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).

26.2. AIFD shall,

a) Make proposals, programs and publications to ensure better perception and enforcement of the Code of Promotional Practice;
b) Organize training seminars directed at its stakeholders;
c) establish 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) Establish a platform that enables rules to be interpreted according to changing conditions,

e) Develop common operating proposals, provided that these are compliant with Competition Law. Such proposals shall be 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 shall be added to the AIFD Code of Promotional Practice.

26.3. AIFD shall share and discuss 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 27- Following up of the Enforcement of the Code and Monitoring of Promotion

27.1. 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)

27.2. 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 shall be forthwith fulfilled. (Reg. Art.12.1)

27.3.* 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.

27.4.* 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.

Article Clarifications and Justifications

26. Competition Law

For Articles **27.3.* and 27.4.*** of the Code, application shall be made to the Competition Board for the establishment of negative clearance.

26. Sanctions:

a) The sanctions to be imposed in case of breach of the Code of Promotional Practice have been indicated in the annexed procedure. Sanctions shall be proportionate to the weight and nature of the breach, have a deterrent effect and become more severe where repeated offences or breaching patterns are observed.
b) Announcement and publications of the sanctions are deemed as the most deterrent method. Other sanctions in line with applicable laws and regulations that will not discredit the reputation of the pharmaceutical industry may be applied.
c) For the purpose of increasing awareness, The AIFD Code of Promotional Practice and Standard Operating Procedure will be available on AIFD's website in Turkish and English.

Article 28- 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 I.*

Article 29- Administrative Sanctions

29.1. The Sanctions to be Imposed in actions in breach of the Code of Promotional Practice are detailed in the text presented in APP. VII, entitled "Regulation on the Promotional Activities for Medicinal Products for Human Use".

Article Clarifications and Justifications

28: Administrative Sanctions:

A criminal complaint may be filed at Public Prosecution Offices depending on the nature of the violation, against those who act or operate in violation of the provisions stipulated in this regulation in accordance with general provisions. Provisions of Turkish Penal Code, No. 5237,

dated 26/09/2004, provisions of Law No. 4077, dated 23/02/1995, on Protection of Consumers, Law No. 4054, dated 07/12/1994, on Protection of Competition, Law No. 6112, dated 15/02/2011, on the Establishment of Radio and Television Enterprises and Their Broadcasts, Article 18 of Law No. 1262 on Pharmaceutical and Medicinal Preparations *and* the relevant provisions in other laws may apply.

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 status of limitation in fines has been revoked.

APPENDIX I

AIFD CODE OF PROMOTIONAL PRACTICE: COMMITTEES, SANCTIONS and ENFORCEMENT

Standard Operating Procedure for Complaints; Constitution and Operation

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 of ITUK-GPP

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. In case of adoption of a decision which provides a different interpretation of the Code of Promotional Practice, AIFD Code of Practice Panel (TIDK-CPP) shall share this decision with GPP. Upon being discussed and approved at GPP, enforcement decisions shall become part of the Code of Promotional Practice upon being approved unanimously by the AIFD Board of Directors, without waiting for the General Assembly. Breaches to the enforcement decisions approved by the AIFD Board of Directors and, where deemed necessary, by the General Managers Board, shall fall under the responsibility of the Code of Practice Panel. Breaches to such decisions shall be discussed and settled at the Code of Practice Panel, ex-ufficio or upon application.

3. Code of Practice Panel (TIDK-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 shall 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) shall be circulated to member companies. Each company shall be 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 shall present to the Board of Directors top-voted 15 Marketing and top-voted 15 Medical candidates. AIFD Board of Directors shall select 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 shall propose three candidates each for the Independent Specialist and Independent Physician/Pharmacist memberships of the Panel and submits these to the Board of Directors. AIFD Board shall appoint one of these candidates as the permanent Independent Specialist member, one as the permanent Independent Physician/Pharmacist member and the other four persons as substitute consultant members.

3.5. CPP shall be 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 Specialist member.

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

3.6. It shall be 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 shall 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 shall be adopted by the majority votes of members with the right to vote. At least one member each from Medical, Marketing and Independent member categories shall be present to be able to start the meeting.

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

3.10. CPP shall convene 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, shall be dropped and he/she will be replaced by the next highest voted substitute from the same category. The same procedure shall be 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 shall not have any right to vote.

3.13. CPP shall appoint 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 will be received.

3.14. AIFD Secretary General shall provide the necessary administrative support to CPP.

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

4.1.1. AIFD Code of Practice Appeal Board shall be 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 shall be elected by AIFD's Board of Directors

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

4.2. AIFD-IEIS Joint Panel - Constitution

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

4.2.2. Joint Panel shall be formed when need arises.

4.2.3. The Boards of Directors of AIFD and IEIS shall elect the members to refer to the Joint Panel.

4.2.4. The Joint Panel shall be 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 specialist 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 shall operate similarly to CPAB. Chairmanship shall be 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 shall be formed when need arises.

4.3.2. AIFD and IEIS Secretaries General hall select their members to be referred to the Joint Appeal Board.

4.3.3. Joint Appeal Board shall be 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 shall operate similarly to CPAB.

Chairmanship shall be 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 Appeal Board shall be final.

5. AIFD Code of Practice Appeal Board (TITEK-CPAB) - Operation

5.1. AIFD Appeal Board shall convene, 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 shall be taken by majority voting.

5.3. If a Board member is involved in a case either as a complainant or respondent, he/she shall be 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 shall have no voting rights.

5.5. When an objection is evaluated, representatives of both complainant and the respondent companies shall be invited to the meeting and make their case in person.

5.6. CPAB decisions shall be final.

6. Complaint Handling Process

6.1. Complaints between AIFD members shall 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 shall 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, shall be clearly indicated, and where possible, a sample and evidence or color copy shall be attached to the complaint file;

d- Summary of the complaint: At each case, a summary description shall be provided, indicating the articles breached in the Code by the subject matter of the complaint. In the event of citations from medical publications, the referred publications and misquoted sections shall 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 shall 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 shall 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 shall conduct the examination described below in 6.5.2 and it shall be 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 shall be 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 shall decide 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 shall hold 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 shall be requested to complete the file; the complaint shall not be processed until the completion of the file.

6.5.4. The process mentioned above shall be applied in notifications between AIFD member companies. In complaints received from non-AIFD member companies, media and third parties and institutions, action shall be 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, shall be 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 shall be closed and the complainant will be 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 shall be closed and both parties will be informed about the reasons of closure.

6.6. Timeout

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 shall be sent to the respondent company along with a cover letter and a written response will be 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 shall be responsible for submitting the documents that will prove such claim. Alleged company will be 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 shall 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 shall 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 shall be 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 shall be 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 or an event or a material, it may be reviewed upon making reference to the relevant decision. If the material is not used again or alleged event is not repeated after the decision of the Panel, the case shall be reviewed on the file without requesting the presence of relevant parties. Relevant parties shall be informed about the decision previously adopted about the same matter. The decision shall not conclude that this is a new breach; the file shall be closed, but recorded.

6.9.3. If the complaint is the same as a case previously adjudicated, this shall be indicated in the report of the rapporteur. Where the event or material subject to the complaint is repeated after the decision for stopping it, the case shall be considered as a new complaint.

6.9.4. 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 shall be written. The file concerning the case and the rapporteur's report shall be submitted to the Practice Panel.

6.10. Review by the Practice Panel

6.10.1. Complaint files subjected to the preliminary review shall be 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 shall be distributed to members at least two working days prior to meeting date under normal conditions. Only the rapporteur's report shall be sent to the relevant parties.

6.10.3. CPP shall evaluate the complaints on the basis of submitted files.

6.10.4. Where deemed beneficial 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 shall present their cases. Meetings shall be 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 explanations or documents. In case CPP wishes to take a decision after listening to the explanations or 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 to the meeting again and the examination is continued on the basis of the file.

6.10.6. Company representatives shall be 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, shall be 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 shall examine this matter and request additional information from the respondent company, where necessary. In case time is requested for the preparation of a response, the case shall be finalized at a later date, upon the examination of documents, preparation and distribution of a new rapporteur's report, where necessary, and if deemed necessary by the Panel and after listening to relevant parties.

6.10.8. Pursuant to the discussion of the files and other matters in the panel, separate voting shall be made for each agenda item and decisions are taken according to the majority of those present in the meeting. Names of voters shall not be indicated in the decisions of the panel. When decisions are taken by majority of votes, the number of votes shall be specified.

6.10.9. Results of the evaluation made by CPP shall be recorded and a separate case report will be 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 shall close the case until a legal ruling is made and a decision will be 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 shall close 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 shall present 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 shall be submitted in written form to the relevant parties with the signature of the Secretary General or the Deputy 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 shall be informed in writing about this decision, the sanction and the reasoning behind the decision; the company subjected to sanction shall be 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 shall be 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 shall become final.

7.7. In case of objection, the file shall be 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 shall be 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 shall be submitted to the Appeal Board (CPAB). Decision of the Appeal Board shall be 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 shall 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 event;
- 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 the headquarters of the relevant Multinational Company,
- 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.

10. Case Reports

10.1. At the conclusion of a case under the Code, when a decision is reached about a case, both the complainant and the respondent may be informed about the result verbally at the end of the meeting; the final report of the case shall be sent in writing to the General Managers of both parties.

10.2. The report shall include 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 shall be corrected and the report will be re-distributed.

10.3. Summaries of all case reports shall be 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 shall publish, 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 shall propose 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 shall be submitted to EFPIA Code of Practice Panel and IFPMA. The following will be 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 will share 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 shall benefit from their experiences.

10.6. AIFD shall publish 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. Amendments in the Code, the 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 shall be submitted to the approval of the next AIFD General Assembly.

13.0 Summary Table of Complaint Procedures

Complainant	Complainee	The issue shall be settled as follows:
AIFD member	AIFD member	Between relevant companies; otherwise, the issue will be handled by AIFD CPP .
AIFD member	Member of the Pharmaceutical Manufacturers Association of Turkey (IEIS) / The Pharmaceutical Industry Association of Turkey (TİSD)	Between relevant companies; Otherwise, CPP shall prepare the first report; communicate the matter to IEIS/TISD and follow it up.
Member of IEIS or TISD	AIFD member	CPP will handle the issue.
AIFD member	None	CPP will handle the issue; where deemed necessary, CPP will advise the consultation directly of the Ministry of Health or the Competition Board.
Healthcare professional	AIFD member	CPP will handle the issue.
An individual from the general public or media representative	AIFD member	CPP will handle the issue.

14.0 Summary Table of CPP and CPAB Sanctions

Sanction	*Weight point*	*Additional Communication*	*If repeated within 12 months*	*Decision adopted by:*
Concern Letter	**1**			CPP – CPAB
Admonition *Weight level:1-2*	**5**		3 admonitions= 1 warning	CPP – CPAB
Warning *Weight level:2-3*	**15**	.	3 warnings = condemnation	CPP –CPAB
Condemnation *Weight level:2-3*	**45**	The decision shall be reported to healthcare professionals:	2 condemnations = strong condemnation	CPP – CPAB
Strong Condemnation *Weight level:2-3*	**90**	The headquarters of the relevant company shall be notified thereof	2 strong condemnations = Temporary suspension from AIFD	AIFD Board of Directors
Temporary suspension	**180**	IFPMA / EFPIA shall be notified thereof.		Board of Directors / General Assembly
Expulsion from AIFD		The Ministry shall be notified thereof; a press release will be published.		AIFD General Assembly

APPENDIX II:

AIFD User Guide on Digital Communication Applications in the Pharmaceutical Industry

Q & A

(This Guide is a study document established on the rules stipulated in Article 24 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. The Code of Practice of the Association of Research-Based Pharmaceutical Companies (AIFD) is a detailed self-supervision and communication document, covering promotion of prescription-only drugs to healthcare professionals, communications to and interactions with patient groups, and how health information qualified for public consumption shall be used by pharmaceutical companies. In Turkey, public promotion of prescription-only 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 utilize the benefits of digital communication means, while maintaining compliance with applicable laws and internal rules and avoiding approaches that may be perceived as the promotion of drugs to the general public.

This document is prepared as a guide for the enforcement of Article 24 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
8. Promotion and Information Sharing via Mobile Applications

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 shall 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 shall 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 shall be kept confidential. The website shall 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 shall 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 shall be informative, accurate, current, balanced, reliable, fair and objective, clear and readily comprehensible.

1.5. Every website shall have a homepage. The following information shall 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 shall 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 shall be reviewed by the relevant departments of the company in line with internal company rules and relevant approvals shall be obtained.

1.9. Information offered on the website shall 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 shall 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 shall 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 shall be ensured and it shall 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 shall 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 shall 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 shall reflect balanced and up-to-date information; pages open to the general public and patients shall 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, shall take prompt legal action to cease activity of such website. Such applications shall 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 registration, 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. Website 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 shall 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 shall be suitable for the target audience**.**

3.5. Sources shall be referenced for information relevant to the general public and for any remarks made on diseases**.**

3.6. No section of these pages shall 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.**" shall be included on pages intended for patients and relevant pages shall contain, at all times, the recommendation reading, "**Consult a physician and/or pharmacist for further information".**

3.8. Companies shall 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 shall 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 shall 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 shall 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 shall be ensured as applicable for promotion through conventional means.

4.4. Electronic mailing systems used at company websites shall be regularly monitored for potential adverse reports.

4.5. Requests received from healthcare professionals for literature and professional information shall 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 shall be compliant with the relevant laws, regulations

and guidelines and be in the format approved by the company's legal department. Confidentiality of information collected shall be respected.

4.7. Prior written permission of physicians, dentists and pharmacists – with wet signature or digitally approved - shall 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 shall 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 SmPC shall be used - even if these are approved in other countries.

4.10. In addition to the SmPC (Summary of Product Characteristics), also the Package Information Leaflet (PIL) prepared for patients shall 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 shall 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 shall 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 shall 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 shall be archived in a manner that allows future retrieval. Disputed portions of the content shall 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 shall be clearly disclosed. If speeches or correspondence from the meeting will be published, they shall comply with the Code of Promotional Practice, the references shall be included in the publications according to scientific practice and the copyrights of authors shall 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 shall 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 shall 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 shall be avoided and relevant measures shall be adopted to ensure that the preparation and dissemination of emotionally disturbing messages for others is avoided.

6.6. Mechanisms shall be in place to prevent these individuals from receiving unwanted or abusive messages.

6.7. Care shall 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 shall not be withheld unless justified, and care shall be taken to ensure that identity is clearly indicated under every message. Even when nicknames are used, conduct shall 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 shall 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 shall be forthwith notified thereof.

6.10. Any messages or texts communicated by pharmaceutical sector employees over social media channels concerning their companies, drugs and competitors' drugs shall 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 shall be used at social media channels.

6.11. All company employees shall 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 shall 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 shall never be discussed on public forums; only released/publicized information shall be shared.

6.14. When an adverse reaction report is detected in a digital environment, concerning any company product, the Drug Safety Department shall be promptly notified, following company procedures.

6.15. No groups or accounts involving the name of the company or a product shall be started on Twitter, Facebook or similar environments without informing the Social Media and/or Corporate Communications Department.

6.16. Company employees shall not share any information which may be perceived as promotion of prescription-only 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:

"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 shall 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 shall 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 shall act with the awareness that they shall 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 shall be clearly indicated.

7.4. Content sharing shall be made in compliance with the classification group of stakeholders. For example, an e-newsletter prepared for physicians or pharmacists and containing product promotion shall not be sent to patients and patients' relatives.

7.5. The content to be shared in the internet environment shall 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 shall be obtained for sending it. Notices such as "unsubscribe" or "report unwanted message" shall 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 shall 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.

8. Promotion and Sharing Information via Mobile Applications

8.1. The applications developed for the purpose of being used on smart phones and tablet computers are referred to as mobile applications. Such applications may be downloaded from various application stores depending on the software supported by the devices. Users may search for or list the applications to be downloaded, and view the sample screens without any restriction. If it is not possible to enter a restricted user name in the name of developed applications, on their home page, due to the specified features of the mobile medium, the name of the product or information describing the product and falling under the scope of promotion to the general public may not be used in the whole content and the sample pages to be used.

8.2. There shall be a user name and password in the applications to be prepared specifically for PPRs and the registration, validation and data management shall be compliant with the rules stipulated in the guidelines for websites.

8.3. The developer and owner to the applications shall be clearly indicated on the introduction page of the application.

8.4. If the application is accessible to Turkish users from a Turkish store, the Turkish office shall be responsible for this application and for its follow-up, even if the application has been developed abroad.

8.5. Even if the applications have been developed by pharmaceutical companies, the company which owns the product shall be responsible for the use of any type of promotional material that may be perceived as promotion to the general public.

User Guide on AIFD Code of Promotional Practice Article 24 and Digital Communication

Q&A

Question 1- Is it appropriate for companies to contact physicians through social media channels?

Answer 1- When using any medium for promotion, companies shall 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 on diseases and the use of drugs? At what point would their responsibility begin and end?

Answer 3- Any such activity of company employees shall be compliant with the codes of AIFD and the pharmaceutical sector. Companies shall advise their employees that any communication through such forums shall 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 shall be taken as basis.

Question 4- Is it appropriate for me to use video networking sites, such as YouTube, to post comments on my product as a pharmaceutical company employee using my real name or may I share product videos with my real name on websites for sharing videos?

Answer 4- As 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 shall 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- May a pharmaceutical company open a Facebook account open to the general public, which does not contain products and names of molecules but is intended only to raise awareness 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 no message, news and image that may be associated with product promotion is included. The company shall clearly indicate that it has sponsored this page. Free text boxes (areas where comments are made) shall 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 shall be duly compiled in line with relevant laws and regulations and company rules and the report shall be submitted to relevant authorities.

Question 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 shall not direct to a specific therapy, it shall 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 shall 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 shall be 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 it be a problem if product colors are replicated without using the product name at a website intended for patients?

Answer 8- The rule is to not promote drugs to the general public. Use of colors or compositions shall not be a problem, as long as the rule is respected. When colors (or a logo or visual) are 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 shall 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 Contract Agents”, creating a platform for sharing and discussing views?

Answer 11- It may be possible to hold such a virtual meeting 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 shall be clearly disclosed. When compiling and releasing speeches or correspondence from the meeting, the sponsor shall take care to ensure that Code of Promotional Practice is respected, and that references are included etc.

Question 13- Can the production 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 conducted as long as 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 prevents 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 sponsoring 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 shall 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 shall 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 16- These issues shall 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 shall 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 ling to other websites?

Answer 17- This has been addressed also in the body of the Guide. Reliability and content of linked websites shall be given consideration. Care shall 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 websites such as Wikipedia or Sourtimes on 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 ad 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 shall 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 shall 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- To whom 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 pharmaceutical company which has established/commissioned the establishment of a website designed solely for HCPs promotes the content of this website in a platform such as Twitter where there are not only physicians, would this be in breach of the AIFD Code of Practice (and this Digital Guide which is an integral part of the AIFD Code)?

Answer 26- It is acceptable to provide information via Twitter about websites designed solely for HPCs; however, the text of the tweets shared shall conform with comply with the rules. Only the heading of the newly added services and information may be shared from this account. The page to be directed with the tweets shall be the homepage with the screen for the user name and password and it shall be verified that only HCPs may enter this website. It should

be remembered that all "tweets" are in public domain or that also non-HCP followers may see this "tweet" when the HCPs who receive this message may Retweet (RT) it. ABPI considers mentioning of a drug's name (name of active substance) in the tweet messages as a "promotion to the general public", because, as indicated above, when an HCP retweets such a message, it reaches all the non-HCP followers of that HCP (and non-HCP followers who retweet this message. Such a behavior is not compatible with the AIFD Code of Practice. Please refer to the sections of the Digital Guide on the challenges in the use of Tweets and blogs in the pharmaceutical industry.

Question 27- Would the services provided websites be considered as a "gift"?

Answer 27- Medical services (such as image atlases, calculators, etc.), content (such as online journals, access to books, etc.) or news (such as congress proceedings, presentations, etc.) provided at websites shall not be classified as gifts provided that they are provided as a common service. In case journals and books are made available to all PPRs who access the site upon the payment of a collective fee by the company offering them, this shall not be classified as a "gift". On the other hand, in case the company makes a payment for each HCP who makes a request for accessing online journals and books, this shall be regarded as a personalized payment and will not be compliant with the AIFD Code.

Question 28- Is it possible for companies to offer a gift to HCPs to encourage them to enter the websites?

Answer 28- AIFD shall stop providing any type of gifts and even distributing reminder promotional materials as of 2014 in line with the EFPIA rules. According to the AIFD Code, companies are not allowed to give "gifts" to HCPs.

Question 29- Is it appropriate for companies to sponsor mobile applications developed for congresses?

*Answer 29**-** Companies may sponsor mobile applications developed for congresses; however, they may not share in public domain information containing the name of products and product promotion within the framework of their sponsorship. It is the responsibility of the relevant company to check the service received, verify its suitability, issue a warning in case of non-compliance and annul it where necessary, within this scope of the sponsorship.*

Question 30- In case applications developed and used abroad about the product of a company and if HCPs or the general public download and use these applications in Turkey, would the Turkey representative of the relevant company be responsible thereof?

Answer 30- If the application developed is available in the local application store and is accessible by the users in Turkey, it shall be under the responsibility of the relevant company. The company shall be liable for notifying abroad about the applicable rules in Turkey and adopt the relevant measures.

APPENDIX III Transparency: Sample Standard Information Sharing Chart and Remarks

Model

Updated on June 6, 2014

SCHEDULE 2 - TEMPLATE

Date of publication: .....

	Full Name	HCPs: City of Principal Practice HCOs: city where registered	Country of Principal Practice	Principal Practice Address	Unique country identifier OPTIONAL	Donations and Grants to HCOs (Art. 3.01.1.a)	Sponsorship agreements with HCOs / third parties appointed by HCOs to manage an Event	Contribution to costs of Events (Art. 3.01.1.b & 3.01.2.a) Registration Fees	Travel & Accommodation	Fee for service and consultancy (Art. 3.01.1.c & 3.01.2.c) Fees	Related expenses agreed in the fee for service or consultancy contract, including travel & accommodation relevant to the contract	TOTAL OPTIONAL
	(Art. 1.01)	(Art. 3)	(Schedule 1)	(Art. 3)	(Art. 3)							
HCPs	INDIVIDUAL NAMED DISCLOSURE - one line per HCP (i.e. all transfers of value during a year for an individual HCP will be summed up; itemization should be available for the individual Recipient or public authorities' consultation only, as appropriate)											
	Dr A					N/A	N/A	Yearly amount	Yearly amount	Yearly amount	Yearly amount	
	Dr B					N/A	N/A	Yearly amount	Yearly amount	Yearly amount	Yearly amount	
	etc.					N/A	N/A	Yearly amount	Yearly amount	Yearly amount	Yearly amount	
	OTHER, NOT INCLUDED ABOVE - where information cannot be disclosed on an individual basis for legal reasons											
	Aggregate amount attributable to transfers of value to such Recipients - Art. 3.02				N/A	N/A	Aggregate HCPs	Aggregate HCPs	Aggregate HCPs	Aggregate HCPs	Aggregate HCPs	Optional
	Number of Recipients in aggregate disclosure - Art. 3.02				N/A	N/A	number	number	number	number	number	Optional
	% of the number of Recipients included in the aggregate disclosure in the total number of Recipients disclosed - Art. 3.02				N/A	N/A	%	%	%	%	%	N/A
HCOs	INDIVIDUAL NAMED DISCLOSURE - one line per HCO (i.e. all transfers of value during a year for an individual HCO will be summed up; itemization should be available for the individual Recipient or public authorities' consultation only, as appropriate)											
	HCO 1				Yearly amount	Yearly amount	Yearly amount	Yearly amount	Yearly amount	Yearly amount	Yearly amount	Optional
	HCO 2				Yearly amount	Yearly amount	Yearly amount	Yearly amount	Yearly amount	Yearly amount	Yearly amount	Optional
	etc.				Yearly amount	Yearly amount	Yearly amount	Yearly amount	Yearly amount	Yearly amount	Yearly amount	Optional
	OTHER, NOT INCLUDED ABOVE - where information cannot be disclosed on an individual basis for legal reasons											
	Aggregate amount attributable to transfers of value to such Recipients - Art. 3.02				Aggregate HCOs	Aggregate HCOs	Aggregate HCOs	Aggregate HCOs	Aggregate HCOs	Aggregate HCOs	Aggregate HCOs	Optional
	Number of Recipients in aggregate disclosure - Art. 3.02				number	number	number	number	number	number	number	Optional
	% of the number of Recipients included in the aggregate disclosure in the total number of Recipients disclosed - Art. 3.02				%	%	%	%	%	%	%	N/A
	AGGREGATE DISCLOSURE											
	Transfers of Value re Research & Development as defined - Article 3.04 and Schedule 1									TOTAL AMOUNT	OPTIONAL	

latest update: 11 December 2013 v1

APPENDIX IV TITCK TRANSFER OF VALUE REPORTING FORMATS FOR HCP and HCO

APPENDIX V: 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 shall be signed between the organization and the company. In case the support is not provided directly by the company, it is recommended that the intermediary (intermediaries) 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 event;

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 event (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 shall 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 event;

Names and titles of representatives signing the contract;

Date of contract.

- **APPENDIX VI: CONSENT LETTERS SAMPLES**

APPENDIX VII: REGULATION ON THE PROMOTIONAL ACTIVITIES FOR MEDICINAL PRODUCTS FOR HUMAN USE

Official Gazette Where the Regulation Has Been Published	
Date	**No.**
26/8/2011	28037
Official Gazette Where the Regulation Amendments Have Been Published	
Date	**No.**
30/09/2012	28427
14/10/2012	28441
31/12/2014	29222
03/07/2015	29405

By the Turkish Agency of Medicines and Medical Devices:

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 the products.

Scope
ARTICLE 2 – (1) This Regulation encompasses the promotional activities of the medicinal products for human use, the enteral nutritional products and the medical infant formulas.

Basis
ARTICLE 3 – (1) This Regulation has been drafted based on Law #1262, dated 14/05/1928 on Pharmaceutical and Medicinal Products, and on the Articles 27 and 40 of the Decree Law #663, dated 11/10/2011 on the Organization and Mandate of the Ministry of Health and Affiliated Agencies.

Definitions
ARTICLE 4 – (1) For purposes of this Regulation, the following terms shall apply;

a) Ministry: the Ministry of Health,
b) Medicinal product for human use: Any natural and/or synthetically derived active substance or combination of substances, administered to humans with a view to curing and/or preventing, diagnosing a disease, or correcting, restoring or modifying a physiological function,
c) Scientific Service: The department organized by the registration/permit holder within its own organization to ensure the proper conduct of the promotion of products for which it holds registration/permit in compliance with relevant regulations, and where only physicians/dentists/pharmacists are employed,
ç) Scientific Meeting: Congresses, symposia, workshops, seminars, courses and meetings organized in the country or abroad by the Ministry, national and international associations whose members are healthcare professionals, healthcare institutions and organizations, universities, physician/dentist/pharmacist professional associations or registration/permit holders, with the purpose of giving information on a scientific subject,
d) Demo device: The apparatus which is registered along with the medicinal product for human use, which does not contain the active ingredient, and which is designed to display how the product is used,
e) Summary of Product Characteristics (SmPC): The summary of product characteristics included in the registration dossier of the product,
f) Package Leaflet (PL): The written information prepared for the user supplied together with the product,
g) Agency: The Turkish Medicines and Medical Devices Agency,
ğ) Registration/permit: The certificate prepared by the Agency, showing that a product may be manufactured and marketed with a specific formulation, a specific pharmaceutical form and dosage, and in accordance with approved product characteristics,
h) Registration/permit Holder: A natural or legal person in whose name a registration/permit certificate for its products has been issued by the Agency,
ı) Healthcare Professionals: Physicians, dentists, pharmacists, nurses, midwives or members of other professions defined in the Supplemental Article 13 of Law #1219 of 11/04/1928 on the Practicing Manner of Medicine and Medical Arts and Crafts,

i) Contracted Company: Legal person which is authorized by the registration/permit holder by contract to conduct the processes and procedures concerning promotional activities on its name or together with it, provided that all legal liability shall rest on the registration/permit holder; and whose name the registration/permit holder is obliged to notify to the Agency.
j) Promotion: Any informational activity aimed at informing healthcare professionals on the medical/scientific characteristics of products covered in this Regulation and organized by the registration/permit holder or on the name, request, contribution, support of the registration/permit holder; in this context, as well as the activities of the product promotion representatives, advertisements published in medical or professional books or journals, announcements made through direct mailing or the press, or other means of communication; the scientific meetings, product promotion meetings and activities carried out by similar events,
k) Promotional Materials: Symbolic reminder materials, whose monetary value does not exceed 2.5% of the current minimum monthly wage and which physicians, dentists or pharmacists may use while practicing their professions; any printed materials that provide sufficient and relevant information on a product such as books, booklets, or leaflets; films and slides; audiovisual materials offered through electronic storage devices; any publication and material that may be used as a source of information/data/reference by relevant parties and the ability to access these through electronic media, free samples, demo devices and materials for patient training,
l) Product: Human medicinal product, enteral nutrition product, or medical infant formulas,
m) Product promotion representative: A person holding the qualification certificate, who promotes products to physicians, dentists or pharmacists through visits.
n) Product promotion meeting: Meeting organized by the registration/permit holder for the promotion of its product,
o) Qualification certificate: The certificate issued by the Agency either directly to the graduates from university departments educating product promotion representatives, or to those who successfully pass an examination to be given or commissioned by the Agency following a training in line with the curriculum to be defined by the Agency

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 products covered in this Regulation to physicians, dentists and pharmacists.
(2) Promotion to healthcare professionals occurs through:
a) Using materials for promotion to physicians, dentists and pharmacists
b) Sponsoring or holding scientific meetings and product promotion meetings,
c) Visits by product promotion representatives to physicians, dentists and pharmacists.
(3) The promotion of products to the general public directly or indirectly through any public media or communication channels including the Internet is prohibited, whether through programs, movies, TV series, news reports or similar media. This excludes Agency-approved advertisements placed in newspapers/journals, announcing the market launch of a product to healthcare professionals.
(4) The PL/indications of products that have been approved by the Agency may only be published in media defined by the Agency, or in the own website of the registration/permit holder. Apart from those enumerated, no activities may be conducted for public promotion or information of products, by using partially or completely the Agency approved SmPC/PL/indications.
(5) No healthcare professional may have a role as an actor or actress in the promotional activities of products without the permission of the Ministry. Similarly, universities, professional associations, societies and foundations with activities in the healthcare, are prohibited from taking part in promotional activities of products, without the permission of the Ministry.

Essential Guidelines and Principles for Promotion
ARTICLE 6 – (1) Information to the general public may be provided on products that will be used in vaccination campaigns, organized actions to combat epidemics or other campaigns run by the Ministry to promote health – as they are important to safeguarding public 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 at the international congresses held in Turkey and the information activities provided personally by the scientific service of the registration/permit holder upon the written request of the physician/dentist/pharmacist;

a) Products that have not been registered or permitted in accordance with the relevant Regulation,

b) Indications other than those approved by the Agency for products registered or permitted in accordance with the Regulation,

c) Except the promotional activities for the purpose of pharmacovigilance of products that are procured through international suppliers and are purchased by the Social Security Institute within the scope of alternative reimbursement models and notified to the Agency; the products that are registered or permitted in

line with the relevant Regulation, but for which the Agency gives permission to be imported against prescription as they are not available in the domestic market,

shall not be promoted to the healthcare professionals.

(3) The promotional activity of a product must be consistent with the information and data contained in indications approved by the Agency.

(4) The promotion shall incorporate informative and evidence-based medical data on a product's characteristics that will help healthcare professionals to form their own opinion on therapeutic value of the product.

(5) Where the promotion involves the use of a documentation prepared by utilizing citations, tables or other visual materials from medical journals or other scientific publications, such materials shall be authentically reproduced, providing full reference to relevant sources.

(6) Promotion shall not be made through use of misleading, exaggerated or unproven information which can encourage unnecessary use of a product or lead to unexpected risks, or through use of alluring visuals not directly related with the product.

(7) Promotion may not involve sweepstakes, lottery or similar schemes.

(8) No benefits, whether in cash or in kind, may be provided, or offered or promised during promotion of products to physicians, dentists and pharmacists. Likewise, the aforesaid healthcare professionals are prohibited from accepting or requesting any inducement during the course of such promotional activities directed at them.

(9) Healthcare professionals shall disclose all types of sponsorship they received from registration/permit holders:

a) At the end of each article they author,

b) At the beginning of each speech/presentation they deliver.

(10) Registration/permit holders may donate to public healthcare institutions or organizations, and to non-profit healthcare agencies, institutions and organizations provided that the following conditions are fulfilled:

a) Tender decisions concerning products within the scope of this Regulation are not influenced, unfair competition is not caused,

b) The donation does not lead to any unethical transaction which may be associated with any purchase of products,

c) The donation does not encourage prescribing of a specific product

ç) The intention is to improve either the research, training, health or the patient care,

d) The donation will be utilized by not an individual person, but the entire organization or institution,

e) The name of the registration/permit holder, and not of the product, may appear on the donated materials,

f) The donation is entered in the official books of the registration/permit holder,

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

(11) Healthcare institutions and organizations may only accept donations by receiving permission from their headquarters, or in line with the relevant guidelines issued by their headquarters.

Scientific meetings and product promotion meetings

ARTICLE 7 – (1) Scientific meetings and product promotion meetings should be relevant to the specialty/branch of practice of the healthcare professional. These meetings are held to communicate existing medical data about the products, or to present new information.

(2) Registration/permit holders may sponsor the registration, accommodation and the travel expenses of healthcare professionals participating in scientific meetings taking place in or outside the country on the following conditions:

a) A healthcare professional may benefit from such sponsorships four times in total within the same calendar year; out of these four sponsorships only two may be provided by the same registration/permit holder and only two of these may be used for meetings abroad. Meetings that the healthcare professional attends with the sponsorship of a registration/permit holder as speaker, or researcher making a written or oral presentation are not included in this scope.

b) In meetings organized or supported by the Ministry, participants are exempt from restrictions about participation stated in subparagraph (a) of this Article.

c) Sponsorship will be provided to the organization or organizations holding the meeting, and not directly to individual participants.

(3) In product promotion meetings organized by registration/permit holders, participants' travel and accommodation expenses shall not be met by the registration/permit holder, except for the speakers. However, registration/permit holders may sponsor visits to their manufacturing sites in the country within the scope of paragraph 2 of this Article.

(4) Registration/permit holders may organize or sponsor scientific meetings held abroad on the condition that the meeting is international, or the majority of the participants are healthcare professionals not working in our country. These conditions are not sought for scientific meetings abroad that are organized or supported by the Ministry.

(5) Scientific meetings may be attended by students of faculties and colleges educating healthcare professionals, through sponsorship of the registration/permit holder, depending on the nature of the meeting.

(6) Registration/permit holders are required to notify the Agency about any scientific meetings or product promotion meetings that they organize or sponsor; and supply the information of the healthcare professionals or students of faculties or colleges educating healthcare professionals they sponsor. The Agency collects this information in the database it will create.

(7) Meetings of investigators, sponsored by the registration/permit holder, held in Turkey or in a third country in connection with a national or international multicenter clinical trial, will not be considered attendance to a scientific meeting. For such meetings, application must be submitted for permission to the relevant department of the Agency.
(8) Except international meetings that are held each time in a different country, no meeting can be held or sponsored by registration/permit holders at skiing resorts between 1 December – 1 March. On seaside resorts, no meeting can be held or sponsored by registration/permit holders between 1 June-1 September in 2015 and 2016; and between 15 June-15 September in 2017 and thereafter. These conditions are not binding the scientific meetings held or supported by the Ministry.
(9) In meetings organized or sponsored by the registration/permit holder, a presentation or informative video prepared by the Agency in order to increase awareness on pharmacovigilance must be included. Furthermore, posters and brochures prepared by the Agency for this purpose should be displayed in areas that are easily visible.
(10) At least 60% of all registration/permit holder -sponsored meetings within a calendar year that exceed 6 hours shall include a session in line with the principles and purposes of rational drug use, relevant to the topic of the meeting. The content of presentations to be made during such sessions should be aligned with Ministry-approved educational materials and diagnostic/therapeutic guidelines, and these presentations may be published for the public on the official website of the Agency, by citing the source.
(11) Non-health-care professionals may not be invited to the meetings, nor may their expenses be covered; however, guests of honor are excluded from this provision.
(12) Healthcare inspectors appointed by the Ministry may, with or without prior notice, attend these meetings for inspection purposes.

Promotional Materials

ARTICLE 8 – (1) Only those materials and tools that are defined in this Regulation can be used as promotional materials.
(2) 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 be provided only to physicians, dentists or pharmacists, subject to the following conditions:

a) The registration/permit holder will appoint responsible persons and set up an adequate system of records and monitoring for the production, importation and distribution of free promotional samples. These records will be created in accordance with the relevant recall regulations, and submitted to the Agency on request.

b) Free samples shall contain reduced quantities. However, this requirement will not be applied to enteral nutrition products and the promotional samples of products which, for technical reasons, cannot be reduced.

c) The wording, “Free promotional sample – not for sale,” shall discernibly appear on the outer packaging of promotional samples on at least one surface. As far as printing is possible, the said wording shall also appear on the inner packaging.

ç) A copy of the SmPC and the PL, if available, shall be provided with the promotional sample.

d) Samples shall not be provided or distributed of products containing psychotropic or narcotic substances covered under international conventions, or of substances subject to national control.

e) Samples of products included in the list of “Medicinal Products for which no Sample Distribution are Allowed”, published on the Agency website, shall not be provided or distributed.

f) Free samples distributed for each product may not exceed 5% of the total annual sales in the first calendar year after it is launched, to be determined by monitoring monthly sales realizations; in the second calendar year they shall not exceed 5% of the quantity sold in the previous year; in the third, fourth and fifth calendar years they shall not exceed 3% of the quantity sold in the previous year; and after the fifth calendar year, they shall not exceed 1% of the quantity sold in the previous year. Enteral nutrition products are exempt from the quantity reduction restrictions stated in this article. Annual distribution amounts of the promotional samples of enteral nutrition products with various flavors are accepted and calculated as a single product, independent of the flavor.

g) Promotional samples may not be used as an investigational product during a clinical trial.

CHAPTER THREE
Product Promotion Representatives
Product Promotion Representatives

ARTICLE 10 – (1) The Agency will issue a qualification certificate to those who have graduated from the departments of universities educating product promotion representatives upon submission of their diplomas; and to those who are at least the graduate of an institution of higher education and who have successfully passed an examination given or commissioned by the Agency.
(2) Product promotion representatives;

a) May work with the title of product promotion representative in companies on the condition of possessing the qualification certificate.

b) Upon receiving their qualification certificate, they are registered by the Agency in its electronic register system. Registration/permit holder will issue a “Product Promotion Representative Identity Card”, the format of which is defined by the Agency, to those product promotion representatives who are registered in the system and possessing the qualification certificate. They may not be employed as product promotion representatives if they do not possess the Identity Card.

c) They may not promote any product or analogues or distribute promotional materials to any other healthcare professionals than the physicians, dentists or pharmacists.

ç) They must forward any adverse events/reactions reported to them during product promotion to the scientific service in their companies.

(3) Promotion of human medicinal products by the product promotion representatives at public health institutions during office hours are subject to the following rules:

a) Relevant administrative supervisor 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 time allocation must not disrupt educational functions, or provision of health services to patients.

b) Product promotion representatives will declare which registration/permit holder they represent at the beginning of the visit, and show their product promotion representative identity card.

(4) Product promotion representatives may not be charged any fee, even as donation or otherwise, for access to healthcare the institutions and organizations.

(5) No poster or similar promotional material, which may be perceived as promoting a product, may be exhibited, placed, posted and/or affixed at healthcare institutions. However, 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, are excluded from this prohibition.

CHAPTER FOUR
Responsibility of Registration/permit Holders
Responsibility of Registration/permit Holders

ARTICLE 11 – (1) Registration/permit holders will internally establish a scientific service, responsible for managing information pertinent to their marketed products, to operate according to the below guidelines, and appoint a person among the service personnel as the responsible for these activities.

(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 Agency for authorization. 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.

(3) The scientific meetings and product promotion meetings which a registration/permit holder intends to hold or partially sponsor will be notified to the Agency. The content, a list of likely participants, projected expense items and the events must be notified to the Agency at least fifteen working days before each meeting for meetings held in the country, and at least thirty working days before meetings to be held abroad. A response only in electronic format will be given by the Agency 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 at the latest within thirty days submit to the Agency, digitally and in the prescribed format, the list of the participants, expense items and the events held. The Registration/permit holder concerned should retain examples of information and documents about support provided to participants for a period of five years.

(5) Registration/permit holders shall:

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 Agency, pertinent to promotional activities,

c) Retain a copy of each promotional material used for five years,

ç) Record the names of the product promotion representatives promoting products on their behalf, the districts where they work, the names of healthcare professionals to whom they make promotion and of the products they promote, their dates of hiring and of exit from the company; and to submit these to the Agency upon request,

d) Retain for five years any data and documents pertaining to the information given by the scientific service to physicians/dentists/pharmacists upon their written request as stated in paragraph 2 of Article 6.

e) Add a black inverted equilateral triangle followed by the sentence “This medicinal product is subject to additional monitoring” on the promotional materials of medicinal products included in the list of “Medicinal Products That Are Subject to Additional Monitoring”, issued by the Agency, in accordance with the Regulation on the Safety of Medicinal Products, published in the Official Gazette no 28973, dated 15/4/2014.

(6) The Registration/permit holder may conduct promotional activities through contracted companies. The Registration/permit holder is severally liable for all processes and procedures to be conducted within this scope. In promotional activities conducted through a contracted company, the Registration/permit holder shall;

a) Submit the contract or any amendments to the Agency within thirty days after these are enacted,

b) Notify the Agency personally all promotional processes and procedures conducted through the contracted company,

c) record the names of the product promotion representatives promoting products in their name, the districts where they work, the names of healthcare professionals they promote to and of the products they promote, dates of their hiring and exit from the company for all processes and procedures to be conducted, and to submit these to the Agency upon request,

ç) Retain for five years any data and documents pertaining to this paragraph.

(7) The Registration/permit holder may transfer any values exceeding 10% of current gross monthly minimum wage to healthcare institutions and organizations, universities, to healthcare professionals and professional organizations, unions, associations and foundations with activities in the healthcare industry of which they are members; and non-governmental organizations founded to preserve and improve health, only upon the condition of abiding by the following rules:

a) The Registration/permit holder notifies the Agency of all value transfers made within one calendar year, in a format defined by the Agency and in detail; within the first six months of the following year.

b) For any value transfer to be made within this scope, the Registration/permit holder shall collect written consent from the healthcare professional, and in the institutions and organizations, of the authorized supervisor, for the acceptance of the value transfer and for the transmission of the value transfer to the Agency. The Registration/permit holder shall not make any value transfer if the written consent is not obtained.

(8) Examples of all data and documents pertaining to the value transfer will be retained by the registration/permit holder for five years.

CHAPTER FIVE
Miscellaneous and Final Provisions

Inspections

ARTICLE 12 – (1) The Agency will inspect, ex officio or upon receipt of a complaint, the promotional activities and any materials and methods employed during such activities. The Agency 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 Agency to that effect must be complied with without delay.

Administrative sanctions

ARTICLE 13 – (1) In case product promotions are in violation of Article 13 of Law # 1262, or the promotions are made over the Internet, sanctions stipulated in Article 18 of the aforesaid Law will be imposed upon the Registration/permit holder.

(2) The Registration/permit holder;

a) Will be issued a warning by the Agency if it is established that its promotion activities are in breach of this Regulation.

b) In case any activity in breach of this Regulation is determined within one year following the warning, it will be banned from engaging in any promotional activity for a period of three months,

c) If any act in breach is repeated within the one year following the sanction of banning from any promotional activity for three months, it may not engage in any promotional activities for a period of one year.

(3) For product promotion representatives;

a) For promotional activities conducted in breach of this Regulation, the relevant person is issued a warning by the Agency.

b) If any act in breach of this Regulation is determined within the year following the said warning, the qualification certificate of the relevant representative will be suspended by the Agency for three months.

c) If any act in breach is repeated within the one year following the date when the sanction of suspending the qualification certificate for three months was imposed, the said representative's qualification certificate is suspended for one year.

ç) The representative whose qualification certificate is suspended may not work as product promotion representative during this period, and his/her product promotion representative identity card is withdrawn by the registration/permit holder company where he/she works.

d) Provisions in paragraph two are imposed on the registration/permit holder as a result of the wrongful acts of the product promotion representative within the scope of this paragraph.

(4) The registration/permit holder;

a) Will be issued a warning by the Agency in case of violation of any provisions in Article 7.

b) In case any act in violation of Article 7 this Regulation recurs within one year following the date of the warning, it may not engage in any promotional activity defined in Article 7 for three months.

c) If any act in violation of the provisions of Article 7 recurs within the one year following the date of the sanction of banning from engagement in promotional activities defined in Article 7 for three months; it may not participate in or support any scientific meetings or product promotion meetings for one year.

(5) Disciplinary action shall be initiated for healthcare professionals who act in breach of this Regulation by the organization or professional association that they are affiliated to.

Guideline

ARTICLE 14 – (1) The Agency will issue necessary guideline(s) to provide guidance on the implementation of this Regulation.

Repealed Regulation

ARTICLE 15 – (1) The Regulation on Promotional Activities of Medicinal Products for Human Use, published in Official Gazette #28037 of 26/08/2011, is herewith repealed.

Compliance and Transitional Period

TEMPORARY ARTICLE 1 – (1) Product promotion representatives are obliged to obtain the qualification certificate issued by the Agency by 1/1/2019. The Agency shall issue qualification certificates to those who qualify after an examination conducted before this date and who are at least high school graduates. However, this condition of being a high school graduate will not be sought for those who have actually worked as product promotion representative effectively for two years within the five years preceding the publication of this Regulation.
(2) Registration/permit holders will submit all contracts pertaining to promotional activities conducted through contracted companies and enacted before the date this Regulation is enforced, to the Agency within six months of its publication.
(3) The Agency shall prepare the list of "Medicinal Products for which no Sample Distribution are Allowed" until 1/1/2016, and publish it on the official website of the Agency.

Effectiveness

ARTICLE 16 – (1) Of this Regulation:
a) ninth paragraph of Article 7, subparagraph (e) of the fifth paragraph, and the seventh paragraph of Article 11 will enter into force on 1/1/2016;
b) subparagraph (a) and (b) of the second paragraph; and subparagraph (b) of the third paragraph of Article 10 will enter into force on 1/1/2019;
c) all other provisions will enter into force on the date of the publication.

Enforcement

ARTICLE 17 – (1) The provisions of this Regulation shall be enforced by the Turkish Medicines and Medical Devices Agency.

APPENDIX VIII: Guidelines and Directives Issued in Relation with the Regulation

(*Check the website of the Turkish Medicines and Medical Devices Agency for Updated Texts.)*

i- GUIDELINES ON APPLICATIONS FOR THE DISTRIBUTION OF FREE PROMOTIONAL SAMPLES AND ISSUANCE OF PRESS RELEASES WITHIN THE SCOPE OF PROMOTIONAL ACTIVITIES FOR MEDICINAL PRODUCTS FOR HUMAN USE (16.11.2015)

Purpose

ARTICLE 1 – (1) These Guidelines set forth the rules for distributing free promotional samples of products and placing product-related announcements in the press.

Scope

ARTICLE 2 – (1) These Guidelines apply to human medicinal products, enteral nutrition products and medical foods.

Basis

ARTICLE 3 – (1) These Guidelines are issued based on Article 9 and the second paragraph of Article 11 of the Regulation on Promotional Activities for Human Medicinal Products, as published in Official Gazette #29405 of 03.07.2015.

Definitions

ARTICLE 4 – (1) For the purposes of these Guidelines:

a) Human medicinal product means any natural or synthetically derived active substance or combination of substances, administered to humans with a view to curing, preventing or diagnosing a disease, or restoring, correcting or modifying a physiological function;

b) Summary of product characteristics (SmPC) means the summary of product characteristics included in the marketing authorization file of the product concerned;

c) Package leaflet (PL) means written information prepared for end users, which is provided with human medicinal products;

ç) Agency means Turkish Medicines and Medical Devices Agency;

d) Marketing authorization/license means a certificate issued by the Agency, showing that the product concerned can be manufactured and placed on the market in a specific formulation and in specific pharmaceutical form(s) or strength(s), in accordance with the approved product information;

e) Marketing authorization/license holder means a natural or legal person in whose name the Agency has issued a marketing authorization/licenser for their products;

f) Healthcare professional means a physician, a dental practitioners, a pharmacist, a nurse, a midwife or members of any other professions listed in Appendix 13 to Law #1219 dated 11.04.1928 on the Practicing Procedure of Medicine and Medical Crafts;

g) Promotion means any informational activity organized by or upon the request of marketing authorization/license holders with their name, contribution and support, aimed at informing healthcare professionals on medical/scientific characteristics of products covered in the Regulation, including activities of product promotion representatives, advertisements published in medical or professional books or journals, announcements made through direct mailing or the press, or other means of communication, as well as scientific meetings, product promotion meetings or other similar events;

ğ) Product means a human medicinal product, an enteral nutrition product or a medical food; and

h) Regulation means the Regulation on Promotional Activities for Human Medicinal Products, published in Official Gazette #29405 of 03.07.2015.

Press Announcements

Principles for placing announcements in the press

ARTICLE 5 – (1) In cases where a marketing authorization/license holder wishes to place an announcement in the press to inform healthcare professionals about a product placed on the market, the marketing authorization/license holder will submit an identical copy of the proposed announcement text to the Agency to seek approval. A press announcement may be placed only once on the same day on all daily print publications. For periodicals, the announcement may be placed only once within 30 days after the granting date of the approval.

(2) The product to be announced using the press announcement must be available on the market, as verified by the Agency by checking the active products list on the E-Prescription Drugs List on the Health Coding Reference Server (SKRS).

(3) A press announcement must be:

a) published in black and white;

b) not more than 1/8 of a full newspaper page in size (i.e. A5 paper size); and

c) consistent with the font type used on the Agency-approved outer packaging.

(4) The press announcement text/copy may not contain any information/text or symbols which is not used on the Agency-approved outer packaging.

Principles for press announcement applications

ARTICLE 6 – (1) Marketing authorization/license holders must submit the following documents when making an application to the Agency for placing a press announcement:

a) An identical copy of the announcement text;

b) A photocopy of the marketing authorization/license;

c) An example of the final approved packaging and the approval letter; and

ç) Selling permission approval letter.

(2) Applications for placing a press announcement will be dismissed if any of the requisite documents are omitted from the application.

Free Samples

Principles for distributing free promotional samples

ARTICLE 7 – (1) Free samples may only be distributed to physicians, dental practitioners or pharmacists, ~~without requiring specific authorization by the Agency,~~ provided that the requirements of Article 9 of the Regulation have been met.

(2) The product for which promotional samples will be distributed must be available on the market, as verified by the Agency by checking the active products list on the E-Prescription Drugs List on the Health Coding Reference Server (SKRS).

(3) It is essential that promotional samples do not bear a regular or 2D barcode.

(4) Obtaining specific written authorization by the Agency is mandatory, if there are regular or 2D barcodes on the packaging of free promotional samples, or if it is technically impracticable to reduce the sample size.

Principles for free promotional sample applications

ARTICLE 8 – (1) Marketing authorization/license holders must submit the following documents when making an application to the Agency for free promotional samples:

a) Justification for situations where the product contains a sellable regular or 2D barcode, or where the product cannot be reduced;

b) Examples of promotional samples (2 each);

c) A photocopy of the marketing authorization/license;

ç) An example of the final approved packaging and the approval letter;

d) The final approved package leaflet and the approval letter;

e) For samples bearing a sellable regular or 2D barcode, a letter of undertaking that the 2D barcodes will be deactivated and a printed or electronic list of the products; and

f) A letter of undertaking that the quantity of free promotional samples are prorated to the sales volume, in the meaning of subparagraph (f) of the first paragraph of Article 9 of the Regulation.

Calculating the distribution quantity of free promotional samples

ARTICLE 9 – (1) Subparagraph (f) of the first paragraph of Article 9 of the Regulation, concerning free samples, will be applied as follows:

a) For the first calendar year:

1. If the market launch date (first entry in the Drug Tracking System (DTS)) falls within the first 6 months of the first calendar year, the quantity of samples that may be distributed will not exceed 5% of the total annual domestic sales volume within the same year, according to monthly actual sales figures based on the marketing authorization/license holder's data.

2. If the market launch date falls within the second 6 months of the first calendar year, the period until the end of the next calendar year will be deemed "the first calendar year," the quantity of samples that may be distributed will not exceed 5% of the total annual domestic sales volume within the same year, according to monthly actual sales figures based on the marketing authorization/license holder's data.

Example 1: For a product which was placed on the market on 30.06.2015, the first calendar year is 2015.

Example 2: For a product which was placed on the market on 01.07.2015, the first calendar year is 2016. For the purposes of this example, the annual sales will cover a "first calendar year" of 18 months in total, making it possible to distribute free promotional samples up to 5% of the total sales volume over 18 months.

b) For the second calendar year:

1. If the market launch date falls within the first 6 months of the previous year, the quantity of samples that may be distributed will not exceed 5% of the total annual domestic sales volume, found by linear extrapolation to 1 year from the total domestic sales value, based on the marketing authorization/license holder's data.

2. If the product was on the market for a full calendar year in the previous year, the quantity of samples that may be distributed will not exceed 5% of the total annual domestic sales volume, based on the marketing authorization/license holder's data.

Example 1: For a product which was placed on the market on 30.06.2015, the quantity is calculated as 5% of the 1-year sales volume, calculated by linear extrapolation from a total of 6 months and 1 day in year 2015, i.e. the first calendar year.

The 1-year sales figure is calculated as follows: [(sales volume for 6 months and 1 day) / 6,033] X 12 = “total sales projection from the first calendar year.”

Example 2: For a product which was placed on the market on 01.07.2015, the first calendar year is 2016. The quantity of samples that may be distributed in 2017 will be 5% of the total sales volume in calendar year 2016.

c) For the third, fourth and fifth calendar years:

The quantity of samples that may be distributed will be up to 3% of the total annual domestic sales volume of the previous year, based on the marketing authorization/license holder’s data.

ç) For the sixth, seventh and subsequent calendar years:

The quantity of samples that may be distributed will be up to 1% of the total annual domestic sales volume of the previous year, based on the marketing authorization/license holder’s data.

Repealed guidelines

ARTICLE 10 – (1) The “Guidelines on Applications for Distributing Free Promotional Samples or Placing Announcements in the Press According to the Regulation on Promotional Activities for Human Medicinal Products,” published on 02.01.2013, is hereby repealed.

Effectiveness

ARTICLE 11 – (1) These Guidelines will become effective upon approval by the Agency’s President.

Enforcement

ARTICLE 12 – (1) These Guidelines will be enforced by the President of Turkish Medicines and Medical Devices Agency.

ii- GUIDELINES ON SESSIONS ON 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. A Ministerial policy has been designated in order to promote public consciousness and generate awareness about this topic. Education and promotional activities are essential in generating 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 meeting sponsored by a registration/permit holder shall 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 shall 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 Session on the Rational Use of Drugs shall be aligned with the principles of Rational Use of Drugs, 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 duration of the session should not be shorter than 30 minutes.

The session on the Rational Use of Drugs shall 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 shall be submitted within the deadlines prescribed in the Regulation. The report shall also include a statement that a "Session on the Rational Use of Drugs" will be included. The declared meeting program shall 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 shall 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 the sessions shall 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.

iii- REFERENCE GUIDELINES FOR THE SCIENTIFIC MEETINGS AND PRODUCT PROMOTION MEETINGS WITHIN THE SCOPE OF THE REGULATION ON THE PROMOTIONAL ACTIVITIES FOR MEDICINAL PRODUCTS FOR HUMAN USE (30.06.2016)

Purpose

ARTICLE 1 – (1) The purpose of these Guidelines is to set forth the rules to be complied with in the applications submitted to the Agency by registration/permit holders for the applications regarding scientific meetings and product promotion meetings.

Scope

ARTICLE 2 – (1) These Guidelines encompass the scientific meetings and product promotion meetings organized within the scope of the promotional activities for medicinal products for human use, enteral nutrition products and medical infant formulas.

Legal Basis

ARTICLE 3 – (1) These Guidelines have been prepared on the basis of clauses three and four of Articles 7 and 11 of the Regulation on the Promotional Activities for Medicinal Products for Human Use, published on the Official Gazette dated 03/07/2015, No. 29405.

Definitions

ARTICLE 4 – (1) The following terms shall apply for the purposes of these Guidelines;

a) Medicinal product for human use: Any natural or synthetic origin active substance/combination of substances administered to human beings with a view to treating or preventing a disease or making a diagnosis, correcting, adjusting or modifying a physiological function,

b) Scientific meeting: Any congress, symposium, workshop, seminar, course and meeting carried out in Turkey or abroad by the Ministry, national and international associations of which healthcare professionals are members, healthcare institutes and institutions, universities, professional organizations of physicians/dentists/pharmacists or registration/permit holders for the purpose of providing information on a scientific topic,

c) Summary of Product Characteristics (SmPCs): Summary of product characteristics included into the registration dossier of medicinal product for human use,

ç) Package Information Leaflet (PIL): Written information presented with the medicinal product for human use and intended for the users,

d) Agency: Medicines and Medical Devices Agency of Turkey,

e) Undersecretariat: The Undersecretariat of the Ministry of Health,

f) Registration/permit: The certificate issued by the Agency, indicating that a product has been introduced into the market upon being manufactured with a specific formulation and a specific pharmaceutical form and dose, in accordance with accepted product information,

g) Registration/permit holder: The real persons or legal entities for whom the registration/permit has been issued by the Agency for their products,

ğ) Healthcare authority: The authorized signatory of the chief physician's office, dean's office, association's chairman/authorized signatory and including but not limited to each institute and institution included into the scope of the Regulation and Guidelines,

h) Healthcare professionals: Physicians, dentists, pharmacists, nurses, midwives and the other professionals defined in Supplemental Article 13 of Law No. 1219, dated 11/04/1928, on the Practice of Medicine and Its Branches,

ı) Contracted company: The legal entity authorized to carry out on it behalf or together the work and tasks related with the promotional activities via a contract by the registration/permit holder and required to be reported to the Agency by the registration/permit holder, provided that any type of legal liability rests with the registration/permit holder,

i) Promotion: All informative activities organized by the registration/permit holders on the medical and scientific characteristics of products within the scope of the regulation or to be carried out for healthcare professionals with the name, request, contribution and support of the registration/permit holders; the activities of product promotion representatives within this framework; the announcements placed on medical and professional books and journals; the announcements to be made via direct

mailing or other communication tools; the scientific meetings and product promotion meetings and the activities to be carried out with similar events,
j) Promotional materials: The symbolic reminder call materials, with a monetary value not exceeding 2.5% of the effective monthly gross minimum wage, which may be used by physicians, dentists and pharmacists during the execution of their practice; printed materials such as books, booklets and pamphlets which contain sufficient and necessary information on the product; films and slides; audio/visual materials presented via electronic storage tools; any type of publication which may be used as a source of information/data/reference or the opportunity to access these publications electronically; free samples, demo devices and the materials intended for patient training,
k) International scientific meeting: Any congress, symposium, workshop, seminar, course and meeting in which the participants attend from different countries and which are organized each time in a different country or in the same country,
l) Product: Medicinal products for human use, enteral nutrition products and medical infant formulas,
m) Product promotion representative: The person who has received a certificate of qualification and promotes products via calls to physicians, dentists and pharmacists,
n) Product promotion meeting: The meetings organized by the registration/permit holders and intended for the promotion of a product,
o) Regulation: The Regulation on the Promotional Activities for Medicinal Products for Human Use, published on the Official Gazette dated 03/07/2015, with No. 29405.

Principles for the Organization and Sponsorship of Scientific Meetings and Product Promotion Meetings

Scientific Meetings

ARTICLE 5 - (1) Registration/permit holders may sponsor the registration, accommodation and transportation expenses of the healthcare professionals to attend scientific meetings in Turkey and abroad within the scope of the Regulation and provided that they fulfill the following conditions:
a) A healthcare professional may receive sponsorship from registration/permit holders for four times in total within the same year; only two of these four sponsorships may be provided by the same registration/permit holder and again only two of these sponsorships may be used in the meetings carried out abroad. The meetings attended by the healthcare professional sponsored by a registration/permit holder, as a speaker or investigator presenting a written or verbal abstract, shall not be included into this scope.
b) In the scientific meetings organized or sponsored by the Ministry, the participants attending such meetings shall be exempt from the limitation in the number of meetings attended in item (a) of this clause. The Undersecretariat shall decide on the meetings which may be included into the scope of meetings sponsored by the Ministry and those regarded suitable will be announced on the official website of the Agency. The work and tasks within this scope shall be carried out by the Agency.
c) The sponsorship shall be provided not directly to a person but to the organization(s) organizing the meeting.
(2) Registration/permit holders may organize visits to their manufacturing sites located in Turkey within the scope of a scientific meeting. They may provide sponsorship within the scope of clause two of Article 7 of the Regulation.
(3) Also the students studying at the faculties or colleges training healthcare professionals may attend scientific meetings upon receiving sponsorship by a registration/permit holder depending on the nature of the meeting. The participants within this scope shall also be reported to the Agency.
(4) The investigator meetings to be held in Turkey and abroad of the national and international clinical trials sponsored by a registration/permit holder shall not be regarded as attendance of a scientific meeting. A permit application shall be made to the relevant unit of the Agency for the meetings within this scope.
(5) Except for the international scientific meetings organized each time in a different country; no meeting can be held or sponsored by registration/permit holders in skiing resorts between December 1-March 1. No meeting can be held or sponsored in seaside resorts by registration/permit holders between June 1-September 1 in 2015 and 2016, and between June 15-September 15 in 2017 and beyond. These conditions shall not be sought in the scientific meetings organized or sponsored by the Ministry. The meetings to be included into the scope of meetings sponsored by the Ministry shall be decided by the Undersecretariat and those deemed suitable shall be announced on the official website of the Agency. The work and tasks within this scope shall be carried out by the Agency.

(6) Registration/permit holders shall apply to the Agency for the scientific meetings to be organized or sponsored by them. It is mandatory to notify the Agency at least fifteen workdays prior to each meeting in Turkey and at least thirty workdays prior to the meetings abroad about the content of the meeting, the list of potential participants, the expense items and the activities of the meeting. Notifications where the relevant document receipt formalities have been carried out shall be replied only electronically within ten workdays by the Agency; in case of no reply, the application shall be regarded as approved. The applications not submitted in line with the provisions of this Regulation and these Guidelines shall not be evaluated within this scope.
(7) Upon carrying out the meeting sponsored, the relevant registration/permit holder shall notify the Agency latest within thirty days in the format designated by the Agency and in digital form in detail about the list of participants, expense items and the activities carried out. Samples of the information and documents presented to the participants shall be preserved for a period of five years by the relevant registration/permit holder.
(8) Scientific meetings may be organized/sponsored by registration/permit holders provided that they fulfill the following conditions:
a) Scientific meetings which do not exceed four hours may be organized as a one-day meeting with the sponsorship of a single registration/permit holder.
b) With regards to the scientific meetings exceeding four hours, organized in Turkey or abroad, by the Ministry, national and international associations of which healthcare professionals are members, healthcare institutes and institutions, universities and professional organizations of physicians/dentists/pharmacists should involve the sponsorship of at least two companies/group of companies with a product affiliated with the topic of the meeting. The speaker(s) and those verbal abstract presenters shall not be included into this scope.
c) The sponsorship of a second registration/permit holder shall not be necessary for international scientific meetings, including but not limited to global and continental congresses, the surgery courses and training programs organized in the training and research hospitals in Turkey and in the university hospitals located in Turkey and abroad.
ç) In the event that the scientific meeting is organized/sponsored by the representatives abroad/licensees of the registration/permit holder and is intended for product promotion, the registration/permit holder may only sponsor speakers.
d) No product promotion may be carried out in the meetings organized/sponsored by a single registration/permit holder. Registration/permit holders may not pay an honorarium fee to speakers or provide sponsorship for booth participation and satellite symposia to the organizing associations/institutions. The sponsoring registration/permit holder may use their corporate logo in such meetings.
(9) In at least 60% of the meetings lasting longer than six hours, organized or contributed by registration/permit holders within a calendar year, a session related with the topic of the meeting will be included within the scope of the principles and goals of the rational use of drugs. The content of the presentations in this session shall be within the framework of the training materials approved by the Ministry and diagnostic therapeutic guidelines and these presentations may be placed on public domain via the official website upon indicating the source.
(10) Sponsorship to scientific meetings may only be provided as described in detail below in the form of general meeting sponsorship, the payment of the fee of the participants, satellite speakers, satellite symposia and booth participation. Sponsorship applications made under the sponsorship of a session, sponsorship of a panel, inaugural cocktail, gala dinner, social program, etc. shall not be included into this scope.
a) The general sponsorship of a scientific meeting refers to the sponsorship provided to the organizers of a meeting for holding that meeting. The organizers of the meeting may not cover the registration, accommodation and transportation expenses of the participants with the sponsorships provided within this scope.
b) The sponsorship for participants and speakers refers to the sponsorship provided with the payment of the registration fees, accommodation and transportation expenses of the participants/speakers/abstract presenters and the honorarium fees within the scope of the Regulation. The registration/permit holder may pay the honorarium fee only for the speakers in the satellite symposium of its company in the scientific meetings.

c) Satellite symposia refer to the sessions where a product is promoted within a scientific meeting. The meeting organizers shall not cover the registration fees and accommodation and transportation expenses of the participants with the sponsorships provided for conducting the satellite symposium.
ç) The sponsorships for booth participation refer to the sponsorships provided for the expenses made for catering in the booth area upon renting a booth space from the organization for the purpose of promoting the product or company of the registration/permit holder. The meeting organizers may not cover the registration fees and the accommodation and transportation expenses of the participants with the sponsorships provided within this scope.
d) Registration/permit holders may provide sponsorship in the scientific meetings held abroad only by covering the registration fees and the accommodation and transportation expenses of the participants.
(11) The name of the scientific meeting shall be reported to the Agency in the first registration application as well as the name of the meeting, the country and city where the meeting will take place, the beginning and ending date of the meeting, the association/institution carrying out the organization, the venue of the meeting and the website via which the meeting is announced on the page of the association/institution organizing the meeting.
(12) In the sponsorship applications for the meetings the scientific name of which has been approved by the Agency, it is mandatory to report the name of the agency undertaking the organization (in the international meetings held abroad, the registration/permit holder shall enter the name of the agency used in Turkey), the cost of the satellite symposium where applicable (the program, the name of the product to be promoted, the speaker and the fee paid to the speakers, where applicable, shall be disclosed), the payment made to the speakers where applicable, booth participation where applicable (the name of the product to be promoted) and the speaker(s) and the abstract presenter(s) where applicable, as well as the payments to these participants upon entering information in the relevant sections.
(13) Approval shall be received from the authority of the healthcare institution where the meeting will be held by the registration/permit holders in the meetings where an interventional procedure will be performed.
(14) In the scientific meetings composed of modules extended over a period of time, each module shall be regarded as a separate scientific meeting.
(15) The names of healthcare professionals shall not be reported to the Agency in the one-day scientific meetings carried out without covering the registration fee and the accommodation and transportation expenses.

Product promotion meetings

ARTICLE 6 - (1) Product promotion meetings may be organized by registration/permit holders for the promotion of their products to physicians, dentists and pharmacists. Also the meetings intended for other healthcare professionals, where the use and administration of the product is demonstrated, shall be included into this scope. These meetings may be carried out as a one-day meeting which does not last longer than four hours.
(2) Registration/permit holders may receive scientific support from specialized associations, medical academic staff, healthcare institutes and institutions and the institutions providing education in the fields associated with the product for product promotion meetings.
(3) The transportation and accommodation expenses of the participants, except for the speakers, shall not be covered by the registration/permit holders in the product promotion meetings.
(4) Product promotion meetings may only be organized by the registration/permit holders. The meetings falling into this scope may not be organized by a donation together with an association or other institutions.
(5) Product promotion meetings may not be organized for the students studying at the faculties or colleges training healthcare professionals.
(6) The following shall be reported to the Agency during the application in the sponsorship applications for product promotion meetings;
a) Name and topic of the meeting,
b) Beginning and ending date of the meeting,
c) The agency undertaking the organization (the tourism agency or the organization company)
ç) Venue of the meeting,
d) Where applicable, the total payment paid to the speaker and the other expenses.

e) The company and foreign speakers and the speakers on the program other than those affiliated with the scientific topic but who are not healthcare professionals shall be entered into the system.
(7) In the reports submitted to the Agency, the province, institute or institution where the invited participants work, the profession and branch of the healthcare professional, the product to be promoted, approximate number of participants and the commitment information indicating that the participants will be entered into the system in the feedback shall be included on the cover letter.
(8) The program of the meeting shall comprise the topic, the name(s) of the speaker(s), the time and the dates.
(9) The name of the meeting should be associated with the topic of the meeting.
(10) In web-based product promotion meetings, the fees paid for all the participants listening to the meeting via remote access simultaneously and in the location where the speaker is speaking shall be reported as the total amount. The list of participants shall be reported to the Agency during feedback submission along with the details stipulated in clause seven of this article.

General principles

ARTICLE 7 - (1) The electronic applications of scientific meetings and product promotion meetings shall be prepared and performed in line with the "Guidelines on the Electronic Application for Scientific Meetings and Product Promotion Meetings".
(2) The annulments of scientific meetings and product promotion meetings shall be reported to the Agency in written by the registration/permit holder prior to the feedback date.
(3) Changes in the name (hotel, etc.) of scientific meetings and product promotion meetings shall be reported to the Agency via an official letter by the registration/permit holder at least three days prior to the meeting date.
(4) Changes in the date of a scientific meeting shall be reported to the Agency via an official letter for the annulment of the meeting application. A new application shall be made to the Agency for a new meeting date.
(5) Changes in the date of a product promotion meeting shall be reported to the Agency via an official letter by the registration/permit holder at least five days prior to the meeting date. Request can be made only for a future date in case of change of the date.
(6) Changes in the venue of a product promotion meeting shall be reported to the Agency via an official letter.

Repealed guidelines

ARTICLE 8 - (1) The "Reference Guidelines on Scientific Meetings and Product Promotion Meetings", published on 27/05/2016, have been repealed.

Entry into force

ARTICLE 9 - (1) These Guidelines shall enter into force on the date they are published.

Execution

ARTICLE 10 - (1) The provisions of these Guidelines shall be executed by the President of the Medicines and Medical Devices Agency of Turkey.

iv- GUIDELINES ON THE PRINCIPLES AND PROCEDURES FOR THE PRODUCT PROMOTION REPRESENTATIVE EXAMINATION AND QUALIFICATION CERTIFICATION APPLICATIONS ACCORDING TO THE REGULATION ON PROMOTIONAL ACTIVITIES FOR HUMAN MEDICINAL PRODUCTS (16.11.2015)

Purpose

ARTICLE 1 – (1) These Guidelines set forth the principles and procedures for the qualification examination of product promotion representatives and the rules for making an application to the Agency for obtaining a qualification certificate.

Scope

ARTICLE 2 – (1) These Guidelines apply to product promotion representatives who promote human medicinal products, enteral nutrition products and medical foods.

Basis

ARTICLE 3 – (1) These Guidelines are issued based on Article 10 and subparagraph (ç) of the fifth paragraph of Article 11 of the Regulation on Promotional Activities for Human Medicinal Products, as published in Official Gazette #29405 of 03.07.2015.

Definitions

ARTICLE 4 – (1) For the purposes of these Guidelines:

a) Human medicinal product means any natural or synthetically derived active substance or combination of substances, administered to humans with a view to curing, preventing or diagnosing a disease, or restoring, correcting or modifying a physiological function;

b) Unit means the Rational Drug use and Drug Supply Management Department of the Agency's Vice-Presidency for Economic Assessments and Information Management;

c) Agency means Turkish Medicines and Medical Devices Agency;

ç) Agency's official website means the official website of Turkish Medicines and Medical Devices Agency;

d) Examiner means a university announcing that it will give an examination for Product Promotion Representative (PPR) qualification certification;

e) Promotion means any informational activity organized by or upon the request of marketing authorization/license holders with their name, contribution and support, aimed at informing healthcare professionals on medical/scientific characteristics of products covered in the Regulation, including activities of product promotion representatives, advertisements published in medical or professional books or journals, announcements made through direct mailing or the press, or other means of communication, as well as scientific meetings, product promotion meetings or other similar events;

f) Product means a human medicinal product, an enteral nutrition product or a medical food;

g) Product Promotion Representative (PPR) means a person holding a qualification certificate and promoting products to physicians, dental practitioners or pharmacists by making direct visits;

ğ) PPR database means the database that the Agency maintains for keeping information and records of PPRs;

h) Qualification certificate means a certificate issued directly to graduates of university programs for developing product promotion representatives, or to anyone who successfully passes an examination given, or caused to be given by the Agency, according to the curriculum designated by the Agency for this purpose;

ı) Qualification certification examination means the examination which every PPR must take; and

i) Regulation means the Regulation on Promotional Activities for Human Medicinal Products, published in Official Gazette #29405 of 03.07.2015.

General principles

ARTICLE 5 – (1) Upon presenting their diploma, graduates of university programs for developing product promotion representatives will be issued a qualification certificate by the Agency.

2) Persons who hold at least an associate degree and successfully pass an examination given or caused to be given according to the curriculum posted on the Agency's official website will be issue a qualification certificate by the Agency.

3) Product promotion representatives must obtain a qualification certificate issued by the Agency by 01.01.2019. Those who are at least a high school graduate and who have successfully passed an examination and

become eligible to obtain a qualification certificate prior to said deadline will be issued a qualification certificate by the Agency. The requirement of holding a high school diploma is not mandatory for persons who worked for two full years as a product promotion representative over a five year period before the publication date of the Regulation.

Product Promotion Representative Examination

Designation of examiners

ARTICLE 6 – (1) Examiners will be designated by the Agency for a four-year term, including 2018, among universities who express willingness to be an examiner and meet all of the requirements to be established by the Agency and communicated to universities in writing in 2017.

2) Examiners will be posted on the Agency's official website along with their commission term.

Examination application

ARTICLE 7 – (1) PPR candidates will personally make an application to an examiner.

2) PPRs candidates who fail the examination must personally apply again to retake the examination.

3) The examination fee will be payable to the examiner.

4) All arrangements pertinent to the examination will be announced by the examiner.

Examination

ARTICLE 8 – (1) The distribution of questions across courses and the total number of examination questions will be announced on the examiner's official website.

2) The examiner will make available on its official website a databank of test questions comprising not less than 500 questions, of which not more than 40% may appear in the examination.

3) Examinations questions:

a) will be prepared by a scientific board within the examiner, comprising faculty members for the courses concerned, in accordance with the curriculum announced by the Agency;

b) may not include "all of the above" or "none of the above" as choices;

c) may not contain any identical questions from the previous two examinations.

4) The examination schedule will be announced by the examiner.

5) The examination will be held at the locations and on the dates as announced by the examiner, as a supervised examination.

6) At least 2 (two) qualification examinations will be held every year.

7) The passing examination grade will be 60 (sixty) or above.

8) The number of questions correctly answered in the examination will be used as the number of correct answers providing basis for scoring.

9) Examination results will be announced by the examiner in the form of grades.

Issuing of a Qualification Certificate and Identification Card

Qualification certificate

ARTICLE 9 – (1) Candidates who successfully pass the PPR qualification certification examination, becoming eligible to receive a qualification certificate, and graduates of university programs for developing product promotion representatives will be issued a qualification certificate by the Agency, upon presenting the relevant unit of the Agency with the following documents:

a) Notarized duplicate of the diploma or graduation certificate, or a copy whose authenticity has been certified by the issuing institution with a wet signature.

b) For non-high-school graduates, a formal letter issued and submitted to the Agency by the marketing authorization/license holder, confirming that the person in question has actually worked for two full years as a product promotion representative over a five-year period before the publication date of the Regulation.

c) Photocopy of the national identification card.

ç) 2 passport photographs.

d) Bank slip, showing deposit of the qualification certification fee into the Agency's bank account.

2) The qualification certification and renewal fees will be announced in the Agency's annual tariff of fees.

3) Holders of a qualification certificate will be recorded in the Agency's PPR database.

4) Aspects related to the use of the PPR database will be announced by the Agency in a guideline.

Issuing PPR identification cards

ARTICLE 10 – (1) PPRs holding a qualification certificate registered in the system will be issued a PPR identification card by their employer, in the format designated by the Agency.

2) The PPR identification card format will be announced by the Agency on the Agency's official website by 31.09.2018.

Repealed guidelines

ARTICLE 11 – (1) The "Guidelines on the Principles and Procedures for Training Product Promotion Representatives and the Training Schedule According to the Regulation on Promotional Activities for Human Medicinal Products," published on 29.06.2013, is hereby repealed.

Effectiveness

ARTICLE 12 – (1) These Guidelines will become effective upon approval by the Agency's President.

Enforcement

ARTICLE 13 – (1) These Guidelines will be enforced by the President of Turkish Medicines and Medical Devices Agency.

v-GUIDELINE ON THE PRINCIPLES AND PROCEDURES FOR TRANSFERS OF VALUE ACCORDING TO THE REGULATION ON PROMOTIONAL ACTIVITIES FOR HUMAN MEDICINAL PRODUCTS (8.12.2015)

Purpose

ARTICLE 1 – (1) These Guidelines set forth the principles and procedures for transfers of value, made according to the Regulation on Promotional Activities for Human Medicinal Products, published in Official Gazette #29405 of 03.07.2015.

Basis

ARTICLE 2 – (1) These Guidelines are issued based on the seventh paragraph of Article 11 of the Regulation on Promotional Activities for Human Medicinal Products, published in Official Gazette #29405 of 03.07.2015.

Definitions

ARTICLE 3 – (1) For the purposes of these Guidelines:

a) Human medicinal product means any natural or synthetically derived active substance or combination of substances, administered to humans with a view to curing, preventing or diagnosing a disease, or restoring, correcting or modifying a physiological function;

b) Transfer of value means any direct or indirect payment the value of which exceeds the monetary equivalent of 10% of the monthly gross minimum wage, made in cash or in kind under any designation whatsoever by a marketing authorization/license holder to any healthcare organization or institution, university, healthcare professional or their professional organizations, any union, association or foundation operating in the field of healthcare, including any non-governmental organization established to protect or advance health;

c) Agency means Turkish Medicines and Medical Devices Agency;

ç) Marketing authorization/license means a certificate issued by the Agency, showing that the product concerned can be manufactured and placed on the market in a specific formulation and in specific pharmaceutical form(s) or strength(s), in accordance with the approved product information;

d) Marketing authorization/license holder means a natural or legal person in whose name the Agency has issued a marketing authorization/license for their products;

e) Healthcare organization/institution means any public or private healthcare organization or institution, including universities, unions or professional organizations of healthcare professionals, associations or foundations operating in the field of healthcare, and any non-governmental organizations established to protect or advance health;

f) Healthcare professional means a physician, a dental practitioners, a pharmacist, a nurse, a midwife or members of any other professions listed in Appendix 13 to Law #1219 dated 11.04.1928 on the Practicing Procedure of Medicine and Medical Crafts;

g) Contract company means any legal person authorized by a marketing authorization/license holder, the entire legal responsibility remaining with the marketing authorization/license holder, under contract to conduct promotional activities and actions on own behalf of jointly, and whose name is notified to the Agency by the marketing authorization/license holder;

ğ) Promotion means any informational activity organized by or upon the request of marketing authorization/license holders with their name, contribution and support, aimed at informing healthcare professionals on medical/scientific characteristics of products covered in the Regulation, including activities of product promotion representatives, advertisements published in medical or professional books or journals, announcements made through direct mailing or the press, or other means of communication, as well as scientific meetings, product promotion meetings or other similar events;

h) Product means a human medicinal product, an enteral nutrition product or a medical food;

ı) Written consent means a written document issued by a healthcare professional or healthcare organization/institution, consenting to the reporting to the Agency of the transfers of value made to them;

i) Regulation means the Regulation on Promotional Activities for Human Medicinal Products, published in Official Gazette #29405 of 03.07.2015.

General Principles

ARTICLE 4 – (1) Marketing authorization/license holders or contract companies may perform any transfers of value to healthcare professionals or healthcare organizations or institutions subject to the conditions set forth below.

a) Any transfer of value will be reported to the Agency, if its value exceeds the VAT-inclusive monetary equivalent of 10% of the monthly gross minimum wage applicable on that date;

b) When calculating individual value per participant for an event, the basis will be the amount found by dividing the total expenditure incurred by the marketing authorization/license holder for holding the event to the number of participants;

c) Marketing authorization/license holders will use the format in Appendix 1 to report to the Agency the transfers of value they completed in a calendar year, within the first six months of the following year;

ç) For transfers of value falling in this scope, the acceptance of the transfer of value and reporting thereof to the Agency must be based on written consent received by the marketing authorization/license holder or the contract company from the healthcare professional or from the competent supervisor at the healthcare organization or institution concerned. A transfer of value may not be made unless such written permission is received.

d) The marketing authorization/license holder must personally file all applicable reports with the Agency concerning any actions or transactions involving a transfer of value through a contract company.

e) Any reports under these Guidelines must be exclusively made electronically by the marketing authorization/license holder, using the dedicated system established by the Agency for transfers of value.

f) A separate guidance regarding the use of the system for transfers of value will be issued by the Agency and published by the end of 2016.

Scope and Responsibility for Transfers of Value

ARTICLE 5 – (1) For transfers of value made directly or indirectly by marketing authorization/license holders where the value per healthcare organization or institution exceeds the VAT-inclusive monetary equivalent of 10% of the monthly gross minimum wage, the name of the recipient organization or institution, tax number and the province of registration will be reported to the Agency, along with particulars based on the examples of scope listed below:

a) Donation.

b) Contribution to covering event-related costs.

c) Sponsorship agreement.

ç) Honorarium or Consultancy Fee.

d) Any other transfers of value.

2) For transfers of value made directly or indirectly by marketing authorization/license holders to healthcare professionals, where the value exceeds the VAT-inclusive monetary equivalent of 10% of the monthly gross minimum wage, the name of the healthcare professional, their national identification number, and work address will be reported to the Agency, along with particulars based on the examples of scope listed below:

a) Contribution to covering event-related costs, i.e. registration fee, travel, lodging and meals.

b) Honorarium or Consultancy Fee.

c) Any other transfers of value.

3) Transfers of value which are considered off-scope for disclosure include the following:

a) Free promotional samples.

b) Transfers of value not exceeding 10% of the currently applicable monthly gross minimum wage (e.g. meals or beverages).

c) Transfers of value having the nature of a qualified investment for Research and Development (R&D).

Reporting Period

ARTICLE 6 – (1) Marketing authorization/license holders will report to the Agency in detail within the first six months of the following year, on the transfers of value made during the calendar year.

(2) Collection of data under these Guidelines will commence from 01.01.2016, and the first report to the Agency will be submitted by 30.06.2017.

Reporting Location and Table

ARTICLE 7 – (1) Marketing authorization/license holders will report particulars of transfers of value using the dedicated system established by the Agency for this purpose, in the format provided in Appendix 1.

Requirement to Obtain Written Consent of Healthcare Professionals or Healthcare Organizations or Institutions

ARTICLE 8 – (1) Before performing a transfer of value, the party performing the transfer of value, whether directly or indirectly, must obtain written consent of the healthcare professional or the competent supervisor of the healthcare organization or institution concerned, for accepting and reporting the transfer of value to the Agency. A transfer of value may not be made unless such written consent is received.

(2) The written consent may be obtained on a case-by-case basis, or on a time-limited basis covering a period of time.

(3) The consent given to the reporting of a transfer of value to the Agency may not be withdrawn after the transfer of value is completed based on the written consent of a consenting individual or competent official.

(4) At healthcare organizations or institutions, the competent supervisor is the office of the chief physician, office of the dean, association president/authorized signatory or, without limitation, the authorized signatory of any organization or institution covered by the Regulation and these Guidelines.

(5) Where an event is jointly held by multiple healthcare organizations or institutions, each individual organization or institution to which a value will have been transferred is subject to reporting, and the written consent of each of the organizations or institutions involved must be obtained for the sponsorship request and reporting to the Agency.

The Procedure

ARTICLE 9 – (1) The following rules apply to documenting payments:

a) For service agreement fees, donations, grants and sponsorships, the value for the calendar year in which the transfer of value was recognized will be disclosed, including agreements covering more than one year.

b) Transfers of value for travel (e.g. flight, coach, bus tickets), accommodation (e.g. lodging costs) and registration fees related with events, e.g. congresses or meetings, will be disclosed in the calendar year in which the event occurred.

c) For other transfers of value, the date of payment is regarded as basis.

ç) Where a healthcare professional is unable to attend an event or a part of an event for any reason, only that portion of such expenditures which was transferred to the healthcare professional will be included in the disclosure of the transfer of value.

d) If the attendance of a participant was cancelled prior to the event for which payments were made, but the transfer of value to the person was not cancelled, the total value of such transfers must be reported to the Agency all the same, if it exceeds the VAT-inclusive monetary equivalent of 10% of the monthly gross minimum wage applicable on that date.

e) Where a contract is signed with a healthcare professional through a healthcare organization or institution which they work for, and the payments are made to the healthcare organization or institution, the transfer of value will be reported for the healthcare organization or institution, stating the name of the healthcare professional concerned. Any other expenses related to the individual, such as travel, registration and accommodation, will be separately reported for the healthcare professional.

Documentation and Retention of Records

ARTICLE 10 – (1) Any information or documents related to transfers of value will be retained by the marketing authorization/license holder for a period of at least five years.

Effectiveness

ARTICLE 11 – (1) These Guidelines will be effective on the date they are published.

Enforcement

ARTICLE 12 (1) These Guidelines will be enforced by the President of Turkish Medicines and Medical Devices Agency.

APPENDIX IX: 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:** 898
Last Amended On: 02/01/2014-6514/31-33 **No. of Official Gazette:** 28886

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 - 3977/ Art. 4.)*

Article 2 - *(Amended Article: 04/01/1943 - 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 Article: 08/02/1954 - 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 Article: 04/01/1943 - 4348/Art. 1)*
To obtain permission for manufacturing preparations in line with the conditions prescribed in Article 5 above, an official application shall be made with the Ministry of Health. Such application shall 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 Article: 04/01/1943 - 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 possess 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 Article: 04/01/1943 - 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 shall be made with the Ministry of Health to obtain permission for such preparations.

The application shall 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 shall be legalized by a Turkish Consulate, and the submission shall 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 shall employ a pharmacist as qualified person according to applicable provisions of Law No. 984 on pharmaceutical enterprises.

Article 9 - *(Amended Article: 04/01/1943 - 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- he 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 - 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 shall be clearly specified in Turkish on the preparation's outer packaging and a discernible warning and statement shall 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 shall be clearly stated.

Article 13 - *(Amended Article: 04/01/1943 - 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 shall 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 Article: 25/05/1938 - 3402/Art. 2)*

Article 17 - *(Repealed Article: 25/05/1938 - 3402/Art. 2)*

Article 18 - *(Amended Article: 04/01/1943 - 4348/Art. 1; Amended Article: 23/01/2008-Law No. 5728/Art. 42, Amended Article 02/01/2014-6514/31 (OG 28886))* If, following the analyses described in article 10 above, it is detected that the substances into the composition of preparations are not pure or are incompliant with the approved formulation submitted for receiving registration or have 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 by not less than ten thousand Turkish Liras and not more than five hundred thousand Turkish Liras.

Those who promote and sell preparations in violation of this Law, market them off-label and thus encourage generation of prescription in this direction shall be subject to an administrative fine of up to five times of the relevant product's total sales of the last one year. However, this fine shall not be less than one hundred thousand Turkish Liras.

If promotion and sales are performed via the Internet, the Ministry shall forthwith rule for blocking their access and such ruling shall be communicated to the Information Technologies and Communication Agency for the enforcement of this ruling.

For those who promote and sell products with a health declaration without the permit of the competent authority or in violation of the permit issued shall be subject to an administrative fine ranging from twenty thousand Turkish Liras up to three hundred thousand Turkish Liras.

In case of repetition of such acts, the administrative fine to be applied shall be twofold higher than the previously imposed fine.

Article 19 - *(Amended Article: 04/01/1943 - 4348/Art. 1; Amended Article: 23/01/2008-Law No. 5728/Art. 43, Amended Article 02/01/2014-6514/32 (OG 28886))*
Those who manufacture without registration or whoever sells, supplies or causes selling of these preparations knowing that they were manufactured in such state shall be sentenced to imprisonment ranging from one year up to five years. If it is detected that these preparations do not bear the curative properties attributed to them or that were manufactured in a manner to derogate or eliminate such properties or were manufactured with impure substances, such penalty shall be increased by two-thirds. Those who sell, market or advertise any product with the claim that it diagnoses and treats diseases, even though it is not a preparation, shall be sentenced to imprisonment for a period ranging from one year up to five years. Furthermore, in case of the promotion or sales of such products are performed over the Internet or any other electronic media, clause three of Article 18 shall be 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 offence described in this paragraph shall be prosecuted according to the Anti-Contraband Law.

Article 20- *(Amended Article: 23/01/2008-Law No. 5728/Art. 44)*
Whoever violates this Law, except circumstances described in Article 18 and 19 provided above, shall be subject to an administrative fine of 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 is 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 shall 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 imposing a tax on them.

Article 23 - This Law shall be enforced by the Ministry of Justice, Ministry of Finance and the Ministry of Health.

Supplemental Article 1 - The registration certificate granted shall 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 Article: 11/06/2010 – Law No. 5996/Art. 47)
(Repealed Article: 11/06/2010 – Law No. 5996/Art. 47)

Supplemental Article 4 - *(Amended Article: 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 shall be penalized according to the Turkish Penal Code and other applicable legislation.

Supplemental Article 5 - *(Repealed Article: 23/01/2008-Law No. 5728/Art. 578)*

Supplemental Article 6 - *(Repealed Article: 23/01/2008-Law No. 5728/Art. 46)*
Preparations becoming the subject of misdemeanor acts described in Articles 18 and 19 of this Law shall 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.

TEMPORARY ARTICLE 1 - *(Supplemental Article 2/1/2014-6514-33 (OG 28886)* In accordance with the Council of Ministers Decisions and amendments, with No. 2004/6781, dated 06/02/2004 and with No. 2007/12325, dated 12/06/2007, on the pricing

of medicinal products for human use effective prior to the enforcement of this article, remaining part of the amount transferred to the Social Security Institution from the amounts collected from registration holders detected by the Ministry of Health due to the unlawful profits arising from the non-notification of the price change associated with the reference price application within the time foreseen shall be recorded as revenue to the general budget, provided that the rights on legal interest and the remaining balance are reserved. On the basis of the period corresponding to half of the period to be calculated retrospectively, spanning from the enforcement date of the first price designation made within the framework of the Council of Ministers decisions with No. 2004/6781, dated 06/02/2004 and with No. 2007/12325, dated 12/06/2007, concerning the pricing of medicinal products for human use by the Ministry of Health, following the date on which registration holders should notify the price changes, and the date on which relevant money is collected by the Ministry of Health, and upon applying the legal interest rate effective on the referred dates, the Ministry of Health shall collect from the registration holders also the legal interest rate to be jointly calculated by the Ministry of Health and the Ministry of Finance over the total amount deposited by the registration holders.

APPENDIX X: SUPPLEMENTAL ARTICLE 13 TO LAW NO. 1219, DATED 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.

d) 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.

e) 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.

f) 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.

g) 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.

h) 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.

i) 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.

j) 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.

k) 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.

l) 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.

m) 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.

n) 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.

o) 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.

p) 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.

q) 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.

r) 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.

s) 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.

t) **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.

u) 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.

v) 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.

w) **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.

x) 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.

y) 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.

z) 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.

Job descriptions added to aforementioned list in the Regulation on HCPs and Members of Other Professions Workign in the Field of Healthcare

Physician and Attending Physician
Dentist and Specialized Dentist
Pharmacist
Midwife
Nurse
Optician
Emergency medicine operator/technician
Nursing Aide
Midwife Aide
Healthcare technician

Psychologist
Biologist
Child Development Specialist
Social work/social service specialist
Health educator
Medical technologist

Healthcare administrator
Environment Health Technician/operator
Elder care operator/Home care operator
Medical Secretary
Biomedical device operator

APPENDIX XI: DECLARATION OF TURKISH MEDICAL ASSOCIATION ON INTERACTIONS BETWEEN PHYSICIANS & THE PHARMACEUTICAL INDUSTRY

Adopted in the "Ethical Declarations Workshop of the Turkish Medical Association" held in Ankara on April 4-5, 2008. Updated in the "2nd Ethical Declarations Workshop of the Turkish Medical Association", held in Ankara on June 20, 2009.

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 shall 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 shall be strictly avoided. Prescribing patterns of physicians and their diagnostic/therapeutic practices shall be guided by current scientific data, and physicians shall follow the guidelines for rational use of drugs and good medical practice.

Meticulous scientific and ethical norms shall 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 shall be raised among physicians, both during and after medical school.

ii. Adequate and continuous information should be provided to physicians on the guidelines for rational use of drugs and appropriate use of technology.

iii. Availability of independent sources shall be ensured for scientific research.

iv. Promotional activities shall 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 shall be encouraged for industry sponsorship to support scientific/educational activities.

vi. Use of institutional intermediaries shall be encouraged for industry sponsorship to support scientific/educational activities.

vii. Such contributions shall 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 shall be placed on ethical responsibilities of the intermediary.

viii. Promotional materials, invitations to a scientific meeting and any associated accommodation acceptable to physicians shall be of an educational character, have scientific functionality, and bear relevance to the practice, and their value shall not exceed reasonable limits. Physicians shall never permit provision, proposal or implication of any contribution of equipment or pecuniary benefit to them during promotion. Physicians shall reject and never request any inducement or gift contrary to above provisions.

ix. No studies – including those for dissertations – shall 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 shall disclose any funding provided to them by the industry for scientific research or any honoraria they received in capacity of an advisor, instructor, speaker or stakeholder.

xi. Promotional activities shall be conducted according to a set of rules. The frequency and duration of industry representatives' calls shall 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 shall highlight the meeting's scientific character, and care shall 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 encourage.

xiii. No promotional materials of the industry shall be displayed at locations where CME/CPD activities are taking place.

xiv. The upper limit of congress participation fees shall be periodically set by physician organizations, and congresses exceeding such limits shall be considered for crediting.

xv. Accommodation offered by the industry during scientific events shall be reasonable, secondary to the actual purpose of the meeting, and shall not be extravagant. Industry sponsorship shall be limited to covering the cost of travel, meals, accommodation, and registration fees. Physicians shall never request industry to cover participation costs of their

companions, including spouses, children or other relatives; and physicians shall reject and report to their professional organization any proposals they receive to that effect.

xvi. Any disbursements to investigators in industry-sponsored research shall be transparent and compliant with institutional guidelines.

APPENDIX XII: GUIDELINES ON INTERACTIONS BETWEEN PHYSICIANS & THE PHARMACEUTICAL INDUSTRY

TTB-UDEK- Ethics Task Force; 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 shall 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 shall disclose the nature of their affiliation to the audience, when they are fulfilling a speaker role or a representative function for them.

5. Physicians shall 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 shall 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 shall 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 shall 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 is 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 shall be brought to the attention of company representative or company head office, and any gross inaccuracies shall be exposed to the professional community.

11. Physicians shall 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 shall 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 games of chance.

12. Physicians shall 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 shall 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 shall decline offers to speak at meetings organized by pharmaceutical manufacturers on topics in which they lack instructor-level expertise. They shall refuse any fees beyond travel and accommodation costs, and an honorarium for their time and service.

16. Physicians shall 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 shall decline any offer of tickets for recreational events, such as movies, theater plays, sport events, or concerts.

19. Physicians shall avoid events organized or sponsored by companies such as trips, parties, meals, or birthday parties, and shall not ask companies to sponsor their personal events.

V - SPONSORSHIP OF CONTINUING MEDICAL EDUCATION AND SCIENTIFIC MEETINGS

20. Physicians shall 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 shall 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 shall 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 shall 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 shall 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 shall 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 shall 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 shall 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 shall 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 shall 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 shall 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 XIII: REGULATION ON THE CODE OF ETHICS OF PUBLIC OFFICIALS AND APPLICATION PROCEDURES AND PRINCIPLES

Selected Article (Official Gazette Dated: Official Gazette 13.04.2005 No: 25785)

Purpose

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 Turkish Grand National Assembly (Parliament), members of Council of Ministers, Turkish Armed Forces, members of judiciary, and universities.

…

Avoiding conflicts of interest

Article 13 — Conflict of interest refers to 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 shall 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 economic, 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.

The following shall be outside the scope of the prohibition on receiving gifts;

a) 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
b) Books, magazines, articles, cassettes, calendars, compact discs or the like,
c) Gifts or rewards received in publicly held competitions, campaigns and activities,
d) Gifts having the value of souvenir which are given in publicly held conferences, symposium, forum, panel, meal, reception or similar activities,
e) Advertisement and handicraft products which are distributed to everyone and which have symbolic value,
f) Credits taken from financial organizations according to the market conditions.

a) Transactions which are made from unreasonable prices according to the market price when buying, selling or hiring movable or immovable goods or service,
b) All sorts of gifts including jewelry, clothes, food or any other goods given by those benefiting from the service,
c) Loans and credits taken from the people, who have work or service relations with the institution.

The following are within the scope of the prohibition on 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.

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 clause 5 of this article and item (a) in clause 6 to the Council until the end of January without waiting for any warning.

APPENDIX XIV: LAW NO. 6502 ON THE PROTECTION OF CONSUMERS

Selected Articles (Official Gazette Date: 28/11/2013, Official Gazette No: 28883)

SECTION SIX

Commercial Advertising and Unfair Commercial Practices

Commercial Advertising

ARTICLE 61 – (1) Announcements qualified as a marketing communication and performed in written, audio-visually or via similar routes on any media by advertisers for the purpose of enabling the sales or rental of a product or service, to inform the target audience or to convince them, in relation with a commercial advertisement, trade, business, artisanship or profession.

(2) It is essential for commercial advertisements to comply with the principles designated by the Board of Advertisement, public decency norms, and be accurate and honest.

(3) It is prohibited to make commercial advertising which misleads consumers or abuses their lack of experience and knowledge, jeopardizes their security of life and property, encourages the act of outrage and committing a crime, deranges public health, abuses sick, elderly, children and disabled people.

(4) The inclusion of names, logos or other distinguishing figures or statements affiliated with products or services as well as commercial titles or names of enterprises in articles, news, broadcasts and programs without specifying explicitly that this is an advertisement for the purpose of advertising and their presentation like a promotion is regarded as covert advertisement. It is prohibited to make covert advertisement in written, vocally or visually in any type of media.

(5) Comparative advertisement can be made for competing goods or services fulfilling the same needs or directed at the same purpose.

(6) Advertisers shall be obliged to prove the accuracy of the claims presented in the commercial advertisements.

(7) Advertisers, advertising agencies and media companies shall be obliged to comply with the provisions of this Article.

(8) The restrictions to be imposed on commercial advertisements and the procedures and principles to be followed in these advertisements shall be designated by regulation.

Unfair commercial practices

ARTICLE 62 – (1) A commercial practice shall be regarded unfair when it fails to fulfill the requirements of professional care or significantly disrupts the type of economic behavior towards the goods or services of the average consumer reached or the average member of the group addressed, or bears the potential of significantly disrupting them. Especially practices which are deceptive or offensive in nature and the practices presented in the appendix of the regulation shall be regarded as unfair commercial practice. It is prohibited to conduct unfair commercial practices directed at consumers.

(2) In case it is claimed that the commercial practice is unfair, those performing such commercial practice shall be obliged to prove that the referred practice is not an unfair commercial practice.

(3) In cases where unfair commercial practices are performed via advertisement, provisions of Article 61 of this Law shall apply.

(4) The procedures and principles relating to the designation of commercial practices and their inspection as well as practices to be designated anyhow as unfair commercial practice shall be designated by regulation.

APPENDIX XV: LAW NO. 6698 on THE PROTECTION OF PERSONAL DATA

Law No 6698 Published on 7 April 2016