

MedTech Europe Compliance Panel Internal Procedural Rules

Approved 15/01/2018

Preamble

The present Internal Procedural Rules establish the rules for the MedTech Europe Compliance Panel (“the Panel”) as established under Article 7 of the Procedural Framework to hear and decide on disputes concerning alleged infringements or questions of interpretation of the MedTech Europe Code of Ethical Business Practice (“the Code”).

1. Submission and reception of complaints

- 1.1. A complaint concerning an alleged breach by a MedTech Europe Member Company (together “Member Companies” or individually “Member Company”) of the Code, can be lodged by any organisation or individual directly affected by the activities of MedTech Europe Member Companies, such as but not limited to Member Companies, sickness funds, individual Healthcare Professionals (HCPs), Healthcare Organisations (HCOs) or patients and Patient Organisations (“Complainants”). Manufacturers of Medical Technology products that are not a Member Company shall prove their adherence to the ethical standards of the MedTech Europe Code of Ethical Business Practice in order to be able to lodge a complaint.
- 1.2. In the event that the MedTech Europe Secretariat becomes aware of information or facts which could involve a breach of the Code by a MedTech Europe Member Company, the MedTech Europe Secretariat may itself file a complaint with the Panel.
- 1.3. Upon submission of a written complaint to the Panel, the Complainant shall pay an administrative fee of € 500. The complaint handling procedure shall not start unless the administrative fee has been paid or a waiver has been granted by the Panel upon duly reasoned request. For a request as provided under Article 2.7, no such fee shall have to be paid.
- 1.4. Prior to launching a formal complaint against another Member Company under this Procedure, the Complainant is encouraged to first attempt a genuine direct conciliation, or mutual settlement in order to reach an amicable solution.

Nevertheless, if a Complainant believes that such direct conciliation or mutual settlement is not suitable, it may lodge a mediation request with the Secretariat of MedTech Europe subject to Section 2 below. A mediation request shall only be receivable for disputes between Member Companies. Any other formal complaint shall follow rules provided in Section 2 below.

1.5. Any complaint and/or the mediation request shall be submitted in English or with an English translation and shall include, as a minimum, the following:

- The name in full, description and address of the Complainant and Respondent;
- A concise description of the nature and circumstances of the facts giving rise to the complaint(s);
- Reference to the provisions of the Code allegedly infringed;
- Short reasoning explaining the nature of the alleged infringement;
- A statement of the relief sought;
- And where available, supporting documentary evidence.

For the mediation request, in addition to the above, the Complainant shall indicate whether its identity should remain undisclosed to the Respondent.

1.6. The date of the receipt of the complaint shall be the date of confirmed receipt of the complaint sent by the MedTech Europe Secretariat to the Complainant.

2. Processing of complaints and mediation request

2.1. General Rules

- a The Panel shall ensure that industry and non-industry complaints are processed according to the same principles, without regard to who has made the complaint, and in respect of the fee provisions provided for in Article 1.3 of these Internal Procedural Rules.

In all cases, the Panel should know the identity of the Complainant.

Anonymous claims will not be receivable, being understood that as regards claims initiated by a Member Company against another Member Company, the identity of the Complainant may remain undisclosed to the Respondent (in accordance with Article 1.6 during the mediation phase).

The Identity of the Complainant will be held in confidence by the MTE Secretariat and the Panel and not revealed to any third party (not directly involved in the processing of the Complaint), save to the extent disclosure is required by any law, governmental or regulatory authority or by a court or other authority or competent jurisdiction. Disclosure to the Respondent of the identity of the Complainant shall also be permitted, in the discretion of the Panel, when necessary for the Respondent to mount a full and adequate defence.

- b The Panel may join several complaints into a single procedure if the Panel decides that the subject matter of the complaints is identical or sufficiently connected.
- c The Panel shall act impartially and shall respect fair procedure rules, allowing all parties to be heard fairly. Whenever a Complaint (or Mediation request) appears receivable, copy of the corresponding documents will be notified to the Respondent without delay. Respondent will be requested to provide a written answer within thirty (30) days from such notification.
- d At the discretion of the Panel, oral hearings or meetings may be convened at any location it considers appropriate unless the parties select a location by mutual agreement.
- e The Panel shall take decisions and pronounce any sanctions listed in the Procedural Framework to be applied on the basis of the provisions of the Code.
- f The Panel shall suspend or discontinue a procedure where a formal investigation by criminal law enforcement authorities is in process or where civil or criminal proceedings or proceedings at any ordinary court with respect to the same or a substantially similar subject matter have commenced.
- g If a complaint fails (after assessment by the MTE secretariat or the Panel) to establish a prima facie case of breach of the Code, such complaint shall be dismissed.
- h At any time of a proceeding, the Panel may decide (after consultation with the MTE Secretariat) that given the nature of a complaint or the facts sustaining it, it is not appropriate to allow the complaint to proceed and it may invite the Complainant to further pursue the case via competent government agency or court.
- i In all proceedings, the Panel shall respect all applicable data protection legislation and guidelines.

2.2 Specific Rules for the Mediation process

If the Complainant has requested a Mediation process, the procedural steps shall be as follows:

- a. After receipt of the Complaint, the MedTech Europe Secretariat shall inform the Panel and proceed with a fact review to assess if a prima facie case of breach of the Code appears to be established.
- b. If there are sufficient indication that a breach of the Code provisions may have taken place, the MedTech Europe Secretariat, in coordination with the Panel, shall contact the Respondent to seek clarification on the alleged infringement.

- c. In this phase, the Respondent may be given a reasonable amount of time (between 10 20 working days) to proceed with any internal enquiry necessary to investigate if the alleged infringement took place.
- d. In the event the Respondent acknowledges the infringement, the Panel shall propose to the Respondent the ruling it considers appropriate, taking into account in particular the remedial actions the Respondent may propose to implement.
- e. If the Respondent does not acknowledge the infringement of the Code or refuses to accept the ruling proposed by the Panel, the Complainant will be informed of the negative outcome of the Mediation and will have to determine if it wishes to pursue the proceeding through the formal complaint process.

2.3 Specific Rules to the formal Complaint process.

If mediation has been considered as not appropriate (given the nature of the claim or the identity of the claimant) or has failed, the following procedural steps shall apply.

- a. The MTE Secretariat shall inform Complainant that it may further pursue the Complaint via the Panel (unless the Complainant determines that a claim through competent governmental agency or court is preferable).
- b. After receipt of the Complaint, the MTE Secretariat shall inform the Panel and proceed with a fact review to check if a prima facie case of breach of the Code appears to be established.
- c. The parties may submit any relevant documents and information shall be transmitted to the Panel for instruction and decision.
- d. In its review of the case, the Panel will have all liberty to:
 - decide to hear witnesses, company representatives, experts or any other person appointed by the parties or by the Panel;
 - invite any party at any time during the proceedings to provide additional evidence;
 - decide the case solely on the documents submitted by the parties, unless any of the parties request a hearing;

The Panel will in any case maintain confidentiality of sensitive business information, trade secrets and any other confidential information.

3. Sanctions

- 3.1. Where the Panel rules that there is a breach of the Code, the Panel shall advise the Complainant and the Respondent of such in writing and give the reason for reaching this decision. The ruling shall be signed by the Panel members and be notified to the parties. The original of each ruling shall be deposited with the MedTech Europe Secretariat. Additional copies certified true by the MedTech Europe Secretariat shall be made available on request and at any time to the parties but shall not otherwise be made available unless and to the extent required by law, by any governmental or regulatory authority or by a court or other authority of competent jurisdiction.
- 3.2. Any decisions by the Panel will be final and no appeal will be available.
- 3.3. A Member Company which is found by the Panel, to have breached a provision of the Code, shall reimburse the administrative fee paid by the Complainant at the introduction of the Complaint and, at the discretion of the Panel, all reasonable costs incurred by the Panel on behalf of MedTech Europe for conducting the proceedings.
- 3.4. The list of sanctions available to the Panel is listed in Article 8.1 of the Procedural Framework. In addition to the Sanctions there listed, the Panel may impose the withdrawal of the MedTech Europe Ethical Business Logo.
- 3.5. Notwithstanding the foregoing, the MedTech Europe Secretariat shall ensure that any final decision taken in individual cases shall be rendered in writing, detailing the reasons for reaching this decision and signed by the members of the MedTech Europe Compliance Panel. At the minimum, copies of such decisions shall be made available to the parties of a proceeding.
- 3.6. The MedTech Europe Secretariat shall ensure that rulings on questions of interpretation on the Code are published in its entirety.
- 3.7. Notwithstanding the publication of any decision or sanction which may be imposed under Article 8 of the Procedural Framework, when the Panel considers that a final decision taken on any specific matter would help Member Companies and National Associations in interpreting the Code they may choose to make available to Members an anonymised version of the decision. The MedTech Europe Secretariat will keep a document containing all such anonymised decisions and will make it available to Members.

4. Provision of interpretation

- 4.1. If a question of interpretation of the Code is introduced in writing to the Panel by a national panel, the Panel may at its discretion either:

- Decline to entertain the matter if it is felt that no question of principle is at issue or where the same question has already been answered by a previous ruling by the Panel; or
 - Accept the interpretation referral, review, where appropriate consult the MedTech Europe Code Committee and provide guidance on the interpretation of the Code (i.e. but not rule on merits/facts) with a view to ensuring harmonised interpretation and enforcement of the principles of the Code and the Procedural Framework.
- 4.2. The MedTech Europe Compliance Panel shall promptly issue guidance on the interpretation, which shall be no later than 60 days from receipt of a request for interpretation.