

I forrige nummer av Hjerterforum presenterte vi sammendraget av et «policy statement» fra ESC som tar for seg samspillet mellom legenes organisasjoner og industrien når det gjelder faglig oppdatering og medvirkning til kontinuerlig etterutdanning. I likhet med andre nasjonale kardiologitidsskrifter i Europa publiserer vi den mer detaljerte fulltekst-artikkelen i dette påfølgende tidsskriftnummeret.

ESC REPORT

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**

First published in Eur Heart J. 2012 Mar;33(5):666-74.

Physicians have an ethical duty to keep up-to-date with current knowledge. Professional medical associations such as the European Society of Cardiology (ESC) support these obligations. In Europe, the costs of continuing medical education (CME) are insufficiently supported from governments and employers; however, medical associations have been criticized for accepting alternative financial support from industry. Medical education and training in research include learning how to assess the

quality and reliability of any information. There is some risk of bias in any form of scientific communication including intellectual, professional, and financial and it is essential that in particular, the latter must be acknowledged by full disclosure. It is essential that there is strong collaboration between basic and clinical researchers from academic institutions on the one hand, with engineers and scientists from the research divisions of device and pharmaceutical companies on the other. This is vital so that new diagnostic methods and treatments are developed. Promotion of advances by industry may accelerate their implementation into clinical practice. Universities now frequently exhort their academic staff to protect their intellectual property or commercialize their research. Thus, it is not commercial activity or links per se that have become the target for criticism but the perceived influence of commercial enterprises on clinical decision-making or on messages conveyed by professional medical organizations. This document offers the perspective of the ESC on the current debate, and

* Presidential Office, European Society of Cardiology, The European Heart House, 2035 Route des Colles—Les Templiers, 06903 Sophia Antipolis, France. Tel: +33 4 9294 7600, Fax: +33 4 9294 7608, Email: escboard@escardio.org Published on behalf of the European Society of Cardiology. All rights reserved. & The Author 2012. For permissions please email: journals.permissions@oup.com

it recommends how to minimize bias in scientific communications and CME and how to ensure proper ethical standards and transparency in relations between the medical profession and industry.

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

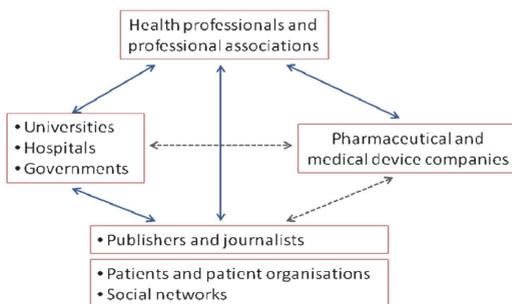


Figure 1. Links between providers of continuing medical education and scientific communications. Solid arrows indicate the preferred channels of communication; dotted arrows are those links where an added impartial expert commentary could be useful.

Table 1. Settings and providers of continuing medical education

Settings	Providers
Hospital meetings	Educational supervisors
CME courses	Clinical colleagues
Distance learning programmes	Hospital meetings, grand rounds
Medical textbooks	Universities and medical schools
Medical journals	Governmental ministries and official advisory or regulatory authorities
Clinical guidelines	Professional medical associations
Internet resources	Charitable foundations
Webinars	Pharmaceutical and device companies
Word of mouth/social networks	For-profit CME companies
Industry-sponsored meetings	Journalists and lay press
Medical congresses	Patient associations and organizations

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)⁶ and the International Federation of Pharmaceutical Manufacturers Associations,⁷ as well as national recommendations.⁸ International anti-bribery and anti-corruption laws include the Antibribery Convention of the Organisation of Economic Cooperation and Development, published in 1997 and revised in 2009.⁹ 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.⁷ 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.⁶⁻⁻⁸ 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.¹⁰

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.¹¹

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.^{12,13} This may affect prescribing patterns and the selection of drugs for hospital formularies,^{14,16,20} and it might bias publications¹⁷ or influence the content of industry-funded CME activities.³ 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.^{12,13,21} Unsurprisingly, authors from different perspectives have widely divergent views.²²

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.²³ 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.

Table 2. Sources of bias in scientific communication and education

Context	Examples of possible bias
Teacher in university or hospital	Limited depth and range of knowledge or understanding of lecturer Disproportionate presentation of material of greatest interest to lecturer Failure to keep content up-to-date
Lecturer at an educational meeting or course	Inadequate preparation Lack of objectivity—presentation of personal view as consensus on topic
Invited lecturer at a professional congress	Concentration on lecturer's own research, without acknowledging precedence or results from other research groups Favourable references to studies performed by friends and acquaintances Failure to disclose holding of patents, or other financial interests, relating to topic
Lecturer at a sponsored satellite symposium	Selective presentation of topic, without reference to alternative products from other manufacturers Omission of material critical of products of sponsoring company
Medical textbook	Dogmatic simplification of topic Space constraints limiting detailed discussion of background, controversies, and unanswered questions relating to topic
Clinical guidelines	Non-systematic review of topic Consensus rather than meta-analysis
Scientific abstract presentation	Premature and selective reporting of results using preliminary data, which may not be confirmed by final analysis
Scientific manuscript in peer-reviewed journal	Scientific fraud Selective statistical analysis and/or presentation of results Preferences or prejudices of reviewers Publication 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.²⁴ Others have suggested that 'competing interests' may be a more helpful indicator of potential bias than 'conflicts of interest'²⁵ and that only 'significant' relationships might disqualify an individual from particular educational roles.²⁶ European drug regulatory agencies have determined that although conflicts of interest cannot be eliminated, the risk of bias can be managed.²⁷

The Association of American Medical Colleges has stated that there are benefits from effective partnerships between industry and academic medical centres.²⁸ 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'.²⁹ 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. Are small companies trusted but large ones distrusted? Are links by physicians or academics with small companies acceptable, but links with large companies not so? Inconsistent standards are illogical.

Current patterns of provision

Throughout Europe, comprehensive programmes for undergraduate and postgraduate medical education are organized by university medical schools, but equivalent



Figure 2. Interaction of academic and industry bias in scientific communication. The risk of intellectual or 'academic' bias can be represented on a continuous scale from 'Low' (an impartial and objective presentation) to 'High' (a partisan or subjective presentation). The chance of bias resulting from sponsorship or involvement by industry ranges from none ('Low') to probable ('High'). Any scientific communication can be evaluated on both scales. Those plotted in the green zone are highly reliable; those in the orange zone must be interpreted with caution. Examples of activities judged to fall at the limits of these scales might be as follows: a = A clinical scientist gives a lecture on his own research, referring to an invention which he has patented but not yet commercialized, but without disclosing his interest or reviewing alternatives. b = An academic cardiologist gives a balanced and critical lecture at an educational meeting in a university, which has been organized without commercial sponsorship. c = An interventional cardiologist presents the results of a nonrandomized, open study of a new device that was developed in his institution in collaboration with a company, at a sponsored symposium during a congress. He does not declare that the results of the intervention were analysed by the clinical research organization of which he is the principal shareholder or that he will receive a fee for speaking. A fee is paid by the company to the congress organizers but this is not disclosed. d = A clinical trialist reviews recent randomized trials of a new drug, at a special symposium organized by the company which sponsored the trials. All the participants have all their expenses paid by the company. The lecturer reviews alternative drugs produced by other companies and gives a balanced account, concluding with the recommendations from recent guidelines produced independently by a medical society. e = A clinical pharmacologist whose research group developed a new drug presents the results of its first randomized controlled trial, at a satellite symposium during an international medical congress. She discloses that she was the chairman of the steering committee. The results are presented fully and then reviewed critically by a discussant who has been given access to the database for independent statistical review. The manufacturers of the new drug sponsor clinicians to attend the congress.

provision has not been made for the continuing professional development (CPD) of established clinical specialists in the form of CME. The gap is filled mostly by medical associations and sometimes by other CME providers, often supported by industry. A professional association such as the ESC is a very appropriate body to provide CME since it is a way to accomplish our mission and since its members include a critical mass of experts within each field of cardiovascular medicine.

If support from the health-care industry for educational activities was to be abolished then the onus would fall on others, such as governments or health insurance providers or employers, to provide financial support for the continuing education of physicians. Ultimately, whatever model is adopted—whether educational costs are included in the costs of drugs or devices, or health service charges, or university budgets, or individual doctors' salaries or fees—then society and patients

will pay. To abolish the current models of funding without replacing them by an alternative would be unacceptable, as CME is critical for the maintenance of high clinical standards and quality of healthcare. 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.³⁰⁻³²

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,³⁴ 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;^{31,35} 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,³⁶ 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 €5000 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.³⁸ 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.³⁸ 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 afford 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,¹³ 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.²⁵

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.⁴⁰

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 (EACCME)⁴¹ 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 lectures⁴² and increased provision of small-group practical sessions based on clinical cases, which may be more effective in changing physicians' behaviour.⁴³⁻⁴⁵ 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.^{5,46}

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.⁴⁷ 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^{16,48-54} 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.

Congresses 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 subspecialty 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

1. 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).
2. Satellite symposia should be held at special times that do not coincide with any scientific sessions.
3. Company products must not be advertised in the lecture theatre, meeting room, or conference hall.
4. Academic invited speakers are accountable for the information presented on their slides.

Trade exhibitions

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

Unrestricted grants

1. 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

1. 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

1. Academic independence and integrity is especially important in the development of clinical guidelines, and so particularly rigorous standards are required.
2. No employee of a pharmaceutical or medical device or technology company can be a member of a Guidelines committee.
3. Any form of direct company support for the development of a guideline is not permitted.
4. 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.
5. 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.

6. 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.
7. 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.
8. 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.
9. 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.
10. 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

1. 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.⁵⁵ Open disclosures of interest of individual authors are mandatory.
2. 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.
3. 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.

4. All manuscripts must be subject to anonymous, independent peer review. There should be an independent statistical review of every accepted manuscript.
5. 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.
6. 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

1. 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.
2. 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 health-care 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.

Acknowledgements

This document was approved by the Board of the ESC on 26th October 2011. Members of ESC Board 2010–12: Michel Komajda (President), Roberto Ferrari (Past President), Panagiotis Vardas (President Elect), Fausto Jose Pinto (Vice-President national societies and affiliates), Eva Swahn (Vice-President Web, communications, press, fellows), Adam Torbicki (Vice-President Associations, Working Groups, and Councils), David Allan Wood (Secretary/Treasurer), Raffaele Bugiardini (Councillor), Genevieve Anne Derumeaux (Councillor), Josef Kautzner (Councillor), Luc Pierard (Councillor), Martin Borggreffe (Councillor),

Muzaffer Degertekin (Councillor), Michael Boehm (ex-officio member), Otto Smiseth (ex-officio member), Jeroen Bax (ex-officio member), Thomas Felix Luescher (ex-officio member), Frans Van de Werf (ex-officio member), Christi Deaton (ex-officio member), Luigi Tavazzi (ex-officio member), Kurt Huber (ex-officio member), Piotr Ponikowski (President HFA), Luigi Paolo Badano (President EAE), Jean Fajadet (President EAPCI), Pantaleo Giannuzzi (President EACPR), Angelo Auricchio (President EHRA), Isabel Bardinet (ESC CEO), Alan G. Fraser (Vice-President External Affairs, Board 2008–10 participated in the preparation of the manuscript). The preparation of this statement was initiated by discussions in a Task Force on the Future of Scientific Communication, organized by the Cardiovascular Round Table of the ESC.

Funding

No funding was received for the preparation of this manuscript. The ESC receives funds from pharmaceutical / device / diagnostic companies including unrestricted grants and space renting for booths or satellite symposia in its scientific meetings. Luigi Paolo Badano received research funding from GE Healthcare. Jeroen Bax received research funding from Servier, Edwards Lifesciences, GE Healthcare, Lantheus Inc, Boston Scientific, Medtronic, St Jude Medical, Biotronik. Christi M. Deaton received research funding from Novo-Nordisk. Muzaffer M. Degertekin received research funding from Tubitak. Genevieve Anne Derumeaux received research funding from Brahms, Trophos, Astra Zeneca, Actelion. Roberto Ferrari received research funding from Biosense Webster, Schering-Plough, Angelini, Bayer, GlaxoSmithKline, Fondazione Salvatore Maugeri, Villa Maria Research Hospital, Biotronik, Novartis, Boston Scientific, Sigma Tau, St Jude Medical, Servier. Alan Fraser received research funding from GE Healthcare, Aloka. Thomas Felix Luescher received research funding from Sanofi Aventis, Eli Lilly, Abbott, Boston Scientific, Invatec AG, Medtronic, St Jude Medical, Astra Zeneca, Genzyme, Shire HGT, Pfizer, Pycnogenol GmbH, Geneva. Luc Pierard received research funding from Astra Zeneca. Fausto Jose Pinto received

research funding from Servier, GE Healthcare. Eva Swahn received research funding from Schering-Plough. Frans Van de Werf received research funding from Merck Sharp & Dohme, Boehringer-Ingelheim. Panagiotis Vardas received research funding from Astra Zeneca, Sanofi Aventis, Servier, Medtronic. David Allan Wood received research funding from Pfizer.

Conflict of interest

Luigi Paolo Badano received speaker fees, honoraria, consultancy, advisory board fees, investigator, committee member, etc. from Malesci, Medtronic, GE Healthcare and also received speaker fees, honoraria, consultancy, advisory board fees, investigator, committee member, etc. from Actelion through institution. Jeroen Bax received speaker fees, honoraria, consultancy, advisory board fees, investigator, committee member, etc. Heart.org, Astra Zeneca, Servier, Philips, GE Healthcare, Lantheus Inc, Boston Scientific, Medtronic, St Jude Medical, Biotronik, Impulse Dynamics. Michael Boehm received speaker fees, honoraria, consultancy, advisory board fees, investigator, committee member, etc. from Astra Zeneca, Bayer AG, Boehringer-Ingelheim, Daiichi-Sankyo, MSD, Novartis, Pfizer, Sanofi-Aventis, Servier and also received speaker fees, honoraria, consultancy, advisory board fees, investigator, committee member, etc. from AstraZeneca, Bayer AG, Boehringer-Ingelheim, Novartis, Pfizer, Sanofi-Aventis, Servier through institution. Martin Borggreve received speaker fees, honoraria, consultancy, advisory board fees, investigator, committee member, etc. from St Jude Medical, Bard, Boehringer-Ingelheim, Sanofi Aventis, Bayer Healthcare, Medtronic, Impulse Dynamics, Boston Scientific, received speaker fees, honoraria, consultancy, advisory board fees, investigator, committee member, etc. from Boehringer-Ingelheim, Pfizer, Sanofi Aventis, Medtronic, St Jude Medical, Impulse Dynamics through institution and also received royalties for intellectual property from Thieme Verlag. Christi M. Deaton received speaker fees, honoraria, consultancy, advisory board fees, investigator, committee Member, etc. from St Jude Medical, Daiichi Sankyo, Eli-Lilly. Muzaf-

fer M. Degertekin received speaker fees, honoraria, consultancy, advisory board fees, investigator, committee member, etc. from Novartis, Abbott, and Medtronic. Genevieve Anne Derumeaux received speaker fees, honoraria, consultancy, advisory board fees, investigator, committee member, etc. from Boehringer-Ingelheim, Actelion, Medtronic, Toshiba Medical Imaging, General Electric, Servier and also received speaker fees, honoraria, consultancy, advisory board fees, investigator, committee member, etc. from Brahms, Medtronic, Bayer Healthcare, Actelion through institution. Jean Fajadet received speaker fees, honoraria, consultancy, advisory board fees, investigator, committee member, etc. from Boston Scientific, Abbott, Medtronic, Cordis. Roberto Ferrari received speaker fees, honoraria, consultancy, advisory board fees, investigator, committee member, etc. from Bayer, Boehringer-Ingelheim, Fondazione Salvatore Maugeri, Medical Trials Analysis, Roche Pharma, Servier. Josef Kautzner received speaker fees, honoraria, consultancy, advisory board fees, investigator, committee member, etc. from Biosense Webster, Abbott, Boehringer-Ingelheim, Sanofi Aventis, Actelion, GE Healthcare, Boston Scientific, Medtronic, Biotronik, St Jude Medical, Hansen Medical, Siemens Healthcare and also received speaker fees, honoraria, consultancy, advisory board fees, investigator, committee member, etc. from Biosense Webster, Endosense, CardioFocus, Rhythmia, Boston Scientific, Medtronic, Biotronik, Viacor through institution. Michel Komajda received a direct personal payment for speaker fees, honoraria, consultancy, advisory board fees, investigator, committee member, etc. from Servier, BMS, Nile Therapeutics, PLB organisation, Sanofi Aventis, Merck Sharp & Dohme, Duke University, Astra Zeneca, Boehringer-Ingelheim, Menarini, GlaxoSmithKline, Torrent. Thomas Felix Luescher received speaker fees, honoraria, consultancy, advisory board fees, investigator, committee member, etc. from Bayer and also received speaker fees, honoraria, consultancy, advisory board fees, investigator, committee member, etc. from Eli Lilly, Duke University, Merck Sharp & Dohme, Vifor International, Servier, Astra Zeneca, Genzyme, Shire HGT, BMS/Pfizer

through institution. Luc Pierard received speaker fees, honoraria, consultancy, advisory board fees, investigator, committee member, etc. from Novartis, Merck Sharp & Dohme, General Electric, Astra Zeneca through institution. Fausto Jose Pinto received speaker fees, honoraria, consultancy, advisory board fees, investigator, committee member, etc. from Boehringer-Ingelheim, Servier, GE Healthcare and also received speaker fees, honoraria, consultancy, advisory board fees, investigator, committee member, etc. from Servier through institution. Piotr Ponikowski received speaker fees, honoraria, consultancy, advisory board fees, investigator, committee member, etc. Schering-Plough, Amgen, Sanofi Aventis, Merck Sharp & Dohme, Sanofi Aventis, Novartis, Pfizer, Servier, Duke University, Johnson & Johnson, Bayer Healthcare, Merck Sharp & Dohme, Respicardia, Vifor International, F. Hoffman La Roche Ltd. and also received speaker fees, honoraria, consultancy, advisory board fees, investigator, committee member, etc. from Schering-Plough, Amgen, Merck Sharp & Dohme, Novartis, Servier, Johnson & Johnson, Bayer Healthcare, Duke University, F. Hoffman La Roche Ltd. through institution. Adam Torbicki received speaker fees, honoraria, consultancy, advisory board fees, investigator, committee member, etc. from Boehringer-Ingelheim, Sanofi Aventis, Pfizer, Actelion, Lilly, Bayer Healthcare. Frans Van de Werf received speaker fees, honoraria, consultancy, advisory board fees, investigator, committee member, etc. from Eli Lilly, Merck Sharp & Dohme, Astra Zeneca, Boehringer-Ingelheim. Panagiotis Vardas received speaker fees, honoraria, consultancy, advisory board fees, investigator, committee member, etc. from Sanofi Aventis, Servier, Boehringer-Ingelheim. David Allan Wood received speaker fees, honoraria, consultancy, advisory board fees, investigator, committee member, etc. from Roche Pharma, Bayer Schering Pharma, Astra Zeneca, Zentiva, Merck Sharp & Dohme, Chugai Pharma UK, Pfizer.

References

1. Choudhry NK, Stelfox HT, Detsky AS. Relationships between authors of clinical practice guidelines and the pharmaceutical industry. *JAMA* 2002;287:612-617.
2. Jibson MD. Medical education and the pharmaceutical industry: managing an uneasy alliance. *Acad Psychiatry* 2006;30:36-39.
3. Moynihan R. Doctors' education: the invisible influence of drug company sponsorship. *BMJ* 2008;336:416-417.
4. Podolsky SH, Greene JA. A historical perspective of pharmaceutical promotion and physician education. *JAMA* 2008;300:831-833.
5. Lo B, Field MJ, eds. *Conflict of Interest in Medical Research, Education, and Practice*. Washington: Institute of Medicine; 2009. ISBN: 978-0-309-13188-9.
6. EFPIA. EFPIA code on the promotion of prescription-only medicines to, and interactions with, healthcare professionals, 2007. www.efpia.eu/Content/Default.asp?PageID=559&DocID=3483 (20 January 2012).
7. FPMA. IFPMA Code of Pharmaceutical Marketing Practices 2006 Revision. Appendix 1. 2006. www.ifpma.org/fileadmin/templates/EthicalPromotion/pdfs/IFPMA-TheCodeOperatingProcedure-2006.pdf.
8. ABPI. Code of practice for the pharmaceutical industry, 2006. www.abpi.org.uk/links/assoc/PMCPA/pmpca_code2006.pdf.
9. Organisation for Economic Co-operation and Development. Recommendation for Further Combating Bribery of Foreign Public Officials in International Business Transactions. Paris, France: OECD; 2009. http://www.oecd.org/document/20/0,3343,en_2649_34859_2017813_1_1_1_1,00.html (20 January 2012).
10. Hager M, Russell S, Fletcher SW, eds. *Continuing education in the health professions: improving healthcare through lifelong learning*. Proceedings of a conference sponsored by the Josiah Macy, Jr. Foundation. New York, 2008. ISBN 0-914362-49-6. www.josiahmacyfoundation.org (20 January 2012).
11. Mazmanian PE. Commercial support of continuing medical education in the United States: the politics of doubt, the value of studies. *J Contin Educ Health Prof* 2009;29:81-83.
12. Chimonas S, Rothman DJ. New federal guidelines for physician-pharmaceutical industry relations: the politics of policy formation. *Health Aff (Millwood)* 2005;24:949-960.
13. 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;301:1367-1372.
14. Chren MM, Landefeld CS. Physicians' behavior and their interactions with drug companies. A controlled study of physicians who requested additions to a hospital drug formulary. *JAMA* 1994;271:684-689.
15. Wazana A. Physicians and the pharmaceutical industry: is a gift ever just a gift? *JAMA* 2000;283:373-380.
16. Hatton RC, Chavez ML, Jackson E, Maurey J, Barriere SL, Couchenour R, Evens RP, Gunning K, Hume AL, Hutchison LC, Matzke GR, Noviasky JA, Rospond RM, Kelloway JS, Stevenson JG, Vanderveen RP, Verme-Gibbonney CN, Walters D. Pharmacists and industry: guidelines for ethical interactions. *Pharmacotherapy* 2008;28:410-420.
17. Dickersin K. The existence of publication bias and risk factors for its occurrence. *JAMA* 1990;263:1385-1389.
18. Stelfox HT, Chua G, O'Rourke K, Detsky AS. Conflict of interest in the debate over calcium-channel antagonists. *N Engl J Med* 1998;338:101-106.
19. Friedberg M, Saffran B, Stinson TJ, Nelson W, Bennett CL. Evaluation of conflict of interest in economic analyses of new drugs used in oncology. *JAMA* 1999;282:1453-1457.
20. Ross JS, Hill KP, Egilman DS, Krumholz HM. Guest authorship and ghostwriting in publications related to rofecoxib: a case study of industry documents from rofecoxib litigation. *JAMA* 2008;299:1800-1812.
21. Pellegrino ED, Relman AS. Professional medical associations: ethical and practical guidelines. *JAMA* 1999;282:984-986.
22. Ross JS, Coutts G, Tiner R, Angell M, Gottlieb S. Doctors, patients and the drug industry: partners, friends, or foes? *BMJ* 2009;338:326-329.
23. Harrington RA, Califf RM. There is a role for industry-sponsored education in cardiology. *Circulation* 2010;121:2221-2227.
24. Gelberman RH, Samson D, Mirza SK, Callaghan JJ, Pellegrini VD. Orthopaedic surgeons and the medical device industry: the threat to scientific integrity and the public trust. *J Bone Joint Surg Am* 2010;92:765-777.
25. Bruyere O, Kanis JA, Ibar-Abadie ME, Alsayed N, Brandi ML, Burlet N, Cahall DL, Chines A, Devogelaer JP, Dere W, Goel N, Hughes N, Kaufman JM, Korte S, Mitlak BH, Niese D, Rizzoli R, Rovati LC, Reginster JY. The need for a transparent, ethical, and successful relationship between academic scientists and the pharmaceutical industry: a view of the Group for the Respect of Ethics and Excellence in Science (GREES). *Osteoporos Int* 2010;21:713-722.
26. Drazen JM, Curfman GD. Financial associations of authors. *N Engl J Med* 2002;346:1901-1902.

27. Lexchin J, O'Donovan O. Prohibiting or 'managing' conflict of interest? A review of policies and procedures in three European drug regulation agencies. *Soc Sci Med* 2010;70: 643-647.
28. Association of American Medical Colleges. Industry Funding of Medical Education. Report of an AAMC Task Force. Washington, DC: AAMC; 2008. <http://services.aamc.org/publications/showfile.cfm?file=version114.pdf>.
29. European Commission, SEC(2010) 1161. Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions. Europe 2020 Flagship Initiative. Innovation Union. Brussels, 6.1.2010. http://ec.europa.eu/research/innovation-union/pdf/innovation-unioncommunication_en.pdf.
30. Merkur S, Mossialos E, Long M, McKee M. Physician revalidation in Europe. *Clin Med* 2008;8:371-376.
31. Maisonneuve H, Matillon Y, Negri A, Pallares L, Vigneri R, Young HL. Continuing medical education and professional revalidation in Europe: five case examples. *J Contin Educ Health Prof* 2009;29:58-62.
32. Fras Z, Destrebecq F, Creplet C, Welling C. Survey of European CME/CPD. Continuing Medical Education and Professional Development. Brussels: European Union of Medicine Specialists (UEMS); 2008. <http://www.uems.net/> (20 January 2012).
33. Garattini L, Gritti S, De Compadri P, Casadei G. Continuing medical education in six European countries: a comparative analysis. *Health Policy* 2010;94:246-254.
34. Desbois EJ, Pardell H, Negri A, Kellner T, Posel P, Kleinoeder T, Maillet B, Maisonneuve H. Continuing medical education in Europe: evolution or revolution, 2010. <http://www.continuingmedicaleducation-europe.com/> (20 January 2012).
35. Organisme Gestionnaire Conventionnel. Rapport d'activite' FPC (Formation professionnelle conventionnelle) 2009;10-11.
36. Royal College of Physicians. (RCP). Innovating for health: patient, physicians, the pharmaceutical industry and the NHS. Report of a Working Party, 2009. <http://www.rcplondon.ac.uk/pubs/content/76673804-76c5-4ab3-89a0-92d44e45edc3.pdf>.
37. Netherlands Federation of University Medical Centres. Collective agreement for University Medical Centres, 1 January 2008-1 March 2011. NFU-083083, article 15.9.1. <http://www.nfu.nl/fileadmin/documents/Werkg-NFU20083083-OFF-ENG-CAOv081016.pdf>.
38. Accreditation Council for Continuing Medical Education (ACCME). Annual Report Data 2008. http://www.accme.org/dir_docs/doc_upload/1f8dc476-246a-4e8e-91d3d24ff2f5bfec_uploaddocument.pdf.
39. American Heart Association. AHA annual report 2009. http://www.nxtbook.com/tristar/tristar/aha_annualreport09/index.php#/30 (20 January 2012).
40. Camilleri M, Parke DW 2nd. Perspective: conflict of interest and professional organizations: considerations and recommendations. *Acad Med* 2010;85:85-91.
41. Criteria for international accreditation of CME. European Union of Medical Specialists, 2007. <http://admin.uems.net/uploadedfiles/1411.pdf>.
42. Fletcher S. Pharma and CME: view from the US. *BMJ* 2008;337:a1023.
43. Davis DA, Thompson MA, Oxman AD, Haynes B. Changing physician performance: a systematic review of the effect of continuing medical education strategies. *JAMA* 1995;274: 700-705.
44. Davis D, O'Brien MAT, Freemantle N, Wolf FM, Mazmanian P, Taylor-Vaisey A. Impact of formal continuing medical education. Do conferences, workshops, rounds, and other traditional continuing education activities change physician behavior or health care outcomes? *JAMA* 1999;282:867-874.
45. Bowen Judith L. Medical education: educational strategies to promote clinical diagnostic reasoning. *N Engl J Med* 2006;355:2217-2225.
46. Kahn N. Industry support and professional medical associations—letter to the editor. *JAMA* 2009;302:737.
47. Smith CD, Buyske J, Talamini MA. Industry support and professional medical associations—letter to the editor. *JAMA* 2009;302:738-739.
48. Coyle SL. Physician-industry relations. Part 1: individual physicians. *Ann Intern Med* 2002;136:396-402.
49. Coyle SL. Physician-industry relations. Part 2: organizational issues. *Ann Intern Med* 2002;136:403-406.
50. European Medicines Agency (EMA). Policy on the Handling of Conflicts of Interests of Management Board and Scientific Committee Members and EMEA Experts. London: EMA; 2006. <http://www.ema.europa.eu/pdfs/general/direct/conflicts/3165303en.pdf>.
51. Boyd EA, Bero LA. Improving the use of research evidence in guideline development: 4. Managing conflicts of interest. *Health Res Policy Syst* 2006;4:16.
52. Guyatt G, Akl EA, Hirsh J, Kearon C, Crowther M, Gutterman D, Lewis SZ, Nathanson I, Jaeschke R, Schunemann H. The vexing problem of guidelines and conflict of interest: a potential solution. *Ann Intern Med* 2010;152:738-741.
53. Mitchell PB. Winds of change: growing demands for transparency in the relationship between doctors and the pharmaceutical industry. *Med J Aust* 2009;191:273-275.

54. Schünemann HJ, Osborne M, Moss J, Manthous C, Wagner G, Sicilian L, Ohar J, McDermott S, Lucas L, Jaeschke R; ATS Ethics and Conflict of Interest Committee and the Documents Development and Implementation Committee. An official American Thoracic Society Policy statement: managing conflict of interest in professional societies. *Am J Respir Crit Care Med* 2009;180:564-580.
55. International Committee of Medical Journal Editors. Ethical Considerations in the Conduct and Reporting of Research: Conflicts of Interest. ICMJE; 2009. http://www.icmje.org/ethical_4conflicts.html (20 January 2012).