

Eucomed Code Of Business Practice

Eucomed is an association representing the interests of European medical technology/device manufacturers. Eucomed believes that high quality, cost-effective medical technologies and related services can make a significant contribution to the safety and well being of patients and the improvement of healthcare systems.

Eucomed's members recognise that compliance with applicable laws and regulations and adherence to ethical standards are both an obligation and a critical step to the achievement of the aforementioned goals and can enhance the reputation and success of the medical technology/device industry.

This Code of Business Practice (hereinafter referred to as the "Code") is intended to provide guidance as to the minimum standards which should apply to its members' business practices in Europe and, generally, elsewhere. It is not intended to supplant or supersede national laws or regulations or other professional or other business codes (including company codes) which may apply to its members.

The associations that are members of Eucomed ensure that their respective codes of practice, if any, are compatible with the Eucomed Code of Business practice.

Specific Policies

Quality and Regulatory Compliance

Eucomed's members are committed to the production and supply of high quality medical devices and related services in the interest of patient safety and well-being.

Members should comply with the legal and regulatory requirements of the countries where they do business. These include both regulations specific to medical devices and general legal requirements applicable to the medical device and other industries.

The following paragraphs are not intended to be an exhaustive list of requirements but they do highlight areas of particular relevance to the medical device industry.

Interactions with Health Care Professionals

Compliance with applicable laws and adherence to ethical standards are important to the medical technology/devices industry's ability to continue to collaborate effectively with health care professionals. Such collaboration can take the form of:

- ▶ developing medical technologies;
- ▶ providing training, education, service and support to enable the safe and effective use of medical technologies; and
- ▶ supporting medical research, education, and enhancement of professional skills.

These activities are necessary to advance medical science, improve patient care.

To ensure ethical interactions with individuals or entities that purchase, lease, recommend or use members' products, members should duly consider the [Eucomed Guidelines on Interactions with Health Care Professionals](#).

Advertising and Promotion

Members should ensure that all promotional presentations, including product claims and comparisons, are accurate, balanced, fair, objective and unambiguous. They should be justified by appropriate evidence. Statements should not mislead the intended audience.

Unlawful Payments and Practices

Members should not directly or indirectly offer, make, or authorize payment of money or anything of material value, to unlawfully (a) influence the judgment or conduct of any individual, customer, or company; (b) win or retain business; (c) influence any act or decision of any governmental official; or (d) gain an advantage. This requirement extends not only to direct inducements, but also to indirect inducements made by a member in any form through agents, consultants or other third parties. Members should have particular regard to laws and regulations prohibiting or restricting inducements aimed at influencing clinicians or customers.

Competition/Antitrust and Procurement Laws

Members should conduct their business activities in accordance with the requirements of applicable competition and public procurement laws. Prohibited activities may consist of: a) agreements or understandings with competitors to fix prices, allocate customers or territories or restrict sales; b) exchange of pricing or other confidential information with competitors; and c), price discrimination or refusals to sell. Members should duly consider the [Eucomed Guidelines on Competition Law](#).

Export Controls and Sanctions

Members should ensure compliance with applicable export control laws and other rules restricting trade with certain countries.

Environmental Issues

Members should conduct their business in compliance with all applicable environmental laws and regulations.

Data Privacy

Members should ensure that patient data and other types of confidential or personal data be maintained and used in accordance with applicable legal requirements.

Compliance and enforcement

Members should take measures to ensure compliance with the principles of this Code by their employees, agents and representatives. Members should adopt effective compliance programs by issuing written policies and procedures, and in the case of corporate members, by conducting training programs and implementing clear procedures, controls and enforcement mechanisms.

Eucomed reserves the right as a last resort - in application of the relevant provisions or principles of its statutes - to withdraw membership from any member which Eucomed is convinced, does not follow the principles of this Code of Business Practice.