



Dear Minister Philpott,

In every healthcare system, the therapeutic relationship is built on trust. Patients should have full confidence that healthcare professionals make decisions focused on their needs without hidden conflicts of interest. It is accordingly essential that those involved with the prescribing and dispensing of medicines—doctors, nurse practitioners, dentists, and pharmacists, among others—not be influenced by undisclosed financial conflicts involving manufacturers of pharmaceutical products.

We understand that interactions between the pharmaceutical industry and prescribers occur in healthcare settings worldwide. With rigorous safeguards, pharmaceutical companies also have a role to play in sponsoring research and continuing professional education. Regardless, the basic principle of transparency requires that patients and the public be informed when a prescriber has taken payment directly from any party with a financial interest in one or more drugs.

This consideration is particularly important given that the evidence regarding most drugs is seldom iron-clad. A large body of evidence indicates that industry relationships and payments can influence the positions taken by experts involved in the creation of decision tools such as clinical practice guidelines. While such payments may not necessarily preclude an expert from participation in guideline development and continuing professional education, this would be the preferred option except in unique situations. Participation by experts with financial relationships in creating clinical practice guidelines should depend on details such as whether they had an ongoing relationship, how long ago the relationship has taken place and whether it just involved the receipt of research funding or other activities on behalf of one or more companies. Similar distinctions can be drawn regarding any clinical studies an expert has undertaken with the support of a company.

We believe these distinctions can be readily accommodated even as payments and relationships are publicly disclosed. Other countries have already made major strides in the direction of public disclosure. In the United States, the Physician Payments Sunshine Act of 2013 makes it mandatory to report payments of as little as \$10 to the federal government. France, Australia and Denmark also have similar

laws requiring disclosure of prescriber payments. The question therefore is not whether Canada should proceed in a similar direction but how.

One path forward is for mandatory disclosure to become part of the ongoing bargaining between the pan-Canadian Pharmaceutical Alliance and major drug companies, or for it to be a prerequisite for any drug's inclusion in provincial or national formularies. Another option is that provincial and territorial licensing bodies could mandate disclosure by prescribers from different professions. However, to avoid serious inter-jurisdictional variations in disclosure, this approach depends on a national consensus involving perhaps thirty regulatory bodies. As well, regulators would not know if an individual prescriber was non-compliant unless individual-level payment data were released by the relevant companies.

Fortunately, there is an obvious mechanism to mandate disclosure at the national level without trespassing on provincial jurisdiction over health care. Under section 80 of the 1985 Patent Act, the Patent Medicine Prices Review Board [PMPRB] has statutory authority over “the costs of making and marketing the medicine where that information is available to the patentee in Canada or is within the knowledge or control of the patentee”. Given this jurisdiction, all that is needed now is an amendment to the Patented Medicines Regulations that legally obliges patentees to disclose payments to prescribers, health care institutions, societies and organizations. While the manufacturers of generic drugs would be excluded, the bulk of the payments of greatest interest involve drugs that are subject to patent protection.

What would the amendment stipulate? In keeping with existing wording of the Act, the relevant information would include (a) the identity of the patentee or former patentee; (b) the generic name and brand name of the medicine; (c) the date, amount, and purpose of any contribution, whether in cash or in kind, given to each person in Canada authorized to prescribe the medicine or to each healthcare institution, society and organization; and (d) notwithstanding the Privacy Act, the name and address of each person receiving a contribution referred to in paragraph (c).

Four other sections are needed. The first should stipulate that the required information be submitted each calendar year (say, within 60 days after year end). The second would require the PMPRB to publish this information within 90 days of receiving it. The third would exclude very small payments below a certain threshold (say, C\$25.00 or less). The fourth would stipulate meaningful penalties for patentees that fail to disclose the required information.

Care is needed to delineate how the reporting system would apply to payments made to institutions and professional societies. It would be unhelpful for, say, the director

of continuing professional development at a medical faculty or the vice president of research at a major academic hospital to be listed as the recipient of large sums of money from a wide variety of pharmaceutical companies when the money is given to the institution or society itself. In these cases, all that would be required is the name of the institution or professional society. Additional details on such events or research studies may be warranted, including clarity as to how the funds flowed to individuals or for projects.

In conclusion, it is long past time for Canada to follow the lead of other developed nations in bringing transparency to the financial dealings between pharmaceutical companies and prescribers. The rationale is clear and the machinery already exists for its implementation. Such reporting is not intended to shame prescribers or impede partnerships between industry and professionals. Rather, disclosure will help ensure that potential conflicts of interest that result from receiving payments are openly acknowledged so that patients and prescribers can make more informed decisions. It will also promote payments to institutions and professional societies rather than direct dealings that allow companies to influence individual professionals. In turn, this will reinforce the need for such intermediaries to develop and apply rules that prevent sponsors from skewing the content of continuing education programs or distorting the design, execution, analysis and publication of research studies.

We thank you for your time and consideration.

Sincerely,

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