Bookends

PAAB

The Pharmaceutical Advertising Advisory Board

REVIEW

Ray Chepesiuk, Commissioner

During this past summer, two topics held the focus of the PAAB staff, acting as bookends around everything else. The two topics were the independently produced information exemption under PAAB Code section 6.6.(a) and the PAAB Guidelines for making market share claims in advertising.

Information exemption: Is your project really independent?

I saw a report in June that the US Congress is investigating 24 drug companies regarding their use of educational grants. The report stated, "Some companies have awarded educational grants to health-care providers as inducements to prescribe their drugs." I have often said there is no such thing as an "unrestricted educational grant" with respect to commissioned projects; it seems the US pharma industry has pushed this to the point where the US Congress is now investigating to see if that is true.

I would rather not see that happen in Canada.

The PAAB has been getting phone calls from marketing personnel in pharma companies about the exemption from PAAB review for the distribution of independently produced information. It seems some "independent" publishers have been providing confusing information to pharma company personnel. To clarify, there is no loophole.

Continuing Medical Education (CME) experts may tell you that, in Canada, CME is an interactive event or program and enduring materials are not accredited in Canada (unlike in the US). Commissioning a report about preselected material that focusses on the sponsor's product, then distributing it to physicians who were not at the meeting, is promoting the sale of a product—hence, "advertising."

Publishers may argue this is "high-quality" information. Quality is not the issue; if the PAAB logo appears on an advertising piece, that is high-quality information. We also hear the argument, "A doctor wrote it." Who wrote it doesn't supercede the criteria of content related to sponsorship; it is important to follow the federal regulations and PAAB guidelines regarding advertising, and to begin your project with a decision to either make it advertising or information.

Section 6.6 of the PAAB Code of Advertising Acceptance lists types of material that are exempt from PAAB review. This includes 6.6(a):

> Information materials that have been independently controlled and prepared, with industry involvement limited to purchase and/or sponsorship of the distribution (example: a textbook).

The definition of advertising or promotion subject to section 11.1 of the PAAB Code section is:

> Any paid message communicated by Canadian media with the intent to influence the choice, opinion or behaviour of those addressed by commercial messages.

Distribution of any unsolicited material about a pharmaceutical product is deemed to be advertising if the information or its distribution serves to promote the sale of that product, either directly or indirectly. This definition applies even if the information:

- has been published independently of the manufacturer,
- is from an independent authoritative source,
- is unchanged and complete or
- is claimed to be educational material.

Therefore, reports that are commissioned by a sponsor about a subject that show emphasis on the sponsor's product(s) and are distributed to an audience broader than the original meeting attendees would be deemed to be advertising subject to review by the PAAB. It is important to focus your attention on section 6.6.(a) of the PAAB Code rather than the definition of "independent publisher " in section 11.12; distribution of complete accredited CME programs may not be advertising if the subject matter is not focused on the sponsor's products. When in doubt, call the PAAB office for "high quality" advice.

Market share guidelines

In July, PAAB distributed the "Supplementary Guideline for Market Share Claims Used in Advertising," review through two mailings. One mailing was to all PAAB client companies and the other to 2,400 individuals in the pharmaceutical industry.

The guidelines came into existence because IMS informed the PAAB that they would no longer validate advertising claims based on IMS data. Therefore, advertisers will be submitting supportive data for market share claims directly to the PAAB, and we thought it would be helpful to publish guidelines to help advertisers create valid claims. These supplementary guidelines have the same status as explanatory notes to the PAAB Code of Advertising Acceptance, and are intended to clarify the application of the PAAB Code within this category of non-clinical market share claims.

The guidelines are a written compilation of previous practice principles; we have consulted with the PAAB board member organizations, selected companies who were identified as frequent users of market share claims and the two major pharmaceutical market share data companies in Canada. All market share claims, regardless of the source and sponsors, must adhere to market research company guidelines. Market share claims must be based on an authoritative, recognized, independent source that is reflective of the Canadian marketplace. Market share claims are based on non-clinical parameters and may not imply any clinical significance.

One new change is that the PAAB will not accept claims based on the IMS Canadian Disease and Therapeutic Index (CDTI) database (a change supported by IMS). It is believed that the CDTI data are not hard numbers and a claim of "recommended" could be misleading if it did not reflect actual prescriptions.

The guidelines can be seen on the PAAB Web site at **www.paab.ca**. CPM