The Pharmaceutical Advertising Advisory Board

REVIEW

By Ray Chepesiuk, Commissioner

The Good, The Bad, and The Ugly

Some of you may not know that the PAAB Commissioner is a voting member of the R_x&D Marketing Practices Review Committee. This committee rules on complaints about its members' marketing activities with respect to the R_x&D Code of Marketing Practices. The committee decides if there is a violation of the Code, in which case, a financial penalty is assessed by R_x&D, and details of the violation are published in its public newsletter. This appears to be a useful system, and one I would hope other industry associations would develop and enforce for their member companies.

Based on my experience assessing complaints at the PAAB and R_x&D, I have seen the good, the bad, and the ugly of Canadian pharmaceutical marketing.

In general, compliance with the PAAB is pretty good. On the positive side, the PAAB had a remarkable year with respect to the number of advertising/promotional systems (APS) that came in for review. The new reviews totalled a record 3,745, which represents a 36% increase over the 2001 total and a 16% increase over 2002. Detail aids, which are very labour-intensive per unit, represented 45% of the total. These figures indicate a very good level of compliance with the PAAB Code of Advertising Acceptance by the Canadian pharmaceutical industry.

On the other hand, we were made aware of some less than ethically stellar marketing practices through the PAAB and R_x&D complaint reports and through our own monitoring. I would hope these practices are isolated cases by single companies, and not indicative of an industry trend.

What is advertising?

From a regulatory perspective, how do we know if something is "advertising"? The Food and Drugs Act states that "advertising includes any representation by any means whatever for the purpose of promoting directly or indirectly the sale or disposal of any food, drug, cosmetic, or device."

To interpret the Food and Drugs Act & Regulations in the manner that Health Canada does, one should contemplate the Health Canada policy guideline, which lists factors to consider in determining whether or not something is classified as advertising. Also, there are sections in the guidelines specific to activities, such as CME/scientific symposia/exhibits, patient information, press releases, journal supplements/inserts, and unsolicited requests for information.

Advertising is defined in section 11.1 of the PAAB Code of Advertising Acceptance 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:

- *has been published independent of the manufacturer,*
- *is from an independent authoritative source,*
- *is unchanged and complete,*
- *is claimed to be educational material."*[1]

One area that needs some regulatory attention is the practice of calling advertising "CME", "education", or a "health initiative".[2] This is an area I call pseudo-CME, and one that will be addressed in our upcoming cover-to-cover review of the PAAB Code of Advertising Acceptance.

What is pseudo-CME?

There are several types of violations regarding pseudo-CME. First, there are meeting reports. In 1996, PAAB established a guideline (available online at *www.paab.ca*) to help the industry create meeting reports which would be exempt from PAAB review. In essence, the guideline was created to be consistent with the Health Canada policy guideline. The purpose was to allow sponsors to distribute information that was presented at bona fide, independently organized, accredited CME meetings. The information was to be about a specific therapeutic area, and be balanced, objective, and scientifically rigorous.

It appears that some suppliers and sponsors have interpreted this as a loophole regarding the need for PAAB preclearance, and, in my opinion, there is a direct conflict with the PAAB definition of advertising. I have seen reports that promoted the sponsor's drug with off-label claims, comparative information that was disparaging to competitors, and scientific methodology that was rather weak. One company sent us a copy of the signed agreement dated after the meeting, indicating that the supplier wrote the report then sold it to the sponsor. Does that sound objective?

Also under pseudo-CME, we have seen the distribution of "accredited CME" that was not evidence-based. I have heard others state that the standards of evidence in PAAB-approved advertising have exceeded those of CME. I am also hearing about doctors approaching pharma companies with the offer to produce "independent" educational material. I have seen a hospital newsletter that carries articles promoting individual drugs with information rejected by the PAAB during a requested review. I have heard allegations that the sponsor's product manager wrote or edited the piece, and the expert specialist doctors allowed their names be used as authors. In a few cases, I have seen doctors send out information about specific drugs on their own letterhead, with no mention that a drug company sponsored the creation and distribution of the material. Does that sound deceptive?

A trend of guideline abuse by sales representatives appears to be developing. I have seen cases of an overzealous representative handing out material that was rejected by the PAAB. While the companies may argue that this was the act of an individual representative, in some cases, there is indication that more than one representative had the same material. Another excuse is that the representative handed out "training material", and that the head office did not condone its distribution. The company is responsible for representatives' training and is accountable for their actions.

Another area of abuse is pseudo-market research. In this case, a representative performs a "market research" survey (before a notice of compliance has been granted) with the aid of a laptop, therefore, leaving no paper trail; this survey eventually leads to promotional claims about the sponsor's unapproved drug.

One of the worst marketing practices is the use of pseudo-clinical, or "seeding" trials. These are clinical studies which sponsors refer to as compliance studies or experience trials. It is suspected that most physicians prescribe by habit. The purpose of seeding trials is to get physicians to prescribe the sponsor's drug and see how it works to form a new habit. In one example, the physician did not even follow-up with the patient after the drug was prescribed. Of course, physicians get paid an honorarium to cover the administrative costs of creating a patient record. The physicians will also bill the provincial health authority for reimbursement for the same examination and paperwork. Does that sound like fraud?

What can we do? It has been suggested that the PAAB should require a review of medical communications because the marketplace has been fuzzed by all the "pseudo-whatever" that is out there. A few years ago, the PAAB Code was amended to cover patient information because of the violative material put into the marketplace by the pharmaceutical industry. Now, PAAB reviewers advise companies on patient information during the review process instead of the commissioner having to rule on complaints. This is an example of effective change.

In 2004, the PAAB will conduct a review to amend the Code as necessary. It will be interesting to see where that leads. CPM

References
1. PAAB: Code of Advertising Acceptance. Available online at www.paab.ca/eleven_en.html (Accessed on February 25, 2004).
2. Chepesiuk R: Supported by an unrestricted educational grant. CMAJ 2003; 169(5):421-2.