The Pharmaceutical
Advertising Advisory Board

REVIEW

By Ray Chepesiuk, Commissioner

"Is it in the product monograph?"

A question PAAB Reviewers frequently ask these days is, "Is it in the product monograph?". That question is related to PAAB Code section 3.1, the section considered to be a cornerstone of the PAAB Code, it is based directly on a legal requirement found in the Food & Drugs Act. Ensuing discussions and numerous letters related to this issue serve to slow down the review process and lengthen PAAB review turnaround times.

Some of the examples of problematic reviews that have been brought to my attention include:

- Claims and data presentations from end-organ prevention trials using angiotensin II antagonists.
- Mortality and cancer prevention claims for Hormone Replacement products (I guess it was a good thing PAAB Reviewers were saying "NO" prior to the Women's Health Initiative study results announcement).
- Mortality and sub-group specific claims for lipid-lowering agents.
- Extension trial efficacy and/or safety data in a number of therapeutic areas.
- Cardiovascular events reduction (*i.e.*, stroke) for antihypertensive agents.
- Claims regarding incidental findings and their implied importance *i.e.*, microalbuminuria reduction.
- Dosage regimens used in published clinical trials that are not consistent with the Product Monograph, thus invalidating use of the study in advertising (s3.1).

Did you recognize any of your files related to that list?

For those of you who don't know, Health Canada issues a Notice of Compliance (NOC) after they have approved a drug for marketing in Canada. As part of that approval, the product monograph that is attached to the NOC sets the terms for marketing that drug. Advertising claims are limited to, and must be consistent with, the content of the approved product monograph.

Pharma company regulatory departments know that. That is why we have included a section on the PAAB Preclearance Review Form that allows the sender of the advertising to tell us whether or not the sponsor's regulatory department has reviewed and approved the final draft before it is sent to the PAAB for review. Having that regulatory review built into your procedure should save a lot of time for both you and the PAAB. Product managers and agency account people should consult the regulatory people, and listen to them.

We have had a few direct or indirect encounters with physicians who have been hired as writers or consultants for advertising projects. They are often perturbed by the restrictive PAAB review comments. What they do not understand is that the PAAB is usually not questioning the science or clinical practice element of the presentation. The PAAB refusal is usually based on the regulatory requirement.

Therefore, to provide consistency of advertising claims with the product monograph, it is important

to brief your physician experts regarding regulatory requirements for drug company advertising materials.

Are we getting more ethical?

Based on what is happening to the stock market, it appears that society regards ethical business practices as very important to their decision as to whether or not to invest. I believe that society places an even higher value on ethical business practices when health-care products or services are involved.

In the U.S., in reaction to the threats of elected officials, there have been significant voluntary actions by the pharma industry and physicians to clean up some of the unethical marketing practices that have become commonplace and regarded as the way business had to be done to be able to compete. The Pharmaceutical Research and Manufacturers Association (PhRMA) decided to institute guidelines for their members as a first step. The American Medical Association (AMA) has a training program for physicians to help them understand the ethical limits of their interaction with the pharma industry. Other adventures, such as the "No Free Lunch" program, have brought awareness of this issue.

Some action has been initiated in Canada as well. It is refreshing to note that both Rx&D and the Canadian Medical Association have recognized a need to provide some leadership in making their members aware of their own code and guidelines. It will be more difficult for code violators to argue they "didn't know" or that "everybody else is doing" what they did. I am aware of several upcoming conferences that will include a section on the ethical practices of agencies and CME suppliers to the pharma industry.

The PAAB has always tried to convey the importance of ethical marketing activities to the pharma industry. After years of the same message from the PAAB and others, the pharma industry appears to be catching on to the idea that, without public trust, they can have no credibility in their communication messages. Coincidentally, about half a dozen Canadian television programs about unethical pharma company marketing practices have aired within the past two years. When the public sees the dirty laundry, there is interest to clean it up.

The PAAB has a broad understanding of the marketplace and we have always acted in the industry's best interest to make you aware that others may have a different perception of your activities. We will continue to do that. CPM