The Pharmaceutical Advertising Advisory Board

REVIEW

By Ray Chepesiuk, Commissioner

The U.S. War on Drug Marketing

One thing I have learned during my time at the PAAB is to follow trends regarding drug advertising in the U.S. because sooner or later they become prevailing practices in Canada. Those of us involved in the pharmaceutial industry closely monitor enforcement activities in the U.S. Sometimes we are proud to say the same activities do not occur in Canada, possibly because of the presence of the PAAB. At times, similar activities do occur and we are better able to handle them because of knowledge gained from the U.S. precedent. At the moment, there appears to be a war on inappropriate marketing practices in the U.S.

In late February of this year, I attended a conference: "Marketing of Pharmaceuticals—Defining the New Regulatory Paradigm." It was the 15th annual conference sponsored by the Drug Information Association (DIA) and every year a number of top U.S. Food and Drug Administration (FDA) officials are invited to present. This meeting offers one-stop shopping for information about drug advertising and regulatory activities in the U.S.

The conference is accredited as continuing pharmaceutical education. There are three learning objectives:

1. To discuss the latest policies from the FDA affecting drug marketing, advertising, and promotion.
2. To explain the significance of recent enforcement actions in this area.
3. To understand the application of FDA advertising and promotion policies on a day-to-day basis.

About 250 people attended this year's conference, which is designed for marketing, legal, regulatory, public affairs, and advertising executives in the pharmaceutical and biologics industries, as well as their consultants and agencies. This year the theme was based on the new paradigm which is developing for the regulation of pharmaceutical and biological product marketing.

All pharmaceutical companies seek to be aggressive in their marketing strategies, but must remain in compliance with FDA rules and regulations. However, the FDA has recently renewed interest in first amendment issues and the government has expressed concern over drug costs and is asking questions about the cost associated with marketing. Even the Pharmaceutical Research and Manufacturers of America (PhRMA) has issued a new code, setting a new standard for relationships with physicians.

The DIA conference focused on how this new paradigm affects each company. The agenda included an update on new FDA policies and the latest enforcement action, hypothetical cases that provide insights into FDA enforcement priorities, discussion of off-label promotion, direct-to-consumer advertising, and other promotional activities, as well as insights into future innovations in pharmaceutical marketing.

It appears all promotional activities are open to public scrutiny. During the conference the following sessions took place:

- An update from FDA officials on current policy and enforcement action, including presentations from the directors of the divisions involving advertising and labelling.
- An address from Bruce Kuhlik, the general counsel for PhRMA, about the meaning of the new PhRMA code.

- A panel discussion on the meaning of the PhRMA guidelines and the Office of Inspector General (OIG) Compliance Guidance.
- A panel discussion on emerging continuing medical education (CME) issues, standards, provider independence, education, and promotion.
- A panel discussion on international promotional issues.
- A panel discussion on non-traditional promotional activities, such as peer-to-peer communications (*e.g.*, dinner meetings), event marketing, sample programs, public relations, e-detailing, Web site management, pharmacy renewal programs, and product placement on entertainment programs.
- A closing question and answer session with current and former FDA officials and an industry representative.

An opening panel of legal experts discussed prevalent FDA issues and provided an update of activities during the past year. It was noted that there is a new FDA commissioner, Mark McLellan, and a new general counsel for the FDA, Daniel Troy, who is a first amendment scholar. Therefore, a shift in enforcement policy is expected. General Counsel is now reviewing compliance letters for all divisions to ensure consistency with FDA policy. Last year, several letters dealt with conference exhibits, indicating that the FDA was showing a monitoring presence in the marketplace.

It was also noted during the conference that the FDA Division of Drug Marketing, Advertising, and Communications (DDMAC) was being reorganized and new positions were being created. As well, we learned that the PhRMA Code of Marketing Practices, a voluntary code with no enforcement action, was only released in July 2002 and, therefore, it is too early to know if it is affecting the marketplace. Finally, the Accreditation Council for CME distributed a new draft showing a shift in thinking of standards regarding the pharmaceutical industry's involvement in CME activities for physicians. The draft is generating some controversy because 52% of financial support for CME comes from commercial funding and the new standards may be so restrictive that they will reduce that funding.

There appears to be a heightened awareness that pharmaceutical companies are pushing the envelope too far in their marketing practices and, consequently, third-party payers and state governments appear to have initiated a counter response to curtail these activities. There was a buzz in the audience when one speaker reported that a pharmaceutical representative may be indicted for fraud because of a payment to a doctor for a staff party. There have been prosecutions of some companies that have resulted in large settlements. The American Medical Association will conduct an educational program to help physicians.

It appears that the U.S. FDA is looking for a "Coalition of the Willing" to help in their battle to ensure appropriate marketing activities.

Overall, there was a consensus that there was a need in the U.S. for transparent, efficient, and effective marketing and advertising guidelines. Personally, I believe they need a self-regulation mechanism, similar to the PAAB Code of Advertising Acceptance, with its preclearance requirement, to keep the playing field level for all parties. CPM

JEAN-MICHEL HALFON CONTINUES AS PRESIDENT OF PFIZER

Ian Read, senior vice-president, Pfizer Pharmaceuticals Group and president of the Europe/Canada region, announced that Jean-Michel Halfon will continue as president of Pfizer Canada Inc. and as head of the Pharmaceuticals Group in Canada upon completion of Pfizer's acquisition of Pharmacia Corp.

Mr. Halfon has more than 25 years experience in the pharmaceutical industry and has held diverse positions within Pfizer and its operating division. He began his career with Pfizer France in 1977, eventually assuming the role of pharmaceuticals division manager from 1990 to 1998. In 1998, he moved to Pfizer world headquarters in New York City to lead a global development team. Mr. Halfon was first appointed to head Pfizer Canada in August 1999.

The completion of the proposed Pharmacia acquisition will reinforce Pfizer's therapeutic strengths in cardiovascular diseases, arthritis, pain, diseases of the central nervous system, women and men's health, anti-infective medicine, and respiratory diseases, as well as provide access to new therapeutic categories including oncology, ophthalmology, and endocrine disorders.

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