

Industry Practices Review Committee (IPRC) Decisions/Comments  
November 28, 2016 Meeting\*

Company X v. Company Y

**Allegation:** That Company Y’s patient support programs violate Guiding Principles 2, 3, 8, as well as sections 2.1 (Privacy of Patient Information), 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 of Ethical Practices.

**Conflict of Interest.** Prior to discussing the complaint, the IPRC panel members reaffirmed the absence of conflict(s) of interest amongst themselves and the parties to the complaint.

**Timeliness.** Company Y argued that the complaint was procedurally flawed, alleging that it was not filed with Innovative Medicines Canada “within 120 days of the event(s) giving rise to the complaint(s) or the date when the events became known to or reasonably out to have been known to, the complainant”, as per section 19.2 of the Code. While the IPRC had significant concerns around the timeliness of the complaint, there was insufficient evidence that Company X either knew or reasonably ought to have known of the events giving rise to the complaint prior to the commencement of the aforementioned period of prescription.

**Substantive Issues.**

The IPRC clarified that its responsibility is to adjudicate whether or not there had been an infraction under the Code. Accordingly, while Innovative Medicines Canada members are required to act in accordance with all applicable laws and regulations, it is outside of the IPRC’s jurisdiction to address those elements of the complaint relating to compliance with other Canadian legislation, regulations, or other relevant association or professional codes.

With respect to potential changes to Section 14 of the Code under consideration by the association and its membership, the IPRC wishes to clarify that its mandate is to adjudicate complaints on the basis of the Code as of the date of the complaint, without regard to subsequent actual or potential changes.

With respect to the argument that the complaints may not be heard by the IPRC due to alleged improper underlying motivations, the IPRC found that there was insufficient evidence that the complaints were “frivolous, vexatious, abusive to IMC or its member companies, or otherwise made in bad faith”.

Furthermore, with respect to the IPRC being an improper forum, the IPRC notes that all Members must adhere to the Code – including its complaint adjudication process – as a condition for their continuing membership in the association.



With respect to any potential *Competition Act* issue arising from an infraction, and given the finding that there was no infraction, this issue did not need to be considered.

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 decided – on a consensus basis – that no infraction had occurred, for the reasons set out below.

- Allegations re: Guiding Principles 2, 3, 8. The IPRC noted that the Guiding Principles are intended to provide interpretations of the Code and to assist Members where no specific provisions of the Code apply. As such, the IPRC considered the Guiding Principles in their interpretation of section 14 but, given the existence of a specific section pertaining to Patient Support Programs, there was no need to assess compliance with these principles on a standalone basis.
- Allegations re: section 2.1 (Privacy of Patient Information). The IPRC found insufficient evidence to support Company X's allegation that patient privacy has been violated as a result of their involvement in Company Y's patient support programs.
- Allegations re: sections 14 (Patient Support Programs and Medical Practice Activities).
  - The IPRC noted that there is a certain degree of ambiguity arising out of section 14 of the Code when interpreted as a whole, which allows for payments to be made to Health Care Professionals (HCPs) for patient support programs (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).
  - The IPRC also noted that "standard of care" is not a defined term in the Code, meaning that companies must interpret this important term independently and will inevitably lead to differing interpretations.
  - With respect to particular methods of payment, the IPRC did not consider the structuring of payments by member companies for patient support programs (i.e. either directly to HCPs or indirectly to HCPs through third party intermediaries) to be material. In its opinion, either of the aforementioned methods of payment, which are both permissible under Section 14, can potentially raise ethical concerns depending upon the amounts in question, frequency of payments, contractual provisions, the structure of the program, and other factors.

As a result, the IPRC found insufficient evidence that the Company Y patient support programs under review do not comply with subsections 14.1.1, 14.2.2 and 14.2.3, including, without limitation, whether: (a) the benefits to participating HCPs were more than "incidental"; (b) whether any practices "bring the industry into disrepute"; or (c) whether any "undue inducement" had occurred. Indeed, based upon the evidence presented by Company Y, there appears to have been a good faith effort made to comply with the requirements set out in Section 14.



### **Recommendations and Comments of the IPRC.**

- The IPRC recommends that Innovative Medicines Canada review the language of section 14 of the Code, with the objective of ensuring 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 – with a specific focus on reimbursable services and the applicable definition of standard of care.
- It was moreover noted that there might be confusion among companies regarding which services are reimbursable in different Canadian jurisdictions.
- In conclusion, the IPRC notes that Section 14 is intended to facilitate, rather than to restrict, patient support programs. Such programs are beneficial for Canadian patients and the healthcare system because they provide increased access to innovative medicines. However, the IPRC cautions that, where HCPs are eligible for reimbursement from public plans for services provided in relation to patient support programs, Members must not knowingly provide HCPs with compensation for the aforementioned services. Companies must demonstrate due diligence in ensuring that all of their programs and policies are compliant in this regard.

\*The complaint was heard by a panel of four IPRC members. Before hearing, the complaint or receiving any complaint materials, a fifth IPRC member recused from hearing the complaint because of a potential perception of conflict of interest.