

REGULATION ON OPERATING PROCEDURES AND PRINCIPLES OF THE IEIS PROMOTION PRINCIPLES SUPERVISORY BOARD

Purpose

Article 1 This Regulation was prepared to determine structure, functioning, operating principles and procedures of IEIS Promotion Principles Supervisory Board (hereinafter referred to as the Board) that supervises the implementation of IEIS Regulation on Promotion Principles of Pharmaceuticals and Relations with Healthcare Members. The Promotion Principles Supervisory Board supervises the compliance of member companies with the promotion ethics principles. It carries out the task of being a mediator/negotiator between companies. The Board has no authority to investigate actions that are considered crimes within the scope of the Turkish Criminal Law.

Definitions

Article 2 - In this Regulation;

Regulation: shall mean IEIS Regulation on Promotion Principles of Pharmaceuticals and Relations with Healthcare Members

Board: Refers to IEIS Promotion Principles Supervisory Board

Joint Board: Refers to AIFD-IEIS-TISD Supervisory Board of Promotion Principles

Regulation: Refers to Regulation on Operating Procedures and Principles of the IEIS Promotion Principles Supervisory Board

Foundation: Refers to Pharmaceutical Foundations (IEIS, AIFD, TISD)

SECTION I

Structure and Operation of IEIS Promotion Principles Supervisory Board and AIFD-IEIS-TISD Supervisory Board of Promotion Principles

IEIS Promotion Principles Supervisory Board (Board)

Article 3-

a) Formation

It is comprised of a General Secretary and/or Assistant, at least two members of teaching staff serving in the Pharmaceutical, medical or other faculties of Universities or who have left/retired from these faculties and at least 6 individuals who represent the pharmaceutical industry for a total of 11 members. After the Board has been formed once, new members may be included by the Board of Directors; new appointments may be made to vacant membership positions. The General Secretary and/or assistant may transfer this duty to another Syndicate personnel or may appoint another Syndicate personnel in their place to participate in the board meeting.

b) Qualifications and Terms of Office of Members

Secretary General is the natural head of the Board, in his absence a vice-chairman is elected among Board members at the first meeting.

Company representatives to be part of the council are elected by the Board of Directors, upon the recommendation of firms. In case of need, experts other than the above mentioned groups may attend the meetings as a consultant. However, these people cannot vote.

The membership of members who do not participate in three consecutive meetings without notifying in writing in advance will be invalid.

c) Meeting Time and Meeting Call

Upon invitation of the Secretary-General or with IEIS Board of Directors decision or upon written request of two-thirds of the Board members to the Chairman of Board, The Board gathers immediately and evaluates the applications and complaints.

d) Meeting Procedure and Decision

The Board may gather with participation of absolute majority.

The number of decision is the absolute majority of the members attending the meeting. People other than members are not considered and cannot vote. Members cannot vote for the verdict of applications in which the company they represent complain or being complained. The Board's agenda, working order and the secretary are carried out by the IEIS General Secretariat. IEIS Board of Directors is informed about the decisions of the Board.

The companies who complained and complained about have the right to participate in the relevant section of the Board meeting while a case is evaluated.

AIFD-IEIS-TISD Supervisory Board

Article 4 - Complaints from AIFD and TISD members about IEIS members are discussed on the Board. In case the complainant AIFD or TISD member appeal against the decision made by IEIS the complaint concerned is re-examined on the Board. In case the complainant appeals the decision of the Board made after Re-examining, the subject is discussed in AIFD-IEIS-TISD Supervisory Board. A similar process applies for IEIS complaints about TISD and AIFD members.

The Joint Board consists of;

- General Secretaries of AIFD, IEIS and TISD
- Two people each from AIFD, IEIS and TISD Board of Directors,
- Two people each from AIFD, IEIS and TISD Promotion Policy Supervisory Boards,
- Three independent experts chosen by AIFD, IEIS and TISD's joint decision with at least one from the field of medical and pharmaceutical sciences. Substitute members are also elected in the same number of permanent members.

The Joint Supervisory Board is formed when needed. AIFD, IEIS and TISD Board of Directors elect members to send to the Joint Board. Members elected by IEIS serve for three years. New appointments may be made by the Board of Directors in place of members whose term has ended. The term of the member who has just been appointed is the same as the term remaining for the member who has just departed. The same people may be re-elected in future periods.

The work method of the Board is similar to that of the Promotion Principles Supervisory Board. The chairmanship of the board is carried out by the General Secretaries of each of the three establishments in order.

Article 5 -Until the Joint Board is formed complaints about non-member companies is made by IEIS to the relevant organization or to the Ministry of Health by the applicant company.

SECTION II

Complaints Regarding Violations of the Guide and Operations to Be Done Following a Complaint

Processes Before Complaint

Article 6

It shall be the priority to resolve all complaints made by companies from among IEIS members or outside of its members concerning the violation of IEIS Promotion

Principles of Pharmaceuticals and Relations with Healthcare Members provisions by a an IĒIS member company, among the companies.

If, as of the date that the first correspondence is made to the company that is the source of the complaint following correspondence and meetings that are conducted with the company that is complained about to find a solution, a satisfactory result is not able to be achieved by two weeks at the latest the complaint is sent to IĒIS.

In fact, if the conditions below take place the complainant company may directly submit the complaint to IĒIS without trying to find a solution with the company being complained about:

- If the material or activity which has previously been the subject of complaint between the two companies was not made the subject of a complaint because a solution was reached but despite this has been used/applied again,

A violation has been determined by the Promotion Principles Supervisory Board about the Company concerning a similar complaint and despite a decision being made to stop the material/activity action is not being taken in accordance with the decision and the use/application of the materials/activity is being continued.

Submission of a Complaint

Article 7 –

A complaint is submitted in the form of a petition addressed to the IĒIS General Secretary. If the complainant is a real individual the complaint petition must be signed by the real individual and if it is a legal entity it must be signed by an authorized person/persons representing the legal entity.

The following matters must be included in the complaint:

- Complainant: The identification and company address of the complainant (telephone and fax number and e-mail address if any),
- The name and address of the company a complaint is being submitted about,
- The material that is the subject of the complaint: In each incident the material/activity that is the subject of the complaint or what the other evidence is must be specified and a sample must be attached to the petition,
- Complaint date,
- If the violation being claimed is against material, the period in which it was used and if it is an activity the date and location,
- Summary: In each incident a summary should be provided of which article of the IĒIS Promotion Principles of Pharmaceuticals and Relations with Healthcare Members Regulation the complaint is based on. If an error has been made in medical publication excerpts, the subject publications and the incorrect interpretations should be specified clearly. If the excerpt is an article, the whole article and if it is a book, a sufficient reference and photocopy of the relevant section must be added to the complaint.
- If a solution has been attempted before the complaint as specified in Article 6, the information and documents pertaining to this (correspondence, etc.)
- Sample of the signature circulars

The complaint petition with annexes (on the condition that printed material samples are in color) is sent in 5 copies to the IĒIS. If possible a complete application file is sent to IĒIS by e-mail.

Validity of the Complaint

Article 8 -

When a complaint informing that the IEIS Promotion Principles of Pharmaceuticals and Relations with Healthcare Members Regulation has been violated reaches the Syndicate, the General Secretary determines whether the following are valid

- The subject is in the scope of the IEIS Promotion Principles of Pharmaceuticals and Relations with Healthcare Members Regulation,
- There is enough information and documents in the complaint petition for the complaint to be processed (see Article 7),
- A single complaint may be about more than one promotional material made for the different products of one company/ more than one product within the same activity for the same company. In this situation each item in the scope of IEIS complaint may be processed separately. Each item will be looked at to determine whether the matters specified in Article 7 are present in the complaint petition and annexes.

If it is determined that there is a deficiency in the complaint submittal, the General Secretary will write what the deficiencies are to the complainant company and a period of fifteen days will be allowed to complete these deficiencies. In the event that the complainant makes a written request 15 additional days are allowed. If the deficiencies are not provided within the allowed period the complaint is removed from processing. The status is notified to those concerned with the complaint.

If it is determined that there are no deficiencies in the complaint it is submitted to the Board by the General Secretary.

Timeout

Article 9 -Complaints about promotional materials or practices won't be taken into consideration if the use of these materials or applications has stopped since the last twelve months.

Answer Inquiry from the Complained

Article 10 -

For all complaints, complaint letter and appendices are sent to the complained company along with a letter that identifies the subject prepared by IEIS, and written response is required. The company can also make verbal description, if desired.

If the complaint questions the scientific ground of claims made in product promotion material, the complained company is obliged to provide appropriate data, scientific publications and/or technical reports documenting the reason behind the manner of promotion in subject.

A response to the complaint is submitted within the scope of principles specified in Article 8, with its annexes (on the condition that information and documents that are submitted in print are in color) in 5 copies to the IEIS. If possible the complete complaint file is sent to IEIS via e-mail.

If the complainant is a legal entity it must be signed by an authorized person/persons representing the legal entity.

Extra Time

Article 11 - The complained company must answer IEIS's post within 15 working days of receiving the document. If no response is received from the complained company during this time processing will continue without delay. However at the request of the company, and if there are proper reasons adduced, the company is given additional time to respond to the text.

The Board must discuss the complaint, within 2 months from the date of the first assessment.

Pre-Review

Article 12 - File that contains complaints and response shall be subject to prior review. For this, one or more faculty members predetermined by the Board are asked to review the Board member's file and prepare a brief note for each complaint file. The file is referred to the Board with this assessment note.

If the complaint has been decided on before the reporter will specify this in the report.

If the activity or material that is the subject of the complaint is a subject that has been assessed as a violation of the IÉIS Promotion Principles of Pharmaceuticals and Relations with Healthcare Members Regulation before and it has been repeated, the case will be handled as a new complaint. The reporter will clarify this in their report.

Board Review

Article 13 - Complaint files are put on the agenda according to the order of arrival following pre-review with stating the subject of complaints. If available issues other than the complaints such as requests for opinions are added on the agenda.

The agenda is determined and distributed to the members with the reports of the reporter minimum 3 days before to the meeting.

If deemed necessary by the Board or at the request of the company the company that is being complained of is given the right to an oral explanation during the examination. While the complained company gives an explanation, the complainant company representative shall be present in the hall. If the Board accepts the request of making an oral statement of one party, it should grant the same right to the other party. Board members may ask questions to both company representatives.

The Board members may ask questions to representatives of both sides and ask for additional documents. If the Board wishes to make a decision after the new documents have been examined or after an additional investigation has been conducted, they may continue in the next meeting. In this case the parties may not be called back again; the meeting may be conducted on the file.

After the presentations and questions the company representatives are escorted outside the hall. If representatives of the parties are also members of the Board they will be invited to step outside the hall.

If during the investigation or discussion of a complaint, a reporter or Board member encounters a situation which is not in the complaint but could be interpreted as a violation of the IÉIS Promotion Principles of Pharmaceuticals and Relations with Healthcare Members Regulation, the Board will investigate the matter and if necessary is authorized to ask the company for more information. If time is requested to prepare a response the case may be postponed to a later date after the documents have been examined and if necessary the reporter has prepared and distributed a new report and the parties have been listened to, a decision is issued.

After separate discussions have been made on the files and other issues individually, a vote is taken and an assessment is made separately for each matter of the agenda. In Board decisions, who has made what decision is not specified. The decision is made based on majority vote. The number of votes is specified. If there is a tie of votes in the evaluation the decision is issued according to the side that the chairman is on.

The evaluations made by the Board are entered and a record is prepared. The prepared record is sent to the Discipline Board

Sanctions

Article 14 -

The Discipline Board may decide on the application of the following actions in accordance with the Promotion Principles Supervisory Board record:

- Drawing attention,
- Warning,
- Reprimand.

The sanctions must be in correct proportion with the seriousness of the violation. If the severity of the situation does not require the application of another sanction, the Board may decide on the application of “drawing attention” as a bottom limit. If it is decided to apply more severe sanctions (“warning” or “reprimand”) the reason (bad will, repeated violation, etc.) will be written clearly in the record.

Also in addition to these sanctions the following additional sanctions may be decided on against the company:

- Stopping the use of the material or the repetition of the activity,
- Recalling the material.

In the event of unnecessary and malicious complaints which target a particular product, which cannot be proven and are issued without realistic claims and the company making the claims is found to be unjustified, the sanctions that are set forth in the Regulation may also be applied against the company making the claims.

The Discipline Board notifies its decision to the Board of Directors within one week at the latest with its justification. The notification of the decision to the concerned parties is done pursuant to the Board of Directors directive by the General Secretary to the General Managers of the concerned companies in writing.

Notification of the Decision to the Complaint Parties

Article 15 –Notification of the Decision to the Complaint Parties is done pursuant to the Board of Directors directive by the General Secretary to the General Managers of the concerned companies in writing with justifications included.

Depending on the situation the notification of corrective precautions to prevent the violation may be requested.

Appealing Board Decision

Article 16 -The complained company may appeal the Board’s evaluation within 15 working days from the date of notification in a reasoned writing. The Board reviews and re-examines the objection letter by inviting an elected representative of the concerned company to the Board meeting. If necessary, the Board can negotiate after a group consisting of three members elected by the Board reviews the appeal.

Keeping Annual Inventory about Complaints and Sanction Applications and Other Transactions

Article 17 -

a) Companies violating the Guide and the sanctions imposed on them are collected annual tables; the corrective measures to be taken reported by firms are specified in these tables.

- b) Numbers of sanctions that have been applied to firms are monitored by continuously controlling the table.
- c) At the end of the calendar year, complaints about the violation of the decisions made in that year are grouped according to companies and reported to Board in a table.

General Precautions to Be Taken By the IEIS Supervisory Board of Promotion Principles In Order To Promote Compliance with the Guide and Minimize Violations

Article 18 - IEIS Supervisory Board of Promotion Principles takes the following general measures to avoid infringement in addition to taking measures to stop violation events after their occurrence by evaluation and prevent their recurrence as specified in this Regulation;

- To promote the companies to prepare their own promotion policies and guides and organize for this issue
- To advise companies according to the experience gained so far to show them a path subject if requested
- To organize periodic meetings with the participation of interested parties to ensure discussion and consensus on issues related to promotion and marketing and make contacts,
- To collect information about the improvements and actions on the subject at the level of European Union and various countries and deliver it to the companies.
- To contribute the education of firm employees working on these issues (medical, marketing) or beginners in ethical practices by organizing trainings.

SECTION III

Final Provisions

Enforcement

Article 19 - This Regulation shall be effective following April 3 2013.

Complaint Processes

Article 20- Depending on the quality of the company being complained about, the processes in the Complaint Processes Summary Table included in Annex I are followed.

Temporary Article - This Regulation shall be applied for evaluation of complaints that were filed on the date of entry into force of this Regulation and not yet concluded.

ANNEX I Complaint Processes Summary Table:

The Organization to Which the Complainant Company is a Member	The Organization to Which the Company Being Complained About is a Member	Method of Resolving Problem
iEiS	iEiS	Between Companies; Otherwise the iEiS will monitor the matter.
iEiS	AiFD or TiSD	Between companies; Otherwise, after iEiS has met with the company making the complaint they will send a letter to AiFD or TiSD requesting that the matter be followed up on by iEiS, AiFD or TiSD.
AiFD or TiSD	iEiS	The iEiS will monitor the matter.
iEiS	None	The iEiS will monitor the matter or if necessary notify the Ministry of Health directly.
Not Company	iEiS	The iEiS will monitor the matter.
Public + media	iEiS	The iEiS will monitor the matter.

