Policy of the Canadian Association of Emergency Physicians Guidelines For Physicians In Interactions With Industry

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Canadian Association of Emergency Physicians | 104-1785 Alta Vista Drive | Ottawa, Ontario | K1G 3Y6

The history of health care delivery in Canada has included interaction between physicians and the pharmaceutical and health supply industries; this interaction has extended to research as well as to education. Physicians understand that they have a responsibility to ensure that their participation in such collaborative efforts is in keeping with their primary obligation to their patients and duties to society, and to avoid situations of conflict of interest where possible and appropriately manage these situations when necessary. They understand as well the need for the profession to lead by example by promoting physician-developed guidelines.

The following guidelines are based on the CMA Policy: *Guidelines For Physicians In Interactions With Industry*, and adapted by the Canadian Association of Emergency Physicians (CAEP) to reflect CAEP's specific needs, to assist CAEP members, Directors, Sections, Committees and staff in determining when a relationship with industry is appropriate. These guidelines focus on the pharmaceutical companies, however CAEP considers that the same principles apply to relationships between physicians and all commercial organizations, including manufacturers and suppliers of medical devices, health products and informatics, and other service suppliers.

These guidelines are to serve as a resource for physicians in helping them to determine what type of relationship with industry is appropriate. They are not intended to prohibit or dissuade appropriate interactions of this type, which have the potential to benefit both patients and physicians.

Although directed primarily to individual physicians, including residents, and medical students, the guidelines also apply to relationships between industry and CAEP as an organization.

General Principles

1. The primary objective of professional interactions between physicians and industry should be the advancement of the health of Canadians.
2. Relationships between physicians and industry are guided by the CAEP's Code of Conduct and by this document.
3. The practising physician's primary obligation is to the patient. Relationships with industry are inappropriate if they negatively affect the fiduciary nature of the patient–physician relationship.
4. Physicians should resolve any conflict of interest between themselves and their patients resulting from interactions with industry in favour of their patients. In particular, they must avoid any self-interest in their prescribing and referral practices.
5. Except for physicians who are employees of industry, in relations with industry the physician should always maintain professional autonomy and independence. All physicians should remain committed to scientific methodology.
6. Those physicians with ties to industry have an obligation to disclose those ties in any situation where they could reasonably be perceived as having the potential to influence their judgment.

Industry-Sponsored Research

7. A prerequisite for physician participation in all research activities is that these activities are ethically defensible, socially responsible and scientifically valid. The physician's primary responsibility is the well-being of the patient.
8. The participation of physicians in industry sponsored research activities must always be preceded by formal approval of the project by an appropriate ethics review body. Such research must be conducted according to the appropriate current standards and procedures.
9. Patient enrolment and participation in research studies must occur only with the full, informed, competent and voluntary consent of the patient or his or her proxy, unless the research ethics board authorizes an exemption to the requirement for consent. In particular, the enrolling physician must inform the potential research subject, or proxy, about the purpose of the study, its source of funding, the nature and relative probability of harms and benefits, and the nature of the physician's participation and must advise prospective subjects that they have the right to decline to participate or to withdraw from the study at any time, without prejudice to their ongoing care.
10. The physician who enrolls a patient in a research study has an obligation to ensure the protection of the patient's privacy, in accordance with the provisions of applicable national or provincial legislation and CMA's Health Information Privacy Code. If this protection cannot be guaranteed, the physician must disclose this as part of the informed consent process.
11. Practising physicians should not participate in clinical trials unless the study will be registered prior to its commencement in a publicly accessible research registry.
12. Because of the potential to influence judgment, remuneration to physicians for participating in research studies should not constitute enticement. It may cover reasonable time and expenses and should be approved by the relevant research ethics board. Research subjects must be informed if their physician will receive a fee for their participation and by whom the fee will be paid.
13. Finder's fees, whereby the sole activity performed by the physician is to submit the names of potential research subjects, should not be paid. Submission of patient information without their consent would be a breach of confidentiality. Physicians who meet with patients, discuss the study and obtain informed consent for submission of patient information may be remunerated for this activity.
14. Incremental costs (additional costs that are directly related to the research study) must not be paid by health care institutions or provincial or other insurance agencies regardless of whether these costs involve diagnostic procedures or patient services. Instead, they must be assumed by the industry sponsor or its agent.
15. When submitting articles to medical journals, physicians must state any relationship they have to companies providing funding for the studies or that make the products that are the subject of the study whether or not the journals require such disclosure. Funding sources for the study should also be disclosed.
16. Physicians should only be included as an author of a published article reporting the results of an industry sponsored trial if they have contributed substantively to the study or the composition of the article.
17. Physicians should not enter into agreements that limit their right to publish or disclose results of the study or report adverse events which occur during the course of the study. Reasonable limitations which do not endanger patient health or safety may be permissible.

Industry-Sponsored Surveillance Studies

18. Physicians should participate only in post-marketing surveillance studies that are scientifically appropriate for drugs or devices relevant to their area of practice and where the study may contribute substantially to knowledge about the drug or device. Studies that are clearly intended for marketing or other purposes should be avoided.
19. Such studies must be reviewed and approved by an appropriate research ethics board. The National Council on Ethics in Human Research is an additional source of advice.
20. The physician still has an obligation to report adverse events to the appropriate body or authority while participating in such a study.

Continuing Medical Education/ Continuing Professional Development (CME/CPD)

21. This section of the Guidelines is understood to address primarily medical education initiatives designed for practicing physicians. However, the same principles will also apply for educational events (such as noon-hour rounds and journal clubs) which are held as part of medical or residency training.
22. The primary purpose of CAEP's CME/CPD activities is to address the educational needs of physicians and other health care providers in order to improve the health care of patients. Activities that are primarily promotional in nature, such as satellite symposia, should be identified as such to faculty and attendees and should not be considered as CME/CPD.
23. The ultimate decision on the organization, content and choice of CME/CPD activities for physicians shall be made by the physician-organizers approved by CAEP.
24. CME/CPD organizers and individual physician presenters are responsible for ensuring the scientific validity, objectivity and completeness of CME/CPD activities. Organizers and individual presenters must disclose to the participants at their CME/CPD events any financial affiliations with manufacturers of products mentioned at the event or with manufacturers of competing products.
25. The ultimate decision on funding arrangements for CME/CPD activities is the responsibility of the physician-organizers. Although the CME/CPD publicity and written materials may acknowledge the financial or other aid received, they must not identify the products of the company(ies) that fund the activities.
26. All funds from a commercial source should be in the form of an educational grant payable to CAEP.
27. Industry representatives should not be members of CME content planning committees. They may be involved in providing logistical support.
28. Generic names should be used in addition to trade names in the course of CME/CPD activities.
29. Physicians should not engage in peer selling. Peer selling occurs when a pharmaceutical or medical device manufacturer or service provider engages a physician to conduct a seminar or similar event that focuses on its own products and is designed to enhance the sale of those products. This also applies to third party contracting on behalf of industry.
30. If specific products or services are mentioned, there should be a balanced presentation of the prevailing body of scientific information on the product or service and of reasonable, alternative treatment options. If unapproved uses of a product or service are discussed, presenters must inform the audience of this fact.
31. Negotiations for promotional displays at CME/CPD functions should not be influenced by industry sponsorship of the activity. Promotional displays should not be in the same room as the educational activity.
32. Travel and accommodation arrangements, social events and venues for industry sponsored CME/CPD activities should be in keeping with the arrangements that would normally be made without industry sponsorship. For example, the

industry sponsor should not pay for travel or lodging costs or for other personal expenses of physicians attending a CME/CPD event. Subsidies for hospitality should not be accepted outside of modest meals or social events that are held as part of a conference or meeting. Hospitality and other arrangements should not be subsidized by sponsors for personal guests of attendees or faculty, including spouses or family members.

33. Faculty at CME/CPD events may accept reasonable honoraria and reimbursement for travel, lodging and meal expenses. All attendees at an event cannot be designated faculty. Faculty indicates a presenter who prepares and presents a substantive educational session in an area where they are a recognized expert or authority.

Electronic Continuing Professional Development (eCPD)

34. The same general principles which apply to "live, in person" CPD events, as outlined above, also apply to eCPD (or any other written curriculum-based CPD) modules. The term "eCPD" generally refers to accredited on-line or internet-based CPD content or modules. However, the following principles can also apply to any type of written curriculum based CPD.

35. Authors of eCPD modules are ultimately responsible for ensuring the content and validity of these modules and should ensure that they are both designed and delivered at arms'-length of any industry sponsors.

36. Authors of eCPD modules should be physicians with a special expertise in the relevant clinical area and must declare any relationships with the sponsors of the module or any competing companies.

37. There should be no direct links to an industry or product website on any web page which contains eCPD material.

38. Information related to any activity carried out by the eCPD participant should only be collected, used, displayed or disseminated with the express informed consent of that participant.

39. The methodologies of studies cited in the eCPD module should be available to participants to allow them to evaluate the quality of the evidence discussed. Simply presenting abstracts that preclude the participant from evaluating the quality of evidence should be avoided. When the methods of cited studies are not available in the abstracts, they should be described in the body of the eCPD module.

40. If the content of eCPD modules is changed, re-accreditation is required.

Advisory/Consultation Boards

41. Physicians may be approached by industry representatives and asked to become members of advisory or consultation boards, or to serve as individual advisors or consultants. Physicians should be mindful of the potential for this relationship to influence their clinical decision making. While there is a legitimate role for physicians to play in these capacities, the following principles should be observed:

A. The exact deliverables of the arrangement should be clearly set out and put in writing in the form of a contractual agreement. The purpose of the arrangement should be exclusively for the physician to impart specialized medical knowledge that could not otherwise be acquired by the hiring company, and should not include any promotional or educational activities on the part of the company itself.

B. Remuneration of the physician should be reasonable and take into account the extent and complexity of the physician's involvement.

C. Whenever possible, meetings should be held in the geographic locale of the physician or as part of a meeting which he/she would normally attend. When these arrangements are not feasible, basic travel and accommodation expenses may be reimbursed to the physician advisor or consultant. Meetings should not be held outside of Canada, with the exception of

international boards.

Clinical Evaluation Packages (Samples)

42. The distribution of samples should not involve any form of material gain for the physician or for the practice with which he or she is associated.
43. Physicians who accept samples or other health care products are responsible for recording the type and amount of medication or product dispensed. They are also responsible for ensuring their age-related quality and security and their proper disposal.

Gifts

44. Practising physicians should not accept personal gifts of any significant monetary or other value from industry. Physicians should be aware that acceptance of gifts of any value has been shown to have the potential to influence clinical decision making.

Other Considerations

45. These guidelines apply to relationships between physicians and all commercial organizations, including but not limited to manufacturers of medical devices, nutritional products and health care products as well as service suppliers.
46. Physicians should not dispense pharmaceuticals or other products unless they can demonstrate that these cannot be provided by an appropriate other party, and then only on a cost-recovery basis.
47. Physicians should not invest in industries or related undertakings if this might inappropriately affect the manner of their practice or their prescribing behaviour.
48. Practicing physicians affiliated with pharmaceutical companies should not allow their affiliation to influence their medical practice inappropriately.
49. Practicing physicians should not accept a fee or equivalent consideration from pharmaceutical manufacturers or distributors in exchange for seeing them in a promotional or similar capacity.
50. Practicing physicians may accept patient teaching aids appropriate to their area of practice provided these aids carry at most the logo of the donor company and do not refer to specific therapeutic agents, services or other products.