



ARTED

Association of Research Based Medical Technologies
Manufacturers

**THE PROCEDURE TO BE TAKEN IN CASE OF A BREACH OF ARTED CODE
OF ETHICS' PRINCIPLES, THE ASSESSMENT OF COMPLAINTS AND
SANCTIONS**

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I. General Principles

1. The actions of the ARTED members, which are incompliant with ARTED Principles on Interactions with Healthcare Professionals, Ethic Rules and Code of Conduct Guidelines ("ARTED Code of Ethics") and current legislation, may be subject to complaints filed by ARTED members.
2. ARTED Ethic Board is the authorized body to investigate, examine, resolve and sanctions, ex-officio or upon complaint, in relation to the actions of ARTED members, which are incompliant with the Code of Ethics. An application may be filed before ARTED Ethic Board in relation to the interpretation of the ARTED Code of Ethics text. ARTED Ethic Board consists of the ARTED Ethics Working Group members, formed by one representative from each member firm, with the exception of the representatives of the firms, which filed the complaint and which is the subject matter of the complaint.
3. ARTED Ethic Board holds regular meetings every months, but August. In case there is no agenda for ordinary meetings, the meeting for such month shall be adjourned.
4. ARTED Supreme Ethic Board is the body authorized to examine oppositions made against ARTED Ethic Board decisions. The Supreme Ethic Board consists of the members of the discipline committee and two independent members excluding representatives of the firms who are parties to the complaint.
5. ARTED may appoint a board established within its own structure or a third person or an establishment in order to implement the principles of the Code of Ethics and to inspect any material or method, used by the member firms within the framework of promotional activities.

II. Complaint Process

6. In case an ARTED-member firm believes that another ARTED-member firm breached the ARTED Code of Ethics; first of all, it may choose to notify the highest level executive of such firm in Turkey and to make efforts for the resolution of the disputed issue through negotiations between the firms.
 - a. In case no satisfactory conclusion is provided from this negotiation process within 2 (two) weeks, the member firm submits its complaint to Secretary General.

- b. In case a satisfactory conclusion is reached from the negotiation attempt, the parties shall share a joint declaration, summarizing the negotiation process and the reached conclusion, with the Secretary General.
7. The complaints, submitted to ARTED, must contain at least the following elements:
 - a. Name of the firm, subject to the complaint;
 - b. The name, contact details and e-mail address for notification to the complaining firm/institution or related person;
 - c. Date of complaint;
 - d. Promotional material(s) or activity/activities subject to complaint; in each case, the activity, promotional materials or other relevant documents subject to complaint shall be clearly specified and if any, a copy must be annexed.
 - e. Summary of complaint: in each case, the principles of the Code of Ethics which are believed to be breached by the subject matter of the complaint and the requested sanction shall be specified.
 - f. The term of use of the material subject to complaint; in case it is an activity, the place and date.
 - g. Information concerning negotiation process.
 8. If 1 (one) year has passed after becoming aware of the situation subject to the complaint and in any case 2 (two) years has passed after the occurrence of such situation, the complaint will not be considered and this matter shall promptly be notified to the complainant.
 9. The initial examination concerning the complaint is conducted by ARTED Secretary General within 15 (fifteen) working days and in case additional information/documents are requested, the deadlines shall be suspended.
 10. If the Secretary General, within 15 (fifteen) working days,
 - a. Determines that information and documents are insufficient for the consideration of the complaint, he/she shall promptly communicate with the complainant and shall request the missing information and documents by granting extra time. In case necessary information and documents are not provided, a nonsuit decision will be given, the file will close and the matter shall be notified to the complainant. The complainant may file an opposition before the Ethic Board within 15 (fifteen) working days against the nonsuit decision.
 - b. Determines that there is sufficient information and documents for the consideration of the complaint or in case missing information and documents are provided by the complainant in due time, the Secretary General shall send a copy of the complaint file by excluding the confidential

documents, to the firm subject to the complaint and shall request the firm to send a written response within 15 (fifteen) working days. The firm may request a time extension during response period. The request for time extension is resolved within 2 (two) working days and in case the decision is not notified within this time, it shall be deemed to have been dismissed.

11. Following the written responses of the party subject to the complaint or the expiry of response term and in any case after 15 (fifteen) days initial examination period beginning from the date of complaint, ARTED Ethic Board shall examine the complaint in question by adding it to the first agenda.
12. In case there is more than one complaint in relation to the same subject, it may be handled and decided during the same meeting.
13. The Chairman of ARTED's Board of Directors, ARTED Secretary General and ARTED's attorney shall attend to the ARTED Ethic Board meeting as observers, where the complaints are examined, however they shall not vote. The meeting, where the complaints are examined and decided, shall be held with the participation of at least $\frac{3}{4}$ of the number of members of ARTED Ethic Board; the decisions shall be taken by majority of the votes. In case the votes are equal, a decision in favour of the firm subject to the complaint shall be taken. The voting shall be conducted by secret ballots.
14. During the evaluation of the complaints, ARTED Ethic Board shall always observe the equality between the parties, make efforts to hear the parties properly, and make its best efforts to take fair decisions within fair time periods with respects to the particulars of the case. In addition, it is the responsibility of ARTED to keep the complaints and decision-making process confidential during the process and to prevent disclosure of the trade secrets or confidential information of the firms.
15. The decision taken concerning the complaint and if any, the sanction decided to be imposed, shall be notified by ARTED Secretary General to the parties of the complaint. ARTED Ethic Board, within 15 (fifteen) working days after the notification, prepares the reasoned decision and serves it to the parties. Notification is served to the e-mail address, designated by the firm under Article 9/b.
16. Within 10 (ten) working days after the notification of the reasoned decision to the firm subject to complaint, shall send a written declaration or undertaking, signed by the highest level of executive of the firm in Turkey, stating that the sanctions decided to be imposed on the firms are fulfilled and/or necessary precautions for the fulfilment of them are taken. In case the letter of commitment is not given in due time and/or corrective action is not taken, an upper level sanction shall be imposed.
17. The parties of the complaint may file oppositions before ARTED Supreme Ethic Board, against the decision taken by ARTED Ethic Board, within 10 (ten) working days after the notification of the

reasoned decision, by clearly specifying their grounds for opposition. Decisions against which no oppositions are filed within this period become final. Chairman of ARTED's Board of Directors, ARTED Secretary General and ARTED's attorney shall attend to the ARTED Ethic Board meeting as observers, however they shall not vote. The meeting, where the complaints are examined and decided, shall be held with the participation of at least $\frac{3}{4}$ of the number of members of ARTED Supreme Ethic Board. The voting shall be conducted by secret ballots. The decision taken by ARTED Supreme Ethic Board is final.

III. Sanctions

18. Following the finalization of the decision of ARTED Ethic Board or as a result of the final decision of ARTED Supreme Ethic Board, in case it is determined that subject matter of the complaint, constituted a breach of the current legislation, ARTED shall be obliged to notify the related authorities, including the Ministry of Health.
19. Attention shall be paid to ensure that the sanctions to be imposed by ARTED Ethic Board and ARTED Supreme Ethic Board, are proportional to the severity of the breach and have a deterrent effect. Examples to possible sanctions and conditions requiring such sanctions are as follows:

- a. **Notice:** In case of a breach of the Code of Ethics is foreseen, such as taking steps by a firm for a promotional activity constituting a breach, depending on the severity of breach, a notice is sent to the member firm requesting the firm to refrain from conducting such activity and the sanction to be imposed otherwise shall be stated.

Contacting physicians and/or requesting permission from their affiliated institutions for sponsorship to participation in congresses, which do not satisfy the criteria for the proper place and time, may be given as an example to this situation. ARTED Ethic Board issues a notice to refrain from providing sponsorship in connection with such congresses.

- b. **Warning:** In case the promotional activity conducted by a member firm constitutes a breach, depending on the severity of the breach, a warning shall be issued in order to cease the breach of the Code of Ethics, to perform a remedial action, to avoid the repetition of the breach and the sanction to be imposed otherwise shall be stated.

Reimbursement of travel and accommodation expenses by a member firm for participation of healthcare professionals in the series of meetings, organized by the member firm, where promotion of products comes before the scientific content may be given as an example to this situation. ARTED Ethic Board considers that travel and accommodation costs of the meetings in question are not included in the categories of meetings eligible for reimbursement; therefore

warns that the sponsorship constitutes a breach and requests the avoidance of such sponsorship in subsequent meetings.

- c. **Reprobation:** In case the Code of Ethics is clearly and deliberately breached and/or an activity, concerning which a correspondence was made before and/or resulting in any of the sanctions indicated above, is maintained, a reprobation decision shall be taken and the parent firm abroad shall be notified in writing.

Sponsorship of the member firm for participation of family members of healthcare professional to a congress who may not provide a benefit from the congress may be given as an example to this situation.

- d. **Temporary Suspension of Association Membership:** In case of deliberate breach of Code of Ethics in a clear and severe manner, an activity, concerning which a correspondence was made before and/or resulting in any of the sanctions indicated above, is maintained, a decision for temporary suspension of Association Membership, may be taken. The decision shall be notified in writing to the parent firm abroad and to MEDTECH. In case the breach in question is caused by the internal procedures of the member firm, which are incompliant with the Code of Ethics, during suspension, the member firm is requested to take remedial actions and to remedy internal procedures on its own expense and to share the results of audits conducted by neutral institutions with ARTED. The firms, whose association memberships are temporarily suspended, shall continue to pay their membership dues. However, during the suspension of membership, they will be ineligible to participate in the bodies of the association and working groups.

Despite a reprobation decision, the sponsorship of a member firm for participation of family members of healthcare professional to a congress who may not provide a benefit from the congress, the repetition of this breach may be given as an example to this situation.

- e. **Expulsion from Association:** In case of endangering public order and public health, failure to conduct, implement and/or deliberately delay the implementation of remedial actions during suspension of association membership on the grounds of severe breaches, damaging the objectives and principles of the Association, the member firm may be expelled from the Association. The breach shall be notified to the public with a press release and shall be notified to the related institutions and establishments, including the Ministry of Health.

These sanctions shall be implemented gradually. A point is identified for each sanction according to the severity of breach. In case the member firm is subject to more than one sanction within the same year, the points, corresponding to sanctions are added together and the sanction, corresponding to the sum, shall be implemented.

Sanction	Objective	Weighted Point	Additional Sanction
Notice	To prevent a possible breach	25	
Warning	To cease the existing breach, to prevent repetition	50	
Reprobation	To cease clear and deliberate breach, to prevent repetition	75	The decision shall be notified in writing to the parent firm abroad.
Temporary Suspension of Association Membership	To cease the severe, clear and deliberate existing breach, to prevent repetition, to provide correction of internal procedures by the member firm	150	The decision shall be notified in writing to the parent firm abroad and to MEDTECH.
Expulsion from Association	To provide termination of severe breaches threatening public order, public health, as well as the objectives and principles of the Association.		The decision shall be notified to the public with a press release and shall be notified to the related institutions and establishments, including the Ministry of Health.

20. In addition, if it is considered appropriate, considering the severity/degree of the breach in that particular case, it may be requested to conduct corrective/preventive actions, including but not limited to the ones provided below:

- a. To cease use of breaching material or repetition of such activity;
- b. To collect breaching promotional materials;
- c. To request avoidance from participation and/or direct/indirect support from organizations, which do not satisfy the standard of the Code of Ethics,
- d. To publish the details of the decision made regarding the firm in proportion to the severity of breach, ,
- e. To request inspection and if necessary, improvement of the firm's process in relation to the principles of the Code of Ethics which have been breached,

- f. To request the breaching firm to make corrective statements in applicable media and to publish corrective announcements,
- g. If the breaching firm is a multinational firm, to notify in writing the firm's head office regarding this situation,
- h. To notify other international organizations of which the firm is a member.