

Industry Practices Review Committee (IPRC) Decision

Company X v. Company Y

Overview

Allegations:

- Company Y's funding of a webinar conducted by a patient organization contravenes many sections of the Innovative Medicines Canada Code of Ethical Practices ("Code") including Annex A, Innovative Medicines Canada Guidelines for Transparency in Stakeholder Funding.
- Some of Company Y's Other Learning Activities ("OLA") contravene the Code as well as Health Canada's Guidance on distinction between advertising and other activities for health products.

There were three main questions at issue with respect to the complaint:

1. Whether or not the product in question is out of scope of the Code given that it is not a prescription medicine per Health Canada's definition of "prescription drugs" (section A.01.010 of the *Food and Drug Regulations*)
2. Whether or not the webinars conducted by the patient organization with funding by Company Y were in contravention of the Code.
3. Whether or not the Other Learning Programs (OLAs) conducted by Company Y were in contravention of the Code.

Decision: No infraction. The IPRC reviewed all materials presented to it by the parties to the complaint. In light of their interpretation of the relevant provisions of the Code and of their assessment of the evidence before it, the panel members decided that no infraction had occurred. A summary of the reasons for this decision is outlined below.

Conflict of Interest: Prior to discussing the complaint, each panelist reaffirmed that they had no conflict of interest to declare in respect of the parties to the complaint.

Summary of the reasons for the decision

Scope of IPRC jurisdiction

The IPRC's responsibility is to adjudicate whether or not there has been an infraction under the Code based on the written record before it. While IMC members are required to act in accordance with all applicable laws and regulations, it is outside of the IPRC's jurisdiction to address elements of the complaint relating to compliance with other Canadian legislation and regulations.

The IPRC reviewed the allegations, responses and evidence submitted by both parties. In light of their interpretation of the relevant provisions of the Code, the panel members unanimously decided that the Code applies to Company Y and the product in question and that no infractions of the Code had been proven.

1. Scope of the Code:

Company Y submitted that given that the IMC Code is limited to activities for the purpose of commercializing “prescription medicines” and, given that the product in question is not a prescription medicine per Health Canada’s definition but rather is a Schedule D drug (not prescription), the complaint is out of scope of the Code. The IPRC did not agree that the product in question is out of scope.

The Code covers the activities of IMC members who interact with stakeholders for the purpose of commercializing all innovative products launched by IMC members (except medical devices and over-the-counter products). An interpretation of prescription medicines that would exclude Schedule D drugs such as insulin, biologics and vaccines would be contrary to the purpose and intent of the IMC Code. Furthermore, the IMC Code does not define prescription medicines and does not reference the *Food and Drugs Regulations* in this context. Although the Code makes reference to “prescription” products, the spirit of the Code clearly intends to cover products such as Schedule D biologics that are prescribed or ordered or otherwise delivered to patients under the care and direction of a healthcare professional. If the intention had been to exclude products other than medical devices or over-the-counter products, this would have been specifically addressed under the scope of the Code.

2. Webinars conducted by the patient organization with funding by Company Y

The IPRC determined that there had been no infraction of the Code as it relates to either the funding provided by Company Y to patient organization or the conduct of the webinars themselves. The IPRC determined that Company Y complied with the provisions of the Code as they relate to the funding of patient organizations as well as the guidelines related to transparency in stakeholder funding.

However, the IPRC noted that while Company Y respected the guidelines for transparency in stakeholder funding and adopted a hands-off approach with patient organization, there remained a potential perception of a conflict of interest in relation to the patient group’s statements and activities.

3. OLAs conducted by Company Y

The IPRC determined that the evidence provided by Company X regarding improper conduct relating to OLAs was not sufficient to support a finding of breach of the Code. Company Y denied the allegations. As with all Code complaints, the burden of proof rests with the complainant rather than the defendant. IPRC noted that it was guided by the written evidence and supporting documents provided, which did not support the serious allegations made with respect to this issue.

Recommendations of the IPRC

The IPRC has three recommendations for IMC’s consideration arising from this complaint:

1. The IPRC recommends that IMC clarifies in the Code, either by way of amendments or annotations, what is meant by prescription medicines and that Schedule D biologics and products prescribed or ordered or otherwise delivered to patients under the care and direction of a healthcare professional are in scope of the Code.
2. The IPRC further recommends that IMC, either by way of amendments or annotations to the Code, provides additional guidance to its Members seeking to comply with the Code and its Annex A on how to ensure that while patient organizations maintain their independence they are not seen as

proxies for Members funding programs or activities. Topics covered in the guidance could include, among others, the sponsors' obligations under the Code, the content of funded programs, the presentation of information, balanced materials, the use of Member logos, and funding acknowledgments.

3. The IPRC encourages all complainants to provide complete and compelling evidence to support their complaints. The burden of proof with respect to a complaint's validity rests with the complainant, and the IPRC adjudicates complaints based on the written record provided by the parties to a complaint. Submitting a complete file with supporting documentation and materials will help the IPRC in fulfilling its mandate to review and adjudicate whether there has been an infraction under the Code.