

EUCOMED COMPLIANCE



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WHAT IS EUCOMED



- Eucomed members include national trade and pan-European product associations and internationally active manufacturers of all types of medical technology.
- Eucomed represents 4500 designers, manufacturers and suppliers of medical technology used in the diagnosis, prevention, treatment and amelioration of disease and disability.
- The mission of Eucomed is to improve patient and clinician access to modern, innovative and reliable medical technology.

EUCOMED'S ETHICAL STATEMENT



- Eucomed's Members recognize that compliance with applicable laws and regulations and adherence to high ethical standards are both an obligation and a critical step to the achievement of Eucomed's mission, which is to provide innovative and cost-effective solutions that transform patients' lives. Moreover, Eucomed is taking a leadership role in promoting a culture of integrity and ethical business practices across the medical technology industry.

EUCOMED CODE OF EITHICAL BUSINESS PRACTICE



- Eucomed Code of Ethical Business Practice - Guidelines on Interactions with Health Care Professionals (September 2008)
- Eucomed Guidance Document - Q&A on the Eucomed Guidelines On Interactions with Healthcare Professionals (October 2010) (version 4)
- Eucomed Competition Law Compliance Guidelines (February 2004)
- Eucomed Code of Ethical Business Practice: Procedural Framework (October 2009)(amended February 2010)

Purpose of the Code and Implementation



- The Code of Ethical Business Practice is intended to provide ethical standards and principles within Europe for the medical technology industry. It is not intended to supplant or supersede national laws or regulations or other professional or other business codes which may apply to its members.
- However, Member associations must implement the principles included in the Eucomed Code.

Driving Factors



- Compliance is being driven by:
 - ✦ A desire to meet ethical standards which should apply to any industry
 - ✦ Public and government expectations
 - ✦ Local law (for example, France, Belgium, UK bribery act)
 - ✦ The US Foreign Corrupt Practices Act

Code Updates and Enforcement



- Eucomed Board
- Compliance Network
- Legal Affaires Focus Group
- Code Committee
- Secretariat

- Compliance Panel

Eucomed Compliance Panel



- Mandate set out in the Eucomed Procedural Guidelines, includes
 - Helping local device associations set up compliance panels
 - Providing Advisory Opinions referred by the Eucomed Secretariat
 - Giving advice to local compliance panels
 - Acting as a panel of first instance, where required
 - Assisting in European device compliance harmonization

Compliance Differences Between Pharma and Devices

Despite Pharm and Device convergence, there are differences:

- HCPs are “tied” to certain products for legitimate medical and safety reasons.
- HCPs are required for training.
- HCPs develop many medical device technologies and, as a result, act as consultants for certain device companies.
- HCPs rely heavily on device companies for technical and logistics support because of device costs and hospital budget restrictions.

Training, Education & Conferences



- The Eucomed Code Includes Two Sections Covering Training, Education and Conferences
 - Eucomed-Member Sponsored Product Training, Education and Conferences
 - Sponsoring Third-Party Educational Conferences

Rules to Follow with Regard to Third Party Conferences, Congresses and Exhibits



- HCP Sponsorship and financial support of Third Party Conferences by Eucomed Members is permitted but they must be « Bona Fide » educational, scientific or policy making conferences designed to promote scientific knowledge, medical advancement and assist in the delivery of effective health care.

Health Care Professional Sponsorship



Where permitted under national and local laws, regulations and professional codes of conduct, Eucomed Members may provide financial support to cover the cost of conference attendance by individual Health Care Professionals. Such financial support should be limited to the conference registration fee and reasonable travel, meals and accommodation costs relating to attendance at the event.

Conference Location



The Conference must be held at an “appropriate location” in an “appropriate setting”.

- a) The location should not be the main attraction
- b) Appropriateness applies no matter who organizes the event
- c) Eucomed Members should consider the location and image that it may project to the public when supporting an event.

Conference Attendees



At least some of the HCP attendees should be from the country or area where the conference is held.

Hotels



Hotels are permitted as conference locations but should not be the main attraction of the event. The hotel should not normally be a top category or luxury hotel.

Leisure Activities



Many hotels and conference centers provide leisure facilities. Conferences should not be organized in such a way as to permit HCPs attending to make use of such facilities during any significant part of a working day.

Eucomed Members may not pay for the use of leisure facilities, sports or similar activities by HCP's whom they sponsor to attend Conferences.

Direct Third Party Conference Support



- Eucomed Members may provide financial grants directly to third party conference organizers to reduce the overall cost of attendance for participants and to cover reasonable honoraria, travel, meals and accommodation expenses of Health Care Professionals who are *bona fide* conference faculty members.
- A written request must be made by the conference organizer, to the Eucomed Member and any sponsorship must be paid directly to the conference organizer or training institution.
- However, direct HCP attendee and faculty expense reimbursements are allowed against receipts.

Direct Third Party Conference Support



The conference organizer alone is responsible for the program content and the faculty selection.

Members may not have any detailed involvement in determining the content of the conference other than recommending speakers or commenting on the program where requested to do so.

Satellite Symposia



Eucomed Members may sponsor satellite symposia at third party conferences and provide presentations on subjects that are consistent with the overall content of the third party conference provided that all information presented is fair, balanced and scientifically rigorous. Members may determine the content of these events and be responsible for faculty selection. The arrangement must be documented by written contract and the support of the member must be disclosed in all materials relating to the satellite event.

Family, Spouses, Partners



Eucomed Members are not permitted to facilitate or pay for meals, travel, accommodation or other expenses for spouses or guests of Health Care Professionals, or for any other person who does not have a bona fide professional interest in the information being shared at the meeting.

Transparency



- Sponsored Faculty members should disclose that they are recipients of company sponsorships
- Members should require written notification of sponsorships to the HCP's hospital administration, superior or locally designated competent authority.

Conference Overlap Expenses



Generally, travel and accommodation support given by Eucomed Member companies to Healthcare Professionals should be strictly tailored to the duration of the conference or the event. However, where travel expenses incurred are significantly reduced by the Healthcare Professional travelling at alternative times, the travel arrangement may be extended. Any accommodation expenses relating to the extended stay must be met by the HCP.

Distributors and Agents



- Eucomed Members should require distributors, agents and others who interact with HCPs on their behalf to comply with standards equivalent to the Eucomed Code.

Eucomed Program Assessment



- Pilot Project for Conferences
- Traffic Light Tool
- Provides Guidance Only

EUCOMED WEBSITE



<http://www.eucomed.org>

Principles Set out in the Code



- ❑ Separation
- ❑ Transparency
- ❑ Equivalence
- ❑ Documentation

Interactions Between Healthcare Professionals (HCPs) and Eucomed Members



- Advancement of Medical Technology
- Safe and Effective Use of Medical Technology
- Research and Education

Research and Education



- Eucomed Members' support of *bona fide* medical research, education, and enhancement of professional skills contribute amongst others to patient safety and increase access to new technology.