The Pharmaceutical Advertising Advisory Board

REVIEW

By Ray Chepesiuk, Commissioner

"Do we have to send it in for PAAB

PAAB Code section 6.6 outlines six types of activities that do not require PAAB review (available at www.paab.ca.) However, the section does not say all of these activities are not "advertising" within the purview of the Food & Drugs Act. It just means PAAB review is not required.

There appears to be some confusion about what is exempt. Remember, you are part of the Canadian self-regulation process for drug advertising.

First on the list are "educational materials that have been independently controlled and prepared, with industry involvement limited to sponsorship of the distribution." "Materials" implies any pieces of information that have had zero input or control from the drug company. Usually, a good sign is accreditation from a source recognized by the medical community. Another form of exemption is explained in the PAAB Educational Meeting Report Guideline. This guideline was created by the PAAB in 1996 to recognize the fact that there are some independent meetings that provide valuable information about published peer-reviewed studies. The meetings were being entirely independent of the sponsor distributor, therefore it was believed the meeting notes could be reported accurately and distributed to health professionals without the need for PAAB review.

So much for theory. We have seen abuse of this exemption category, such as meeting reports about unpublished or incomplete studies that were single-drug oriented and related to unproven superiority claims or off-label uses. I am told by senior industry people that the PAAB is seeing about half of the educational pieces that are really "advertising." In many cases, the sponsor had some degree of control in the meeting set-up or in the editing of materials. This does not meet the PAAB requirement. If the report appears to promote the sale of a single drug, it would be viewed as advertising under the Food & Drugs Act, even if it does not require PAAB review. If the PAAB receives complaints about those types of materials, we will adjudicate them. Exposing violators through the complaint process can help clean up this area, and not mess up serious continuing medical education (CME) professionals.

Next up is "personal correspondence." This means a health professional has initiated a request for information and the company can provide almost anything. This does not mean that the field rep waves a paper in a doctor's face and asks if he or she would like the material. It also doesn't mean you can distribute BRCs with specific information on them. We advise companies to direct all requests through their corporate medical information or regulatory service for proper documentation of the request and the materials that were provided. Slides requested by physicians also fall into this category. Requests should be unprompted or unsolicited. You can advertise the availability of your medical information service.

Then we come to "government agency correspondence requirements (*i.e.*, drug recalls, warnings) over which PAAB has no jurisdiction." This means that a government organization, usually Health Canada, has been involved in negotiating the wording of a communication that will be sent to health professionals. If it is a "safety issue," then Health Canada wants to know about it and act on it. Please, don't send a letter to Health Canada the same day the letter goes out to health professionals and then claim Health Canada was involved. You should know that Health Canada is filling up their Web site with safety advisories.

"Company price lists containing no therapeutic claims, price comparisons or claims of company or product merit, status or issues" are exempt. These items are commercial information.

There is also an exemption on "institutional messages which do not contain product information or lists." If a drug name is mentioned, send the document to the PAAB for review.

Last on the exemption list is "patient information direct from and consistent with the product monograph." Examples of patient information subject to PAAB review are company-controlled brochures, Internet and other electronic presentations and 1-800 number scripts. A patient is someone who has been treated by a doctor and has been prescribed a certain drug. The information should be about the proper use of the drug to optimize patient outcome. This does not include promotional claims, tag lines, comparative claims, market share claims, or irrelevant pharmacokinetic data. The product monograph "information to the consumer" section tells you the type of information about a particular drug that should be included. Companies augment the specific drug information with other information about diet, exercise or lifestyle choices. This is not a loophole for direct-to-consumer advertising. You can advertise prescription drugs to the public only with regards to name, price and quantity.

"If you don't see it on the above list, PAAB-it."

PAAB Strategic Planning

You may have heard that the PAAB has undertaken a major strategic planning initiative to help see our way into the future. Board members, staff, clients and external organizations will be directly involved in identifying issues for board discussion in November. We hope to have a plan approved by the board in January 2003.

Myth Dispelled

I have heard several comments about how frequently the PAAB Code changes. This is a perception and not a reality. Since 1988, there have been four printings of the PAAB Code with different covers to signify important changes. We have had less than one code section change per year for the last six years. Section 5 was rewritten as of January 1999. Perhaps code section changes are being confused with several "clarifications" of the PAAB Code application to advertising reviews that have been published. These were not changes, but may have been "news" to the uninformed.

The application of the PAAB Code is a dynamic process and reflects the marketplace. All code changes have had marketplace stakeholder consultation. The science of what is good evidence has changed and the application of the PAAB Code will change to reflect prevailing knowledge. It has been my experience that marketing personnel are resistant to scientific, clinical or regulatory changes in the marketplace, especially if those changes are not helpful to the sale of their products. Marketing is getting more complex and the PAAB has to educate marketers about changing standards. That is a challenge faced by the PAAB reviewers, and it does slow down the review process when marketers are resistant to change. PAAB reviewers help you to comply with standards agreed upon by a wide group of stakeholders and the PAAB horizon is a bit further than your next quarter's budget goals. CPM