

Torys' Video Podcast Series: Pharmaceuticals

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Promotion of Drugs and Devices at International Conferences Held in Canada

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Eileen McMahon discusses the regulations regarding the promotion of drugs and devices by U.S. pharmaceutical and medical device companies at international conferences held in Canada.

Edited transcript

More and more often we're getting questions from U.S. pharmaceutical and medical device companies regarding conferences held in Canada. In recent years, the United States Department of Justice has started paying a lot of attention to "off-label" promotion of drugs and devices, and marketing of drugs and devices before they are approved. As a result, these companies are sensitive to what they can and can't do in Canada in terms of compliance with laws.

Let's consider Canada's *Food and Drugs Act* and its regulations. That law contains a general prohibition that a company cannot sell a product, such as a medical device or drug, that hasn't been approved for sale in Canada. This creates some concern about whether a company may be marketing a product off-label (in other words, not in accordance with its approval) or may be marketing a product before it is actually approved for sale in Canada — that would be a violation of our *Food and Drugs Act* and its regulations.

So what laws apply if a conference is held in Canada and is attended mostly by American physicians? How does a U.S. company seeking to comply with Canadian laws and applicable policies ensure that compliance is achieved? Health Canada publishes guidelines and policies on what it considers to be compliant activity. One factor to consider is whether the conference is an international conference. In other words, whether it's attended by Americans or people from other countries outside Canada. If that's the case, then there's more flexibility in terms of the marketing practices that can take place at that international conference. [So if the medical device or drug is not yet approved for sale in Canada or if the indication is not yet approved for sale in Canada, certain marketing activities can still take place at international conferences held in Canada.]

You might ask "What are the types of violations of Canada's laws on marketing drugs and devices that happen regularly?" Well, one violation that does happen has to do with the promotion of products off-label, or the promotion of products before they are approved.

What's an easy way to comply with this law, then? Sales representatives who are interacting with physicians may wish to restrict their promotional activities to activities that are within the confines of the approval. If the product is approved for a particular use, the product can be marketed for that use.

Keep in mind that the Health Canada policy allows companies to respond to requests for information, provided that those requests are unsolicited. If a doctor approaches a sales rep or a medical liaison person

and asks a question about a product that is not yet approved, the company can answer that question. Where do companies typically go offside? Well, at times sales reps can stray into areas of discussion that aren't "on-label" – aren't approved uses of the product.

One approach companies can take is to direct questions that come to them about unapproved uses for products to a medical support liaison person. This person can be instructed on how to respond to those questions in a way that is in full compliance with our laws.

In summary, international conferences can take place in Canada in full compliance with our laws. There are a few tips to consider when setting up these conferences, but U.S. companies can rest assured that their sales reps and their medical support liaison persons can attend the conferences and interact with physicians in a way that complies with Canadian laws. **T**