

CPME/AD/Brd/160607/028/EN

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At its Board meeting in Mondorf-les-Bains on 16 June 2007, the CPME adopted the following resolution: **Joint Declaration of CPME – Eucomed on cooperation between physicians and the medical technology industry** (referring to CPME 2007/028 EN/FR)

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## **Joint Declaration of CPME – Eucomed on cooperation between physicians and the medical technology industry**

The medical profession, represented by the Standing Committee of European Doctors (CPME), and the medical technology industry, represented by Eucomed, aware of their responsibilities vis-à-vis patients and society, consider it essential to establish guidelines on the relationship between the medical profession and the medical technology industry.

Cooperation between the medical profession and the medical technology industry is both important and necessary in the development of medical technology and for the appropriate use of medical devices in healthcare. Collaboration is required at all stages of medical device development, as well as when they become available for use. The medical technology industry should make product training available to the physicians. Use of medical devices must be safe, efficient and useful for the patient.

It is of vital importance that the collaboration between physicians and the medical technology industry is based on respect for ethical principles, the rights of patients and the expectations of society, and is transparent whilst ensuring the independence of both parties when conducting their activities.

Competent authorities have set a legal framework within which collaboration in some areas is regulated. In addition to legal provisions, CPME and Eucomed consider it necessary to strengthen the adherence of both parties to their respective ethical principles. The medical profession and the medical technology industry have each adopted ethical principles which apply to the conduct of their activities. This joint declaration aims at identifying common principles and the most important aspects of the cooperation.

However, the ethical rules set out by the relevant national and international medical bodies, and the Eucomed Code of business practice cannot be superseded by the principles set out in this declaration. In addition, where local laws and

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regulations apply to interactions between physicians and the medical technology industry, the stricter rule should prevail.

The principles of this declaration shall apply also for activities taking place outside EU, EFTA and EEA countries when EU, EFTA or EEA physicians or industry are involved.

## **EDUCATION AND TRAINING ORGANIZED OR SPONSORED BY INDUSTRY**

Industry may arrange or sponsor education and training for physicians. Such events must have an identifiable and predominant educational content.

1. The information given should be based on scientific and medically relevant data.
2. Activities which form part of continuing professional development (CPD) should be, where applicable, certified by relevant bodies
3. In the announcement the purpose of the event should be stated.
4. The venue should be appropriate for the scientific purpose of the meeting, and should not involve travelling beyond what is reasonable.
5. Industry may pay for lecturers, study material and facilities that are needed for the meeting. It can also pay reasonable participant travel and lodging expenses but not for any accompanying persons.
6. Other forms of hospitality during such meetings should be modest and strictly limited to the purpose of the event. As an example, organising and sponsoring sporting events are prohibited.

## **SALES AND PROMOTION**

Information given to physicians by the industry is essential for the proper management of patient care. The content of information and promotional materials should be accurate, objective and balanced. During sales and promotional activities, both parties should observe certain principles.

1. Industry must:

- a) provide honest and up-to-date information regarding products and technologies, based on current scientific evidence;

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- b) ensure that sales representatives and other industry personnel providing information are adequately qualified and trained;
- c) disclose clinically relevant scientific data about their products and technologies;
- d) disclose without undue delay clinically relevant information obtained from post marketing studies;
- e) follow scientific and clinical reports concerning their products and technologies;
- f) offer and provide only modest and reasonable hospitality or gifts/benefits; the latter must be relevant to the practice of medicine.

## 2. Physicians must:

- a) not ask for gifts/benefits from industry;
- b) refuse excessive hospitality,
- c) report back to the manufacturer on adverse events associated with the use of the medical technology, irrespective of what national legislation may provide for;
- d) provide feedback of the technology performance at the request of the manufacturer.

## CLINICAL TRIALS

The cooperation between the medical technology industry and physicians in conducting clinical trials is essential to:

- the development of products,
- an in-depth knowledge of the products,
- their optimal use,

in order to obtain quality and safety regarding treatment of patients.

Clinical trials have to be conducted in such a way that the parties are scientifically as well as economically independent.

All partners in a trial must follow ethical and professional principles and guidelines such as the Declaration of Helsinki. Publishing of results should follow the highest editorial standards, such as the guidelines of the International Committee of Medical Journal Editors (ICMJE).

The aim of each trial must be stated beforehand and it should have a relevant scientific aim. The aim must always be the improvement of therapy, diagnostic methods and/or medical knowledge for the benefit of patients.

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The protocol must be drafted in such a way to ensure that the aim, design, methodology, planning and organization, statistical and scientific considerations, economical conditions, publishing and information to the participants in the trial are addressed.

As regards the participants the protocol must contain relevant clinical information and, wherever applicable, financial information.

The contract for clinical trials must be in writing and contain a detailed budget. Only persons with clinical relevant education, experience and training can be responsible for a trial. Aspects concerning responsibility and insurance have to be clear in the contract, including the insurance of participants.

A physician must not receive payment or other benefits for referring patients to clinical trials.

A physician may receive compensation for his/her work in the trial related to the work done and this compensation must be part of the information to the ethical committee reviewing the protocol. The compensation must not be linked to any expected outcome of in the study.

## **CONSULTANCY**

Physicians may act as consultants to the medical technology industry. In this capacity they may for example provide a service or give expert advice to industry, participate on advisory boards, in educational activities, research and product collaboration.

Connections to the medical technology industry of this kind must not compromise the clinical autonomy of the consulting physician, who always has to abide by the ethical duty to make medical decisions independently and practice medicine for the benefit of patients.

Consulting arrangements should be written, signed by the parties and specify all services to be provided. The arrangements must be consistent with the regulations of the country where the physician is licensed to practice.

Compensation for the consultancy should be commensurate to the work performed.

The venue and circumstances for meetings should be appropriate to the subject matter of the consultation.

When consulting physicians are presenting work which concerns the medical field of the consultancy to other parties, a declaration of interest should be presented to ensure transparency to all parties.

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