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

May 2001

PAAB ADVISORY: IMPORTANT PAAB CODE REVISION

USE OF ABSTRACTS FROM MEETING POSTER AND ORAL PRESENTATIONS AS SUPPORTING REFERENCES IN PHARMACEUTICAL ADVERTISING

Background

Generally, anonymous peer review for publication in scientific journals evaluates the scientific validity of a study, the newness of the findings and its conclusions, its interest for the readers of that journal, and the importance to the scientific literature. The author is provided with a detailed review that may question the methods, challenge a conclusion, ask why certain resources were or were not considered, or make other suggestions. The author is expected to respond to every comment and the response is evaluated by the editor. At larger journals, the final editorial review is done by a committee of editors, which may include a statistician, and the study design and analysis are assessed prior to a decision to accept or reject.

Scientific conferences usually include abstract or poster presentations to let participants know what research is underway and what trends they can expect in their specialty. An abstract is a precis of clinical or research findings, usually between 150-250 words. The review process includes a ranking scale to assess: the perceived importance of the topic, the interest of the study to a particular audience, inclusion as an oral or poster presentation, the clarity of the presentation, the significance of the conclusions, and whether it fits into the basic science or clinical practice categories. Abstract sessions allow preliminary findings to be presented and ensuing discussion among the meeting participants. Physicians would not change their practice based on such an exchange of information for the following reasons: the supporting documentation that details the methods, study design, results, discussion and conclusion is not available; in some cases the research has not been, or never will be, published; there is not enough space to include all of the science and thus, the validity of the science cannot be determined; discussion at the session may change the interpretation of the results, yet the abstract will remain unchanged in published form; it will provide preliminary data which may be substantially altered in the published paper or even between the time of acceptance of the abstract and its presentation at a meeting.

The PAAB consulted the following organizations on the use of abstracts as evidence for statements made in pharmaceutical advertising: Canadian Medical Association, Canadian Pharmacists Association, Canada's Research-Based Pharmaceutical Companies, College of Family Physicians of Canada, Féderation des médecins spécialistes du Québec, Royal College of Physicians and Surgeons of Canada and the Therapeutics Product Programme of Health Canada. The majority of these groups favoured outright rejection of abstracts with respect to their use to support statements in pharmaceutical advertising. Doctors will still have access to the information in abstracts through the attendance of meetings, journal subscriptions and unsolicited person-to-person correspondence with pharmaceutical companies.

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Based on these advisory comments, the PAAB Commissioner proposed revisions to several sections of the PAAB Code of Advertising Acceptance to the PAAB Members at the General Meeting of April 20, 2001. The report was approved unanimously by the PAAB Members. The Members agreed on an implementation date of July 1, 2001 for PAAB Reviewers to apply this revision. Advertising approved prior to July 1, 2001 that included abstracts as references will lose their PAAB acceptance on their renewal date or January 1, 2002, whichever comes first. Following are the changes to the PAAB Code.

PAAB Code Revisions Effective July 1, 2001

Section 3.1.1 Clinical/therapeutic claims ***must*** be based on published, well-controlled studies with clinical significance clearly indicated. Publication in peer-reviewed journals is usually a good criterion for establishing scientific rigor.

Section 3.1.2 Unpublished data are regarded as having received independent review when:
i) There is evidence that the full study manuscript has been accepted by the editor of a peer-reviewed journal for future publication, or alternatively when
ii) The data have been reviewed as part of a submission to Health Canada and there is evidence of acceptance (such as inclusion in the Product Monograph).

When presented only in the following form, study design and results analyses are not regarded as having been subject to independent review and are not sufficient evidence to be used as reference support for advertising claims:
i) Abstracts presented at conferences and in journal supplements
ii) Papers published in journal supplements unless the advertiser can demonstrate that the supplement has also been subject to an adequate peer-review process

Section 5.8.2 When presented only in the following form, study design and results analyses are not regarded as having been subject to independent review and are not sufficient evidence to be used as reference support for advertising claims:
i) Abstracts presented at conferences and in journal supplements
ii) Papers published in journal supplements unless the advertiser can demonstrate that the supplement has also been subject to an adequate peer-review process

For more information please speak to PAAB Commissioner Ray Chepesiuk or Senior Reviewer John Wong.

Ray Chepesiuk
Commissioner