

Industry Practices Review Committee (IPRC) Decision/Comments
January 10, 2018 Meeting

Company X v. Company Y

Overview

Allegation: That Company Y's patient support programs (PSPs) violate sections 1.1 (Guiding Principles), 14.1.1 (Patient Support Programs), 14.2.2 (Ensure Integrity of the Industry) and 14.2.3 (Conflict of Interest) of the Innovative Medicines Canada Code of Ethical Practices (the "Code").

Decision: *No infraction.* For the reasons set out below, the IPRC determined that there has been no infraction of the enumerated sections of the Code.

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.

Substantive Issues

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 are outlined below.

❖ **General Comment regarding Payments to Physicians:**

- The panel was unanimous in its decision that payments to physicians for valid, clinically relevant services, that are not standard of care, and not otherwise reimbursed, are permitted by the Code (Section 14.2.3).

❖ **Allegations regarding Sections 1 and 14 of the Code:**

- Four of the five panel members found no infraction of the Code on the following bases:
 - **Section 1 (Guiding Principles).** The IPRC noted that, as per Section 1.1 of the Code, the Guiding Principles "are intended to provide interpretations of the Code and to assist Members where no specific provisions of the Code apply". Accordingly, the panelists considered the Guiding Principles in their interpretation of the relevant provisions of the Code and upon their review of the submissions and evidence presented by both parties.

The IPRC moreover clarified that its responsibility is to adjudicate whether or not there had been an infraction under the Code. Although not its traditional practice, the IPRC may consider evidence that a member has not acted in accordance with all applicable laws and regulations (Guiding Principle #3). However, it pointed out that any evidence with respect to adherence to laws and regulations must be specific to the complaint, and thorough



where both parties have an opportunity to present their evidence before a ruling by the relevant authority.

Notwithstanding the above, and considering the specific provisions in the Code for PSPs, the IPRC did not find reason to determine that Company Y was in violation of any of the Guiding Principles on a standalone basis.

- **Section 14 (Patient Support Programs and Medical Practice Activities).** The IPRC recalled its 2017 decisions, in which panelists concluded that Section 14 of the Code – when interpreted as a whole – allows for payments to be made to Health Care Professionals (HCPs) for PSPs (14.1.1), establishes overarching principles for program integrity (14.2.2), and also advises against the making of payments to HCPs for acts inherent to their standard of care (14.2.3). At that time, the IPRC noted the possibility that Section 14 may allow for different interpretations in different circumstances.

As such, the IPRC focused on the divergent set of circumstances before it – i.e. general guidance from the Collège des Médecins du Québec in relation to payments to physicians (not with respect to the specific program subject to the complaint adjudicated by the IPRC), and anonymous statements from two physicians allegedly indicative of undue inducement to prescribe Company Y's products. On balance, the majority of panelists concluded that the evidence provided was insufficient to prove that there had been a violation of Section 14 of the Code.

- One of the five panel members was in disagreement with the majority decision that there was no infraction of the Code. The dissenting panelist concluded that not all of the services offered by Company Y were clinically relevant and, in the panelist's opinion, some services were more administrative in nature. The same panelist was also concerned with the level of remuneration provided by Company Y for some of the services.

❖ **Recommendations of the IPRC:**

- The IPRC once again noted that repeated Code complaints on the topic of PSPs warrants renewed efforts by the association's Ethics & Integrity Core Team and its Board of Directors to comprehensively review of the language of Section 14 of the Code. As currently drafted, reasonable but differing interpretations of Section 14 are possible and disputes regarding compliance are likely to continue. The IPRC recommends that such a review should aim to ensure that sufficient guidance is afforded to Members seeking to comply with the section as a whole – either by way of amendments or annotations to the Code.