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Association of Research-Based Pharmaceutical Companies

(AİFD)

Code on the Good Promotion Practices for Medicinal Products for Human Use to Healthcare Professionals (AİFD Code of Good Promotional Practice)

Questions and Answers

This document has been prepared in consideration of;
AİFD Code of Good Promotional Practice_v3, effective as of July 1, 2008 and the Regulation Regarding the Promotional Activities on Medicinal Products for Human Use issued by the Ministry of Health of the Republic of Turkey, published on October 23, 2003 on the Official Gazette with No. 25268.

Question 1: What is Ethical Pharmaceutical Promotion? What type of activities does it encompass?

Answer 1: Promotion or Marketing: Refers to all informative and reminder activities performed by the registration holder or permit holder (pharmaceutical company) for a medicinal product for human use or another entity with the approval of this company in order to ensure the procurement of this product, its proper prescription and adequate usage.

Question 2: Which healthcare professionals can be addressed in product promotion?

Answer 2: According to the Promotion Regulation of the Ministry of Health of the Republic of Turkey (Regulation), only physicians, dentists and pharmacists can be addressed in pharmaceutical promotions. Pharmaceutical promotions cannot be addressed to other healthcare professionals such as nurses, midwives and healthcare officials. No promotion can be made and no conference support may be provided to healthcare officials other than this group.

Question 3: If we view the pharmaceutical sector as a whole, can Turkish pharmaceutical companies also be encompassed by the AIFD umbrella as much as the foreign companies?

Answer 3: All pharmaceutical manufacturers operating in Turkey as well as those engaged in commercial trade of pharmaceuticals must comply with the Promotion Regulation published by the Ministry of Health of the Republic of Turkey. The AIFD Code of Good Promotional Practice has been prepared in conformity with the Promotion Regulation of the Ministry of Health.

Turkish Pharmaceutical Industry Association (TİSD) implements a Code of Ethics that corresponds nearly one-to-one with the AIFD Code of Practice. The Guidance on the Code of Practice of the Pharmaceutical Manufacturers' Association (İEİS), overlaps with the AIFD Code of Good Promotional Practice, with the exception of a few articles.

Discussions are underway to formulate a single text with which members of all three organizations would comply.

Question 4: Does the AIFD Code also encompass promotion to the public?

Answer 4: In parallel with the Promotion Regulation of the Ministry of Health of the Republic of Turkey, AIFD Code of Good Promotional Practice does not allow the promotion of prescription drugs to the public.

Question 5: Does the AIFD Code encompass OTC products as well?

Answer 5: This topic is considered in detail in section 3 of the Promotion Regulation of the Ministry of Health of the Republic of Turkey. In summary, OTC products with reimbursement status may be promoted like other prescription

products to Healthcare Professionals within the scope of the AİFD Code of Good Promotional Practice.

Question 6: Marketing budgets of companies may be larger than their R&D budgets. How does AİFD evaluate this situation?

Answer 6: Investments of AİFD-member pharmaceutical companies depend on their own strategies and may vary from company to company. This variability may also be reflected in the distribution of investments among countries. AİFD supports the increase of R&D investments in Turkey, actively works towards this goal and engages in collaborations with pertinent authorities.

Question 7: Subsequent to the distribution of brochures on behalf of AİFD, will you continue to undertake projects to advocate for AİFD and its rules? What will these projects be?

Answer 7: AİFD has been organizing educational meetings pertaining to this issue since 2004 and will continue to engage in work in order to introduce and ensure the adoption of national and international rules regarding ethical promotion and rational drug use. Brochures distributed by all sales teams of AİFD-member companies in May of 2007 represent a portion of AİFD activities pertaining to ethical promotion and rational drug use. The Committee on Good Promotional Practice and the Code of Practice Panel established under the AİFD umbrella continue to work actively.

Question 8: Is there any plan to also collaborate with organizations other than the entities within the association with regard to the issue of code of promotional practice?

Answer 8: Work is underway to reach a consensus on code of promotional practice with the Pharmaceutical Manufacturers' Association (İEİS) and the Turkish Pharmaceutical Industry Association (TİSD).

Question 9: For whom are AİFD rules binding?

Answer 9: AİFD rules are binding for all AİFD-member companies.

Question 10: Which international associations is AİFD a member of?

Answer 10: AİFD is a member of the European Federation of Pharmaceutical Industries and Associations (EFPIA) and the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA).

Question 11: Can medical sales representatives of pharmaceutical companies create an opportunity to see the physicians they have difficulty in seeing during working hours outside working hours by inviting them to a sportive/leisure/meal activity?

Answer 11: It is possible to see physicians in conditions and locations suitable for a promotional activity outside the working hours due to difficulties in seeing the

physicians; “locations which are indicated to be unsuitable for promotional activities are places where sports and leisure activities are conducted! (Hospitality cannot be offered to healthcare professionals in the form of participation in holidays, sportive events and offering entertainment)

Question 12: Under what conditions can free samples be provided to pharmacists?

Answer 12: In compliance with the effective Turkish legislation and upon considering the relevant EU directive, AİFD deems it adequate to provide prescription drug samples to pharmacists under the following conditions:

- a) if the product has just been introduced into the market;
- b) for the purpose of enabling the pharmacists to learn the package, package insert, galenical form, tablet color and similar features of the product;
- c) provided that one sample is provided once;
- d) if the sample distribution is conducted in return of a document including the stamp, signature of the responsible pharmacist and the distribution date.

Question 13: According to the effective AİFD Code, is it possible to give a gift to the physicians for celebration purposes on special days (such as New Year, Medicine Day, birthdays, etc.)?

Answer 13. Personal gifts (such as flowers, chocolate, etc.) will not be given to healthcare professionals not even on special days.

Question 14: Can a pharmaceutical company pay membership fees of professional associations on behalf of the physicians?

Answer 14: Pharmaceutical companies will not pay the membership fees of Medical associations for healthcare professionals.

Question 15: What is allowed as a promotional material? According to the effective AİFD Code, is it possible to give as gift to physicians materials such as CDs, Novels, Books, bearing the logo of the product and company on them?

Answer 15: Printed materials such as books, booklets, brochures that provide sufficient and necessary information regarding the medicinal product for human use, audio/visual materials such as films, slides and electronic media, free samples of medicinal products for human use, notepads, pens, pen cases, calendars and materials of a modest financial value which may be used during professional activities, and reminder call materials such as national and international publications that may be used as information or data resources in certain milieus are defined as Promotional Materials in the Promotion Regulation of the Ministry of Health.

Small gift items used as promotional materials should be of use for the healthcare professional/pharmacist and have a “modest monetary value”. “Modest monetary value” is defined as no more than 20 YTL. per item.

In addition to the small gift items, a positive list of items suited to medical and professional use is provided in Annex I. For the items suiting the Positive List, the upper limit for monetary value should be 200 YTL.

Conditions for inclusion in the Positive list:

- a) Items should not induce physician's prescriptions.
- b) Their value should be limited (200 YTL or less per item).
- c) The items should exclusively be suited for use in medical practice.
- d) The gift items intend to cover the gaps of insufficient funding of social medicine.

Scientific books and journals are not subjected to restriction.

Negative List:

The Regulation forbids the distribution of the listed materials as well as materials or tools not suiting the scope, objective and principles of the Regulation to healthcare professionals.

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

Question 16: We have established a soccer team; can you get us the uniforms?

Answer 16: Gifts and awards which not comply with the definition of Promotional Material cannot be distributed to healthcare professionals.

Question 17: Under what conditions should pharmaceutical companies evaluate the commercial requests of pharmacies?

Answer 17: Commercial relations with pharmacies and pharmacists are not encompassed by the AIFD Code of Good Promotional Practice.

In the commercial relations with pharmacies and pharmacists, companies should evaluate pharmacists as healthcare professionals and make sure that the relations do not violate the essence of the AIFD Code of Promotional Practice.

Question 18: Should AIFD approach Family Medicine Specialists providing service in the field of public health and operating a private office as private institute physicians or public institute physicians in terms of the code of good promotional practice?

Answer 18: Donations to Family Health Centers should be made to the Public Health Center authorized to keep record of fixed assets.

Question 19: Is it possible to make donation in kind or in cash to private hospitals?

Answer 19: Donations can be made to non-profit organizations (such as public hospitals, university hospitals, foundation hospitals, etc.) provided that inventory record is conducted. As private hospitals are not non-profit organizations, no donations can be made to them.

Question 20: If a physician, who participates in a congress upon the invitation of our company, provides for his transportation via his own vehicle, can the company cover his gas expenses? Can we pay for the gas expenses in meeting participations?

Answer 20: The payments relating to the travel expenses arising during participation of Healthcare Professionals to scientific meetings should be made to the company organizing the trip (agency). No payment in cash or similar payment forms (gift vouchers) can be offered to healthcare professionals. In order to prevent that the travel tickets to be provided to healthcare professionals are not misused, if possible, ticket changes should only be made by the pharmaceutical company.

Question 21: According to the AIFD Code, a reasonable and modest meal can be offered pursuant to scientific presentations and meetings. What type of presentations and meetings are included into this scope and what to which are the conditions to be fulfilled in the meal to be offered?

Answer 21: Pursuant to a scientific or educational meeting/presentation organized within or outside a unit, a reasonable meal can be offered to healthcare professionals provided that it remains secondary to the main purpose of the meeting. The hospitality activity should be in manner so that the meal follows the meeting. The hospitality for a meeting held during working hours in a hospital cannot be provided as a dinner in a restaurant outside. The meeting and the hospitality activity should not be separated from each other.

Question 22: Is offering pizza, cake, etc. during working hours to assisting healthcare professionals serving in the hospital compliant with the AIFD Code?

Answer 22: The Healthcare Professionals defined for promotional practice are limited to physicians, pharmacists and dentists.

Question 23: In a meeting held by a pharmaceutical company for the purpose of sharing the scientific facts of one of its products, the said company offered a book voucher amounting to 40 YTL. to each participant in addition to serving tea and coffee in the meeting. Would this practice be compliant with the AIFD Code?

Answer 23: No matter what their value is, it is not suitable to offer cash or similar (book vouchers, gift vouchers, etc.) to healthcare professionals.

Question 24: Which activities can we financially support among the activities that a congress organization committee asks us to sponsor? (Gala dinner, Inauguration meal, Guest House)

Answer 24: Activities such as gala dinners, cocktails, gala dinner artists or inaugural meals should not be organized by pharmaceutical companies or participation should not be supported by them. Activities such as guest houses which may detach the participants from the scientific content should not be supported.

Question 25: Can I fulfill the request of a physician asking to stay in a location other than the city where the congress is held?

Answer 25: Hospitality should be provided in the city where the scientific activity takes place. Hospitality towards healthcare professionals should not be offered in the form of holiday, participation in sportive events and leisure (cultural activities, excursions, arts exhibitions, museum visits, theater, opera, movie, musical concert, shopping tours, spas and relaxation activities).

Question 26: Can I finance a one-month professional course to be attended by a physician and held in London by an international professional organization?

Answer 26: Pharmaceutical companies can provide educational grants in Turkey and abroad for the purpose of supporting the education of Healthcare Professionals. In this case, the purpose and nature of the training should be clearly defined and the person to receive the grant should be designated by the committee not including the company employees (hospital, university, association) and be openly declared. The amount of grant to be designated should be reasonable and the grant should be gratuitous.

Question 27: Can we rent a vehicle for the physicians to enable their participation in a meeting?

Answer 27: If necessary, a car can be rented for enabling the participation of healthcare professionals in a scientific meeting in cases where there is no or limited air transportation so as to make optimum use of limited time. The vehicle should be of a quality that does not exceed the objective of safe transportation and remain within modest limits. The vehicle should be organized by a car rental company and the payment should not be made to the healthcare professional by any means whatsoever.

Question 28: A company plans to hold a training program including a 2-night stay for 300 physicians in a holiday village. Consequently, these physicians will be proposed to become speakers in local meetings. Can their spouses also come? Can the healthcare professional bring his/her spouse to the meal provided that he/she pays for her/him?

Answer 28: No financial contribution will be made to persons other than those who present scientific presentations such as communiqués, publications, posters and participate in the meetings for educational purposes. Hospitality/reception activities towards meeting participants will remain subordinate to the objective of the meeting. Even if the meeting participation fees of spouses and other relatives are covered by the relevant Healthcare Professional, this would not be adequate.

Question 29: Upon providing a meal during the presentation and discussions, we also would like to offer a gift; would this be adequate?

Answer 29: No gifts can be given to Healthcare Professionals. However, if is related with the application field of their profession or duty and if the financial value is also modest, then reminder materials can be distributed. The limit for the modest monetary value is defined as maximum 20 YTL. per material.

Question 30: What is meant by hospitality activities within modest limits pursuant to the meetings?

Answer 30: Hospitality venues should be subordinate to the main purpose of the meeting. The hospitality activity should be organized in the same place or in an adjacent restaurant at consequent hours. The meeting and the hospitality activity should not be separated from each other.

The accommodation, travel, meal costs and registration fees of the healthcare professionals invited to the meetings can be covered by companies. The payment of the accommodation cost cannot encompass minibar, paid TV, dry cleaning service and other paid services.

Hospitality towards healthcare professionals should not be offered in the form of holiday, participation in sportive events and leisure (cultural activities, excursions, arts exhibitions, museum visits, theater, opera, movie, musical concert, shopping tours, spas and relaxation activities).

As a general rule, hospitality costs will not be higher than the level that can be generally paid by the invitees.

Question 31: Can we sponsor a congress organized during the summer season (high season) in Antalya?

Answer 31: As per the circular dated March 7, 2008 of the Ministry of Health of the Republic of Turkey, organization of and/or participation in scientific meetings in coastal vacation resorts during the summer season (between June 1-August 31) and in winter sports centers during the winter season (November 1 – March 31) is not regarded as adequate.

Question 32: Can pharmaceutical companies purchase Consulting Services from Healthcare Professionals?

Answer 32: Pharmaceutical companies can receive consulting services from healthcare professionals. The consulting service agreement indicating the persons from whom the consulting service will be received as well as the characteristic, purpose, duration and fee compatible with the reasonable market

value should be signed by both parties and the minutes of the consulting meeting should be preserved.

Question 33: Under what conditions can pharmaceutical companies organize a meeting outside Turkey? Under what conditions can a meeting outside Turkey be supported? Can pharmaceutical companies take physicians abroad so as to introduce their main production facilities or headquarters?

Answer 33: Companies cannot organize meetings abroad and support meetings held abroad, except for the following cases, where;

The meeting is international, a major part of the participants (more than 50%) are from abroad and it is more suitable to conduct the meeting in another country in for the logistics and security of the participants; the topic or purpose of the meeting necessitates the conduct of the meeting in the selected country for logistics reasons.

If the topic or objective of the meeting necessitates going to an immovable facility or observing an experiment, the meeting can be held abroad only under these conditions. In such a case, the requirements should be clearly defined and be acceptable.

For the purpose of preventing an action in violation to the rules of the Regulation on the Ethical Behavior of Public Officials, published in April 2005, it should be adequately reminded to public official invitees that they need to obtain a permit from their employer institute for participating in the meeting. It should be taken into account that the Ministry of Health requests concrete evidences from companies regarding this topic.

Question 34: Which is the country accepted as the country of the healthcare professional?

Answer 34: The country where the Healthcare Professional provides service is regarded as basis.

Question 35: A company convenes a group of 15 physicians, enabling them to discuss various medical issues. Consequently, a speaker's fee is paid to these physicians and it is planned to repeat this at regular intervals. Would this be in compliance with the Code? Would it be suitable for the spouses and children to accompany them?

Answer 35: It would suitable if gathering the physicians to discuss a topic and paying them a fee consequently corresponds to receiving a consulting service for fulfilling a real requirement of the company. It would not be suitable to pay a speaker's fee. The consultants should fulfill the needs in qualitative and quantitative terms. A written agreement should be made with the consultants and the scope and duration of the service expected from them, the criteria for the remuneration and the full payment to be made to them should be clearly indicated in this agreement. The payment should be made at an adequate level and in a suitable manner in compliance with the laws and regulations of the institutes and institutions to which the physician is affiliated. The selection of the meeting venue

and its duration as well as the content and duration of the social program conducted during the meeting will be subjected to general code of promotion. Even if the costs are covered by the relevant participant, it is suitable that spouses and children accompany them to any of these meetings.

Question 36: What is the road to be pursued in case pharmaceutical companies receive consultancy from Healthcare Professionals?

Answer 36: Compensation and reimbursement that would be inappropriate in other contexts can be acceptable for bona fide consultants and clinical investigators relating to pre-approval studies. Copyrights are compensated according to the relevant provisions.

On the other hand, token consulting or advisory arrangements should not be used to justify compensating health professionals for their time to travel, lodging, and other out-of-pocket expenses.

The following factors indicate the presence of a consulting arrangement: (it is not necessary for all factors to exist at once)

- a) The characteristics of the services to be provided as well as the compensation to be made in return for these services have been determined by a written agreement;
- b) The requirement of the company for the referred services have been clearly indicated before the service is requested and an arrangement is made with potential consultants;
- c) The criteria used in the selection of consultants is affiliated with the designated objective; the persons carrying the responsibility to select the consultants will avail of the knowledge and skills to evaluate whether the relevant healthcare professionals fulfill these criteria;
- d) The number of healthcare professionals hired as consultants will not be higher than the number required to reach the designated objective;
- e) The company will keep relevant records and use the services provided by consultants in line with the indicated objective.

The venue and circumstances of any meeting with consultants should be conducive to the consulting services and activities related to the services are the primary focus of the meeting, and any social or entertainment events are clearly subordinate in terms of time and emphasis.

Question 37: How can payments be made physicians providing consulting to pharmaceutical companies or assuming a role as speaker, in return for their services? Is there a difference between the payments made to half-time or full-time working physicians?

Answer 37: Check Article 15 and relevant remarks in the AIFD Code of Good Promotional Practice in relation with payments. In the payments to be made to the physicians working in a public institute or a university, the legislation of the institute or institution to which the healthcare professional is affiliated, should be taken into account.

Question 38: Do the rules which apply for physicians also apply for pharmacists?

Answer 38: In the Regulation Regarding the Promotional Activities of Medicinal Products for Human Use, physicians, pharmacists and dentists have been defined as Healthcare Professional. Within this scope, all rules relating to promotion are the same for physicians, pharmacists or dentists. The rules relating to promotion apply in the same manner.

Question 39: Does it interfere with the commercial sales conditions of AIFD members?

Answer 39: Commercial sales conditions are managed by the rules, laws and regulations of the Competition Board and fall outside the sphere of intervention of AIFD.

Question 40: Under what conditions can the Hotline on devices used in relation with diseases or drug administrations be arranged?

Answer 40: Article 26 of AIFD Code of Good Promotional Practice should be taken into account in relation with this topic. Live or recorded hotlines supported by companies can offered provided that appropriately trained, medically qualified personnel is on the line and no drug or product promotion is made.

Question 41: Can information relating to the a disease or the use of a device be posted on the internet? Can the official web sites of pharmaceutical companies include product information? If so, under what conditions?

Answer 41: Article 16 and Article 17 of the AIFD Code of Good Promotional Practice, relating to internet should be taken into account in relation with this topic.

Question 42: We know that AIFD members conduct meetings on various periods and adopt decisions: What is the degree of the sanction power of these decisions over the companies?

Answer 42: AIFD's Code of Good Promotional Practice have been developed by the Good Promotional Practice Committee (GPPC). In addition to providing a large platform of communication between companies, it is also responsible for providing recommendations, guidance and training on the Code of Practice. The Committee is also responsible for assuming the role of a mediator/conciliator and continually improving the evaluation system of the complaints and warnings to be made by all relevant parties, particularly pharmaceutical companies, healthcare professionals, media, healthcare authorities and politicians.

Complaints relating to the promotional materials, promotional activities and the used methods within the scope of the Code will be evaluated by the Code of Practice Panel (CPP) and, where necessary, by the Code of Practice Appeal

Board (CPAB). CPP and CPAB members may initiate an ex-officio investigation without waiting for the complaints. The reports relating to the cases will be arranged by AIFD on an annual basis.

Question 43: Within what framework can we make ethical sales and promotional practice of AIFD members become a topic of complaint?

Answer 43: The topics which you observe to be in violation of the AIFD Code of Good Promotional Practice or believe may result in a decrease of the reputation of the healthcare and pharmaceutical sector, pharmaceutical industry and trade or a in the trust towards the industry may be a subject of complaint as indicated in the AIFD AIFD Code of Good Promotional Practice, Annex II AIFD GOOD PROMOTIONAL PRACTICE BOARDS Procedure on Standard Handling of Complaints; Constitution and Procedures.

Question 44: Within what framework can we make the non-ethical sales and promotional practices of non-AIFD member companies a subject of complaint?

Answer 44: As indicated in AIFD AIFD Code of Good Promotional Practice, Annex II AIFD GOOD PROMOTIONAL PRACTICE BOARDS Procedure on Standard Handling of Complaints; Constitution and Procedures, complaints can be made also in relation with non-AIFD member companies.

The complaints made by IEIS members on AIFD members are discussed at the CPP (Similarly, also the complaints of AIFD members of IEIS members are discussed at the IEIS Code of Practice Panel.) If the complainant IEIS member is not satisfied with the decision adopted in AIFD, the decision will be taken up again at CPP. If the complainant company objects once again to the decision, the topic will be taken up at the AIFD-IEIS Joint Code of Practice Panel (AIFD members apply a similar process in the complaints relating to IEIS members).

Question 45: Which institutes and professional groups are encompassed by the inspection function of the Association of Research-Based Pharmaceutical Companies?

Answer 45: The AIFD Code of Practice Panel (CPP) inspect the activities of AIFD member companies.

Question 46: How do you achieve inspection on the practices?

Answer 46: When communicating and interacting with healthcare professionals, AIFD member companies and company employees commit to respect legal requirements as well as the current highest ethical standards and a transparent application. Furthermore, AIFD members are determined to display utmost efforts to ensure that their interactions with healthcare professionals are not perceived negatively by healthcare authorities, healthcare professionals, patients, public and their own employees.

The AIFD Code of Practice Panel and Code of Practice Appeal Board accept the complaints of member companies, physicians, pharmacists as well as the public

and the news appearing on the media as a denouncement and process them accordingly and apply various sanctions in relation with them (admonition, warning, condemnation, strong condemnation, temporary suspension, suspension).

The AIFD Code of Good Promotional Practice, Code of Practice Panel and Code of Practice Appeal Board get their sanction power from the goodwill, mutual tolerance and commitment to the code of ethics of AIFD members who are committed to their vision and mission and pay due respect to laws.