

RELATIONS BETWEEN PROFESSIONAL MEDICAL ASSOCIATIONS AND THE HEALTHCARE INDUSTRY, CONCERNING SCIENTIFIC COMMUNICATION AND CONTINUING MEDICAL EDUCATION – A POLICY STATEMENT FROM THE EUROPEAN SOCIETY OF CARDIOLOGY

EXECUTIVE SUMMARY DECEMBER 2011

Introduction – the perceived problem

In recent times, cardiology has become a complex and fast moving specialty. Medical advances have often come from basic and clinical research carried out by academics, pharmaceutical and medical “device” companies alike. However, communicating these findings to medics and clinicians could, it is naturally perceived, lead to a degree of bias as organisations look to promote their findings in a positive light.

In other words, communication may lack objectivity for commercial reasons, and so when industry supports medical educational activities or scientific meetings, there is a risk of bias.

To minimise the chance that commercial influences might sway clinical decisions, there have been calls for medical societies to be funded from membership dues, subsidies and foundations rather than through grants from industry.

Examples include the Macy report in the US, or the position taken by the Royal College of Physicians in the United Kingdom which favours cutting ties between industry and medical education. Indeed there are many divergent views from different quarters on the issue and how it might best be addressed.



There is disquiet both within the medical profession and in the media about the influence of the healthcare industry on prescribing patterns and on the use of medical devices by healthcare professionals. The fundamental concern is that ties with the pharmaceutical and device industry lead to real or perceived ethical conflicts. This may affect prescribing patterns and the selection of drugs for hospital formularies.

The White Paper from the European Society of Cardiology aims to address these concerns and outline why it believes certain actions should and should not be taken, and how the best interests of patients are to be served.

Why continuing medical education is vital

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. All cardiologists must be familiar with the latest developments so as to offer to patients the best possible care.

One of the best ways of making sure clinicians are at the cutting edge is through continuing medical education (CME). Indeed in 16 European countries it is already

mandatory for the revalidation of their licence to practice.

However, CME is expensive and relying completely on public funding is not a viable option for Europe at the current time, and nor is it likely to be so in the foreseeable future. It is therefore the ESC's view that in the absence of alternative funding, maintaining links with industry is appropriate – and indeed necessary – as long as educational and scientific products remain independent, effective and unbiased, and as long as the relationships between ESC experts and industry are transparent and appropriately disclosed.

CME needs financial support but it also needs to be independent and unbiased

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, other CME providers, industry, or regulatory bodies, should adhere to essential guiding principles. They should be evidence-based, have both clearly defined educational objectives and target audiences and also 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 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.

For example, the ESC Congress is attended by some 25,000 professional delegates from around 140 countries. Scientific, educational, and clinical practice

sessions are organised by the Congress Programme Committee, which has about 50 members, none of whom are industry employees. Roughly 10,000 scientific abstracts are submitted and approximately 40% are selected for presentation after a systematic and anonymous peer review process.

Its website (www.escardio.org) offers educational resources such as e-learning programmes, webcasts, slide archives and on-line access to the scientific abstracts of its congresses. In addition, the ESC publishes seven peer-reviewed general and specialist cardiology journals, from which around 4.5 million electronic downloads are made each year.

While these activities are organised independently by the ESC, their costs are offset both indirectly and in part by funding that the Society receives from the healthcare 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. Finally, and importantly, satellite symposia organised and supported by industry are clearly identified in the programme as being separate from the scientific sessions organised by the Congress Programme Committee.

Who should provide CME?

CME is provided by several different types of organisation, from societies such as the ESC, pharmaceutical and device companies and more recently for-profit CME companies. These for-profit companies provide educational meetings for doctors that are not organised by pharmaceutical or device companies, though these meetings are often on behalf of industry and their profitability may depend on how well they satisfy that industry's expectations.

Even if their meetings are not for industry, they may well be funded by it. In the USA these CME organisations received \$1.2 billion in 2007, and much of that money is likely to have been channelled into activities that are relatively ineffective in changing clinical behaviour and improving

patient outcomes. This funding is what the Macy report advises should be stopped.

The ESC is ideally placed to provide CME since its members represent a critical mass of experts in every field of cardiovascular medicine across Europe and the Society is already at the forefront of CME 'best practice' by bringing professionals together at its major Congresses and keeping them up-to-date through initiatives such as e-learning, for example. The ESC also has robust code of conduct (see below) which ensures transparency, while its role in this important area will help it to accomplish its mission of reducing the burden of cardiovascular disease in Europe.

Ensuring transparency

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 a specific code of conduct; this assures the provision of unbiased, evidence-based and high-quality continuing medical education in cardiovascular medicine. (The full code can be read on page 13 of the White Paper).

A sample of these well established, effective and robust measures include the following:

- Every member must fill in a declaration of interest form
- Sessions for any programme must be based solely on scientific merit
- All chairpersons and speakers must (when delivering a session) show a slide with their disclosure of interests and the audience must have time to read all of its contents
- Company products must not be advertised in the lecture theatre, meeting room or conference hall

The requirements for transparency are the same for distance learning courses and internet-based educational activities

The requirements for transparency when it comes to Clinical practice guidelines are equally robust and rigorous (also on page 13 of the White Paper). There are also guidelines regarding ESC cardiology journals, observational research and registries details.

What should happen in the future?

Links between industry and clinicians are essential, especially given the lack of government or alternative funding. However, when industry is supporting medical educational activities or scientific meetings, whether directly or indirectly, communication may lack objectivity and that is causing concern.

The links between industry, healthcare professionals and medical associations must be reviewed critically to ensure these relationships are both ethical and transparent. Of course, private companies only have a future if they are profitable and in a market economy they have a legitimate right to promote their products and need to do so to remain successful.

Healthcare 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. Thus "unrestricted grants" may be a way forward, where money is given with no say in how it is spent in terms of education or course content.

Already all promotional and education activities of industry are bound by strict regulations, from bodies such as the European Federation of Pharmaceutical Industries and Associations (EPFIA), the International Federation of Pharmaceutical Manufacturers Associations and the US Foreign Corrupt Practices Act of 1977.

Healthcare providers, educators, professional associations and industry must act both collectively and individually to acknowledge and eliminate real or perceived bias.

Conclusion

The ESC advocates a principled and balanced approach that acknowledges disclosures of interest between healthcare professionals and industry, and aims to provide honest and unbiased education for healthcare professionals. It does not believe severing ties with industry is in the patients' best interest.

Medical societies need to develop a constructive partnership with industry, in a transparent, productive, and ethical manner. To achieve this, 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.

Acknowledgements

The full White Paper on CME was approved by the Board of the ESC on 26th October 2011

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