

## **Industry Practices Review Committee (IPRC) Decisions/Comments March 20, 2012 Meeting**

**Complaint: Company Y – Complaint Regarding Alleged Promotion of Product Z**

**Complainant: Individual X, Patient Group Member**

It is important to have open channels with members of the public in order to receive their suggestions and complaints. A complaint about a violation of the Code can be filed both by an Rx&D Member Company and by any other interested person. Genuine complaints relating to the infringement of the Rx&D Code are to be encouraged and dealt with in an efficient and transparent manner. The IPRC thanks Individual X for bringing forward concerns.

**Allegation:** That Company Y engaged in “disguised marketing and advertising to patient group members for Product Z”, in contravention of the *Food and Drugs Act* and Section 12 (Market Research) of the Code of Ethical Practices.

Please note that given the date of the complaint and the alleged infraction, the applicable version of the Code is the January 2010 edition, and all citations to the Code below are with respect to this edition.

**Decision: *No infraction.*** The IPRC believes there has been no infraction of Section 12 (or any other Section) of the Code of Ethical Practices.

***Preliminary Issue Relating to the Food and Drugs Act and CADTH Guidelines:*** The mandate of the IPRC relates to member compliance with the Code. It is not within the purview of the IPRC to make determinations with respect to member compliance with the FDA, or other applicable laws and regulations.

Accordingly, while Rx&D members are required to follow the requirements of the Food and Drugs Act (FDA), and other applicable legislation and regulations, the IPRC did not address those elements of the complaint related to the FDA.

Other elements of the complaint allege potential issues with respect to CADTH guidelines. For the same reasons cited above with respect to the FDA, it is beyond the mandate of the IPRC to make determinations with respect to compliance with CADTH guidelines, and therefore the IPRC did not address those elements of the complaint.

In the event that a complainant believes that applicable laws, regulations or guidelines have been breached by an Rx&D member company, the IPRC suggests that the complainant contact the relevant governmental agencies (in this case, Health Canada and CADTH) directly, copying Rx&D. In the event that the relevant agencies determine that there has been a contravention of applicable laws, regulations or guidelines, then the IPRC may be seized of the matter.

## Section 5 (Scientific Exchanges)

“Members must provide full and factual information on products, without misrepresentation or exaggeration. Statements must be accurate and complete. They should not be misleading, either directly or by implications.”

**a. Presentation.** The IPRC was provided a copy of the presentation delivered by the Company Y representative. The IPRC finds that this presentation did not infringe Section 5 of the Code. The information provided was detailed, exhaustive and factual in nature. The presentation itself was at the request of the patient group. There is nothing in the evidence that was presented to the IPRC to suggest that the presentation was anything other than the dissemination of factual, non-promotional information. It was not intended to be a balanced representation of all treatment options for the disease condition. This presentation provided information on the Product Z clinical trials and attempted to help the patient group membership understand the results of the Product Z clinical trials, as specifically requested of Company Y. While the information presented may possibly have been somewhat too detailed or technical in nature for the intended audience, this is not a violation of the Code.

## Section 12 (Market Research):

**b. Survey.** With respect to the survey questions or comments, Company Y notes that the Executive Director of the patient group has indicated that Company Y had no input into either the survey design, content, or related correspondence. No evidence was presented to the contrary. On the basis of this evidence, IPRC concludes that there was no infraction of Section 12 by Company Y.