ADVISORY

May 2000

From Commissioner Ray Chepesiuk

PAAB Code Revision

At the PAAB General Meeting of April 29, 2000, the PAAB members agreed to revise PAAB Code of Advertising Acceptance section 7.8 and Explanatory Note section 7.8.1. This revision will help clarify to advertisers that pre-Notice of Compliance advertising is not acceptable within the PAAB Code. Messages paid by pharmaceutical companies to provide information about therapeutic classes of drugs or treatment of disease require PAAB preclearance review. Some messages may not be deemed to be "advertising" by the Health Canada definition but are deemed to be advertising by the PAAB Code definition. This includes "teaser ads" that may not comply with the PAAB Code. Therefore, it necessitates the need for PAAB review of this type of advertising.

7.8 Editorial Advertising/Promotion Systems (APS)

Editorial advertisements are used to present company opinions on current issues, and disseminate updated information relative to therapeutic areas in which the company has a vested interest. This may include information with discussion of therapeutic aspects of, or research related to drugs.

They comprise company generated open letters, editorials, congress, conference and seminar reports, etc. published as paid advertising. They must be clearly identified as advertising to distinguish them from other editorial presentations.

All such materials must be submitted for PAAB review and clearance prior to distribution to health professionals.

7.8.1

Publication by the company of independently produced editorial reports in compliance with the company's Health Canada approved product(s) information is acceptable. In addition to identifying the article as advertising the author(s) should be identified along with any link to the sponsoring company.

The material may make reference to investigational research and must include pertinent qualifying information (a disclaimer that a drug has not been approved for such use in Canada). Data presentations or any claims of clinical efficacy, safety, dosage, administration etc for products which have not yet been authorized for marketing (pre-NOC) will not be accepted.

All copyright regulations must be respected.

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Fair Balance in Drug Advertising

Recently, PAAB has received a request from Health Canada to improve the legibility of safety information in drug advertising directed to health professionals. In fact, Health Canada has filed several complaints about specific advertising with respect to lack of safety information, poor legibility, poor contrast, improper location or small type size. PAAB has also seen commentary in medical journals about the lack of fair balance in drug advertising.

PAAB Code sections 2.1, 2.4 and 3.5 speak to the necessity of presenting balanced information about drug features (e.g. indications and limitations), safety to efficacy claims and positive to negative claims.

When ads fail to convey the whole story, as the approved labeling does, the overall message is potentially misleading. Not only is an incomplete message communicated to the health professional, there is also a false sense of the clinical efficacy and safety profile of the product. Therefore, PAAB is increasing its efforts in enforcing the fair balance requirements of the Code with the important objective of continually improving the quality of Canadian drug advertising and enhancing patient safety through rational drug use.

One particular area that requires improvement is the current practice of presenting safety information in small type at the end of the main text portion. This secondary positioning hardly balances the degree of prominence given to the positive selling points and often fails to communicate important safety information that health professionals need to be aware of when considering the drug product. The main portion of the ad should include reference to the safety profile and clinically significant adverse events. Special warnings, precautions or use limitations which are emphasized in the product monograph deserve a similar level of emphasis in advertising. Health professionals require a well-rounded profile of the drug in order to help ensure safe and effective use in their patients. Inclusion of important risk information only in fine print may be too easily overlooked and has been criticized as only marginally better than no safety information at all.

The indication and limitations seen in the product mongraph should be fully and clearly stated in the body copy of the advertising piece. This is especially important for new products.

PAAB invites all advertisers to join in increasing the profile of safety information within drug ads. We ask you to increase the type size, improve the contrast and position the safety information with prominence. Fair balance serves to ensure that advertising persuades usage of the product in a rational manner where the benefits and risks have been considered and the health professional is well-informed. Pharmaceutical advertising should strive for an image of credibility and trust – fair balance is an integral part of establishing that image. At PAAB, we often see advertisers pointing out the faults of the advertising of their competitors. We issue the challenge to pharmaceutical advertisers to be leaders in their field and provide useful, balanced information that serves to enhance rational drug prescribing. You will serve to raise the standard of drug advertising in Canada and promote the credibility of your communications.

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