Industry Practices Review Committee (IPRC)
Decision

Complaint filed against Pfizer Canada ULC ("Pfizer")

Overview

Allegations:

- Pfizer, through communications made in the context of its Patient Support Program ("PSP"), contravened several provisions of the IMC Code of Ethical Practices (the "Code"), including Section 5, Section 15, and the Guiding Principles.

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

1. Did Section 5.1.1.1 of the Code apply to the communications at issue, and if so, was a finding under that section warranted?
2. Did the communications disseminated in connection with Pfizer's PSP breach Section 15.2.2 of the Code by failing to meet the required standards of ethical conduct, oversight, and industry integrity?
3. Did the communications breach the Guiding Principles of the Code by failing to ensure fair balanced information, ethical conduct, and/or adequate oversight of third-party representatives?

Decision: Infraction Found. Upon reviewing the complete written record submitted by both parties, including the complaint, response, additional submissions, and related documentation, the IPRC unanimously determined that certain sections of the Code were breached by Pfizer, as outlined below.

Conflict of Interest: Both parties confirmed they had no objection to the members of the IPRC who adjudicated the complaint. All IPRC members reaffirmed that they had no conflicts of interest to declare with respect to the parties.

Jurisdiction and Scope of Review: The IPRC is tasked with determining whether there has been a violation of the IMC Code of Ethical Practices based on the written record before it. While IMC members are required to act in accordance with all applicable laws and regulations, allegations related to compliance with other Canadian legislation and regulations, and professional association codes, fall outside the jurisdiction of the IPRC.

Factual Overview

The complaint concerned two communications issued in connection with Pfizer's PfizerFlex Patient Support Program ("PSP") for a biosimilar product. The first communication, an email sent by a healthcare professional ("HCP") to a number of colleagues, described information that

had been conveyed to them by a representative of Pfizer. The second was a fax communication sent directly to a physician's office, bearing the PfizerFlex PSP branding.

The Complainant alleged that the communications conveyed that patients could no longer access their existing biologic therapy and would need to transition to a different Pfizer product in order to continue receiving PSP support. The Complainant raised concerns that this messaging was misleading and failed to acknowledge the continued availability of the original product under a different brand name. The complaint alleged that this created confusion for HCPs, may have impacted prescribing decisions, and failed to meet the standards of transparency, accuracy, and fair balance required by the Code.

Summary of the reasons for the decision

Overview of the Evidence Submitted by Complainant

The complaint centered on two pieces of evidence:

- An email communication from one HCP to multiple other HCPs that was subsequently forwarded to Complainant, the contents of which were attributed by the HCP to Pfizer.
- A fax communication, purportedly sent from Pfizer's "PfizerFlex" PSP to an HCP's office.

The IPRC concluded, based on the evidence before it, that the content of these communications originated from individuals acting on behalf of Pfizer, most likely from individuals employed by a third-party contracted by Pfizer to administer its PfizerFlex Patient Support Program.

1. Applicability of Section 5.1.1.1

While the complaint referenced Section 5.1.1.1 (which prohibits misleading promotional claims), the IPRC determined it was not necessary to make findings under this section. The communications at issue arose in the context of a PSP, and while their impact may have overlapped with promotional considerations, the IPRC declined to characterize the communications as promotional per se.

The IPRC instead focused its findings on Section 15.2.2 and the Guiding Principles, as these provisions more appropriately reflect the duties of Members in managing PSP communications, ensuring proper oversight of third-party vendors, and protecting the integrity of industry interactions.

2. Section 15.2.2 – Integrity of the Industry and Ethical Conduct of PSPs

Section 15.2.2 of the Code states that Patient Support Program activities should not bring the industry into disrepute. It further requires that member companies ensure that staff and third-party vendors have the requisite training and expertise so as to proceed in an ethical and

professional manner, and that all elements of PSPs and related services should be appropriate, reasonable, and in accordance with relevant Code sections.
The IPRC found that the communications in question:

- Provided incomplete and misleading information;
- Failed to make it clear that HCPs retained a choice between keeping patients on the same therapy through an alternative PSP program or transitioning to a different Pfizer product and remaining in the PfizerFlex PSP;
- Were made without adequate oversight or control by Pfizer, who did not take sufficient steps to supervise or audit the communications issued by its third-party PSP provider.

Accordingly, the IPRC found that Section 15.2.2 was breached. The IPRC emphasized that while there was no evidence of deliberate misconduct on Pfizer's behalf, the lack of clarity and oversight in its management of its third-party provider(s) resulted in communications that were incomplete, potentially misleading, and not fair balanced, as required by the Code. The fact that HCPs quickly contacted the Complainant regarding these communications, while not determinative, supports this finding.

Pfizer did not ensure its third-party provider(s) had the requisite training to conduct its PSP activities in accordance with the Code, and the resulting communications failed to uphold the integrity of the industry which, in the view of the IPRC, by necessary implication brought the industry into disrepute.

3. Guiding Principles – Accurate and Fair Balanced Information

The Guiding Principles of the Code (Section 1) require that all product information provided to stakeholders be accurate and fair balanced (Principle 7), and that all interactions be conducted professionally and ethically (Principle 2). Members must also ensure that third-party representatives acting on their behalf are appropriately trained in, and abide by, the requirements of the Code (Principle 4).

The IPRC found that the communications in question:

- Lacked fair balance by failing to mention the continued availability of the Complainant product under a different name;
- Did not provide sufficient context to enable adequately informed prescribing or transition decisions by HCPs;
- Reflected a failure by Pfizer to ensure that its third-party representative was appropriately trained in, and adhered to, the requirements of the Code.

Accordingly, the IPRC found a violation of the Guiding Principles. As with the finding under Section 15.2.2 the IPRC noted that there was no evidence of deliberate misconduct on Pfizer's behalf; however, deliberate intent is not a prerequisite criterion for finding a breach under these sections of the Code.

Decision

The IPRC finds that:

- Pfizer violated **Section 15.2.2** of the Code by failing to ensure adequate oversight of its third-party provider(s), resulting in communications that were incomplete, potentially misleading, and not fair balanced. The IPRC also found that Pfizer did not ensure its third-party provider(s) were appropriately trained in the Code, and that the resulting PSP activities failed to uphold the integrity of the industry.
- Pfizer violated the **Guiding Principles** of the Code by failing to ensure that its third-party representative(s) was/were adequately trained and that the communications disseminated through its PSP were fair balanced, complete, and consistent with the standards of professionalism and accuracy required under Principles 2, 4, and 7.

Recommendations

In addition to the decision, the IPRC has the following recommendations:

1. **To Pfizer:** The responsibility for PSP activities cannot be abdicated or diminished due to program scale, complexity, or the use of third-party providers. The IPRC recommends that Pfizer strengthen its oversight and auditing processes for PSP activities. This should include:
    - Ensuring third-parties and their personnel are appropriately trained and fully understand their obligations under the IMC Code;
    - Regularly reviewing and auditing communications disseminated through PSPs to ensure they are accurate, fair balanced, and aligned with Code expectations;
    - Implementing prompt investigative and corrective action when concerns are raised;

    To IMC Members: Although not raised in the complaint, the IPRC feels that it is important to remind all members that: (i) PSPs are offered for the benefit of patients, not as an undue inducement to prescribe; and (ii) PSPs must avoid offering services that substitute for the routine operational expenses of medical practices.

2. **To IMC Members:** The IPRC recommends that all IMC member companies apply robust oversight to their PSP activities, including those managed by third-party vendors. Member companies must recognize that PSPs are an extension of the company itself, and all conduct and communications within the PSP are attributable to the member. This includes training, supervision, messaging review, and adherence to both the letter and the spirit of the Code.

3. **To IMC:** The IPRC encourages IMC to consider whether additional guidance or clarifying commentary is warranted in future versions of the Code or related resources to reinforce expectations for PSP oversight and the boundaries of appropriate PSP structure and support.