

Supported by an unrestricted educational grant

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§ See related articles pages 405 and 425

Pharmaceutical companies use various means to communicate messages about their products. They produce advertisements and original research articles that are published in peer-reviewed journals, they use direct advertising through a variety of media, and they produce “educational” meeting reports and newsletters that appear in publications or are sent directly to physicians. The purpose of this article is to increase awareness of trends in this third category: some of these meeting reports and newsletters may in fact be advertising disguised as educational material.

Material in the first 2 categories goes through independent assessment before reaching its intended audience. Prescription drug advertising is for the most part overseen by an autonomous organization, the Pharmaceutical Advertising Advisory Board (PAAB). PAAB is endorsed by Health Canada, the ultimate legal authority on drug advertising in Canada, and the 2 organizations have a working relationship. Advertisements published in medical journals are independently assessed by PAAB, as is direct advertising material delivered to physicians electronically, through the mail or by hand by company representatives. Original research articles that appear in medical journals undergo the independent scrutiny of the peer review process. Many journals have endorsed the policies of the International Committee of Medical Journal Editors¹ to ensure that the involvement of the organizations supporting a research study is clearly described.

The situation is less clear-cut for material in the third category. Educational articles, meeting reports and newsletters sponsored and distributed by the pharmaceutical industry can help physicians keep abreast of current medical information. They promote awareness of recent consensus statements and provide information on new classes of therapeutic products, the latest safety data and new treatment options. However, this type of material is often not externally vetted. It is important that physicians are able to determine whether what they are reading is intended to be advertising.

Advertising is defined in the Food and Drugs Act as “any representation by any means whatever for the purpose of promoting directly or indirectly the sale or disposal of any food, drug, cosmetic or device.”² For example, if a pharmaceutical company sponsors the distribution of an article that describes a meeting presentation of clinical trial

results involving one of their products, the material would fit the definition of advertising. Advertising regulations cover material such as newsletters and quasi-scientific publications that promote sales directly or indirectly.

If this type of material is classified as advertising according to the Food and Drugs Act, and if advertising is independently reviewed by PAAB, why is there a problem? In 1996, PAAB instituted its Guideline on Educational Meeting Reports,³ which exempts educational meeting reports from being classified as advertising and thus exempts them from PAAB review. This guideline was instituted so that physicians could receive objective and balanced information about therapies from presentations given at accredited continuing medical education meetings in a timely manner. Health Canada and PAAB require independence of the process and objectivity of the contents for material to qualify for this exemption; publishers of these materials are expected to act responsibly.

PAAB will not approve off-label claims, claims based on poor evidence, safety claims that lack balance or unfair comparisons with competitors’ products. Thus, the appeal of an exemption that allows publishers to bypass PAAB review is clear. Many meeting reports and educational newsletters are of high quality, but I have also seen reports based on preliminary trial data, incomplete scans of the literature, unfair comparisons, suggestions for off-label uses and inappropriate descriptions of safety measures.

What can physicians do? Physicians and scientists who are asked to contribute to a medical newsletter or meeting report should be cautious. Pharmaceutical companies want physicians to be involved in creating these documents to give the material credibility, and often pay well for participation. To meet the exemption’s requirement for independence of the process, participating physicians must be truly independent of the sponsoring company, that is, they would have to enter into a contract with a health care organization that is not considered to be an agent of the company. If physicians are hired to participate directly by the sponsoring pharmaceutical company or by a commercial publisher representing that company, the resulting document is usually not considered to be independent by PAAB.

Physicians who are invited to participate in an educational project should obtain the name of the sponsor from the publisher or organization that has approached them, and they should ask whether the project is considered to be

advertising by PAAB. If it is, then the material should be clearly identified as advertising and it should be reviewed by PAAB. If the originator of the project indicates that the material constitutes continuing medical education because it is "supported by an unrestricted educational grant," then it should meet all of the requirements of continuing medical education material.⁴⁻⁶ If it is not clear to which category the material belongs, contributors should be aware that it will most probably be perceived to be advertising. Remember, if a pharmaceutical company sponsors the distribution of material containing information about its products, the material is likely considered by law to be advertising, despite the involvement of physicians or scientists and the claim that the project was funded by an unrestricted grant.

Physicians who receive these types of material should also exercise caution. The PAAB logo should be displayed on all advertising material that it has approved. If the logo is not displayed on material that appears to be advertising, readers are encouraged to send a letter of complaint with the original material and a description of how they received the material to the PAAB Commissioner, Suite 200, 375 Kingston Road, Pickering ON L1V 1A3. Reports on previous complaints can be found in the quarterly *PAAB Update*, which can be found in the Newsletters section of the PAAB Web site (www.paab.ca).

This article has been peer reviewed.

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Competing interests: Mr. Chepesiuk is employed by PAAB.

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