IEIS
REGULATION ON PROMOTION PRINCIPLES OF PHARMACEUTICALS AND RELATIONS WITH HEALTHCARE MEMBERS

INTRODUCTION

The Pharmaceutical Industry Employers Union (IEIS) operates to provide more efficient working conditions in economic, legal and social aspects, be effective on drug policies to be formed in accordance with the member's opinions and contribute to the development of a healthy competitive environment in the generic pharmaceutical industry and the Turkish pharmaceutical market.

IEIS is a member of Confederation of Employers' Unions of Turkey (TISK), European Generic Medicines Association (EGA), and Association of the European Self-Medication Industry.

The pharmaceutical industry is obliged to ensure that all pharmaceutical products are marketed and manufactured in accordance with internationally recognized standards and reliable quality, and contribute to improve the conditions of human health. Within the framework of this obligation, it is the responsibility and obligation of the pharmaceutical industry to provide training and accurate information to healthcare professionals about their products and ensure that they clearly understand exactly how to use medicines.

Promotional activities (marketing practices) must comply with the highest ethical standards, and information to be provided to healthcare professionals should be designed in order to help them better serve their patients. This information must be objective, accurate, easily comprehensible and in accordance with all existing laws and regulations. The opinions regarding treatment indications and conditions must be based on sound scientific evidence and the side effects, contraindications and precautions to be taken should be included.

Adopting this basic principle, IEIS prepared and invoked the Promotion Principles of Pharmaceuticals Guide in 1990, in addition to the regulations of the Ministry of Health on promotion in order to more effectively fulfill its obligation. The mentioned Guide's name has been changed to "Regulation on IEIS Pharmaceuticals Promotion Principles and Relations with Health Members" on the April 14, 2012 General Assembly. (It will be referred to hereafter as the IEIS Regulation or Regulation).

Containing parallel provisions to the Regulation on Promotion of the Ministry of Health; this guide functions as a self-regulatory mechanism among IEIS members. The functioning of this mechanism is provided by the IEIS Disciplinary Committee which has the power of sanction from a legal point of view.

This Guide, with which all member companies are required to comply, will make the necessary contribution to our industry regarding the protection of ethical standards in pharmaceuticals promotion.

INTRODUCTION and AIM

The regulation is prepared by IEIS for the industry to achieve the highest ethical standards in marketing the medical products for human use and to sustain this level under the responsibility of the relevant divisions of the member companies.

IEIS sees the accurate and unbiased informing of medical doctors, dentists and pharmacists in terms of rational drug use as a fundamental right. This information and promotion must comply with ethical values and public interest criteria within the framework of the established legal practices of the Ministry of Health.

In accordance with the determinations above; the regulation entirely acts as a self-regulatory mechanism. Companies' compliance with this self-control Regulation is of great importance in terms of prestige in the eyes of the public and all persons and organizations concerned with the industry.

Explanations on the implementation of this Regulation are listed below. These applications are controlled by the IEIS Promotion Principles Supervisory Board (hereinafter referred to as the Board). All in all, when a violation of the promotion principles is detected one or more of the sanctions specified in the Regulation of the Supervisory Board Promotion Principles are applied together according to the resolution of the Disciplinary Board and Supervisory Board's assessment. The Ministry of Health's legislation shall be taken into consideration for issues not included in this Regulation. Issues that are not included in both and found to be contrary to the general rules are assessed by the Board.

1. SCOPE AND DEFINITIONS

1.1. Scope

As covered in the Regulation, "medical product for human use" (preparation, medication), is a pharmaceutical or biopharmaceutical product that is used to prevent, treat or diagnose diseases in humans or affect any function of the human body; intended to be administered with physician's prescription and under the supervision of health care professionals. Drugs and pharmaceutical products are used synonymously in the Regulation.

This Regulation covers the activities for promoting medical products for human use to healthcare professionals, and pharmaceutical companies' relations with specialist associations, professional associations and patient organizations in Turkey. The Regulation also includes the delivery of medical and pharmaceutical information to the assistant and administrative health care staff.
The provisions of the national regulations and relevant decisions of the Ministry of Health shall be the primary concerns during the implementation, interpretation, and adaptation of the Regulation to unwritten situations and new requirements arising, and to encourage compliance in those concerned. In cases other than that, operations can be done according to the Board's policy decisions.

The provisions of Regulation cannot be in conflict with the provisions of the applicable legislation and interpreted through the provisions of the current legislation. In cases where the provisions of Regulation are in conflict with the provisions of the legislation in force, the contrary provisions of Regulation will be considered void.

IEIS member companies must take the necessary measures to ensure that their consultants, market research firms, advertising agencies, tourism and conference organization companies, product promotion personnel who are working with contract and others alike - including subcontracted workers - comply with the Regulation on behalf of their firm. Member companies should take reasonable steps to ensure that third firms that are not included in the above-mentioned definitions such as joint venture or licensor and have operations in the pharmaceutical industry that might be covered by the Regulation regarding the member firms also act in compliance with the Regulation.

IEIS,

a) Offers recommendations, applications and publications for a better understanding and implementation of the Promotion Principles,

b) Organizes training seminars for stakeholders,

c) Communicates with other stakeholders including physician organizations, advertising agencies and convention organizers and tourism companies and other organizations, associations, trade unions established for the same purpose, and shares its own understanding and comments regarding the special status and special rules and restrictions of the pharmaceutical industry with them,

d) Creates a platform for the interpretation of the rules according to changing conditions,

e) Develops joint practice proposals that do not prevent competition.

1.2. Definitions

1.2.1. Medicinal Product for Human Use/ Product / Pharmaceutical

Medicinal Product for Human Use/ Product: Combination of active substance or substances of natural and/or synthetic origin including biological products, enteral nutrition products, medical infant formulas, traditional herbal medicinal products, and immunological products that are administered to humans in order to treat and/or prevent diseases, make a diagnosis, or correct, sort out or modify a physiological function.

1.2.2. Promotion or Marketing

Shall mean all activities in which information is provided to members of the health profession about the medical and scientific features of human pharmaceutical products, the activities of product promotion employees in this context, the advertisements to be given in medical and professional books and journals, advertisements to be made through communication tools such as direct mailing, press and other channels, scientific /educational activities, meetings and similar activities.

The regulation regulates the following activities:

a) The use of promotional materials, the activities of the product promotion employee including other printed materials and verbal introduction,

b) Advertisements that are given through medical and professional journals,

c) Advertisements made by direct mail,

d) Activities that include reminder promotion,

e) Distributing free samples,

f) Scientific, educational and promotional meetings organized for members of health professions,

g) Participation in fairs and exhibits, use of sound cassettes, films, records, tapes and video recordings; radio, television, internet, electronic media, interactive data systems, sound or video CD's, DVD's, flash discs and similar materials for promotional purposes.

h) Announcements made through the press or other communication tools.

I) Programs and materials for educating patients,

i) Reasonable support and hosting done for promotional purposes;

j) The organization of and support for scientific educational and promotional meetings participated in by members of health professions; direct or indirect (through a company) support or organization including the payment of relevant travel, accommodation and conference registration expenses;

All of the public information activities which are done in the framework of principles specified in section 2.7 of the Regulation shall not be considered promotion. However, care must be shown to making sure that the nature and quality of information used and activities that are applied during this process, including keeping records, are done completely in accordance with the provisions of the Regulation.

1.2.3. The following are not covered by the promotion of the principles applied

a) Promotion of medicinal products for human use sold without prescription to society,
b) Promotion of the traditional herbal medicinal products to the community,
c) Promotion of the infant formula and nutritional products for infants, medical infant formulas to the community,
d) Promotion of the enteral nutrition products to society,
e) Promotion of in vitro diagnostic tests, kits, medical equipment, supplies and consumables that are sold directly to the public,
f) Promotion of products with Ministry of Agriculture approval and offered for sale with health
g) Announcements and reference material that are; based on data, accurate and informative such as packaging changes, adverse reaction warnings, trade catalogs and price lists related with licensed products provided they do not include any claims for the product
h) Replies and correspondence to the questions forwarded by health professionals or relevant administrative staff, or scientific notifications submitted as questions or comments by these people (these include letters on professional publications which are related to the subject or question, have the right content, and do not have a misleading or advertising nature),
i) Commercial applications that are regularly used by the pharmaceutical industry including price, discount, or terms of sale.
j)Summary of Product Characteristics (SPC),
k)Medicine labels, pharmaceutical package inserts, and instruction manual (IM),
l)Corporate promotions.

1.2.4. License / Permit

Licenses for medicinal products for human use, biological products, vaccines and traditional herbal medicinal products and permits for medical infant formulas and enteral nutritional products that are granted by the Ministry

1.2.5. License / Permit owner: real individuals or legal entities in whose name license/permit certificates are issued for products by the Ministry,

1.2.6. Marketing Authorization

Quality conformity certificate received after the product's License Certificate or Permit is issued, by sending a sample of the sales product to the Ministry before the release of the first sale.

1.2.7. Promotional Materials:

Refers to any material used in the promotion or advertisement via directly or through product promotion elements, including but not limited to the articles below;

a) Printed materials, such as booklets, books, brochures, advertisements that provide information about the product;
b) Films, slide,
c) Audio/visual materials that are presented with storage tools such as a flash drive and CD/DVD,
d) Free samples of products for human use;
e) Reminder visit materials with a value that does not exceed 2,5% of the monthly gross minimum wage which is in force, such as notepads, pens, penholder, calendar, that can be used during the professional activities of healthcare members;
f) Programs and materials for the patient education;

g) National and international publications that can be used as info / data source in related circles.

Monetary value of these promotional materials cannot exceed the limit determined by the Ministry. This limit shall be published on the website of the Ministry.

1.2.8. Healthcare professionals

Refers to the physicians, dentists and pharmacists, nurses, midwife and other professionals as defined in the 13th article of Practice of Medicine and Medical Sciences Law of No. 1219, dated 04.11.1928,

1.2.9. Product promotion staff

On the condition of having obtained a sufficiency certificate as of January 1, 2015, refers to the people who promote the medicinal product directly through visits to physicians, dentists and pharmacists,

1.2.10. Assistant Healthcare Professional

Refers to the person who supports the healthcare professional in professional activities, or implements the prescribed methods and treatments on patients, such as nurses, midwives, medical technicians, health officers and so on,

1.2.11. Health Reporter

Refers to the journalist or media reporter who is involved with an accredited press agency, newspaper, periodicals or audio-visual publisher, and covers especially or only health related news,

1.2.12. Summary of Product Characteristics (SPC)

On the condition that the definition in the Human Medical Products Licensing Regulation is reserved, the brochure (prospectuses will be used in place of product information summaries in products where a transition has not been made to Product Information Summary yet) including information about the product which has been prepared for members of the health profession.

1.2.13. Instruction Manual (IM)

On the condition that the definition in the Human Medical Products Licensing Regulation is reserved, the instructions which are prepared in order to inform the patient about the product and which is required to be included in the package.

1.2.14. Science Service (Medical Management, Medical Directorate, Medical Support Directorate, etc.)

The department(s) that are established by the license/permit owner to supervise the compliance of the information they present to the market on products and other activities with the provisions of laws and IEIS Regulations,

1.2.15. Ministry

Refers to Ministry of Health and the relevant units,

1.2.16. Pharmaceutical Company – Company

Refers to the owner of the license or permit of the medicinal product for human use.

1.2.17 Calendar Year: The period between January1 and December 31

2. GENERAL PRINCIPLES

2.1. Ethical Criteria for Medical Pharmaceuticals Promotion

Ethical criteria for medicinal drug promotion are all promotional activities to remain within the framework of TRUTH and SCIENTIFIC OBJECTIVITY and PROFESSIONAL HONOR and required efforts to be made in order to avoid behaviors that may jeopardize dignity of the pharmaceutical industry, professional solidarity and the principle of mutual respect between members.

2.2. Promotion Standards

The information on the materials to be used for pharmaceutical promotion must be in accordance with high ethical standards and be easily understood by the promoting person. Opinions and claims that are set forth must be within the limits that scientific proofs permit and uncertainty must be avoided.

2.2.1. In situations of public importance such as immunization campaigns and combating infectious diseases or to promote good health, permission must be obtained from the Ministry concerning the products to be used and the public may be informed within the framework of procedures and principles that are determined by the Ministry.

2.2.2 Excluding the promotions that will be done at international conferences organized in the country and information that is provided by the license/permit holder scientific department authority in response to written requests made by health profession members;
The following may not be promoted to health profession members
a) human medical products that have not been licensed or issued permission in accordance with the relevant regulation,
b) human medical products that have been licensed or permitted according to the relevant regulation outside of the areas of use that are defined in their Ministry approved SPCs.

2.2.3. The promotion of a product must be in accordance with the information and data that is included in its up to date SPC.

2.2.4. The promotion of a product should provide members of the health profession with informative and evidence based information about the features of the product that will help them form their own opinions about the product's therapeutic value.

2.2.5. When the promotion is prepared with documentation using excerpts, tables and other visual materials from medical journals or other scientific works they may be used only in original form and with the sources clearly specified.

2.2.6. Promotion cannot be done using misleading, exaggerated information or information that has not been proven to be accurate or by means of using attention drawing images that do not have relevance with the product itself, which may lead to the use of the human medical product being used unnecessarily or risky situations.

2.2.7. Promotion cannot be done through such tools as games of chance and drawings.

2.2.8 No cash or in kind advantage can be provided to physicians, dentists or pharmacists while introducing a human medical product to them and no such proposal or promise may be made. The said members of the health profession may not accept or request any kind of incentive during promotion activities.

2.2.9. Members of the health profession must declare any kind of support they receive from license/permit owners:
a) At the end of every article that is written,
b) At the beginning of a speech/presentation when it is given. Companies will remind the health profession members of this requirement before providing support.

2.3. The Quality of Information and Scientific Proofs

The promotion of the medicine should be informative, accurate, realistic, complete based on the context, verifiable, reliable, and understandable enough for the physician to decide on the drug's therapeutic, diagnostic or other medical value, and pharmacist to make an opinion on the use of the drug and its features.

Information on promotion materials must be based on the updated assessment of the scientific evidence available and comply with SPC / prospectus and the IM information approved by the health authorities. Scientific evidence to be used to support the comments and suggestions put forward must be available if requested by a healthcare professional.

Derogatory remarks against healthcare professionals and their clinical and scientific views should be avoided.

2.4. Safety Data

Basic information on the safety of medicines; such as contraindications, situations that warrant caution, warnings, adverse effects and precautions that need to be taken should be provided in an appropriate and consistent manner in accordance with the information of product characteristics, legal and medical practices. The "safe" and "reliable" adjectives should be used only if sufficient qualifications exist.

2.5. Promotion to Society

Medicinal products for human use cannot be promoted to society directly or indirectly on all kinds of public broadcasting media and communications environment including the Internet through programs, movies, series, news, and other similar means. Newspaper / magazine ads made with the permission of the Ministry announcing the product has been marketed to the health care professionals are beyond the scope of this provision.

Again, society may be informed in such cases as vaccination campaigns and the combat against epidemics which are important in terms of public health or about the products to be used in health promotion campaigns carried out by the Ministry with the Ministry's permission and within the framework of the principles and procedures to be determined by the Ministry.

Companies are responsible for the information issued by public relations agencies about their products. License holders should take the necessary steps to correct the news with promotion features published in the printed media tools of products which are banned to be promoted to the community, and report to the Ministry with evidence.

2.6. Informing Society

To facilitate a better understanding in society regarding symptoms and signs of diseases, current treatment approaches and especially prevention, and address the need for information, printed information material can be prepared in this context and pharmaceutical companies can help with programs concerning these issues. Events held in these cases should be in accordance with scientific standards, should not directly or indirectly promote the product and should support the role of health service staff on the same subject. During these events, pharmaceutical's name must be identified as collective group name (such as beta-blockers, statins and fluoroquinolones) and/or with general name (INN) and a reference to "a medicinal product for human use" name should be avoided in any case.

Relations with patient associations are also evaluated under this Article.

Live or pre-recorded advice lines supported by the company should be organized as to ensure that only medically qualified and experienced staff is on the line and product promotion is not carried out in any way. It is essential that the questions and calls of patients and their relatives are answered by healthcare professionals and patient information is kept confidential.

2.7. Company Procedures

Pharmaceutical companies shall appoint a member with sufficient background in charge of publicity and to ensure the full compliance with the Regulation and national laws and regulations, and report to IEIS with the member's name and short biography. Companies configure organization of promotional activities as a special unit or service specific for this operation. This person or unit or service should develop and maintain required procedures; monitor and analyze all promotional materials and activities, and prepare standard operating procedures of the company about the promotion principles. There must be a code and date on materials in order to easily determine the promotional material in any case and/or to prevent misunderstanding.
Printed promotional materials;

- Should be clearly stated and straightforward in medical terms,
- Should be kept under registration,
- Must be approved and dated by the company's science service before being released for use;
- A sample of each must be stored for a period of two years to be submitted to the Ministry upon request,
- The Date of Withdrawal of those that are withdrawn from use must be declared and samples should be kept for 2 years following withdrawal.

3.1 Scope of Promotion,

3.1.1. Promotion covers the activities listed in the definition in Article 1.2.2.
Promotion activities include promoting the human medical products, including application and side effects, within the scope of this regulation to physicians, dentists and pharmacists and informing other health profession members.

Promotion directed at health profession members can be carried out:
a) With publications that are distributed/sold to members of the health profession or with scientific context publications in the medical-professional journals,
b) By supporting or organizing scientific meetings,
c) (Different:RG-14/10/2012-28441) Physicians, dentists and pharmacists are given products promotion through visits while the other health profession members are given product promotion by being informed about such information as the application and side effects of products.

3.1.2. Promotional activities can be carried out only for pharmaceuticals that have license / permit that is in accordance with applicable legislation, and for their indications in the license. However information may be given for pharmaceuticals without license / permit on scientific congresses, symposiums and seminars, scientific presentations and discussions and within the framework of medical journals and books with scientific purposes, as specified in Article 2 and Article 6.3.

3.1.3. Medicinal products for human use are promoted to healthcare professionals stated in 1.1. Scope Article.

3.1.4. In cases where the pharmaceutical's promotion is prepared and/or made by third parties (such as advertising agencies, advertising consultants, contract research organizations)responsibility belongs to the license / permit holder. If the pharmaceutical's license is not yet taken, responsibility belongs to the person or organization who applied for license / permit. In this case the promotion content must be approved by the company employee responsible for publicity.

3.2 General Rules Concerning Application

3.2.1. Methods that could damage the public's confidence or the reputation of the pharmaceutical industry can't be used for promotion. In the meantime, untrue allegations that can't be proved, in particular those targeting a product and naming the active substance, can't be made and unnecessary and malicious complaints cannot be revealed about rival firms. Negative statements with using the trade name cannot be made directly or indirectly.

3.2.2. Sample distribution, all activities of the product promotion representatives, hospitality shown in a scientific meeting and other promotional activities should not have qualities that can overshadow the main objective of delivering promotional information.

3.2.3. Chance-based methods such as raffle, lottery, and so on, or events that provide recreational services (touristic travel, etc.)cannot be used for promotion.

3.2.4. Promotion that prescribes use for the medical pharmaceutical products except for indication(s) and application methods (written in SPC / IM) that received permission from the Ministry, cannot be made except in cases mentioned in Articles 2.5 and 6.3.

3.2.5. Pharmaceutical manufacturers, pharmaceutical importers and license holders may execute or support health education activities in order for society to gain positive health behaviors by receiving permission of the Ministry of Health in prior and within the framework of the principles and procedures to be determined by the Ministry.

3.2.6. Other studies on post-marketing surveillance and product monitoring should not go beyond the purpose of gathering information about the company's products and should not be used as a tool to influence physicians by giving the appearance of a research.

3.2.7. Market research, preparation and execution of post-marketing surveillance studies, and similar applications should not be carried out for promotional purposes. Research results of marketing purposes cannot be used for promotion.

3.2.8. The firm's name does not need to be revealed during market research; however it should be expressed that the study was made with the support or the request of a pharmaceutical company.

3.2.9. Name of pharmaceutical companies and/or medication's trade name, or reminder expressions about the preparation cannot be put on documents used by the public and private health institutions.

3.2.10. Nutrient substances or preparations cannot be used as promotional material about the pharmaceutical, either directly or indirectly.

3.2.11. According to Article 13 of Pharmaceutical and Medical Preparations Act No. 1262,prescription medical products for human use cannot be promoted through radio and television.

3.2.12. Attention must be paid to not to exaggerate on the format or the costs of promotional materials.

3.2.13. Postcards, other mailings that are open to the public, envelopes or wrapping papers should not carry features that may qualify for community-oriented advertisement.

3.2.14. Telephone, mobile phone messages, e-mail, tele-messages, fax, and so on, should not be used for promotional purposes except in cases where a person's permission is gained in advance or upon request.

3.2.15. Whether or not for promotional purposes, if there is pharmaceutical company support for medications and activities and materials for their use, the support should be clearly stated.

3.2.16. Companies should not have secret product promotion (publishing through advertisements, news or report, sponsorship hiding).

3.2.17. The responsibility of all activities belongs to the license holder, unless otherwise stated in Co-promotion agreement.

3.2.18. There can be no benefits in cash or similar, or proposal and promise of such benefits when promoting medicinal products for human use to physicians, dentists and pharmacists. Health care professionals mentioned cannot claim or accept any incentive during the promotional activities.

3.3 Standards for Information Used for Promotion

3.3.1. All information used for promoting a product to health professionals, should be accurate, verifiable, and sufficient for healthcare professionals to form their own opinions on the therapeutic value of the product in question. It should be always kept in mind that the first task of the pharmaceutical industry in the context of promotion is to deliver the information needed for physicians and pharmacists -especially in the context of non-prescription products- to choose the right pharmaceutical, in an impartial and thorough manner that is scrupulously faithful to reality.

3.3.2. Statistical significance of the data presented must be clearly stated. Some studies may have faulty designs and reviews. Using this type of data should be avoided.

3.3.3. If the studies used in the promotion of a product were not executed with the product in question, the claims must not be associated with the trade name and molecular name should be used instead.

3.3.4. All information used in promotion must be accurate and provable; the evidence should be ready to be offered if requested, there must never be exaggerated claims that excess the scientific evidence.

3.4. Misleading Promotion

Misleading or invalid information that has not been proven cannot be used for promotion.
The following conditions are within the scope of misleading promotion:

a) To make pharmaceuticals appear as if they possess unproven therapeutic effect and other biological properties
b) To create impressions that the treatment will give certain results with the use of the pharmaceutical or that there can be no harmful effects for long-term use.
c) To provide information that could lead to misconception about the medicine's composition and other pharmaceutical properties of the medicine.
d) To give misleading and/or false information about the pharmaceutical's manufacturer or its employees.
e) To give the data obtained from in vitro experiments and in vivo animal tests without clearly specifying that qualifications and prepare the ground for misunderstanding and interpretation as if they were obtained in human trials.
f) To make misleading comparisons by using the drug potency as efficacy
g) To make a price comparison over the price of a single pharmaceutical form or box of different drugs, without taking the costs of treatment into account and without taking into account the cost of daily dose or the total dose of the treatment period including the equivalent pharmaceutical preparations of the same drug,
h) To make definitive judgments with a scientifically inadequate study that is not based on an adequate sample size and detailed examination.

3.4.1. The product cannot be promoted by declaring that it is approved by national or international institutions such as FDA, EMA, etc.

3.5. Comparative Promotion

Comparison can be made on promotional materials under the following conditions;

a) If it is not misleading,
b) If the drugs and services for the same needs or purposes are being compared,
c) If proven and significant features that are related to each other are being compared,
d) If the scientific and technical studies according to the conditions are directly being compared,
e) If the comparisons are not especially used to create confusion,
f) If it does not contain a derogatory or disparaging expression about the rival product,
g) If unfair advantage is not gained through the reputation of a competitor.

3.5.1. Comparison of the products should be done in a manner that is in accordance with the latest scientific data and publications, honest, verifiable, objective and balanced.

3.5.2. Negative expressions cannot be used directly or indirectly by specifying active substances and/or trade names about another firm's pharmaceutical products in promotion, promotion cannot be made by disparaging another product. Trade name cannot be used for comparisons.

3.5.3. Exaggerated or all-encompassing arguments about the drug should not be put forward except those that are clear and totally proven, and superiority adjectives (the best, most reliable, most effective, excellent, etc.) should not be used.

If there is a new state of being; the new feature should be clearly stated as whether it is new dosage, new strength, a new preparation of a known medicine or a new drug altogether. If more than 12 months have elapsed after the approval of “new” condition in Turkey, the "new" word should not be included in promotional material.

“Reliable” should not be used instead of “safe” in promotional material. The word reliable can only be used if it is supported by adequate and effective medical evidence and the context in which reliability is provided is explained; otherwise it is considered misleading. It should not be stated that there are no side effects, toxicity or risk of addiction for any product.

4. PROMOTIONAL MATERIALS

Promotional materials are (i) printed promotional materials, (ii) product samples and (iii) non-printed reminder promotional materials. Although bags and educational materials are not considered as promotional materials, because of long-standing application, they were included in this subsection.

4.1. Printed Promotional Materials

Printed promotional materials are (i) printed materials that make a claim on the product’s usage and contain integrated information (e.g. brochures) or full ads that resemble it in many ways and (ii) the abbreviated printed promotional materials, or abbreviated ads.

Printed promotional materials should be prepared in a legible manner. Information about products must be compatible with general principles written on the second part of this IEIS Guideline and special provisions described in Section 3.2 and should not contradict with SPC / PIL that are approved by the Ministry of Health.

There is a code on printed promotional materials that determines presentation class of the medicinal product for human use, material’s preparation or last update date, and the material other than information described in more detail below.

4.1.1. Printed promotional materials containing integrated information and allegation

If the printed promotional materials make a claim for the drug’s usage or is an announcement of this nature (full ad) published in a periodic with characteristics described above, it must contain the following information:

- The trade name of the drug,
- INN (International Nonproprietary Names), or the approved general names of the active substance or substances,
- Quantities of the active substances in the composition per unit dosage form,
- Drug’s therapeutic (pharmacological) class or if available sub-class.
- At least one approved indication, (Specifying all indications are preferred. However, in some cases only the promoted indications may be mentioned. In such a case the following information must be provided in terms of indication.)
- Usage form and dosage,
- The main side effects
- Major interactions,
- Contraindications, warnings, conditions that require caution,
- The method of application,
- License / permit number and date
- The manufacturer or distributor's name and address,
- "For more information, consult our company" statement,
- Legal category (drugs or other controlled medications, prescription or non-prescription drugs, etc.).

• Price and date of approval
• Code and/or publication date of printed promotional material, (month and year)
(Since a loose insert could not be regarded as a part of the journal, it should contain a separate number, and date.)

The information above must comply with SPC / PIL information of the promoted preparation. Quotations from medical journals or other scientific studies, tables, and other visual materials outside of these texts are used with a footnote stating the precise sources.

If the medicinal product for human use studied is different from the one promoted on these sources, or drug's generic name (INN) is used on the source these must be identified and these data must not be presented by substituting the name of the medicinal product for human use promoted, or by placing the trade name next to the general name.

If the above-mentioned quote tables and graphs were adapted prior to use, it should be made clear. Vertical / horizontal axis and the column / row descriptions, if available number of subjects and statistical significance degrees should be clearly identified while the tables and graphs are being adapted and the figures should not be distorted.

Claims that are used with reference to scientific studies or medical journals should be in accordance with researcher / writer's interpretation. Also the use of outdated and obsolete claims is a violation of the IEIS Guideline.

4.1.2. Abbreviated Printed Promotional Materials and Abbreviated Ads

Abbreviated printed promotional materials and abbreviated advertisements are advertisements or printed materials that contain only indications to specify the product's therapeutic category, do not contain any claims and give brief reminder information about the product.
They must include only the following information:
a) The drug's trade name,
b) The general names of active substances,
c) The name and address of the manufacturer or license holder,
d) "For more information, consult our company" phrase for the person who writes the prescription.

4.1.3. Other Provisions:

4.1.3.1. Pharmaceutical advertisements cannot be put on magazines apart from the scientific and/or professional medical journals for physicians, dentists and pharmacists and ones that contain "distributed only to physicians / dentists or pharmacists" phrase.

4.1.3.2. Full or abbreviated ads cannot be published in newspapers or periodicals other than magazines with scientific and/or professional contexts that are licensed in accordance with the legal regulations related to press and publications and clearly specified that are for physicians and/or dentists, and/or pharmacists.

In case the license / permit holder announces the release of the product on the market to health professionals through a press release, he/she should get permission from the Ministry by sending a copy of the advertisement text to the Ministry. Press release may be published once. Size of press release to be published in the newspapers cannot exceed 1/8 of a newspaper page. This activity is not considered as a medical product for human use promotion.

4.1.3.3. If the printed promotional material is about the published studies, these must be clearly declared as the source (author, title, volume, page number, and year). Quotations from medical literature or personal communication should not modify or distort the meaning that the author or the clinical investigator wants to deliver or the meaning and importance of the study or research. Congress abstracts can be used as a source for max. 2 years after the date of publication. If data on file is quoted on printed promotional material, these should be presented without delay when requested by healthcare professionals.

4.1.3.4. The frequency and volume of delivery of printed promotional material to healthcare professionals should be at a reasonable level. Physician's requests for the removal of their names from promotional material delivery lists must be respected,

However for the cases of adverse reactions, warnings and precautions, complete mailing lists should be kept to ensure that all physicians are informed on important issues.

4.1.3.5. Provided that they have truly an educational nature, textbooks, reference books, their electronic equivalents and other educational materials may be given to healthcare professionals.

4.2. Samples

Samples can be given provided they are clearly indicated to be samples only to physicians, dentists (only for drugs used in dentistry), and pharmacists, in order for them to get used to the new products and/or to gain experience on professional activities or upon their request if the limits set by the Ministry, and the following conditions are met.

4.2.1. License holder companies set up a sufficient recording, control system for manufacturing, import and distribution on free promotional product samples and determine custodians to be documented and reported to the authorities of the Ministry upon request.

4.2.2. Each sample is presented in a reduced format of the smallest presentation on the market. However this condition is not required for enteral nutrition products and promotional product samples that cannot be reduced for technical reasons.

4.2.3. Packaging of reduced pharmaceutical samples to be distributed must be prepared within the framework of the Ministry principles, and "free promotion sample, not for sale" statement should be written in a legible manner since it has no resale purpose.

4.2.4. Promotion sample is presented with a copy of PIL and SPC if available.

4.2.5. Samples of products containing psychotropic or narcotic substances that are covered in1961 Single Convention on Narcotic Drugs and Convention on Psychotropic Substances of 1971 cannot be distributed or given.

4.2.6. Samples can be given directly to physicians, dentists and pharmacists or the person who is authorized to receive them.

4.2.7. It is essential that there are no barcode / data matrix on packaging of promotion samples. If it is required, permission of the Ministry must be taken by presenting the justifications and will be blocked for sale on Ministry Drug Tracking System. License / permit holders, should establish a system to safely pull back free samples when necessary.

4.2.8. Free samples can be distributed in amounts that for each human medical product, do not exceed 5% of the yearly sales to be monitored by means of monthly sales in the first year; 5% of the previous year's revenue in the second calendar year, 3% of the previous

year’s revenue in the third, fourth and fifth calendar years and 1% of the previous year’s revenue in the years after the fifth year. The distribution of samples shall be done in accordance with the Guides that are published by the ministry on this subject.
4.2.9. Promotion samples cannot be used as a research product on clinical trials.

4.3 Non Printed Reminder Promotional Materials

Prepared for the purpose of promotion of the drug reminder promotional materials other than those printed must meet the following qualifications:

4.3.1. Such materials must be suitable for the medical and professional use and professional level of the receiver, and their monetary value cannot exceed 2.5% of the monthly minimum wage that is in force. Must not be distasteful, degrading, and strange nor have features that hide or deceive the purpose for distribution.

4.3.2. Promotional materials to be distributed should be designed as not to be used in public places, and have qualities to help receivers to practice their professions. Only the trade name of the drug, the active ingredient name, manufacturer and/or importer company’s name can be put on the material.

4.3.3. Should not be able to be used in places other than health care institutions, organizations, areas where drugs are kept and places special to the receiving person. Should not be used especially in public places.

4.3.4. While medical products are promoted to health professionals, any advantage of cash or in kind except for promotional materials within the limits defined in Article 4.3.1 can be provided, offered or promised to these people to ensure that they prescribe, advise or make others to use any medication.

4.3.5. Bags

Only the company's logo is allowed on packaging materials (bags, wrappers, etc.)used for placing the medicines purchased from pharmacies.

Any statement or claim or pictures and drawings indicating the indication of drugs or used for promotional purposes should not be included.

5. COMPANY OBLIGATIONS

Pharmaceutical company is responsible for violations of the promotion principles arising from faulty transfer or misinterpretation of information on promoted drug by medical representatives and correcting them.

5.1. Science Service and Duties

License holder establishes a scientific service responsible for the information presented to the market of medicinal products within one's own organization to operate in accordance with the principles set out below and determines a person responsible for these activities.

Science Service ensures that promotions of all licensed medical products of the company are in compliance with the conditions specified in the related regulations and İEİS Guideline.

Science Service proves and documents that the product promotion representatives employed by the company receive sufficient training, to-date information on a regular basis, and fulfill responsibilities expected of them.

Science Service provides all necessary information and documents related to promotional activities to the Ministry when requested.

Science Service provides an immediate and full implementation of the decisions made by the Ministry regarding promotion of medicinal products.

Application stating the target audience and date of the first announcement of promotion is submitted to the Ministry before the commencement of promotional activity.
All samples used in promotional materials must be kept for at least five years to be submitted to the Ministry if requested.

5.2. Internal Approval Process of Promotional Materials and Activities

The use of promotional materials that are not approved in accordance with this article by the Science Service Officer on behalf of the company is not allowed. The approved final form cannot be modified.

Not only promotional materials but also all promotional activities, including meetings must be approved.

Continuously used materials must go through the process of re-approval at least every two years to confirm that their content continues to be compatible with related regulations and İEİS Guideline.

5.3. Education, Inspection, Certification

It must be ensured that all company personnel including those who work under contract; as well as advertising agency employees who prepared promotional materials, those who work in market research and CRO have sufficient information regarding the conditions and requirements of this guideline and other relevant regulations about their jobs on promotion-related matters such as preparation and approval of promotional materials, informing health professionals and health authorities, public information activities.

It must be ensured that tourism and the organization company employees who provide service for the organization of scientific meetings are informed and have sufficient information regarding the conditions and requirements of this guideline and other relevant regulations about their jobs.

Training and certification are executed under the supervision of authorized departments of Science Service.

5.4. Ethical Rules to Be Observed

Product promotion employees;

a) Must be equipped with complete and sufficient scientific data and information about the product they are promoting.
b) Must be subjected to in person training at work, which is provided by the company they work for or obtained via the company they work for purchasing the services, which includes basic and required information including legal and ethical aspects and is deemed suitable by the Ministry; and must obtain a Ministry issued sufficiency certificate. The certificate of sufficiency is valid until the end of the fourth calendar year and product promotion employees are required to obtain a new certificate before the expiration date. Sufficiency certificates that are issued to the graduates of

"Medical Promotion and Marketing Programs" in Universities are not required to renew within this scope.

c) Those who have started to work in companies as product promotion employees after 1/1/2015 may apply for sufficiency certificates on the condition that they are at least high school graduates and are successful in the exam that will be held.

ç) Sufficiency certificates can be issued to graduates of Universities from "Medical Promotion and Marketing Programs" when they present their diploma, without being subjected to any other kind of evaluation.

d) They are entered on the Ministry's electronic record system by the companies they work for. A Product Promotion Employee Identification Card, for which the details are determined by the Ministry, is issued for the product promotion employees who are entered on the System.

e) If they have no Product Promotion Employee Identification Card they may not work as product promotion employees for companies.

f) No matter what the reason, whenever an employee starts or leaves work, this must be notified to the Ministry within twenty days by the employer.

g) Services may be provided for more than one license/permit holder. Liability belongs to the license/permit holder and the rights of the license/permit holder which are generated by the contract are reserved.

ğ) They may not promote any product or similar item to any health profession members other than physicians, dentists and pharmacists, however they may provide health profession members other than physicians, dentists and pharmacists with information about the application of the product and side effects, on the condition that they inform the relevant authority/responsible physician and obtain their approval.

h) The information they use during the promotions must convey all manner of information, positive and negative, that the physician, dentist or pharmacist needs to know in complete and accurate form.

ı) They will forward any adverse effect/incidents that are reported to them about the product during the product promotions, to the relevant company.

i) They may not give promotional materials concerning the product that is being promoted to anyone other than the physician, dentist and pharmacist.

The license/permit holder and the product promotion employee are jointly responsible for the promotion they have done on a product.

The ability of product promotion employees to promote human medical products in public health institutions during working hours is subject to the following rules:

a) The product promotion employees shall specify which license/permit holder they represent at the beginning of their visit and show their product promotion employee identification card.

b) In a health institution that provides public health services; the concerned administrative supervisor will schedule the most suitable time for the promotion in order to make sure that the product promotion employees can meet with the health profession members with consideration for their work organization. This allocation of time may not disrupt the training services and the services that are provided to the patients.

Under no conditions may money or similar material fees be asked from the product promotion employees who go to a health institution to do promotion, even if it is under any kind of name like donation or something similar.

No posters or similar promotional materials that could be perceived as promotional material can be placed, hung or adhered in health institutions belonging to the public. However, posters and similar promotional materials that are used to promote good health

in campaigns organized by the Ministry on subjects like immunization, epidemics, smoking or obesity are not included in this provision.

In compliance with the regulation in force, the Summary of Product Characteristics for every product must be available by the product promotion employee at the request of the physicians, dentists and pharmacists who are being visited.

The product promotion employees must not offer any kind of monetary or in kind incentive to physicians, dentists or pharmacists to ensure visits. No fee should be offered or paid in exchange for a visit time.

Product promotion employees may not make direct contact with patients or patient relatives.

6. CONGRESSES, SYMPOSIA AND OTHER VERBAL MEANS OF COMMUNICATION

6.1. Objectives

6.1.1. Scientific and educational activities related with drug promotion cannot be used for purposes other than to transfer existing medical information or provide new information. License/permit owners cannot pay the transportation and accommodation expenses of the participants in these activities either directly or indirectly.

6.1.2. Symposiums, conferences and the like are essential environments in terms of sharing knowledge and experience. While arranging such meetings, scientific purposes should be kept in the forefront; hospitality factors should remain in the second plan compared to the scientific objectives. In this context, license / permit holders cannot organize or support meeting organizations held in resorts located on sea shores and ski resorts during the active season announced by the Ministry with the exception of international conferences held in a different country each time.

6.1.3. License / permit holders can support health care professionals to participate in domestic and foreign scientific meetings such as congresses and symposiums under the following conditions;

a) The meeting must be related to healthcare professional's expertise / field of work,
b) A health care professional may benefit from this support for a total of three times in the same year; same license / permit holder may supply only two of these and again they may benefit from only one of these three supports in meetings held abroad. The meetings in which health care professionals participate as a speaker or present the notification with the support of the license/permit holders, shall not be evaluated within this scope.

6.1.4. Healthcare professionals cannot be paid to compensate for the time they have spent to participate in a conference or a meeting. Similarly, health professionals cannot be offered or paid visit fee for the visit time.

6.1.5. The provisions of legal regulations must always be regarded (Relevant Law, KHK and the Regulations and Guides that are published by the Ministry). It is the responsibility of companies to check for compliance with the Regulation and other rules during the preparation of promotional materials to be used in symposiums and conferences.

6.1.6. It is unnecessary to prepare of a list of countries where the product available on the market for products that do not have a license in Turkey or in the country where the meeting

was held. The main industrialized countries (The United States, the European Community, and Japan) where the product is available in the market may be specified in explanatory texts, and it should be emphasized that this product is not available in Turkey.

6.1.7. License / permit holders should report information on health care professionals they plan to support to the Ministry as described in the manual for the rules of scientific meetings published by the Ministry of Health.

6.1.8. Research meetings of national and international multi-center clinical trials supported by the license / permit holder held in domestic or abroad locations are not considered as congress or symposium participation. For these meetings, the nature of the meeting is clearly written on the permit application to the Ministry and the meeting's purpose is indicated.

6.1.9. People other than healthcare professionals cannot be invited to these meetings, and their expenses cannot be met; however the protocol invitees are excluded from this provision.

6.1.10. In at least 60% of the meetings exceeding six hours which the license/permit holder organizes or contributes to within one calendar a session will include the meeting subject of rational medicine use. The content of the presentations in this session will be within the framework of Ministry approved educational material and diagnosis, treatment guides and will be presented to the Ministry in the form that it is specified in the relevant Guidebook that has been published by the Ministry.

6.2. Sponsorship and Rules to Be Followed By Sponsors

License holders may organize conferences, symposiums, scientific, educational meetings etc. that are useful for the discussion and transmission of information or make scientific / financial contributions to such activities. These meetings are in accordance with the suitable format and level.

Conferences, symposiums, seminars and similar meetings which will be organized or contributed to by the license/permit holders are notified to the Ministry. At least fifteen days before each meeting the content of the meeting, the list of likely participants, the items of expenditure and activities must be notified to the Ministry; notifications which have been entered as documents will be responded to within ten business days and if not answered will be considered approved.

License / permit holders report list of participants, the activities and cost items in the format specified and in detail in the digital environment to the Ministry within one month after the meetings are held; license / permit holder shall keep copies of information and documents presented to the participants for a period of two years to be presented at the request of the Ministry.

Such printed, audio-visual or computerized materials that are generated by these meetings must accurately reflect the presentations and discussions that took place in the meeting.

6.2.1. Hosting of physicians, dentists and pharmacists and promotional materials to be given other than those printed should not be as to overshadow the main purpose of the meeting.

6.2.2. The support that may be provided for the participation of healthcare professionals in these meetings should never depend on a preliminary condition - such as a doctor to prescribe a particular product-.

6.2.3. If the program, meeting or symposium is credited by a medical or other professional organization, the content of the program is the responsibility of the organization that gave credit.

6.3. Use of Promotion Materials in International Congresses and Symposia According to Licenses

Promotional materials located in the stands at international congresses or symposia, or distributed to the participants may belong to products that don't have a license in Turkey or received a license under different conditions, provided that the following rules are adhered;

a) Meeting should be truly international and include scientific events and sessions where speakers and participants from abroad take significant parts.
b) A written statement stating that the product is not licensed must be in places where promotional materials of the products do not have licenses in Turkey are given.
c) Stands can be installed for the promotion of the product under these conditions but samples of the products cannot be distributed to participants.

7. HOSPITALITY

Improper financial or other material benefit, including inappropriate size to accommodation (hospitality), should not be offered to Healthcare professionals, in order to influence prescribing of pharmaceutical products or according to the physicians' prescriptions and turnover of pharmacists.
Spouses cannot be supported to participate in Congress, Symposium, and other promotional meetings.

8. PROMOTION BY AUDIO-VISUAL AND E-MAIL

Promotion information to be delivered through these environments must comply with the written general principles on the first section of the Guidelines, special provisions described in section 2, and conditions required for the printed promotional materials. Abbreviated product information may not be given to persons whom the promotion is directed to if the full product information is provided.

9. CONSULTANCY AND OBSERVATIONAL STUDIES

9.1. Consultancy

Companies can benefit from healthcare professionals as consultants and receive support from them. Services of healthcare professionals may be purchased, individually or in groups, in order for them to contribute to, direct or manage scientific / medical studies, various clinical studies, as speakers in meetings, or session / meeting manager; in order to educate employees of the company or other healthcare professionals to participate in market research and company advisory boards; if they have to travel for these services, costs for accommodation and travelling may be met, and they may receive payment.

9.2. Observational Studies

9.2.1. An observational study is a study where data on spontaneous prescribed medication for patients who continue treatment in accordance with current diagnostic and treatment guidelines in approved indications of a drug released are collected and that does not affect the diagnosis or selection and application of the treatment of treating physician. Such studies should be done in accordance with the relevant legislation.

9.2.2. Observational studies cannot be designed and executed by marketing and sales departments of pharmaceutical companies. Product Promotion Representatives cannot take place in monitoring and execution of observational studies.

10. Code of Practice on the Websites Belonging to Pharmaceutical Companies

10.1. Purpose

Undoubtedly the most important responsibility of the pharmaceutical industry is to deliver high quality and reliable drugs to society and to convey information on these pharmaceuticals in accordance with the principles of drug promotion in an accurate and impartial manner in order to ensure rational use. In order to serve this purpose, pharmaceutical companies (drug manufacturers, importers and distributors) may prepare network (web) pages to be reconstituted when needed,
that contains information about their companies, products lists, and SPC / PIL's approved by The Ministry of Health, information about the product promotion for the intended audience, information on health issues and related products and developments in the field of medicine.

10.2. General Rules

• Pharmaceutical companies are responsible for their own sites.
• If personalized information is received from people who visit the site, it must be stored carefully.

10.3. Main Page

The main page features include;

• Information for the public and physicians / pharmacists must be separated into two parts, and partition (s) prepared for the physicians / pharmacists should include "this section is prepared for physicians / pharmacists" warning. In addition, parts for physicians / pharmacists should be password protected to prevent other people from accessing.
• It must be specified to whom the web page (or partitions) were prepared for. Information and links for the community should be placed in the main page.
• Owner of the site the address of the company and the telephone, fax, and can be contacted
Medicinal drug promotion cannot be done on the main page.
• E-mail address must be provided.
• Last update of the page must be indicated.
• The principles on 1.2.2 and 2.6are applied when informing society. References used to prepare the text are written on the bottom of the informative text. References should be cited in the text.
• The information content should be appropriate to the intended audience.
• "Information on this site cannot substitute for consulting a physician and pharmacist" phrase must be available.
• SPC / PIL may be open to the public access if not for promotional purposes.
• Webpage's owner appoints an employee responsible for the webpage and indicates his/her name on the main page.

10.4. Pages for Physicians and Pharmacists

The information given on these pages, the activities and promotional events, must comply with the manual prepared by IEIS.

• Information on the site should be prepared by experts, and the person who prepared the webpage should be indicated with the sources. Otherwise the situation should be clarified in an appropriate way.

• Information conflicting with SPC / PIL approved by the Ministry of Health cannot be used for product promotion by claiming that it is approved in other countries.
• While giving links to other sites for information on the products, there should be a warning indicating that the information given on the linked site is not the responsibility of the drugs organization, and activities may not comply with regulations and differ from the texts approved by the Ministry of Health.

It is the responsibility of the pharmaceutical establishment that owns the webpage to update product-related information according to the changes that have been made by the Ministry.

11.DONATIONS

If license/permit holders meet the below conditions they may make donations to public health institutions or agencies:

a) If they get prior permission from the administration that the institution, agency or family health center which they wish to donate to, reports to,

b) They do not influence the tender decisions of products within the scope of this Regulation,

c) They do not cause a non-ethical application that could be connected with the sale of a product,

ç) They do not encourage the issuing of prescriptions for a specific human medicine product,

d) They have one of the objectives of research, education, health and patient care improvement,

e) They are not oriented toward the use of an individual but towards the general use of an office or agency,

f) They do not write the name of the product in exchange for the name of the license/permit holder being included on the donated material,

g) They enter the donation that is made on the official records of the license/permit holder,

ğ) They make donations of human medicine products, laboratory kits and similar donations for clinical research directly to the responsible researcher.

12. RESPONSIBILITY

All İEİS members accept and undertake to completely comply with the IEIS Regulation on Promotion Principles of Pharmaceuticals and Relations with Healthcare Members