

## **EUCOMED GUIDELINES ON INTERACTIONS WITH HEALTH CARE PROFESSIONALS**

### **I. Preamble**

These guidelines are intended to provide guidance on the interactions of Eucomed members with individuals or entities that purchase, lease, recommend, use, arrange for the purchase or lease of, or prescribe members' medical devices ("Health Care Professionals").

There are many forms of interactions between Eucomed members and healthcare professionals that advance medical science or improve patient care, including:

- **Advancement of medical technology:** The development of innovative medical devices and improving existing products are often the result of collaborative processes between members and Health Care Professionals. Innovation and creativity are essential to the development and evolution of medical devices, often occurring outside the facilities of medical device companies.
- **Safe and Effective Use of Medical Technology:** The safe and effective use of medical technology often requires members to offer Health Care Professionals appropriate instruction, education, training, service and technical support. Regulators may also require this type of training as a condition of product approval.
- **Research and Education:** Members' support of *bona fide* medical research, education, and enhancement of professional skills contribute amongst others to patient safety and increases access to new technology.

Eucomed members recognize that adherence to ethical standards and compliance with applicable laws are critical to the medical technology/devices industry's ability to continue its collaboration with Health Care Professionals. Members should encourage ethical business practices and socially responsible industry conduct related to their interactions with Health Care Professionals. Members should also respect the obligation of Health Care Professionals to make independent decisions regarding treatment.

These Guidelines set out the standards appropriate to various types of relationships with Health Care Professionals. These Guidelines are not intended to supplant or supersede national laws or regulations or professional codes (including company codes) that may impose particular requirements upon members or Health Care Professionals who engage in certain activities in those countries. All members should independently ascertain that their interactions with Health Care Professionals comply with all current national and local laws, regulations and professional codes.

## II. Member-Sponsored Product Training and Education

Where appropriate members should make product education and training available to Health Care Professionals to facilitate the safe and effective use of certain medical technology. Such education and training programs should occur at appropriate locations taking account of the convenience of the attendees and the nature of the training. In particular:

- Programs and events should be conducted in clinical, laboratory, educational, conference, or other appropriate settings, including members' own premises or commercially available meeting facilities, that are conducive to effective transmission of knowledge and any required "hands on" training. The training staff should have the proper qualifications and expertise to conduct such training.
- Members may provide attendees with modest meals in connection with the program, and, for educational programs necessitating overnight stays, additional hospitality may be appropriate. Any hospitality should be modest in value, subordinate in time and focus to the educational purpose of the training and in compliance with the regulations of the country where the Health Care Professional is licensed to practice
- Members may pay for reasonable travel and lodging costs incurred by an attending Health Care Professional, in compliance with the regulations of the country where the Health Care Professional is licensed to practice
- Members should not, however, pay for travel 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. It may be appropriate for spouses or guests to participate in group hospitality, provided that incremental costs to members are nominal.

## III. Supporting Third Party Educational Conferences

Independent, educational, scientific, or policymaking conferences promote scientific knowledge, medical advancement and the delivery of effective health care. These typically include conferences organized by national, regional, or specialty medical associations or accredited continuing medical education providers. Members may support such conferences in various ways:

- *Conference Support.* Members may provide financial grants to cover conference costs and reasonable travel and lodging expenses of Health Care Professionals (and medical students, residents, fellows, and others who are Health Care Professionals in training) when the conference is primarily dedicated to promoting objective scientific and educational activities. Such support should be consistent with the regulations of the country where the Health Care Professional is licensed to practice. The conference organizer should be responsible for and control the selection of program content, faculty, educational methods, and materials. The support by a member should be clearly stated in advance of, at the meeting and in the proceedings.

- *Modest Hospitality.* Members may provide financial support to the conference organizer in the form of modest meals and hospitality for program attendees. Any meals and hospitality should be modest in value and should be subordinate in time and focus to the purpose of the conference.
- *Faculty Expenses.* Members may make grants for reasonable honoraria, travel, lodging, and meals for Health Care Professional who are *bona fide* conference faculty members.
- *Advertisements and Demonstration.* Members may purchase advertisements and lease booth space for company displays at conferences.

#### **IV. Sales and Promotional Meetings**

In the countries where it is appropriate for members to meet with Health Care Professionals to discuss product features, contract negotiations, and sales terms, these meetings should, as a general rule, occur at or close to the Health Care Professional's place of business. In connection with such meetings, members may pay for modest meals and hospitality for Health Care Professional attendees. Members may also pay for reasonable travel costs of attendees when necessary (e.g., for plant tours or demonstrations of non-portable equipment). However, it is not normally appropriate to pay for meals, travel, or other hospitality of Health Care Professional's guest or any other person who does not have a bona fide professional interest in the information being presented at the meeting.

#### **V. Arrangements with Consultants**

Health Care Professionals may serve as consultants to members, providing valuable *bona fide* consulting services, including research, participation on advisory boards, presentations at member-sponsored training, and product collaboration. It is appropriate to pay Health Care Professionals reasonable compensation for performing these services. The following factors support the existence of a *bona fide* consulting arrangement between members and Health Care Professionals:

- Consulting arrangements with Health Care Professionals should be written, signed by the parties and specify all services to be provided. Such arrangements should be consistent with the regulations of the country where the Health Care Professional is licensed to practice
- Compensation to Health Care Professionals consultants should be based on the nature of and commensurate to the services provided and not on the value of medical devices which consultants may use for their own practice; it should be paid based on services actually provided and in accordance with applicable tax and other legal requirements. Members may pay for reasonable expenses incurred by consultants in carrying out the subject of the consulting agreement.
- Consulting agreements should be entered into only where a legitimate purpose for the services is identified in advance.

- Selection of consultants should be on the basis of the consultant's qualifications and expertise to address the identified purpose.
- The venue and circumstances for member meetings with consultants should be appropriate to the subject matter of the consultation. Member-sponsored hospitality that occurs in conjunction with a consultant meeting should be modest in value and should be subordinate in time and focus to the primary purpose of the meeting.
- When a member contracts with a Health Care professional acting as consultant for research services, there should be a written research protocol and all required consents and approvals should be obtained.

## **VI. Gifts**

Members occasionally may provide modest gifts to Health Care Professionals, but these should be modest in value and in accordance with the regulations of the country where the Health Care Professional is licensed to practice. As a general rule, gifts should benefit patients or take a genuine educational form.

In addition, members may occasionally give Health Care Professionals branded promotional items of minimal value related to the Health Care Professional's work or for the benefit of patients. Gifts should not be given in the form of cash or cash equivalents.

This section is not intended to address the legitimate practice of providing appropriate sample products and opportunities for product evaluation.

## **VII. Provision of reimbursement and other economic information**

Members should support accurate and responsible billing to reimbursement authorities and other payors. In doing so, they may provide economic efficiency and reimbursement information to Health Care Professionals and third-party payors regarding members' products. This information should be limited to identifying appropriate coverage, coding or billing of member products, or procedures using those products, or to encouraging the economically efficient delivery of member products. This section is not intended to address the legitimate practice of providing technical or other support intended to aid appropriate use or installation of the member's products.

## **VIII. Donations for Charitable and Philanthropic Purposes**

Members may make donations (including grants) for a charitable or other philanthropic purpose, such as supporting genuine independent medical research for the advancement of medical science or education, indigent care, patient education, public education, or the sponsorship of events where proceeds are intended for charitable purposes. Donations should be made only to organizations or entities entitled to receive them under applicable local laws and regulations. All

donations should be appropriately documented. Examples of appropriate donations and related considerations are:

- *Advancement of Medical Education.* Members may make grants to support the genuine medical education of medical students, residents, and fellows participating in fellowship programs, which are charitable or have an academic affiliation or, where consistent with the preamble to this section, other medical personnel. (For additional considerations regarding educational grants, see Section III, Supporting Third Party Educational Conferences.)
- *Support of Research with Scientific Merit.* Members may make research grants to support genuine medical research. The purpose of the grant should be clearly documented. (For guidance as to the limitations that apply when a member contracts with a Health Care Professional to provide research on behalf of a member, see Section V, Arrangements with Consultants.)
- *Public Education.* Members may make grants for the purpose of supporting education of patients or the public about important health care topics.