EUROPEAN SOCIETY FOR EMERGENCY MEDICINE



7-9 Breams Buildings London, EC4A 1DT, United Kingdom T: +44 (0)20 7400 6101 F: +44 (0)20 7067 1267 E: ruth.klassengreen@eusem.org W: www.eusem.org

EuSEM Policy on Conflict of Interest Issues Pertinent to Industry

In this document, the *Ethics Committee* (EC) of the *European Society for Emergency Medicine* examines the ethical aspects of the complex interactions and relationships with the pharmaceutical and medical device industry. Although, these industries make important contributions to medical progress and continuous medical education, financial exchanges and organisational ties might be prone to *conflicts of interest* that may adversely affect medical education, research, and clinical care.

The *Ethics Committee* aims to protect the interests of EuSEM members, sections and the public and ensure consistency and efficacy in the governance of EuSEM by addressing these issues of *conflict of interest* pertinent to industry.

1. Underlying Principles

1.1. Conflict of Interest

There is increasing concern that the interactions of physicians or professional organisations with the pharmaceutical and device industry lead to real or perceived ethical conflicts that might distort clinical research, medical education and influence clinical decision making. Potential *conflict of interest* is an unconscious process that can be very subtle, introducing bias that violates both the best interests of patients and the standards of scientific integrity. A dependency on industry for support inevitably creates both the perception and reality of conflicts of interest and jeopardises public trust on its mission of conducting educational programs and setting practice guidelines that should reflect only the best scientific knowledge. 9

Conflict of interest with pharmaceutical and device industry exists when:

- a. physicians have motives or are in situations for which reasonable observers could conclude that the moral requirements of the physician's roles are or will be compromised,²
- b. a primary ethical or professional interest clashes with financial self-interest,³

- c. physicians are tempted to deviate or do deviate from their professional obligation to the patient for economic or other personal or institutional gain,¹
- d. industry funding of professional and educational activities might lead to bias and therefore influence and undermine clinical decision making, adversely affecting health care delivery.¹¹

1.2. Definition of Sponsorship

The following is the definition of sponsorship from Commercial Sponsorship—Ethical Standards for the NHS⁴: "Sponsorship is defined as funding from any external source, including funding of all or part of the costs of employing a member of staff, research, training, pharmaceuticals, equipment, meeting rooms, costs associated with meetings, meals, gifts, hospitality, social activities, accommodation and transport costs (including trips abroad), and provision of free services (speakers), buildings or premises". This definition excludes purchasing exhibition space in conferences and paid advertising in journals.

2. Recommendations for Controlling Potential Conflicts of Interest

The EC recognises that there is a requirement for partnerships between EuSEM and industry, but this collaboration must be ethical and transparent and in no way should one party be dependent on the other for its activities. ^{6,8}

The EC believes that there are potential conflicts of interest between EuSEM and the pharmaceutical and medical device industry that might affect the activities of EuSEM and its members. The EC proposes this *Policy* to provide guidance from an ethical point of view with the purpose to ensure independence, scientific integrity and full transparency, and prevent the appearance or reality of undue industry influence.

This Policy addresses, as a first step, the following four areas in relationships with industry:

- 1. unrestricted industry donations grants,
- 2. industry funding of educational events organised or sponsored by EuSEM,
- 3. industry financial support for specific services,
- 4. industry funds for research.

2.1. Unrestricted Industry Donations - Grants

This relates to funding of EuSEM for general activities

- 1) As a matter of policy, EuSEM will never accept donations, sponsorship or support of any kind from manufacturers or distributors of tobacco.
- 2) All funds from industry should be *truly unrestricted*—given for the purpose of supporting the mission of EuSEM and its sections.

- 3) The donor should not have control over the use of the funds, the content of the educational activity or the focus or design of the grant.
- 4) Donations, grants or benefits in kind must be transparent and subject to peer review by *the Executive Committee* and the information relating to this made publicly available with a full declaration of relationships with industry.
- 5) The donated funds should be pooled and administered through the EuSEM Executive Office.
- 6) The EuSEM *Executive Committee* should disburse funds to EuSEM approved CME activities and research programs so that the recipients of funds remain free from influence by the donor.
- 7) EuSEM should restrict support from industry (except for paid journal advertising revenue and congress exhibition fees) to a predetermined amount, which usually should not exceed 25% of the operating budget of EuSEM". In this event the decision shall be with the *Executive Committee*.
- 8) No single industry source should be responsible for the majority of total industry funding of EuSEM.
- 9) Under no circumstances should EuSEM and its sections collaborate in industry marketing activities or profit from them.⁹
- 10) EuSEM and its sections must have the freedom to take positions on health-related issues that may be unfavourable to its funders.⁹
- 11) EuSEM and its sections must set their own agendas and priorities and not allow commercial funding to dictate their activities; neither should proposed industry support for a project alter their agendas.
- 12) EuSEM should not solicit or accept an offer from a drug or device company that would attach EuSEM's name or logo to a commercial product, service, or activity.
- 13) In the interests of transparency when a company makes a donation a simple acknowledgement of the company's name and logo shall be placed on the website.

According to the European Federation of Pharmaceutical Industries and Associations (EFPIA) HCP Code, article 11, "donations, grants and benefits in kind to institutions, organisations or associations that are comprised of healthcare professionals are only allowed if: (i) they are made for the purpose of supporting healthcare or research; ... (iii) they do not constitute an inducement to recommend, prescribe, purchase, supply, sell or administer specific medicinal products".⁵

2.2. Industry Funding of Educational Events organised or sponsored by EuSEM

Scientific Committee of Educational Events

The findings that gifts and payments, even when small, influence physicians' beliefs and behaviours,³ are likely to influence the individuals and committees who select CME topics and the speakers who deliver them.

- The Chairperson and the members of the Scientific Committee must declare openly any interests with industry, which would potentially result in real or perceived conflict of interest, while any previous ties should be *transparently* stated at the outset.
- 2) All members of the Scientific and/or Organising Committee must provide to the EuSEM *Executive Committee* the EACCME® written declarations of potential or actual conflicts of interest (any fee, honorarium or arrangement for reimbursement of expenses in relation to the event) upon submission of the application for accreditation.¹²
- 3) Declarations of conflicts of interest must be made readily available, either in printed form, with the programme of the educational event, or on the website of EuSEM.¹²
- 4) Where there has been an actual conflict of interest involving a member of the Scientific and/or Organising Committee, the Ethics Committee must be advised on how this has to be resolved.¹²

Programme of Educational Events

- 5) Accreditation of congresses and educational courses for CME purposes must be sought from an independent organisation such as EACCME®.
- 6) EuSEM must expressly prohibit industry influence over the choice of speakers and content of programmes.⁹
- 7) Industry should not be allowed to fund or be identified in the programme with specific lectures or individuals. Lectures should not be named after commercial organisations. ¹⁰
- 8) Industry-presented education should not be scheduled to compete with CME activities, should be carefully distinguished and clearly delineated from science and education.
- 9) All educational material must be free of any form of advertising and any form of bias. 12
- 10) The EACCME® accepts a single page acknowledgement, in the scientific programme, where all sponsors are recognised for their support. ¹²
- 11) All advertising components (including the list of exhibitors) must be clearly separated and distinguished from the scientific/educational components of the programme and identified as such. ¹²
- 12) Programmes should include the names of satellite symposia only if they are clearly identified as industry sponsored (see below).

Faculty of Educational Events

13) All chairpersons and speakers must provide written declarations of potential or actual conflicts of interest (e.g. paid consultant, research grants) and show a slide with possible academic conflicts of interest and any links with the health-care industry before presentation.

- 14) Declarations of conflicts of interest must be made publicly available, either in printed form, with the programme of the event, or, in electronic form, on the website of the organiser using the template, available by EACCME®. 12
- 15) The declarations must be retained for at least one year after the event for potential review by the EACCME®. 12
- 16) The EACCME® considers it a responsibility of the head of the Scientific and/or Organising Committee to ensure that actual conflicts of interest are resolved. 12

Satellite Symposia organised and supported by industry

- 17) EuSEM should follow the European Accreditation Council for Continuing Medical Education (EACCME®) policy about commercially sponsored Satellite Symposia. 12
- 18) Satellite symposia should be clearly marked as sponsored by industry, identified as being separate from the scientific programme and listed in a separate and clearly identifiable section.
- 19) Satellite symposia should be held at special times that do not coincide with any scientific sessions and do not interfere, nor compete with, the accredited CME activities.
- 20) Satellite symposia provided by the pharmaceutical and medical equipment industries which form parts of an educational event approved for CME, do not get separate approval for CME credits by EACCME®. 12
- 21) It should be made clear to all participants that EuSEM does not endorse the industry's scientific programmes.

Funding of Educational Events

- 22) Educational grants must be without "strings attached", transparent and subject to peer review and should always be acknowledged in the printed programme.
- 23) All funding must be provided free of any attempt to influence the programme, individual sessions, subjects for discussion, content or choice of Faculty members.¹²
- 24) The Provider must provide to EACCME® documentation confirming the basis of the funding for the Educational Event, whether this is by sponsorship, educational grant, or any other means, but with no need to provide the actual amounts. 12
- 25) In the programme should be clearly written that EuSEM does not explicitly endorse the content or the product that is discussed at an industry sponsored symposia.

Exhibition at Educational Events

26) Any company participating in a trade exhibition at a EuSEM meeting must meet all the requirements included in the industry codes of practice by the European Federation of Pharmaceutical Industries and Associations (EFPIA)⁵ and the International Federation of Pharmaceutical Manufacturers Associations (IFPMA).7.

27) Industry could be allowed to purchase and occupy booths at conferences in adjoining exhibit hall space. Delegates must be able to avoid exhibits if they wish while they are moving between sessions at the event. Marketing and trade exhibits must be clearly designated as such so that attendees understand that they are entering marketing site, and are free to do so or not to do so as they choose.⁹

2.3. Industry Financial Support for Specific Services

<u>Development of practice guidelines or outcome measures</u>

- 1) Academic independence and integrity is especially important in the development of clinical guidelines, and so particularly rigorous standards are required.
- 2) The establishment of guidelines and registries must be independent of all influence from industry, whether, actual or perceived.
- 3) EuSEM and its sections could accept industry support to develop practice guidelines or outcome measures as long as they have no influence on the guidelines' content or the review process, and as long as the travel and accommodation provided to members of such a guideline committee for meetings is reasonable and absolutely transparent.
- 4) All members of clinical practice guidelines committees must complete a full disclosure of interests, which must be mentioned in the publication of the Guidelines.
- 5) At a minimum, persons with a clear conflict of interest, including direct salary support, research support, or additional income from industry whose product sales could be affected by the guidelines, should be excluded from such committees.
- 6) No employee of a pharmaceutical or medical device or technology company can be a member of a Guidelines committee.
- 7) EuSEM publications and documents should always stand alone, and not bear the logo of a drug or device company or be associated with a commercial brand.

Website

- 8) The EuSEM homepage should not be sponsored.
- 9) Any sponsor of EuSEM should be acknowledged on a dedicated sponsor acknowledgement page under agreement with paragraphs 2.1.13, 2.2.10 and 2.2.22.
- 10) Links to sponsored educational sites are permitted but there should be no direct link to commercial sponsors.

2.4. Industry Funds for Research

- 1) Scientific research may be supported by unrestricted grants from industry. Industry should be allowed to provide a grant for a project of its choosing or be associated with a specific project, approved by the research committee, but without any further involvement.
- 2) Industry funding of research should be clearly acknowledged with a full declaration of its involvement and interest.
- 3) All industry funded research should be performed independently of the sponsors and it should not be influenced by industry. EuSEM and its sections should retain full control of the title, scientific content, methodology, results and conclusions.¹⁰
- 4) Industry funding should not affect the outcome or the dissemination of the outcome of any research or when and where findings should be presented and published.
- 5) No industry sponsorship agreement will include the right of the company to 'veto' the publication of the results of the study.
- 6) Research funds from industry, like educational support from industry, should go to the EuSEM Executive Office for disbursement as described above.

2.5. Approval by Legal Advisors

Following the approval of a funding proposal by the EuSEM *Ethics* and *Executive Committees*, any proposed industry funding may need to be discussed with a EuSEM legal advisor prior to final acceptance on the recommendation of the *Executive Committee*.

3. References

- Brennan TA, Rothman DJ, Blank L, Blumenthal D, Chimonas SC, Cohen JJ, Goldman J, Kassirer JP, Kimball H, Naughton J, Smelser N. Health industry practices that create conflicts of interest: a policy proposal for academic medical centers. *JAMA* 2006;295(4):429-33.
- 2. Coleman DL. Establishing Policies for the Relationship Between Industry and Clinicians: Lessons Learned From Two Academic Health Centers. Acad Med 2008;83:882–887.
- 3. Dana J, Loewenstein G. A social science perspective on gifts to physicians from industry. *JAMA*. 2003;290(2):252-255.
- 4. Department of Health. Commercial Sponsorship Ethical Standards for the NHS, 2000. http://www.uhb.nhs.uk/pdf/DohGiftsGuide.pdf Accessed 16 February 2014.
- 5. EFPIA. EFPIA HCP Code on the Promotion of Prescription-Only Medicines to, and Interactions with, Healthcare Professionals, 2011. www.http://www.efpia.eu/uploads/Modules/Documents/efpia-

- $code_promotion_hcp_-_11.06.14_final_editing_07-08-11-mcp-20110630-002-env1_1.pdf$ Accessed 15 February 2014.
- 6. European Society of Cardiology. Relations between professional medical associations and the health-care industry, concerning scientific communication and continuing medical education: a Policy Statement from the European Society of Cardiology. *Eur Heart J* 2012;33:666–674.
- 7. IFPMA. IFPMA Code of Pharmaceutical Marketing Practices, 2006 Revision. http://www.ifpma.org/fileadmin/content/Ethics/IFPMA Marketing Code/The Code/IFPMA Code 2006 Revision EN.pdf Accessed 15 February 2014.
- 8. Letters-Industry Support and Professional Medical Associations. JAMA 2009; 302(7): 737-739.
- 9. Rothman DJ, McDonald WJ, Berkowitz CD, Chimonas SC, DeAngelis CD, Hale RW, Nissen SE, Osborn JE, Scully JH Jr, Thomson GE, Wofsy D. Professional medical associations and their relationships with industry: a proposal for controlling conflict of interest. JAMA 2009;301(13):1367-72.
- 10. Royal College of Psychiatrists. Good Psychiatric Practice. Relationships with pharmaceutical and other commercial organisations. College Report CR148. The Royal College of Psychiatrists 2008. http://www.rcpsych.ac.uk/files/pdfversion/cr148.pdf Accessed 9 December 2013.
- 11. Schofferman Jerome. Ethical Challenges for the Pain Physician: Recognizing Conflicts of Interest. *Pain Medicine* 2006; 7(5): 457-465.
- 12. UEMS Council. The Accreditation of Live Educational Events by the EACCME. UEMS 2012 / 30. http://www.uems.net/index.php?id=70. Accessed 9 December 2013.

For the Ethics Committee

Prof. Helen Askitopoulou

7th March 2015

EuSEM Ethics Committee

Askitopoulou, Helen (chair), Greece

Babakhanlou, Rodrick, UK

Beattie, Tom, Scotland

Bentner, Thomas, Germany

Foex, Bernard, UK

Garcia-Castrillo, Luis, Spain

Graham, Colin, Hong Kong

Hogan, Barbara (ex-officio), Germany

Leach, Robert, Belgium

Sabbe, Marc, Belgium

Spiteri, Anna, Malta

Spruyt, Carolina, Netherlands

Williams, David, UK