



INTELLECTUAL PROPERTY

By Jennifer McKenzie and Tamarah Luk

A look at Rx&D's code of ethical practices

Clarification provided on interactions with health-care professionals.

On March 31, 2012, Canada's Research-Based Pharmaceutical Companies' (commonly known as Rx&D) new Code of Ethical Practices came into effect, binding its member companies. The new code is an overhaul of the previous one to reflect current industry practices. Some of the more significant changes are discussed below.

New additions

For the first time, the new code expressly prohibits the promotion of off-label uses of drugs. With this change, the new code reflects long-standing prohibitions on off-label marketing under the Food and Drugs Act and Regulations. Unsolicited requests for information on off-label uses by health-care professionals are considered non-promotional and thus are not prohibited under the new code. However, members must forward such requests to their medical department and clearly indicate that their response to the request relates to an unauthorized use.

Other new additions include a section on the lending of medical equipment to health-care professionals, and on regulating member-developed patient-support programs.

Expansion and clarifications

The amendments require all members' employees to be trained in the laws and regulations governing their interactions with health-care professionals, governments, and others, as well as the code.

Previously, only sales representatives had to be trained on the code.

The new code also makes substantial changes to Rx&D's position on advisory boards and consultant meetings. First, the code has been broadened to allow members to retain stakeholders (i.e., health-care professionals, government, and any other stakeholder with an interest in or impacted by members' activities) as advisers/consultants.

it must be clear that hiring the stakeholder as an adviser/consultant is not an inducement for prescribing, supplying, recommending, etc., members' products.

The new code also clarifies the section on hospitality. This section [previously set out members' responsibilities when wining and dining stakeholders for "[facilitating] greater interaction." The new code gives this section the clearer title "Business Meetings and Discussions" and delineates members' responsibilities in connection with: (1) selecting venues, and (2) providing meals and refreshments. New provisions have been added to assist members on permissible hospitality activities. For example, the new code prohibits members from conducting business meetings

Other new additions include a section on the lending of medical equipment to health-care professionals, and on regulating member-developed patient-support programs.

Previously, only health-care professionals could be retained.

Second, advisory boards and consultant meetings appear to be redefined. Previously, both were defined based on subject matter: advisory boards were convened to advise on drug development (from discovery to maturity) and consultant meetings were convened to advise on specific product issues. Now, advisory boards will be defined based on their continuous relationship of advising members on different aspects of their business. Consultant meetings will be defined as *ad hoc* meetings on specific aspects of their business. Finally, agreements between members and advisers memorializing the retainer must satisfy expanded criteria under the new code. For example,

or events at personal residences. It also prohibits members from paying a clinic room rental fee, cleanup fee, or any similar fee that could be construed as a payment to gain access to a health-care professional.

Enforcement

Fines for violating the code are also increased under the new code: \$25,000 for a first violation, \$50,000 for a second violation, \$75,000 for a third violation, and \$100,000 for each subsequent violation. Infractions are still being posted on the Rx&D web site. ■

Jennifer McKenzie is a partner with Bereskin & Parr LLP and head of the firm's Regulatory, Advertising & Marketing practice group and Tamarah Luk is an associate in the group.