EDITOR’S NETWORK

Relations between professional medical associations and healthcare industry, concerning scientific communication and continuing medical education: a Policy Statement from the European Society of Cardiology

Relações entre associações médicas profissionais e a indústria dos cuidados de saúde, relativamente à comunicação científica e a educação médica contínua — uma Declaração de Política da European Society of Cardiology

Sociedade Europeia de Cardiologia

ESC Board 2010-2012

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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

ESC Board*

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Introduction

In recent decades, cardiology has been a fast-moving medical speciality. Many advances have come from basic and clinical research conducted by universities and by pharmaceutical and medical device companies. Innovations have been realized in part through productive collaborations between clinicians, academia, and industry. Such links are essential and need to be encouraged and supported by appropriate investment if medical progress is to be sustained.

The implementation of medical advances is possible only if they are communicated effectively to the scientific and clinical communities, and each cardiologist must keep up-to-date to be able to offer patients the best possible care based on medical progress. When new drugs, devices, or diagnostic tools are promoted by industry, the primary motive is commercial. When industry is supporting medical educational activities or scientific meetings, whether directly or indirectly, communication may lack objectivity. Concerns that vested interests may distort education and then clinical decision-making have led to increasing public scrutiny of the relationships between industry, the medical profession, and medical societies.1–5

The links between industry, health-care professionals, and medical associations must be reviewed critically to ensure that...
these relationships are ethical and transparent. For a professional medical association such as the European Society of Cardiology (ESC), this is particularly important within the field of scientific communication and continuing medical education (CME). The purpose of this paper is to address these issues and to describe the policy of the ESC.

### Scientific communication and continuing medical education

The results of medical research are communicated and disseminated by many different providers of CME using a variety of educational tools (Table 1). Educational programmes are often delivered by combinations of organizations acting in partnership (Figure 1).

#### Professional associations: the ESC approach

The educational activities of the ESC, and similar activities by other medical associations, meet important societal and professional needs. The mission of the ESC is ‘to reduce the burden of cardiovascular disease in Europe’. By providing balanced and neutral educational resources and scientific communication, it assists specialists to improve their professional standards.

The annual ESC Congress is attended by about 25 000 professional delegates from 140 countries. Scientific, educational, and clinical practice sessions are organized in total independence by the Congress Programme Committee, which has about 50 members; none of these being an industry employee. Roughly 10 000 scientific abstracts are submitted and 40% are selected for presentation after a systematic and anonymous peer-reviewed process.

The ESC also organizes five subspecialty congresses, meetings dedicated to basic research, and clinical CME courses. Its website (escardio.org) offers educational resources such as e-learning programmes, webcasts, slide archives, and online access to the scientific abstracts of its congresses. The ESC publishes seven peer-reviewed general and specialist cardiology journals, from which around 4.5 million electronic downloads of scientific papers are made each year.

The ESC develops clinical practice guidelines for optimal patient care based on a comprehensive review of the published evidence on a topic. This process involves assessment of the strength of evidence of the benefits and risks of treatments and debate among experts to achieve consensus. Between 2005 and 2010, 26 ESC Clinical Practice Guidelines were published or updated. During 2009 and 2010, other scientific bodies within the ESC published another 50 scientific statements and expert consensus documents on more focused topics and the results of several registries and surveys have also been published by our society.

While these activities are organized independently by the ESC, their costs are offset indirectly and in part by funding that the ESC receives from the health-care industry. The exhibition at the annual ESC congress allows attending cardiologists to receive up-to-date information on diagnostic and therapeutic products which they might consider using in clinical practice. Importantly, satellite symposia organized and supported by industry are clearly identified in the programme as being separate from the scientific sessions organized by the Congress Programme Committee.

#### Health-care companies

Private companies have a future only if they are profitable. In a market economy, they have a legitimate right to promote their products and they need to do so to remain successful. Health-care companies are no exception, but the goals of marketing initiatives include introducing research results and new products to physicians as well as delivering sales. It can be argued that the long-term interests of a medical company will be served better by providing education for clinicians that is accurate and impartial, instead of offering promotion that is commercial. If the correct treatment is applied to the right
patient at the right time, then the maximum benefit may be achieved for both the patient and the company.

All promotional and educational activities of industry are bound by strict regulations. The rules that must be adhered to in Western Europe include those from the European Federation of Pharmaceutical Industries and Associations (EFPIA) and the International Federation of Pharmaceutical Manufacturers Associations, as well as national recommendations. International anti-bribery and anti-corruption laws include the Anti-bribery Convention of the Organisation of Economic Cooperation and Development, published in 1997 and revised in 2009. All international medical companies that operate in the USA must also meet the requirements of the US Foreign Corrupt Practices Act of 1977. According to all these regulations, a company should ensure and take responsibility for full compliance with all relevant laws, codes, or guidelines regarding all promotional activities and materials. In addition, all financial relationships between a company and an individual physician will now be made public following the “Sunshine” Legislation. Marketing initiatives such as satellite symposia are subject to the same regulations as other programmes. All aspects of the participation of a medical company in an exhibition at a medical congress in Europe are also governed by the codes of practice published by EFPIA. Only ‘reasonable and proportionate’ expenditure on promotion of a product is permissible. Compliance is subject to random inspections by external assessors.

**For-profit continuing medical education companies**

In recent years, CME companies have been founded to provide educational meetings for doctors which are not organized by pharmaceutical or device companies. They frequently organize meetings on behalf of industry, however, and their profitability as third-party providers of CME may depend on how well they satisfy the expectations of industry. Even when these new companies organize meetings for universities or professional associations, financial sponsorship may be sought from health-care companies. The Macy report in the USA recommended that such support should be discontinued.

Meetings organized by for-profit CME companies are not guaranteed to be free of influence or bias. Direct sponsorship by industry to professional associations, in the form of unrestricted educational grants, might be more transparent than indirect sponsorship of a similar event run by a CME company. In the USA, nationally accredited CME organizations received $1.2 billion in commercial support during 2007, and much of this was probably used for types of CME that are relatively ineffective in changing clinical behaviour and improving patient outcomes.

**The wider context: current concerns**

There is disquiet both within the medical profession and in the media about the influence of the health-care industry on prescribing patterns and on the use of medical devices by health-care professionals. The fundamental concern is that ties with industry lead to real or perceived ethical conflicts. This may affect prescribing patterns and the selection of drugs for hospital formularies, and it might bias publications or influence the content of industry-funded CME activities. To minimize the chance that commercial influences might affect clinical decisions, there have been calls for medical societies to be funded from membership dues, subsidies, and foundations rather than through grants from industry.

Unsurprisingly, authors from different perspectives have widely divergent views.

If a diagnostic or therapeutic advance in medicine cannot be commercialized, then it is unlikely to be widely promoted and it may not be implemented. It has been suggested that the introduction of new cardiovascular treatments into routine clinical practice would have been much slower if the health-care industry had operated in a vacuum. In this context, some activities that are both educational and promotional may yet lead usefully to the more rapid dissemination and adoption of genuine advances.

The risk of bias in medical education is not restricted to activities that are supported by industry. It can affect any type of scientific communication, even an educational meeting organized independently by a university or medical association (Table 2). Whatever its context, a physician should always be sceptical when interpreting any educational or scientific presentation. The chance of bias can be represented on a continuous scale with subtle shading between grades and with varying combinations of possible intellectual (or ‘academic’) and commercial influence (Figure 2). It is hard to identify where precise boundaries could be drawn between what would be acceptable and what would not; of the examples presented, some (e.g. c) would be judged unacceptable but others (such as a and e) would meet the current ethical standards yet still carry some risk of bias.

It has been argued that conflicts of interest are unavoidable and difficult to recognize and that they cannot be abolished either by disclosure or by education. Others have suggested that ‘competing interests’ may be a more helpful indicator of potential bias than ‘conflicts of interest’ and that only ‘significant’ relationships might disqualify an individual from particular educational roles.

European drug regulatory agencies have determined that although conflicts of interest cannot be eliminated, the risk of bias can be managed.

The Association of American Medical Colleges has stated that there are benefits from effective partnerships between industry and academic medical centres. Basic and clinical scientists are now exhorted by their universities to protect their intellectual property by patenting their discoveries or inventions, and they are encouraged to exploit them or commercialize their research by starting up small companies. The European Commission places great importance on the development of new small and medium enterprises within the health-care sector as a stimulus for economic development; its policy states that ‘cooperation between the worlds of science and the world of business must be enhanced’. Thus, ironically, recent criticisms of links with industry, which have been addressed to medical associations, have coincided with encouragements to individual physicians and researchers to become involved in industry.

It appears that public concerns are not about commercial activity per se, but it is unclear exactly where criticism is directed and when involvement with industry is acceptable or encouraged.
Relations between the medical profession and industry

Doctors have an ethical duty to undertake CME, and in at least 16 European countries, this is already required for the revalidation of their license to practice. 25–32 There are considerable variations around Europe in how CME is provided. 32,33 Detailed data about the expenditure by pharmaceutical and device companies in Europe on CME are not available, 14 but it can vary from about 20% of total provision in Denmark to almost complete support for CME in Italy. 32

In France, the total governmental budget for CME is €64.9 m per year. Since 85% is allocated to family practitioners, only €9.7 m is available to be shared between all 95,000 specialists; 21,33 this works out at €100 per specialist per year. In the UK, the Royal College of Physicians favours cutting ties between industry and medical education, relying instead on the Royal Colleges and the Department of Health to support postgraduate medical education, 34 but no formal budget has been allocated to individual physicians to support this. In Germany, doctors usually have to pay for their own CME activities, 32 but in the Netherlands, academic medical specialists each receive a budget of €5,000 per year for their CPD, 37 and in Belgium, doctors who have been accredited for CPD can charge slightly higher fees. 32 In Finland, the employer should pay 80% of the expenses of CME for its physicians, and the government 20%. 32

In the USA, CME was a $2.3 billion business in 2008 with 44% of income originating from commercial sponsors. 32 Pharmaceutical and device companies spent $1 billion on CME, of which 45% went to for-profit CME companies, 22% to universities, 19% to professional societies, 4% to hospitals, and 10% to other providers. 34 In 2009, from a budget approaching $700 million, the American Heart Association (AHA) spent $82 million on professional education and training. 39 Thus, the USA could perhaps

<table>
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<tr>
<th>Context</th>
<th>Examples of possible bias</th>
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<tr>
<td>Teacher in university or hospital</td>
<td>Limited depth and range of knowledge or understanding of lecturer</td>
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<td></td>
<td>Disproportionate presentation of material of greatest interest to lecturer</td>
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<tr>
<td>Lecturer at an educational meeting or course</td>
<td>Inadequate preparation</td>
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<td></td>
<td>Lack of objectivity—presentation of personal view as consensus on topic</td>
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<tr>
<td>Invited lecturer at a professional congress</td>
<td>Concentration on lecturer’s own research, without acknowledging precedence or results</td>
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<td>from other research groups</td>
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<td>Lecturer at a sponsored satellite symposium</td>
<td>Favourable references to studies performed by friends and acquaintances</td>
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<td>Failure to disclose holding of patents, or other financial interests, relating to topic</td>
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<tr>
<td>Medical textbook</td>
<td>Selective presentation of topic, without reference to alternative products from other manufacturers</td>
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<td>Omission of material critical of products of sponsoring company</td>
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<td>Clinical guidelines</td>
<td>Non-systematic review of topic</td>
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<td>Consensus rather than meta-analysis</td>
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<tr>
<td>Scientific abstract presentation</td>
<td>Premature and selective reporting of results using preliminary data, which may not be confirmed by final analysis</td>
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<td>Scientific manuscript in peer-reviewed journal</td>
<td>Scientific fraud</td>
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<td>Selective statistical analysis and/or presentation of results</td>
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<td>Preferences or prejudices of reviewers</td>
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<td>Publication bias</td>
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Whether or not an unrestricted educational grant afforded to limit or exclude industry support for CME, in order to rely more heavily on public grants.

Should Europe choose to follow the strategy proposed in the USA, severing links between industry and medical societies, CME could be severely compromised. Relying completely on public funding is not a viable option for Europe at the moment. The removal of industry support for medical associations would be followed by increased fees and reduced attendance at congresses especially by clinical trainees and young fellows. It is the view of the ESC that in the absence of alternative funding, or until alternative funding is identified, maintaining links with industry is appropriate as long as educational and scientific products remain independent, effective, and unbiased and as long as the relationships between ESC experts or spokespersons and industry are transparent and appropriately disclosed.

**Recommendations**

Health-care providers, educators, professional associations, and industry must act collectively and individually to acknowledge and eliminate real or perceived bias. The future probity of medical education in Europe depends on devising legitimate and ethical collaborations between health-care providers, academic institutions, professional associations, charitable foundations, and industry.

The ESC advocates a principled and balanced approach that acknowledges disclosures of interest between health-care professionals and industry, and aims to provide honest and unbiased education for health-care professionals.

The goal of CME is to develop, maintain, or increase the knowledge, understanding, procedural skills, and professional performance of physicians, to enable them to provide the highest quality of care for their patients. All educational programmes, irrespective of whether they originate from the ESC, CME providers, industry, or regulatory bodies, should adhere to essential guiding principles. They should be evidence-based, have clearly defined educational objectives, have a clearly defined target audience, and be free of commercial bias.

Courses must be evaluated on the basis of their scientific merit, quality, practical utility, perceived evidence base, potential bias, innovation, and teaching methods. The ESC seeks accreditation of its educational programmes through the European Accreditation Council for Continuing Medical Education (EACME) and the European Board for Accreditation in Cardiology (EBAC), under the auspices of the European Union of Medical Specialists (UEMS).

The providers of CME should endeavour to provide educational resources and opportunities that are appropriate and effective. Over time, this may require a cultural change with less dependence on traditional formats including lectures and increased provision of small-group practical sessions based on clinical cases, which may be more effective in changing physicians’ behaviour.

Whether or not an unrestricted educational grant influences the behaviour of physicians would merit study, since there is little empirical evidence concerning the possible impact of funding to medical associations on the effectiveness of their educational courses.

Cooperation between the academic and private sectors is important for medical research, and it is not incompatible with the provision of some categories of CME as long as appropriate safeguards are in place. Joint educational programmes may be needed for the training of physicians and surgeons in the use of new medical devices. It is particularly important that any collaboration between the medical profession and industry is completely transparent and
that educational objectives are paramount. Recommendations concerning the disclosure and management of possible conflicts of interest have been published in Europe, the USA, and elsewhere and these are broadly accepted by the ESC.

The ESC has adopted the following specific code of conduct. This assures the provision of unbiased, evidence-based, and high-quality CME in cardiovascular medicine.

**Congress and educational courses**

1. Every member of a congress programme committee must complete a declaration of interests. No employee of a medical company can serve as a member of a programme committee.
2. The Chairperson of the Congress Programme Committee should have no relation with industry which would represent a significant conflict of interest during his/her term of office.
3. The joint selection of sessions by members of a programme committee must be based only on scientific merit.
4. Speakers should be selected for a session to provide a balanced view or a comparison between protagonists, with time allocated for questions and discussion.
5. All chairpersons and speakers must complete a disclosure of interests.
6. All chairpersons and speakers must show a slide with their disclosure of interests, for long enough to ensure that the audience has time to read all of its contents. This should include a statement of possible academic conflicts of interest as well as any links with the health-care industry.
7. It is the responsibility of the chairpersons during any session to bring to the attention of the audience any clear conflicts of interest that have not been disclosed, or any apparent major bias in the content of a presentation.
8. Each individual attending a scientific congress or educational course should exercise his or her own judgement when assessing the integrity and quality of each presentation.
9. These recommendations apply to the annual Congress of the ESC, to the subspeciality congresses organized by the ESC Associations, and to other educational courses organized by the ESC and its constituent bodies, such as Update Meetings, and Educational Courses at the European Heart House.
10. Accreditation of congresses and educational courses for CME purposes should be sought from an independent organization such as EACCME or EBAC.

**Satellite symposia**

11. Satellite symposia should be clearly marked as sponsored by industry and the commercial motive and risk of influence in such events should be recognized. If details are included in a conference programme, then they should be listed in a separate and clearly identifiable section (e.g. on differently coloured paper).
12. Satellite symposia should be held at special times that do not coincide with any scientific sessions.
13. Company products must not be advertised in the lecture theatre, meeting room, or conference hall.
14. Academic invited speakers are accountable for the information presented on their slides.

**Trade exhibitions**

15. Any company participating in a trade exhibition at an ESC congress must meet all the requirements included in industry codes of practice.

**Unrestricted grants**

16. The concept of an ‘unrestricted educational grant’ from a pharmaceutical or medical device company is permissible. Funds obtained through unrestricted educational grants will be disbursed for CME activities at the sole discretion of the ESC.

**Webinars, e-learning, and distance learning**

17. The requirements for transparency are the same for distance learning courses and internet-based educational activities, as for congresses and face-to-face educational meetings. All faculty members must complete a disclosure of interests. Direct company sponsorship is not permitted, but support in the form of unrestricted educational grants is allowable.

**Clinical practice guidelines**

18. Academic independence and integrity is especially important in the development of clinical guidelines, and so particularly rigorous standards are required.
19. No employee of a pharmaceutical or medical device or technology company can be a member of a Guidelines committee.
20. Any form of direct company support for the development of a guideline is not permitted.
21. All members of the Clinical Practice Guidelines committee and all members of individual Guidelines Task Forces must complete a full disclosure of interests. In an individual Task Force of the Clinical Practice Guidelines Committee, these disclosures are shared between Members. Disclosures of interest of Task Force Members are mentioned in the publication of the Guidelines and put on the website.
22. Any of the following characteristics disqualifies an individual from serving on a Guidelines committee: part-time employment or salary from a related company, significant stock ownership, or holding of a patent which generates significant revenues or receipt of significant royalties for intellectual property related to the topic of the guidelines. This rule will apply as of 1 September 2012.
23. Receipt of consultancy fees or fees for lecturing would not debar an individual from being a member of a committee but must be fully disclosed.
24. Each Guidelines Task Force should be co-chaired by two chairpersons. At least one of these chairpersons should have no conflict of interest related to the topic during the period of preparation and of production of the guideline. This measure will take place for guidelines decided by the Clinical Practice Guidelines Committee 2012–14.
25. The members of a Guidelines Task Force may have related interests (such as participation in steering committees of clinical trials), but these must all be fully disclosed.
Similar recommendations apply to the members of any expert writing committee or scientific task force, appointed by any constituent body of the ESC. Disclosure of interests is mandatory.

Other individuals and those with interests which disbar them from membership of a Guidelines committee may be invited to give advice because of their academic expertise. Employees of the research and development departments of medical companies may act as advisers on specific scientific or technical issues to task forces, but any such contributions must be disclosed.

ESC cardiology journals

The conduct of the authors, reviewers, and editors of ESC journals should comply with the standards recommended by the International Committee of Medical Journal Editors. Open disclosures of interest of individual authors are mandatory.

If clinical studies supported by industry are submitted, authors should state that they had full access to the database and total freedom in interpreting the results.

The editor-in-chief, editors, and editorial board of each ESC journal must complete a full declaration of interests. Major competing interests would exclude an individual from becoming an editor of an ESC journal.

All manuscripts must be subject to anonymous, independent peer review. There should be an independent statistical review of every accepted manuscript.

Members of the editorial board and reviewers should decline any invitation to edit or review any manuscripts relating to topics, drugs, or devices, in which they have significant commercial or academic interests.

Editors should assign an external consulting editor for any submitted manuscript relating to topics, drugs, or devices, in which they have significant competing interest.

ESC observational research and registries

Scientific registries of clinical practice and post-marketing surveillance of medical devices should be conducted according to high ethical standards, accountable, and subject to peer review.

Observational research may be supported by unrestricted educational grants. Multisponsorship is permissible but not sponsorship by a single company.

Donated funds should be pooled and administered centrally, and these should not influence the content or conduct of the programme.

Disclosures

A revised policy concerning disclosure of interests was adopted by the Board of the ESC in 2010. All members of the Board of the ESC, of the Boards of ESC Associations, and of the Councils and of the Nuclei of the ESC Working Groups must complete a disclosure of interests every year, as well as senior permanent staff. The disclosure form details each category of relationship by nature (grants, speaker fees, consulting honoraria, stockholder, employment by a company, etc.) and by financial level from modest to significant.

Conclusions

Medical progress thrives on a productive dialogue between those involved in research and development and those involved in the delivery of healthcare. Frequent exchanges between academia and industry (in particular, company scientists, and engineers) at educational meetings and congresses can result in some of the best and most innovative research ideas. Disruption of these links might cause more harm to the common good, by suppressing the generation of ideas that could ultimately improve patients’ cardiovascular health, than might result from eliminating any bias associated with industry-funded educational programmes.

Medical societies need to develop a constructive partnership with industry, in a transparent, productive, and ethical manner. To achieve that the trust not only of the public, but also of healthcare professionals, governments, and regulators must be retained and be respected. If the calls to ban industry support of medical associations were to be heeded, before alternatives were in place, then opportunities for CME would be severely compromised. Science-driven collaboration between professional societies and industry can be mutually beneficial, ethical, and appropriate. The personal interests of all parties involved must be stated clearly from the outset. Due care must be paid to ensure that governance and processes are in place to protect the ultimate beneficiary—the patient.

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