PAAB Code Revisions:
Emphasis on Fair Balance Mandate

The Pharmaceutical Advertising Advisory Board

REVIEW

Ray Chepesiuk,
Commissioner

For over 30 years, the PAAB Code of Advertising Acceptance has been a living document, periodically being revised to match the current needs of the health-care professional community.

At the last General Meeting, the PAAB Members approved revisions to the PAAB Code of Advertising Acceptance. The revised Code will come into effect on July 1, 2007 and the PAAB will expect full compliance after that date. Materials approved by PAAB prior to July 1, 2007 under the old Code will be valid for six months, or one year, as provided for in the Code. It is anticipated that advertisers will want to make adjustments to their advertising plans ahead of that date and the PAAB will approve advertising that reflects the changes. It is generally agreed that promotion will influence prescribing habits and thus you will note that the bar is high for the standard of evidence used to support claims in advertising, exceeding the standards required for CME presentations. Stakeholder feedback will be solicited after the implementation of the new Code requirements.

It is anticipated that advertisers will want to make adjustments to their advertising plans ahead of July 1st, 2007 and the PAAB will approve advertising that reflects the changes.

Key change elements include:

- Harmonization with Health Canada terminology throughout the Code
- Section 2.4 and explanatory notes Fair Balance requirement: A modest change designed to redistribute minor information and study parameters from the body copy with a shift to the Prescribing Summary Box (section 7.3). Major safety information and necessary qualifying information (*e.g.*, dosing adjustments in certain patient populations or indication limitations) are still required to be shown. The goal is to redistribute the mass of small-type footnotes on the main display area of the advertising. The reviewers will work with advertisers to adjust to the new code requirement. The end result in each ad will be dependent on the product monograph
- Section 2.8: The requirement for a specific contact person from the sponsor's Medical or Regulatory departments to sign off on the advertising prior to sending it to the PAAB. It is the sponsor's corporate responsibility to designate an accountable person. We want to review market-ready material from the sponsor's viewpoint. The PAAB does not review and approve marketing objectives. The PAAB review is a scientific/clinical/regulatory review and therefore we want to know that qualified people from the sponsors agree with the material we are reviewing
- Sections 3.2.2 and 3.2.3: Revised wording to strengthen the message that statements should be consistent with the Terms of Market Authorization and no literature supporting off-label claims will be acceptable

- Section 5.10.1: Some claims may be supported by peer-reviewed, published meta-analyses. Use caution in interpreting this section because not all meta-analyses are of high enough quality to be accepted as support for advertising. The PAAB will reject sub-standard studies
- Section 5.11, Disclosure of Study parameters: It will be acceptable to put certain study parameters in the Prescribing Summary Box. The reviewers can help you during the review process
- Sections 5.13 and 5.14: New wording regarding equivalence claims and formulation studies
- Section 6.1: A requirement for the use of a new icon in journal ads to link to the indexed prescribing information (PI)
- Section 7: A major shift including extensive changes in the PI format and content requirements. Larger type requirement for "Prescribing Summary Box" information. Deletion of Full and Condensed Disclosure and replacement by requirements for "Advertising With Product Claim PI." This resulted from research with doctors performed by the Canadian Association of Medical Publishers (CAMP) and the PAAB. Health Canada was consulted early and late in the revision process. The approved format was rated high by physicians in readability and usefulness to clinical practice
- Section 11 Definitions: A few changes there

The risk of "information overload" has been highlighted by recent research with medical professionals commissioned by the Canadian Association of Medical Publishers (CAMP) and the PAAB.

Today, traditional medical promotional activities (primarily journal advertising, sales materials and direct marketing) are augmented by a range of other medical information services designed to educate physicians. These include:

- the Compendium of Pharmaceuticals and Specialties (CPS),
- accredited CME,
- promotional meetings and meeting reports,
- public relations and
- the internet.

Never before has access to information been so extensive.

At the same time, demands on physician time have expanded exponentially. The risk of "information overload" has been highlighted by recent research with medical professionals commissioned by the CAMP and the PAAB. They identified the desire for a clearer, more succinct and focused way to receive key pharmaceutical PI and important warnings. We identified what aspects of the PI were important to physicians. Consequently, the PAAB code was revised to:

1. Provide health-care professionals easier access to the most relevant and necessary prescribing and safety information. This will help facilitate the accurate evaluation of a product's suitability for any approved indication and patient profile
2. Allow for clearer communication of the product's key benefit and risks to health-care professionals
3. Demonstrate communication transparency for all products
4. Meet all necessary legal and regulatory requirements

The new format has been extensively reviewed via broad stakeholder and Health Canada consultation and research with health-care professionals. In testing, 93% of physicians selected the new design to become the industry standard and 97% considered it to be more useful than the existing format.

This improved design (with some minor adjustments for different media) will be used for advertising consisting of branded communications to health-care professionals. The definition of "advertising" in the PAAB Code is "... advertising or promotion or advertising/promotion system (APS) is defined as 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:

a) Has been published independently of the manufacturer (*e.g.* clinical reprints and meeting reports)
b) Is from an independent authoritative source
c) Is unchanged and complete

d) Is claimed to be educational material
These would include, but are not limited to:

- Promotional activities
- Medical journal advertising
- Company sales materials
- Branded direct mail
- Faxes
- Leave-behinds
- Branded sample package containers
- Posters
- Slides and materials given out at promotional seminars/meetings
- Press releases targeted to individual addresses or on websites
- Branded opinion leader consultation
- Branded sponsored speaker tour materials
- All promotional or branded "educational" materials
- All branded materials using new technologies: DVD, DVD/ROM, interactive kiosks, *etc.*
- All Canadian-based websites, discussion sites, *etc.*

Upon review, you will find that this new format offers distinct advantages. The most important of which is to succinctly communicate key safety and PI to health-care professionals in a user friendly way. With that objective in mind, the new Code revisions will greatly benefit all PAAB stakeholders and fulfills PAAB's desire to adapt to a changing healthcare environment.

The PAAB will be posting the Code and information related to the changes on *www.paab.ca* early in 2007. There will be open meetings in Toronto and Montreal with PAAB personnel on April 11 and 12, 2007. We will have the Code in print and on CD, available for purchase in January, 2007. **CPM**

Questions? Call Commissioner Ray Chepesiuk or Chief Review Officer John Wong at the PAAB office. I would like to thank Gord Schwab for his contribution to the PAAB code committee and his assistance with this article.