Accepted Manuscript

The Medical Profession, Industry and Continuing Medical Education: Finding the Balance That's Right for Patients

Peter Kearney, Maarten Simoons, Lars Ryden, Paulus Kirchhof, Axel Pries, Colm O'Morain, Jeroen J. Bax

PII: S0002-9343(19)30221-9
DOI: https://doi.org/10.1016/j.amjmed.2019.02.026
Reference: AJM 15050

To appear in: *The American Journal of Medicine*

Please cite this article as: P. Kearney, M. Simoons, L. Ryden, et al., The Medical Profession, Industry and Continuing Medical Education: Finding the Balance That's Right for Patients, The American Journal of Medicine, https://doi.org/10.1016/j.amjmed.2019.02.026

The Medical Profession, Industry and Continuing Medical Education: Finding the Balance That's Right for Patients

Running head: Future of Medical Education

Writing Group:

- Dr Peter Kearney, MB, MD, FRCPI, FESC (Lead author) (Chair Advocacy and Public Affairs Committee - European Society of Cardiology)
- Prof Maarten Simoons, MD, PhD, FESC (Chair of Industry Relations Committee - European Society of Cardiology)
- Prof Lars Ryden, MD, Dr h.c., HMRCP, FESC, FACC, FAHA (Member of Advocacy and Public Affairs Committee - European Society of Cardiology)`
- Prof Paulus Kirchhof , MD, FESC, FRCP (Edin) (Chair Education Committee - European Society of Cardiology)
- Prof Axel Pries, MD (President – Biomedical Alliance in Europe)
- Prof Colm O'Morain, D.Sc FRCPI (Past-President – Biomedical Alliance in Europe)
- Prof Jeroen J. Bax, MD, PhD, FESC, FACC (Corresponding author) (Past-President - European Society of Cardiology)

Funding sources: none.
All authors had access to data and all contributed to the writing of the manuscript.

Conflicts of interest:

Peter Kearney: none
Maarten Simoons: none
Lars Ryden: none
Paulus Kirchhof: Research support for basic, translational, and clinical research projects from European Union, British Heart Foundation, Leducq Foundation, Medical Research Council (UK), and German Centre for Cardiovascular Research, from several drug and device companies active in the cardiovascular field, and has received honoraria from several such companies in the past. PK is listed as inventor on two patents held by University of Birmingham (Atrial Fibrillation Therapy WO 2015140571, Markers for Atrial Fibrillation WO 2016012783)
Axel Pries: none
Colm O'Morain: Chair of DMC for Shire and Pfizer
Jeroen J Bax: Speakers fees Abbott. The Dept. of Cardiology at Leiden University Medical Center, The Netherlands, received unrestricted research grants from Medtronic, Biotronik, Boston Scientific, Edwards Lifescience, GE Healthcare.

Key words: Continuing medical education, healthcare industry, medical professional societies, financial support, conflict of interest

Corresponding author:
Jeroen J. Bax, MD, PhD
Dept of Cardiology
Leiden University Medical Center
The Netherlands
Tel +31 71 5262020
Fax +31 71 5266809
E-mail: j.j.bax@lumc.nl

This article has been endorsed by:

- The Board of Directors of the Biomedical Alliance in Europe
- The Future of CME Task Force composed of the following Biomedical Alliance member societies:

EAACI (European Academy of Allergy and Clinical Immunology), **EAN** (European Academy of Neurology), **EANM** (European Association of Nuclear Medicine), **EAS** (European Atherosclerosis Society), **EASD** (European Association for Study of Diabetes) , **EASL** (European Association for Study of the Liver) , **EASO** (European Association for the Study of Obesity), **EAU** (European Association of Urology), **ECCO** (European CanCer Organisation), **EFIS** (European Federation of Immunological Societies), **EHA** (European Hematology Association), **ERS** (European Respiratory Society), **ESA** (European Society of Anaesthesiology), **ESC** (European Society of Cardiology), **ESE** (European Society of Endocrinology), **ESHRE (European Society of Human Reproduction and Embryology)**, **ESMI** (European Society for Molecular Imaging), **ESP** (European Society of Pathology), **ESPGHAN** (European Society for Paediatric Gastroenterology Hepatology and Nutrition), **EUFOREA** (European Forum for Research & Education in Allergy & Airway Diseases), **EULAR** (European League Against Rheumatism), **UEG** (United European Gastroenterology)

Abstract

Provision and participation in formal external continuing medical education (CME) is costly. Employer or state support of CME is the exception rather than the rule. The medical industry has supported both providers and consumers of educational activities, leading to concerns of commercial bias. Recent medical industry initiatives in Europe to improve the transparency of the relationship between industry and the profession, including the field of medical education, have had the paradoxical effect of the industry playing an increasingly direct role in the provision of physician education. Funding of medical professional society annual congresses has been directly and indirectly jeopardised. Acknowledging that there are areas of co-operation in the field of education between the medical profession and the medical industry from which both can benefit, we argue that medical education requires an objective approach that the primary fiduciary duty of medical industry companies precludes. Medical professional societies, as not-for-profit organisations whose core mission is the development and promotion of best practice, are best placed to guide and deliver medical education to their members.

Key words

Continuing medical education, healthcare industry, medical professional societies, financial support, conflict of interest

Introduction

Everyone in society has an interest in physicians and other healthcare professionals performing well – training doctors is costly and often subsidized by public funds, healthcare consumes a large portion of national finances, and at some time or other, most members of society will become a patient. The pace of scientific progress places a particular onus on medical professionals to adapt continuously to novel and better approaches to manage their patients. Best practice guidelines are helpful but there are important gaps between these recommendations and what is delivered in clinical practice. Maintaining knowledge and skills requires continuous and unbiased medical education for physicians and other health care professionals, and continuing medical education (CME) has become an essential component of efforts to ensure high quality practice.

The greater part of a doctor's development as a physician occurs after qualification; but in contrast to the well-defined and regulated process of undergraduate medical training and the ensuing specialist training, CME is variable in form and scale in Europe and around the world (1). Increasingly, state licencing systems have adopted models of formal continuing professional development (CPD) of which CME is a key part. Regulation varies from no monitoring system of CPD, to an honour-based commitment to engage in a pre-specified minimum amount of CME, to registration of a range of CPD activities, to formal examination and periodic re-certification. National and international CME accreditation authorities have drawn up criteria to ensure high quality CME (2, 3, 4, 5). In an effort to avoid commercial bias in events and programmes that receive financial support from the industry, the European Accreditation Council for Continuing Medical Education (EACCME) requires that 'all funding from sponsors must be provided as an unrestricted educational grant, free of any attempt to influence the programme, individual sessions, subjects for discussion, content or choice of faculty members' (2).

The medical industry has played a prominent supportive role in medical education in recent decades. This support raised ethical concerns related to both industry and healthcare providers. Much has been done to ensure a balanced and unbiased presentation of data, and a robust separation of educational and marketing interests. However, there are indications that the industry intends to play a more direct role in educating healthcare professionals, and in the process, to withdraw or reduce unrestricted financial support of medical professional organisations with whom they have previously partnered. This paper puts forward the position of the Biomedical Alliance in Europe (the

BioMed Alliance), an umbrella organisation representing the views of twenty seven medical organisations and more than 400,000 healthcare professionals and researchers in Europe. We describe the current roles and responsibilities of the medical professional societies and the medical industry in medical education and the development of the Industry adopting a more direct role in CME. We argue in favour of measures that guarantee an ethical and transparent relationship between medical professional societies and the medical industry in the field of medical education that promote the best outcomes for patients through unbiased, high quality CME.

Role of Professional Medical Societies

Doctors seek knowledge in a wide variety of ways. Medical journals, medical websites or other digital resources (social networks, dedicated blogs) and, to a lesser extent, textbooks are used for self-learning. Learning in practice, small group educational meetings, multidisciplinary discussions (both formal and informal) and interactive workshops in particular have been shown to be effective (6,7). Large meetings including national and international symposia and specialty congresses remain the most popular form of external CME for European physicians (8). In this context, medical professional societies play a central role in the provision of CME, based on best available evidence, at national and international level. Their digital learning portfolios are available for continuous self-directed and blended learning. Their congresses are designed to educate professionals by highlighting the key messages of international or national clinical practice guidelines and their application in daily clinical work, the outcomes of the latest research, and increasingly by way of dedicated educational programmes integrated into medical congresses. They offer a unique opportunity for face to face educational engagement with their peers and with experts. Best practice frequently requires an understanding of areas of practice devoid of commercial interest, not least avoiding unnecessary investigations or treatments, and requires an independent and balanced educational perspective. The not-for-profit nature of medical professional societies, their constitution, systems of governance and essentially altruistic goals make them particularly suited to designing and delivering unbiased medical education.

Role of Medical Industry

The medical industry plays a key role in the development of novel technologies, devices and medications, in close collaboration with clinical scientists and physicians. There is a regulatory requirement for the industry to ensure safe use of its pharmaceutical products (9) and devices (10). These requirements mandate a certain level of training in the safe and effective use of products. Procedural training in the use of complex devices is frequently device specific and focused on correct application and handling. Product training has different goals and requirements than medical education which provides an unbiased overview of available approaches. Through the process of research and development of new pharmacological and technical approaches to disease, the industry has built up a deep and wide knowledge base of educational value. The most widely applied, and generally accepted, model of industry involvement in medical education is provision of unrestricted educational grants to CME providers, on the express understanding that all reasonable measures are taken to avoid biased educational messages. Less clearly unbiased educational meetings or online programmes that offer an opportunity to showcase products are funded and designed by industry through intermediary Medical Education and Communication Companies (MECCs). The industry plays an even more direct role in medical education and training through training institutes, educational foundations, 'Excellence Programmes', and, in some parts of the world, is the sole provider of CME. The larger industry companies have workforces numbering into the tens of thousands, and have developed sophisticated educational programmes for their employees, expertise some companies are keen to utilise to educate doctors (11,12).

Greater Industry Engagement in Education and its Impact

Some commentators view any industry involvement in medical education of physicians as unacceptable (13), while others take a more nuanced and pragmatic view (14, 15). Concerns relating to the introduction of bias in physician education and wider concerns regarding the interaction of industry and medical professionals has led to regulation. This includes the Sunshine Act in the United States and 'soft legislation' produced by the European Commission in 2012 when the 'List of Guiding Principles Promoting Good Governance in the Pharmaceutical Sector' was published by the Platform on Ethics & Transparency (16). Soon after, the representative organisation for the pharmaceutical industry in Europe, EFPIA (The European Federation of Pharmaceutical Industries and Associations), and its medical device equivalent, MedTech Europe, produced guiding Codes of Conduct for their members (17,18) outlining appropriate interaction with

physicians, including the nature and support for educational meetings. Our organisation, the BioMed Alliance, produced a Code of Conduct outlining the ethical basis for the interaction of medical professionals and industry (19) (Table 1).

The MedTech code prohibits direct sponsorship of individual healthcare professionals to attend meetings organised by Professional Medical Societies, but allows support of third parties to organise meetings, including medical professional societies and MECCs. The EFPIA code (17) allows support for physicians to attend third party meetings, details of which are published (with the individual's agreement) on an open access national register on the national pharmaceutical organisation's website.

Whereas the anticipated effect of the industry codes was to promote a more transparent and ethically sound interaction between industry and medical professionals, the actual outcome, at least in the field of education, has been contradictory. Some industry companies increasingly adopt a direct role in designing "educational programmes" on their own, without adequate governance to protect such programmes against bias relating to their own products (10).

The industry's fiduciary duty is to its shareholders and owners, a position that introduces inevitable bias in matters relating to information about its products. The narrow focus of drug or device specific training often lack context, and is less likely to promote a balanced approach to patient management. The converse is also true – patent-free and non-pharmacological treatment, and management strategies that have no inherent commercial value, including those that reveal waste or redundancy in current therapeutic approaches, are unlikely to be of interest from an industry perspective, but can be central to promotion of high value patient care.

The ubiquity of bias is put forward as a reason as to why the industry should not be excluded from a more active engagement in medical education (11). Like other stake holders, clinicians, academics, scientists and the organisations to whom they belong certainly have conflicts of interest that can introduce bias into educational programmes. Be they scientific, financial, professional or otherwise, governance systems set out to manage conflict of interest by recognition, declaration and, when it is judged likely they will introduce harmful bias, recusal or exclusion from the relevant activity. Importantly, the fiduciary duty of physicians is towards their patients, not towards shareholders. An argument of moral equivalence of educational bias faced by industry and medical professional societies is misleading.

Proposals for the Future of Continuing Medical Education

Development and delivery of CME by medical professional societies is an expensive undertaking. It is made possible by the input of volunteer professional members as developers, guideline writers, organisers, and faculty; by membership fees; and, to a significant degree, industry financial support. A small proportion of the funding of CME comes from statutory bodies, tax relief or healthcare and academic institutions. Recent developments of diminishing financial sponsorship and a growing move to greater direct involvement of the Industry threatens the role and viability of medical professional societies in provision of balanced, high quality medical education. It can be anticipated the consequences will be felt unequally; physicians in low and middle income countries affected to a greater extent. Civil society is served by medical professional societies in their role fostering and generating independent science, education and training. Policymakers should be aware that measures that erode these activities risk negative consequences for unbiased patient centred clinical decision making and patient safety.

Medical professional societies are best placed to provide independent, unbiased and effective CME. Accreditation authorities have recently reiterated the requirements for high quality CME that must be followed for educational events and programmes to be accredited and for which CME credits may be granted (20). The concerns of external observers, of healthcare professionals and industry relating to inappropriate interactions have led to Codes of Conduct that were meant to pave the way towards a mutually respectful, transparent and ethical relationship between the profession and the industry. A frank discussion between the profession, the industry, payors, the public, and regulators is needed to determine the best environment for unbiased CME. Health care providers and payors, including state and private hospital owners and health insurers, also have a role to play in the funding of CME. The industry has constructively highlighted the importance of contemporary, needs based, outcome oriented, educational approaches (11). For its part, the medical profession should commit to these principles and ongoing innovation in medical education. Although the industry has an overriding commercial responsibility to its shareholders, it also has an ethical responsibility to see its products used safely, effectively and appropriately for the benefit of patients and society. We argue this is better achieved by support of medical professional societies in their role as educators, rather than itself taking on those activities.

References:

1. Study concerning the review and mapping of continuous professional development and lifelong learning for health professionals in the EU: Final Report. EAHC/2013/Health/07
2. UEMS-EACCME. EACCME criteria for the accreditation of live education events (available for download at www.uems.eu) (accessed 30-12-2018)
3. Royal College of Physicians of Ireland. Industry Sponsorship and Support. 2012. (available for download at www.rcpi.ie) (accessed 30-12-2018)
4. Royal College of Physicians of Ireland. Guide to Approval of Events for Continuing Professional Development (CPD). (available for download at www.rcpi.ie) (accessed 30-12-2018) (accessed 30-12-2018)
5. Royal College of Physicians. Provide a CPD event. (available for download at www.rcplondon.ac.uk) (accessed 30-12-2018)
6. O'Brien T, Freemantle N, Oxman AD, Wolf F, Davis DA, Herrin J. Continuing education meetings and workshops: effects on professional practice and health care outcomes (Review). Cochrane Library 2005
7. "Understanding Medical Education: Evidence, Theory and Practice" 2nd edition Tim Swanwick
8. Quekett, J for M3 Global Research. Helping European cardiologists keep up to date. PMLiVE 22nd June 2015 (online access)
9. Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (Consolidated version : 05/06/2013). (https://ec.europa.eu/health/sites/health/files/files/eudralex/vol-1/reg_2004_726/reg_2004_726_en.pdf) (accessed 30-12-2018)
10. Regulation (EU) 2017/745 of the European Parliament and of the council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32017R0745&from=EN) (accessed 30-12-2018)
11. Allen T, Doodle N, Hofstadter-Thalmann E, Keijser S, May v, Murama JJ, Kellner T. Framework for industry engagement and quality principles for industry provided medical education in Europe. Journal of European CME 2017; 6(1):1-8
12. Medtronic announces new, outcome-based learning program. Feb 13, 2017 04:00 CT on-line press release from Medtronic
13. Spithoff S. Industry involvement in continuing medical education: Time to say no. Can Fam Physician 2014;60:694-696
14. DeMaria A. Continuing Education, Industry, and Physicians. J Am Coll Cardiol 2008;12:1035-1036
15. ESC Board. Relations between Professional Medical Associations and the health-care industry, concerning scientific communication and continuing medical education: a Policy Statement from the European Society of Cardiology. Eur Heart J 2012;33:666–674
16. https://web-beta.archive.org/web/20130612031413/http://ec.europa.eu/enterprise/sectors/healthcare/files/docs/outcomes_et_en.pdf (accessed 30-12-2018)
17. EFPIA Board. EFPIA code on the promotion of prescription-only medicines to, and interactions with, healthcare professionals. Consolidated version 2013 (available for download at www.efpia.eu) (accessed 30-12-2018)

18. Medtech Europe. Code of ethical business practice (available for download at www.medtecheurope.org) (accessed 30-12-2018)
19. Biomed Alliance. Code for transparency in the relationship between the pharmaceutical industry and health care professionals. (Available for download at www.biomedeurope.org) (accessed 30-12-2018)
20. International academy of CPD accreditation. Consensus Statement for Independence and Funding of Continuing Medical Education (CME)/Continuing Professional Development (CPD). https://academy4cpdaccreditation.files.wordpress.com/2018/01/consensus-statement-for-independence-and-funding-of-cme_cpd_final.pdf (accessed 30-12-2018)

Acknowledgement:

The following collaborators are acknowledged for their contributions to the manuscript:

- Prof Gunhild Waldemar, MD, DMSc (Board member - Alliance for Biomedical Research in Europe)
- Michel Ballieu (Executive Director - Alliance for Biomedical Research in Europe)
- Prof Peter Hellings, MD, PhD (Secretary General - European Academy of Allergy and Clinical Immunology)
- Prof David B. Vodušek, MD, PhD, FEAN (Chair of Communication Committee - European Academy of Neurology)
- Eveline Sipido (EU Liaison officer - European Academy of Neurology)
- Andreas Felser (Executive Director - European Association of Nuclear Medicine)
- Prof Alberico Catapano, PhD (Past President - European Atherosclerosis Society)
- Dr Lena Wedeken (Scientific Officer - European Association for the Study of Diabetes)
- Mischa van Eimeren (EU Liaison Officer - European Association for the Study of Diabetes)
- Prof Tom Karlsen, MD (Secretary General - European Association for Study of the Liver)
- Prof Francesco Negro, MD (Educational Councillor - European Association for Study of the Liver)
- Dr Mounia Heddad-Masson PhD (Education Manager - European Association for Study of the Liver)
- Euan Woodward (Executive Director - European Association for Study of Obesity)
- Maurice Schlief (Executive Managing Director - European Association of Urology)
- Prof Philip Poortmans, MD, PhD (President - European CanCer Organisation)
- Birgit Beger (CEO - European CanCer Organisation)
- Sapna Sheth (Scientific Affairs Manager - European CanCer Organisation)
- Prof Gert Ossenkoppele, MD, PhD (Chair Education Committee - European Hematology Association)
- Carin Smand (Managing Director - European Hematology Association)
- Prof Mina Gaga, MD, PHD (President - European Respiratory Society)
- Prof Daiana Stolz, MD, MPH (Education Council Chair - European Respiratory Society)
- Prof Guy Brusselle, MD, PhD, FERS (Science Council Chair - European Respiratory Society)
- Werner Bill (Executive Director - European Respiratory Society)
- Carine Pannetier (Science & Education Director - European Respiratory Society)
- Prof Dr Stefan De Hert, MD, PhD (President - European Society of Anaesthesiology)
- Marc Gheeraert (Executive Manager - European Society of Anaesthesiology)
- Prof Barbara Casadei, MD, DPhil, FRCP, FMedSci, FESC (President Elect - European Society of Cardiology)
- Isabel Bardinet (CEO - European Society of Cardiology)
- Aoife Delmas (Director Industry Team - European Society of Cardiology)
- Helen Gregson (CEO - European Society of Endocrinology)

- Dirk De Rijdt (Director of Commercial Services - European Society of Endocrinology
- Prof Roy Farquharson, MD, FRCOG (Chairman - European Society of Human Reproduction and Embryology)
- Dr. Dina Tiniakos, MD, PhD, FRCPath (President - European Society of Pathology)
- Dr Raed Al Dieri, Pharm, PhD (Director General - European Society of Pathology)
- Prof Raanan Shamir, MD (President - European Society for Paediatric Gastroenterology Hepatology and Nutrition)
- Dr Nicolette Moes, MD, Phd (Young ESPGHAN Chair - European Society for Paediatric Gastroenterology Hepatology and Nutrition)
- Dr Benoit Pugin, PhD (Scientific manager - European Forum for Research & Education in Allergy & Airway Diseases)
- Dr Sven Seys, PhD (Scientific manager - European Forum for Research & Education in Allergy & Airway Diseases)
- Prof. Johannes W. Bijlsma, MD, PhD (President - European League Against Rheumatism)
- Prof. Annamaria Iagnocco, MD (Treasurer - European League Against Rheumatism)
- Dr Julia Rautenstrauch, MD (Executive Director - European League Against Rheumatism)
- Prof Heinz Hammer, MD (Chair of Education Committee - United European Gastroenterology)
- Doris Möstl (Executive Director - United European Gastroenterology)
- Birgit Uebelhör (Head of Congress Department - United European Gastroenterology)

Clinical significance

This will be submitted off-line as discussed with the editor in chief. Dr Alpert.

- Maintaining knowledge and skills requires continuous and unbiased medical education

- Accreditation systems have been devised to avoid bias in cases of industry support of continuing medical education (CME)

- Medical professional societies are central to provision of unbiased CME at international level

- The collaboration between the medical professional societies and the medical industry in the field of education involves inevitable challenges as well as important opportunities

- The future lies in agreeing roles and responsibilities and a controlled and transparent cooperation between the medical profession and industry

Table 1
Key legislation and non-governmental organisation codes of conduct relating to ethics and transparency in the relationship between health professionals and medical industry

- Sunshine Act, part of Patient Protection and Affordable Care Act, enacted in the United States 2010
- 'List of Guiding Principles Promoting Good Governance in the Pharmaceutical Sector' published by the European Union Platform on Ethics & Transparency (16) 2012
- Biomedical Alliance in Europe Code of Conduct (19) published 2016
- European Federation of Pharmaceutical Industries and Associations (EFPIA) Disclosure Code (17) activated mid 2016
- MedTech Europe Code of Ethics Business Practice (18) became binding for its Corporate Members from the start of 2017