Pharmaceutical Advertising Advisory Board
Conseil consultatif de publicité pharmaceutique
375 Kingston Rd., Suite 200, Pickering, Ontario L1V 1A3

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PAAB ADVISORY

IMPORTANT REVISION OF PAAB CODE OF ADVERTISING ACCEPTANCE

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 6 months or 1 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 implementation of the new Code requirements.

Key Change Elements Include:

1. Harmonization with Health Canada terminology throughout the Code.
2. Section 2.4 and explanatory notes Fair Balance requirements – a modest change designed to redistribute minor information and study parameters from the body copy with a shift to the Prescribing Summary Box (s7.3). 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 dependant on the product monograph.
3. 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 are "eliminating" the possibility for agencies to play games by sending the materials to the PAAB at the same time as the sponsor. 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 sponsor agree with the material we are reviewing.
4. 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.
5. Section 5.10.1 – some claims may be supported by peer reviewed, published meta-analysis. 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.
6. 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.
7. Sections5.13 and 5.14 – new wording regarding equivalence claims and formulation studies
8. Section 6.1 – a requirement for the use of a new icon in journal ads to link to the indexed Prescribing Information

9. Section 7 – a major shift including extensive changes in the Prescribing Information 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 Prescribing Information". This resulted from research with doctors performed by 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.
10. Section 11 Definitions – a few changes there.

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 April 11 and 12, 2007. We will have the code in print and CD available for purchase in January, 2007. Questions? Call Commissioner Ray Chepesiuk or Chief Review Officer John Wong at the PAAB office.

Ray Chepesiuk
PAAB Commissioner