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ESPGHAN Code of Conduct 2014 General

Summary

International congresses, symposia and educational schools organised by ESPGHAN are important and highly visible scientific meetings where up-to-date scientific data are presented and discussed by specialists from many countries. They also create the opportunity for commercial companies involved in paediatric health care to interrelate face-to-face with doctors and allied health professionals. Relationships between medicine and commerce (such as pharmaceutical, nutritional, biotechnology, and medical device companies) have driven innovation in patient care, contributed to the economic well-being of the community, and provided significant resources (financial and otherwise) for professional education, to the ultimate benefit of patients and the public. However, the interests and obligations of medicine and commerce can diverge. An increasingly urgent challenge for both partners is to devise ways to preserve strong, productive collaborations for the benefit of patients and the public at the same time they each take clear, effective action to avoid relationships that could undermine public good and public trust.

This code of conduct examines financial relationships between medicine and commercial companies. It summarizes the ethical foundations of ESPGHAN's obligation to ensure that paediatricians and allied health care professionals acquire and maintain knowledge, skills, and values that are central to paediatrics and child health without undue bias based on commercial interests. The ESPGHAN Code of Conduct analyses the ethical challenges that can be posed when ESPGHAN members who organize, teach, or serve other roles in medical education have financial relationships with companies that have a direct interest in recommendations and illustrates strategies for mitigating the potential of such financial relationships to influence professional education in undesired ways.

The ESPGHAN Code of Conduct governs the relationship between ESPGHAN and involved industry representatives in the preparation of, during and after events, that are related to research and educational activities as well as position papers in the field of paediatric gastroenterology, hepatology or nutrition. Besides a theoretical document with the identification of the principals of transparency, independence and accountability, this Code of Conduct provides a practical approach how to maintain the independence and integrity of ESPGHAN's related professional education while promoting a trustworthy relationship between ESPGHAN and commercial companies.



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Conclusions and Recommendations

1. Relationships between medicine and commercial companies (such as pharmaceutical, medical device, biotechnological and nutritional and dietetic companies) may help to drive innovation in patient care.
2. In an environment of rapidly changing information and emerging technology, paediatricians and allied health care workers must maintain the knowledge, skills, and values central to a healing profession. ESPGHAN must protect the independence and commitment to fidelity and service that define the profession.
3. Financial or in-kind support from pharmaceutical, nutritional, biotechnology or medical device companies that have a direct interest in physicians' recommendations creates conditions in which external interests could influence the availability and/or content of educational activities. Financial relationships between such sources and ESPGHAN or individual physicians who organize, teach in or have other roles in ESPGHAN activities can carry similar potential to influence these activities in undesired ways.
4. Educational activities that receive funding from sources that have no financial interests in physicians' recommendations promotes confidence in the independence and integrity of ESPGHAN, as do educational activities in which organizers, teachers, and others involved in educating physicians do not have financial relationships with commercial companies that could influence their participation. Where possible, educational activities should be provided without such support or the participation of individuals who have financial interests in the educational subject matter.
5. Sometimes, support from commercial companies or participation by individuals who have financial interests in the subject matter may be needed to enable access to appropriate, high quality educational activities. In these circumstances, physician/learners should be confident that vigorous efforts will be made to maintain the independence and integrity of educational activities.
6. ESPGHAN and individual paediatricians and allied health care workers must ensure that ESPGHAN defines the goals of physician education, determines educational needs independent from other interests and sets its own priorities for educational activities. Physicians who attend educational activities should expect that, in addition to complying with all applicable professional standards for accreditation and certification as listed earlier in this document, their colleagues who organize, teach, or have other roles in educational activities will:
 - be transparent about financial relationships that could potentially influence educational activities.
 - provide the information physician-learners need to make critical judgements about an educational activity, including: - the source(s) and nature of commercial support for the educational activity; and/or - the source(s) and nature of any individual financial relationships with commercial companies related to the subject matter of the educational activity; and - what steps have been taken to mitigate the potential influence of financial relationships.



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- protect the independence of educational activities by:
- ensuring independent, prospective assessment of educational needs and priorities;
- adhering to a transparent process for prospectively determining when commercial support is needed;
- giving preference in selecting faculty or content developers to similarly qualified experts who do not have financial interests in the educational subject matter; - ensuring a transparent process for making decisions about participation by physicians who may have a financial interest in the educational subject matter; - permitting individuals who have a substantial financial interest in the educational subject matter to participate in educational activity only when their participation is central to the success of the educational activity; the activity meets a demonstrated need in the professional community; and the source, nature, and magnitude of the individual's specific financial interest is disclosed; and - taking steps to mitigate potential influence commensurate with the nature of the financial interest(s) at issue, such as prospective peer review

7. Position papers and other recommendations on preventive, diagnostic or therapeutic issues or the daily management of patients made on behalf of ESPGHAN should be completely free of interference in any kind by commercial companies.

Educational activities by ESPGHAN

The practice of paediatrics and allied health care professionals is a “covenant of trust” between patient, parents and the professional. The respect and autonomy that paediatrics enjoys rest on the profession’s commitment to fidelity and service in the patient-parent-physician relationship. To sustain that commitment, we must ensure that paediatricians and allied health care professionals acquire and maintain the knowledge, skills and values that are central to paediatrics. In return, society grants paediatrics considerable authority to set the ethical and professional standards of practice and the autonomy to educate ourselves. ESPGHAN is a professional organisation that supports research, exchange and critical discussion of research findings, and provides education in the field of paediatric gastroenterology, hepatology and nutrition through the organisation of scientific annual meetings, summer schools, networking opportunities, and position papers with recommendations on preventive, diagnostic and therapeutic approaches and standards of care on treatment recommendations and networking opportunities. Individual paediatricians and allied health care professionals have an ethical obligation to dedicate themselves to “continue to study, apply, and advance scientific knowledge” and to “maintain a commitment to medical education.” As professionals, practicing paediatricians and allied health care professionals are expected to commit themselves to post academic education and to maintain their clinical knowledge and skills through education and other professional development activities.

That commitment is reflected not only in ethical expectations and standards, but also in requirements for licensure and certification of individuals and institutions. Paediatricians and allied health care professionals and the patients/parents who rely on them must be confident that treatment recommendations and clinical decisions are well informed and reflect up-to-date knowledge and practice. Educational activities that are pedagogically sound, scientifically grounded,



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and clinically relevant are essential to ensure that paediatricians and allied health care professionals can provide the high quality of care their patients deserve. To achieve these goals, ESPGHAN has an ethical obligation to ensure that the profession independently sets the agenda and defines the goals of professional's education; controls what subject matter is taught; determines paediatricians and allied health care professionals' educational needs; and takes steps to ensure the independence of educational content and of those who teach it.

Financial relationships with commercial companies in education organised by ESPGHAN In the context of education, relationships with commercial companies that may pose challenges for the independence and objectivity of physician education include not only direct commercial support of educational activities, but also financial relationships between commercial companies and individual paediatricians and allied health care professionals involved in education as faculty, content developers, or in other capacities. Commercial company support helps to meet the costs of educational activities in the face of uncertain funding from other sources and may help make education more accessible, especially for paediatricians and allied health care professionals in resource poor communities.

Commercial company engagement and support can be especially helpful in ensuring affordable education activities when educational activities need high cost, sophisticated, rapidly evolving technology or devices. Along with lower costs, commercial company support may encourage greater participation than would otherwise be the case by providing amenities. However, there is growing concern within and outside medicine that commercial funding for education could have undesirable effects, including potentially biasing content toward funders' products or interests, and influencing the overall range of topics covered. Whether and how financial relationships influence ESPGHAN's educational activities is an important question. Paediatricians and allied health care professionals are entrusted with the interests of patients. Importantly, where patients' health and public trust are concerned, the perception of bias, even if mistaken, can be as potentially damaging as the existence of actual bias. Empirical evidence alone is not enough to overcome public scepticism. Even evidence that undesired consequences have not occurred cannot be expected by itself to restore confidence when trust has been compromised. To maintain productive relationships with commercial companies that benefit patients and to sustain the trust on which the patient-parent-paediatrician relationship and public confidence in the profession depend, ESPGHAN must take steps to safeguard the independence and integrity of educational activities related to the society. Therefore, Officers representing ESPGHAN, including the Council Members and the Editor of the journal should not hold positions on advisory boards or communication "institutes" of commercial companies" ..

Ensuring the independence and integrity of medical and post graduate education

As individuals and as a society, paediatricians and ESPGHAN have a responsibility to protect the quality of professional education and the reputation of ESPGHAN. While competing interests cannot be eliminated entirely, prudent judgments can be made about how to minimize potential influence and prevent or reduce undesired consequences.

Minimizing the opportunity for undue influence ESPGHAN should aspire to avoid the potential for undue influence or the chance that confidence in the integrity and independence of their activities



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could be diminished. Avoiding entirely situations in which there is potential for undue influence has the virtue of ethical clarity and practical simplicity. Educational activities that are free of direct financial relationships with commercial companies that have direct interests in recommendations strongly underscores ESPGHAN's defining professional commitment to independence and fidelity to patients and professionals. Avoiding such relationships also has the practical advantage of eliminating the efforts that must otherwise be devoted to mitigating influence, efforts that may be particularly challenging for small educational project providers, such as summer schools and young investigators forum. In their roles as education providers, ESPGHAN as such but also content developers, faculty, paediatricians and allied health care professionals should strive to avoid financial relationships with commercial companies that might influence the content. ESPGHAN should strive for obtaining non-commercial sources of support, should design and conduct educational activities so as to limit costs, and should insist that content developers and

faculty members do not have problematic ties with commercial companies to ensure unbiased, high quality educational programmes and their conduct that best meets professionals' needs and is accessible and affordable for a large number of participants. Defining the terms of financial relationships likewise can help minimize the potential for undue influence. Asking paediatricians and allied health care professionals who teach in or develop content for an educational activity to refrain from accepting personal compensation (honoraria, consulting fees, etc.) could promote independence. That said, it is not always feasible, or necessarily desirable, for professional education to disengage completely from commercial companies. In some situations, collaboration with a commercial company may be necessary to achieve the goals of a research meeting (e.g. provision of diagnostic methodology) or an educational meeting (e.g. provision of endoscopy equipment), and also financial relationships with commercial companies can be ethically justifiable. If not accepting support from a commercial source or not permitting participation by individuals who have financial interests in the educational subject matter would significantly undermine ESPGHAN's capacity to ensure that paediatricians and allied health care professionals have access to appropriate, high-quality education, it can be acceptable to permit such support or participation. In these situations, vigorous efforts must be made to ensure that financial support is not linked to any influence on decisions on programme planning and content, and the selection of participants.

Mitigating Potential Influence

While there should be a presumption that paediatricians and allied health care professionals who organize, design, develop content, or teach in ESPGHAN's educational programmes should not have concurrent financial ties to commercial companies that would influence their educational responsibilities or clinical advices, it is important to recognize that not all relationships with commercial companies are equally problematic. A relationship that is only indirectly related to an educational activity, modest in scope, or distant in time is not likely to adversely affect - or be perceived to affect - the activity in question. For example, having conducted sponsored research or accepted a modest honorarium for speaking on behalf of a company would not necessarily create such clear potential for bias as to preclude an individual with the appropriate expertise from developing content or serving as a faculty member for a given educational activity or co-authoring a position paper. Financial relationships that are direct or substantial, however, have significant



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potential to undermine confidence in educational activities, even if they do not actually compromise those activities. Examples of a direct or substantial financial interest include ownership or equity interest in a company that has an interest in the educational subject matter or royalties or on-going compensated relationships (e.g., consulting arrangements or service on scientific advisory bodies). Relationships that involve responsibilities on behalf of the funder (such as service on a corporate board of directors) or decision-making authority in financial matters can be similarly problematic. In such situations, ethically strong practice requires that steps be taken to mitigate the possible influence of financial relationships on ESPGHAN activities.

Principles for sustaining trust

The goal of mitigation is to promote and enhance confidence in the integrity of continuing professional education. Commitment to transparency, independence, and accountability enables paediatricians and allied health care professionals to achieve that goal, whatever role they may play in ESPGHAN activities. Moreover, being transparent about financial relationships that have the potential to influence educational activities and forthcoming about what steps have been taken to minimize possible influence supports physician-learners in exercising critical judgment individually as “consumers” of educational activities organised or endorsed by ESPGHAN.

Transparency

Transparency, i.e. disclosing the existence of a financial relationship, is a necessary first step in mitigating the potential of financial relationships to create bias (or the appearance of bias), but it is not sufficient and may even have untoward effects. Disclosure places the burden on learners themselves to determine how sceptical they should be about possible bias in an educational activity. To the extent that disclosure fosters the impression that the presenter is particularly honest and trustworthy, it can encourage false confidence in the activity. To the extent that the presenter believes disclosing a financial relationship is adequate to mitigate its potential influence, he or she may be less circumspect in ensuring content is free of such influence. While transparency is essential, disclosing financial relationships is necessary but not sufficient to mitigate the potential for influence in the educational activity.

Independence

Taking concrete steps to ensure that the ESPGHAN educational activity is independent and objective is equally important. Creating a separation between funders and decisions about educational goals, content, faculty, pedagogical methods and materials, and other substantive dimensions of the educational activities can help protect the independence of professional education. ESPGHAN recommends clearly separating decisions about funding from substantive decisions about educational activities. Support of individual educational activities by multiple, competing funders also helps to diffuse the potential influence of any one funder. Carrying out educational needs assessments prior to seeking or accepting commercial support or identifying faculty can similarly enhance the independence of the planning process and resulting educational programming. Likewise, having prospective peer review of a presentation (review of slides or other forms of communication in advance of the presentation by an objective and independent expert who has the power to require changes prior to the public showing) can help ensure that the presentation is free of commercial



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bias. Position papers from the Committees, which serve as guidance for practicing professionals should be made completely independent of any commercial support.

Accountability

Physician-learners, patients, the public, and the medical community as a whole should be made confident that ESPGHAN as society and paediatricians and allied health care professionals who organize, design, develop content, or teach in educational activities will uphold principles of transparency and independence. The expectation that paediatricians and allied health care professionals involved in educational activities will hold themselves accountable to address the potential that financial relationships with commercial companies have to influence professional education is a cornerstone of self-regulation. That responsibility can be greatly enhanced by the efforts of accrediting and certifying bodies, but it cannot be supplanted by them.

In particular, ESPGHAN members in educational activities should be able and willing to discuss how the principles of transparency and independence have been applied in the educational activities with which they are involved or over which they have decision-making authority. **Exceptional Cases** At times it may be impossible to avoid a financial interest or extraordinarily difficult or even impossible to mitigate its potential impact on an educational activity. For the most part, accepting support from a single company or permitting participation by an individual when there is an irreducible financial interest would create increased risk. However, in certain circumstances, it may be justifiable.

Such circumstances include instances when accessible, high-quality educational activities cannot reasonably be carried out without support from sources that have a direct financial interest in physicians' clinical recommendations. Similarly, in the earliest stage of adoption of a new medical device, technique, or technology the only individuals truly qualified to train paediatricians and allied health care professionals in its use are often those who developed the innovation. These individuals may have the most substantial and direct interests at stake, whether through employment, royalties, equity interests or other direct financial interests in the adoption and dissemination of the new technology. ESPGHAN should be transparent about what considerations led to decide to permit an individual with a problematic financial interest to participate in a particular educational activity to ensure that such decisions are justifiable and persuasive to the professional community at large.

Promotional activities by commercial companies

Promotional activities are activities developed by or on behalf of a single commercial entity and under the substantive influence of that entity to provide information on the therapeutic use of a product or service. ESPGHAN should not be connected to these activities.

Transparency of payments to council and committee members or their institutions



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Each year, council and committee members of ESPGHAN should disclose the financial support they receive privately and on accounts of their institutions, and the sources. These payments will include honoraria for lectures, consults etcetera and amounts received to perform research projects. Candidates applying for such positions should disclose this information prior to their election process.

Sources used:

1. Previous code of conduct ESPGHAN
2. Code of Conduct FISPGHAN
3. UEG sponsor brochure (page 24,25) downloaded at (http://www.ueg.eu/fileadmin/user_upload/documents/Week13/UEGWeek2013_InvitationToTheIndustry_FINAL.pdf)
4. Code of Practice of the European Federation of Pharmaceutical Industry Association
5. WHO International code of marketing 1981
6. The International Pharmaceutical Congress Advisory Association's (IPCAA) Code of Conduct and Medical Congress Guidelines and Housing Guidelines
7. Accreditation Council for Continuing Medical Education (ACCME)
8. Financial Relationships with Industry in Continuing Medical Education – AAP
9. Code for Interactions with Companies (<http://www.cmss.org/codeforinteractions.aspx>) from the US Council of Medical Specialty Societies
10. Nationale Borstvoedings Raad (Dutch National Breastfeeding Council)