True or False?

The Pharmaceutical Advertising Advisory Board

REVIEW

Ray Chepesiuk, Commissioner

This past April, the PAAB conducted workshops on the application of its Code of Advertising Acceptance. Over 200 people attended the workshops in Toronto and Montreal, which included information about the Code revisions that came into effect April 1, 2005.

The afternoon sessions, "Advertising versus Information," focused on a case involving a product manager who had to choose from among many promotional activity options for a fictional drug called Arbace in the angiotensin receptor blocker (ARB) class. The goal was to distinguish between advertising and non-advertising activities for regulatory purposes.

Groups of eight recorded their suggestions for appropriate and inappropriate conduct and the suggestions were later collected for input on how to improve casework.

We reviewed the summary sheets, and while some statements were simply untrue, others were real "gems" that show PAAB clients do, in fact, understand the principles of ethical marketing conduct.

At the end of the workshops, attendees completed a fun, true-or-false quiz to reinforce some points about the PAAB. Below is a similar quiz based on some of the aspects of the PAAB Code I believe are important to emphasize.

True or false?

1. One possibility is to create two distinct Web sites—one for disease awareness aimed at consumers without mention of the drug name in the URL and a separate URL that may include the drug name and a unique password entry for patients and health professionals.

True. This can be done, but there must be no linkage to the drug and its therapeutic use on the open-to-the-general-public page.

2. Use market research to influence physicians to further believe ARBs can reduce myocardial infarction (an off-label use).

False. I was shocked someone would actually think this, let alone write it down. Market research should not be a disguise for promotion; it should be done by third-party professionals for marketing planning.

3. Section 6.6.(a)2 states meeting reports, if distributed by sponsor company reps or liaisons, must be PAAB-reviewed due to product/therapeutic claims.

True. The PAAB Code requirement in section 6.6.(a) is for an exemption from review by the PAAB. To qualify for this exemption, all of the criteria in section 6.6.(a) must be met, that is, the report must be derived from an accredited meeting and published by a third party and the content should not be focused on the sponsor's drug.

The PAAB has tried to clarify 6.6.(a)

because some suppliers were telling pharma marketers they could generate single-topic reports about the sponsor's drug and not call it advertising, thus it would not be subject to PAAB review. That is not true! Contact the PAAB for clarification, as needed.

4. Meeting invitations need to be approved by the PAAB if the product name appears on them and if certain content is included.

False. It is not a requirement for the PAAB to review meeting invitations; however, the Rx&D Code of Conduct does cover meetings and what is stated on meeting invitations. Also, if the invitation looks promotional in nature, it is important to be mindful of the Food & Drugs Act and Regulations.

5. If there are data supporting low or no gastrointestinal effects with Arbace, the data can be promoted as a benefit by comparing the drug to a competitor agent that has not been shown to have the same effects.

False. Based on PAAB Code section 5.7, head-to-head studies involving the two drugs are required before comparative claims of safety or efficacy can be promoted. Also, the PAAB encourages advertisers to promote products based on their own merit and not on the shortcomings of others.

6. A representative can't have any role in educating on non-approved indications and must use a third party for any disease information on the indications.

True. Company representatives, including medical science liaisons, should not be promoting off-label uses at company-generated promotional meetings (even if they are referred to as CEs).

Also, the reps should not be involved in the content of accredited educational programs other than to assist with the administrative setup of the meeting site.

It is important to respect the accreditation process and work with academia to provide meaningful health professional education. As well, it is inappropriate to use the term *CE* to call promotional meetings where the sales rep invites the speaker, chooses the topic and/or provides the presentation. Such practices are disrespectful to the principles of accreditation. CPM

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For questions concerning application of the PAAB Code, please call the PAAB office (905) 509-2275 and ask the reviewers. They are there to help you follow the guidelines.