PAAB Code Revision:

Keeping Up With the Pace of Industry

The Pharmaceutical Advertising Advisory Board Review

Ray Chepesiuk, Commissioner

One of the recommendations that resulted from of the PAAB strategic planning process of 2002-2003 was the requirement that the Commissioner ensure consistency of the review process.

The PAAB staff identified a need for the PAAB Code to be modernized to include new provisions and to address deficiency in wording and terminology.

At the PAAB general meeting of November 27, 2003, the directors agreed to the Commissioner's proposal that the PAAB conduct a formal review of the Code of Advertising Acceptance. The Executive Committee agreed on the structure of the committee and Commissioner Ray Chepesiuk was appointed the Chair.

It was agreed the organizations directly affected by the Code, and that could provide expert comment, should make up the membership of the Code Review Committee. Each of the organizations represented on the committee approved their representative. The Canadian Pharmacist Association (CPhA) declined to appoint a representative, preferring to be active in presenting their views during the consultative process. It was agreed that wide consultation should be part of the review process.

The process

The committee met on January 19, 2004, to get organized. Membership consisted of :

- Chair, Ray Chepesiuk, PAAB Commissioner
- Gloria Bowes, PAAB Vice-Chair and Canadian Association of Medical Publishers
- Dean Michelin (Pfizer e-business), Rx&D
- Ron Weingust, Canadian Generic Pharmaceutical Association
- Dr. Jeff Blackmer, Executive Director, Office of Ethics, Canadian Medical Association
- Praveen Chawla, NDMAC
- Paul Hickey, Association of Medical Advertising Agencies
- Sandra Leith, Faculty of Medicine Continuing Education Division, University of Toronto,
- Elgin Cameron (Merck Frosst) Rx&D

The request for participation in the Internet online survey was sent to 427 organizations and individuals representing federal and provincial governments, national health professional organizations, patient advocacy groups and all PAAB clients. The PAAB received 73 responses.

The committee met on June 4, 2004, to prepare for the review of the comments and the issue leaders were directed to make recommendations.

The draft approved by the Code Review Committee was sent to the Board delegates and Health Canada on September 1, 2004, with the request to disseminate it broadly through their membership with a deadline for comments set at

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October 20, 2004. All replies were received by early November, 2004, and the comments were reviewed by the Code Committee members.

The draft was rewritten by the committee Chair to reflect the Committee members' comments and sent back to the PAAB Members two weeks prior to the general meeting. On December 3, the PAAB Members approved the Code Review proposal with the removal of five words and the agreement of setting up two task forces to address outstanding issues.

Outstanding issues

During the course of the Code review project and after the initial phase of stakeholder input and Code Review Committee discussion, it became evident the Committee would not be able to address the issue of Fair Balance (s2.1, 2.4, 3.5) and Prescribing Information Requirements (s7) on the same schedule as the rest of the issues.

It was agreed the good work done on the rest of the Code should move forward. Therefore, a subcommittee chaired by Paul Hickey has been appointed to further investigate the feasibility of revising those sections.

Also, during the final phase review of the comments generated by the PAAB member organizations, it was noted that NDMAC members were requesting a different standard of evidence be required by the Code for nonprescription drugs and natural health products.

This issue was discussed by the PAAB Executive Committee. The PAAB delegates approved the recommendation that a separate task force be struck, under the direction of a chair chosen by NDMAC, to review the standards for nonprescription drugs and natural health products within the Code.

Implementation and communication

Full implementation of the approved revised Code will come into effect April 1, 2005. This would give the Commissioner time to inform the advertising community of the changes.

Proposed communication tools are:

- direct mail to clients,
- the PAAB January newsletter by mail and Internet,
- the Pharmahorizons newsletter, PMCQ and OPMA newsletters,
- PAAB member organization newsletters and publications and the PAAB Internet mail list.

The Code is published on the PAAB Web site for free copying. We are in the process of working with Pharmahorizons to organize a Spring open workshop. CPM

Questions can be directed to Commissioner, Ray Chepesiuk, or to Deputy Commissioner, John Wong, at the PAAB office.

Revisions to the PAAB Code

1. Scope clarifies the inclusion of "health-care products," in particular prescription and nonprescription pharmaceutical products, biologicals and natural health products. The target health professional audience is stated. Also stated is that the PAAB provides an advisory service on direct-to-consumer advertising and information activities based on the Health Canada guidance document, "The Distinction between Advertising and Other Activities."
2. Improved wording throughout the document to help clarify intent, as well as the letter of the Code.
3. Section 2.9 requires the medical/regulatory department of the sponsor approve the advertising before it is sent to the PAAB for preclearance review.
4. Sections 3.1.1 to 3.1.6 clarify what constitutes good evidence for support of claims in advertising.
5. Section 3.2.4 details requirements for promotion of ongoing research studies.
6. Section 4.2.1 provides a definitive minimum type size for statistical data information.
7. Section 5.10.1 provides a new statement about price comparisons.
8. Sections 6.4.2 and 6.4.3 provide some clarity on creating appropriate patient information that does not contain promotional claims.
9. Sections 6.5.1 and 6.5.12 provide new information on standards for appropriate advertising on the Internet.
10. Section 6.6.a and explanatory notes clarify the exemption regarding information derived from Continuing Medical Education events. They also help distinguish when these activities become advertising subject to the requirements of the PAAB Code. This is an attempt to address what was perceived as widespread abuse of this exemption.
11. Section 11 provides new or revised definitions.