
Eucomed Compliance Panel Internal Procedural rules

Board approved, 26 June 2010

Eucomed Code of Ethical Business Practice: Procedural Framework

Preamble

The present internal procedural rules establish the rules for the Eucomed Compliance Panel as established under Article 5 of the Procedural framework to hear and decide on disputes or questions of interpretation of the Eucomed Guidelines on Interaction with Healthcare Professionals and accompanying Guidance Document (Q&A) – as updated from time to time –, hereafter referred to as “Eucomed Guidelines” referred to them.

For the purpose of clarification, the Eucomed Code of Ethical Business Practice encompasses also the Eucomed Guidelines on Competition Law.

Article 1 - Submission and reception of complaints

1.1 A complaint concerning an alleged breach by a Eucomed member company of the Eucomed Guidelines, can be lodged by any organisation or individual directly affected by the activities of Eucomed members, such as but not limited to Eucomed member companies, sickness funds, individual Healthcare Professionals (HCPs) or patients (“Complainants”).

In the event that the Eucomed Secretariat becomes aware of information or facts which could involve a breach of the Eucomed Guidelines by a Eucomed member company, the Secretariat may itself file a complaint with the Panel.

1.2 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.

1.3 Prior to launching a formal complaint against another member company of Eucomed under this procedure, the Complainant shall first attempt a genuine conciliation, mediation or mutual settlement in order to reach an amicable solution, subject to the provision 2.7.

1.4 Complaints received by the Panel shall be processed as follows:

- This procedure shall only apply to complaints regarding alleged infringements of the Eucomed Guidelines.
- The Panel shall respect all applicable data protection legislation and guidelines.

- 1.5 The complaint shall be submitted in English or with an English translation and shall include, as a minimum, the following:
- Where applicable, the name in full, description and address of the Complainant and Respondent;
 - A concise description of the nature and circumstances of the dispute giving rise to the complaint(s);
 - Reference to the provisions of the Eucomed Guidelines allegedly infringed;
 - Short reasoning explaining the nature of the alleged infringement;
 - A statement of the relief sought;
 - And where available, supporting documentary evidence.
- 1.6 The Panel shall send a copy of the complaint and the documents annexed thereto to the Respondent and shall request that the Respondent provides complete answers to the alleged infringements of the Eucomed Guidelines.
- 1.7 The date of the receipt of the complaint shall be the date of confirmed receipt of the complaint sent by the Eucomed Secretariat to the Complainant.

Article 2 – Processing of complaints

- 2.1. The Panel shall ensure that industry and non-industry complaints are processed in the same manner, without regard to who has made the complaint, provided that the Panel may waive the fees as deemed appropriate in accordance with Article 1.2 of these Internal Procedural Rules. As a minimum, the Panel should know the identity of the complainant. Where requested, the identity of Complainants who are individual persons, will be held in confidence by the Panel (and where applicable by the Eucomed Secretariat), save to the extent disclosure is required by any law, governmental or regulatory authority or by a court or other authority of competent jurisdiction.
- 2.2. 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.
- 2.3. The Panel shall act impartially and shall respect fair procedure rules allowing all parties to be heard fairly. The Respondent will have the right to submit a written reply to the complaint within 30 days from the notification by the Panel of the complaint to the Respondent.
- 2.4. 2.4 At the discretion of the Panel, an oral hearing may be convened. The Panel may, after consultation with the parties, conduct hearings and meetings at any location it considers appropriate unless otherwise agreed by the parties.
- 2.5. The Panel shall take decisions and pronounce any sanctions to be applied on the basis of the Eucomed Guidelines.

- 2.6. The Panel may suspend or discontinue a procedure where a formal investigation by criminal law enforcement authorities is in process or where civil or criminal proceedings with respect to the same subject matter have commenced.
- 2.7. The procedural steps for complaint handling shall be as follows:
- a. The first stage of the complaint handling procedure shall be the filing of a written complaint with Eucomed. Where the Panel considers a complaint fails to establish a prima facie case of breach of the Eucomed Guidelines, such complaint shall be dismissed.
 - b. The second stage of the Eucomed complaints handling procedure shall be based on the general principle underlying the Eucomed Procedural Framework, which is that disputes are best resolved amicably and efficiently by conciliation, mediation or mutual settlement. To that end the following steps shall be taken:
 - Within a reasonably short timeframe after receipt of a written complaint by Eucomed, a genuine mediation should be attempted, involving an independent third-party or mediator, who shall not be a member of the Panel. Depending on the nature of the complaint, an attempt shall be made to reach an amicable solution. If the parties cannot agree on a mediator within a reasonable period of time, either party may request the Panel to appoint a mediator. For complaints between companies, mediation shall be a pre-condition for the continuation of the dispute resolution process.
 - In cases of a serious/repeated breach, the mediator may decide to direct complainant(s) to further pursue the matter directly via the Panel.
 - If no amicable resolution of the complaint can be reached within a timeframe set by the mediator or if the mediator decides that the mediation is inappropriate given the nature of the complaint, the mediator shall direct complainant(s) to further pursue the complaint via the Eucomed Compliance Panel or the appropriate government agency or court, which shall ensure that a final decision is taken promptly in relation to each case thus referred to it for consideration.
 - c. The Panel may decide that given the nature of the complaint that it is inappropriate to allow the complaint to proceed and may direct the Complainant to further pursue the case via the appropriate government agency or court.
 - d. Where no amicable resolution of the complaint is reached or commenced and the complaint is further pursued by the Panel, the Panel shall proceed within as short a time as feasible to establish the facts of the case by all appropriate means. As such the Panel:
 - May decide to hear witnesses, company representatives, experts or any other person appointed by the parties, or by the Panel.
 - May summon any party, at any time during the proceedings, to provide additional evidence.

- May decide the case solely on the documents submitted by the parties unless any of the parties requests a hearing.
- Shall maintain confidentiality of sensitive business, trade secrets and other confidential information.

Article 3 – Sanctions

- 3.1 Where the Panel rules that there is a breach of the Eucomed Guidelines, 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 Eucomed Secretariat. Additional copies certified true by the Eucomed 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 that is found by the Panel, to have breached a provision of the Eucomed Guidelines, 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 Eucomed for conducting the proceedings.
- 3.4 At the discretion of the Panel, sanctions may be imposed. Such sanctions must be proportionate to the infringement, predictable (and therefore published), act as a deterrent, and may include: written reprimand; requirement that the Respondent, whose activities have been found in breach of the Eucomed Guidelines, takes steps to conform with the Eucomed guidelines (specific steps may be specified in whole or in part, and may be subject to time limits); inspection and audit by a third party (at the Respondent's cost and expense) of the Respondent's systems for compliance; requiring companies to recover items given in connection with the promotion of products and/or to issue a customer communication regarding future corrective practice; requiring companies to publish or otherwise disseminate corrective or clarifying information or statements; withdrawal of the 'compliance' logo or equivalent accreditation or certification scheme of Eucomed or national Member Associations; publication of any decisions or sanctions imposed in such publications as the Panel shall determine at their sole discretion, including publications at Eucomed meetings; prohibition against company representatives standing for elected office within the institutions of Eucomed; suspension – with specific time limit and detail on conditions of 're-entry' - of membership of Eucomed; recommendation to the Eucomed Board that the Respondent be expelled from Eucomed membership.
- 3.5 The Eucomed Secretariat shall ensure that any final decision taken in individual cases as well as rulings on questions of interpretation on the Eucomed Guidelines shall be published in its entirety or, where only selected details are published, in a level of detail that is commensurate with the seriousness and/or persistence of the breach as follows:

- In cases of a serious/repeated breach, the company name(s) may, in the discretion of Eucomed, be published together with details of the of the case(s);
- In case of minor breach, or where there is no breach, publication of the details of the case should exclude the company name(s).

Article 4 – Provision of interpretation guidance

5.1 If a question of interpretation of the Eucomed Guidelines in writing is introduced 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 Eucomed Code Committee and provide guidance on the interpretation of the Eucomed Code (i.e. but not rule on merits/facts) with a view to ensuring harmonised interpretation and enforcement of the principles of the Eucomed Guidelines and the Procedural Framework.

5.2 The Eucomed Compliance Panel shall promptly issue guidance on the interpretation, which shall be no later than 60 days from receipt of a request for interpretation.