

Eucomed Code of Ethics: Procedural Framework

Adopted by Eucomed General Assembly, 8 October 2009

1. Preamble

The principles set out below are intended to design an effective and efficient complaint-handling process (“Procedure”), the object of which is to ensure compliance with the Eucomed Code of Business Practice including the associated Guidance Document “Q&A document” (together, “Eucomed Code”) and the codes of conduct adopted by Eucomed’s Member Associations. The aim is that the dispute resolution process should enjoy the confidence of all involved stakeholders and have full member support. It is based on principles of proportionality, speed, due process, fairness and transparency.

This procedural framework shall be reviewed when required and in any event every 2 years. This procedural framework may be amended in accordance with the Eucomed Statutes.

2. Organizational aspects

- 2.1. Each Member Association shall include in its national code of conduct, provisions for resolution of disputes and the imposition of sanctions for breaches of its national code.
- 2.2. Each Member Association is required to establish a Panel (i.e. a national body) that is designated to handle complaints. Eucomed strongly recommends that this Panel consist of a non-industry chairman and, that the Panel be composed not only of industry members, but also for obvious reasons of independence, transparency and expertise, of other stakeholders. In the composition of the Panel, Member Associations should balance the need for independence, expertise and knowledge of the industry and industry practices.
- 2.3. Member Associations may – subject to formal recognition by Eucomed – demonstrate that there is an established framework of stringent regulatory and/or legal controls which are as comprehensive in their provisions and application as the Eucomed Code and these dispute resolution principles. Under such circumstances it may be more appropriate for a Member Association not to establish new, duplicative provisions and procedures or extensive Panels. Eucomed also acknowledges that many Eucomed Member Associations have already established their own codes of conduct, which, together with local laws and regulations, may embody the principles set forth in the Eucomed Code. In order to establish that the legal and regulatory framework relied upon by a Member Association

provides for an effective and comprehensive national code and dispute resolution system, each Member Association shall submit a copy (and timely update) of its national code of conduct including its dispute resolution process to the Eucomed Code Committee (as defined below). A specific submission form will be made available by Eucomed for this purpose. The deadline for submission will be set by the Eucomed Board (“Board”) and will be communicated to the Member Associations. When the Eucomed Code Committee finds that a Member Association’s national code of conduct and dispute resolution mechanism do not match substantially the content of the Eucomed Code and/or the Eucomed dispute resolution principles, this will be communicated to the Board and the Board will decide on further actions with respect to such Member Association, in line with the Eucomed Statutes.

- 2.4. Each Member Association must ensure that its national code of conduct, including its national dispute resolution procedure and other relevant information, are easily accessible through, at a minimum, publication of its national code on its website including its dispute resolution process.
- 2.5. These dispute resolution principles shall not preclude complainants from having recourse to the regular courts or other tribunals to seek resolution of complaints.
- 2.6. Eucomed member companies must comply directly with applicable national codes of Member Associations where such codes exist. In all other territories, i.e. where there are no local codes; no local Member Association; or where there are no equivalent laws and regulations, or where a member company is not a member of a local/regional association, the Eucomed Code shall act as a ‘default code’ for the activities of member companies.
- 2.7. Each Member Association must prepare and provide to the Eucomed Code Committee (defined herein) an annual report summarizing the work undertaken by it in connection with the implementation, development and enforcement of its national code during the year, including complaints handled and sanctions applied under the national code of conduct.
- 2.8. In all territories where there is no dispute resolution process which complies with these Eucomed dispute resolution principles, the Eucomed Compliance Panel (as defined below) shall handle complaints, as a first and last instance decision-maker.

3. Applicability of codes

- 3.1. Promotion and interaction which takes place in Europe must comply with applicable laws and regulations as well as codes of conduct and legal requirements which apply to

healthcare professionals. “**Europe**” as used in the Eucomed Code includes those countries in which Eucomed Member Associations’ codes of conduct apply or those countries where Eucomed Members Companies are established. In addition, promotion and interaction which take place within Europe must also comply with each of the following “**Applicable Codes**”:

- (a) (i) in the case of promotion or interaction that is undertaken, sponsored or organised by or on behalf of, or with, a company located within Europe, the Member Association national code of the country in which such company is located; or (ii) in the case of promotion or interaction that is undertaken, sponsored or organised by or on behalf of, or with, a company located outside of Europe, the Eucomed Code; and
- (b) the Member Association national code of the country in which the promotion or interaction takes place.

- 3.2. In the event of a conflict between the provisions of the Applicable codes set forth above, the more restrictive of the conflicting provisions shall apply (unless as otherwise covered by these dispute resolution principles).
- 3.3. Member companies must comply with any Applicable Codes and any laws and regulations to which they are subject. All companies that are members of Eucomed must either (i) be a member of the Member Association in each country where it conducts activities covered by the Eucomed Code (either directly or through the relevant subsidiary) or (ii) agree in writing with each such Member Association that it (or its relevant subsidiary) is bound by such Member Association’s national code (including any applicable sanctions that may be imposed thereunder).
- 3.4. If the parent company is not otherwise subject to this Procedure, the local subsidiary where any action of promotion or the interaction takes place should be attributable to the parent company. No parent company will be responsible for any such activity if the subsidiary company is directly subject to this Procedure.
- 3.5. For the avoidance of doubt, the term “**company**” as used in this Eucomed Code shall mean any legal entity that organises or sponsors promotion, or engages in interactions with healthcare professionals covered by an applicable Code, which takes place within Europe,

whether such entity be a parent company (e.g. the headquarters, principal office, or controlling company of a commercial enterprise), or any subsidiary company that it controls. The term "**control**" as used in this Eucomed Code shall mean having the power to direct or cause the direction of the management and policies of another company, whether through the ownership of voting securities, by contract or otherwise.

4. Eucomed Code Committee

- 4.1. The Eucomed Code Committee shall assist Member Associations to comply with their obligations under these dispute resolution principles.
- 4.2. As a key part of its role, the Eucomed Code Committee shall promote the Eucomed Code, monitor the adoption of compliant national codes and assist member companies and Member Associations to share best practice and harmonized interpretation of the Eucomed Code and Eucomed dispute resolution principles.
- 4.3. The Eucomed Code Committee will be composed of at least one representative of the Eucomed Legal Affairs Focus Group and at least one representative of the Eucomed Compliance Network, at least one representative from Member Associations, and chaired by the Legal Affairs Focus Group chairman.

5. Eucomed Compliance Panel

- 5.1. The Eucomed Compliance Panel shall have the following tasks:
 - Review consistency of interpretation of nationally applicable codes of conduct with the Eucomed Code by national Panels upon request and at its discretion.
 - Provide guidance on interpretation of the Eucomed Code and these dispute resolution principles.
 - Interact with relevant Eucomed groups to further develop the Eucomed Code and guidance
 - Handle complaints directly, as a first and last instance decision-maker, in all territories where there is no dispute resolution process which complies with these Eucomed dispute resolution principles or in cases where a Eucomed member is not a direct member of the relevant Member Association and has not agreed in writing to

be bound by such Member Association's national code in accordance with Point 3.3 of these dispute resolution principles.

- Member Associations shall take due account of the interpretation issued by the Eucomed Compliance Panel.

The Eucomed Board can allocate additional tasks to the Eucomed Compliance Panel as deemed appropriate.

- 5.2. The Eucomed Compliance Panel will be composed of at least three individuals. The chair should have a legal background and not be employed by a corporate member or Member Association. The chair will be appointed for renewable periods of 3 years, with a maximum of 6 years.. The chair shall appoint two other individuals for the Panel. The Panel will be composed not only of industry members, but also for obvious reasons of independence, transparency and expertise, of other relevant stakeholders.

6. Procedural principles

6.1. Reception of Complaints

6.1.1. Complaints may be lodged either with a national Member Association or with Eucomed. Adjudication of complaints shall be a matter solely for Member Associations at a national level, subject to section 2.8.

6.1.2. Complaints received by Eucomed shall be processed as follows:

- (i) Eucomed will forward any complaints it receives (without considering their admissibility or commenting upon them) to the relevant Member Association(s).
- (ii) Eucomed will send an acknowledgement of receipt to the complainant, indicating the relevant Member Association(s) to which the complaint has been sent for processing and decision.
- (iii) In addition, upon receipt by Eucomed of multiple external complaints (i.e. several complaints on the same or similar subjects lodged from outside the industry against several subsidiaries of a single company), Eucomed will communicate these complaints to the national association either of the parent company or of the EU subsidiary designated by the parent company.

6.1.3. Where the complaint relates to a territory in which there is no dispute resolution process which complies with these Eucomed dispute resolution principles, the matter will be referred to the Eucomed Compliance Panel that will act as a first and last instance decision maker. When deciding on such matters, the Eucomed

Compliance Panel will act in line with the Procedure contained in these Eucomed dispute resolution principles and will have the right to impose Sanctions in line with the ones enumerated below in paragraph 7.

6.2. Processing of complaints and sanctions by Member Associations

- 6.2.1. Member Associations shall ensure that industry and non-industry complaints are processed in the same manner, without regard to who has made the complaint. As a minimum, the national Panel should know the identity of the complainant.
- 6.2.2. Each Member Association's national Panel shall respect fair procedure rules allowing all parties to be heard fairly.
- 6.2.3. Each Member Association's national Panel shall take decisions and pronounce any sanctions to be applied on the basis of the national code of conduct in force in its country.
- 6.2.4. A complaint handling procedure should not be initiated or should be suspended in case of a formal investigation by criminal law enforcement authorities or commencement of criminal proceedings with respect to the same subject matter.
- 6.2.5. The procedural steps for dispute resolution should be as follows:
 - a. The first stage of the national dispute resolution procedure shall be the filing of a written complaint with the Member Association or the referral of such a complaint to a Member Association by Eucomed. Where a national Panel considers a complaint fails to establish a *prima facie* case of violation of its national code, such complaint shall be dismissed with respect to that code. Member Associations may also provide that any complaint, which a national Panel considers to be in pursuit of an entirely or predominantly commercial interest, shall be dismissed.
 - b. The second stage of the national complaints handling procedure shall be based on the general principle underlying these dispute resolution principles, 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:
 - o Within a reasonably short timeframe of receipt of a written complaint by a Member Association, a genuine mediation should be attempted, involving an independent third-party or mediator (e.g. national Panel member) or depending on the nature of the complainant an attempt to reach an amicable solution. For complaints between companies,

mediation should be a pre-condition for the continuation of the national 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 Member Association's complaints handling process.
 - If no amicable resolution of the complaint can be reached within a timeframe set by the mediator, the mediator shall direct complainant(s) to further pursue the complaint via the Member Association's complaints handling process, pursuant to which the national Panel shall ensure that a final decision is taken promptly in relation to each case thus referred to it for consideration.
 - When it appears to a Member Association that a company may have breached the code, it may direct its national Panel to treat this matter as a complaint.
- c. Member Associations may establish a national appeal procedure, pursuant to which either party may appeal in writing against a decision of the national Panel.
- d. At any time during a national dispute resolution process,
- Any of the parties (with the permission of the national Panel) or,
 - Within 30 days of a final decision by the national Panel, any of the parties (without permission of the national Panel)

may refer questions of interpretation of the Eucomed Code in writing to the Eucomed Compliance Panel, The Eucomed Compliance Panel. The Eucomed Compliance Panel may at its discretion either:

- decline to entertain the matter if it is felt that no question of principle is at issue or
- accept the interpretation referral, review 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 Code and the Dispute Resolution principles. The national Panel may make a

request for guidance at any time during a national dispute resolution procedure.

- The Eucomed Compliance Panel shall promptly issue guidance on the interpretation and no later than 60 days from receipt of a request for interpretation.

7. Sanctions

- 7.1. The potential sanctions available to Member Associations' national Panels must be proportionate to the infringement, predictable (and therefore published), act as a deterrent, and may include: written reprimand; requirement that the offender takes steps to conform with the national code (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 offender's cost and expense) of the offender'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 clarificatory information or statements; withdrawal of any '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 national Panels shall determine at their sole discretion, including publications at Eucomed meetings; prohibition against company representatives standing for elected office within the institutions of Eucomed/Member Association; suspension – with specific time limit and detail on conditions of 're-entry' - of membership of the Member Association and/or of Eucomed; expulsion from membership of the Member Association.
- 7.2. Member Associations shall ensure that any final decision (including any appeal decision) taken in an individual case 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:
- 7.2.1. In cases of a serious/repeated breach, the company name(s) may, in the discretion of the Member Association, be published together with details of the case(s);
 - 7.2.2. In cases of a minor breach, or where there is no breach, publication of the details of the case should exclude the company name(s).
- 7.3. Member Associations shall publish summaries in English of the main facts and conclusions of the national decisions that have precedent or interpretative value and are of international

interest (keeping in mind that cases resulting in the finding of a breach as well as those where no breach is found to have occurred may each have such value and/or interest). Member Associations are encouraged to publish in English the full decision.

- 7.4. The national Panels and the Eucomed Compliance Panel may consider and issue a statement with respect to non-compliant activities by non members.

