Submission

Consultation on Health Sector Payment Transparency Act, Bill 160

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INTRODUCTION

Innovative Medicines Canada (**IMC**) is the national voice of Canada's innovative pharmaceutical industry. We advocate for policies that enable the discovery, development and commercialization of innovative medicines and vaccines that improve the lives of all Canadians. We support our members' commitment to being valued partners in the Canadian healthcare and regulatory systems.

IMC thanks the Ontario Government for the opportunity to make these written submissions to the Standing Committee on General Government regarding *Bill 160, Strengthening Quality and Accountability for Patients Act, 2017*, which are in addition to the remarks provided at committee on November 20th, 2017. IMC's submissions relate exclusively to Schedule 4, the *Health Sector Payment Transparency Act* (the **Act**).

At the outset, IMC notes that these consultations are particularly important given that any transparency regime adopted by Ontario could impact other Canadian jurisdictions. To the extent that other provinces implement similar legislation, IMC strongly supports harmonization among the jurisdictions to ensure uniform requirements for stakeholders.

As a general principle, IMC believes in transparent relationships with all of our stakeholders, including healthcare professionals (**HCPs**). However, IMC respectfully submits that the Act, in its current form, will not lead to the disclosure and reporting of accurate and meaningful information. As a result, there will be effects on what are otherwise appropriate relationships among stakeholders, and may result in overly invasive and costly impacts to industry, many of which are unnecessary to meet the purpose as set out in s. 1 of the Act. Furthermore, there is significant uncertainty around practical aspects of the Act given the amount of detail that has been left to regulation, which makes it difficult for stakeholders to meaningfully prepare for the introduction of the transparency regime.

The innovative pharmaceutical industry collaborates with HCPs in many critical and legitimate ways to support scientific advancement and serve the best interest of patients. IMC member companies communicate vital information about the use of medicines and vaccines, and conduct research that is essential for developing new medicines to address unmet or inadequately served medical needs. In turn, HCPs share firsthand knowledge about patient experiences with medicines with the innovative pharmaceutical industry – feedback that is critical to improving patient outcomes. Cooperation between HCPs, healthcare organizations and the innovative pharmaceutical industry is important at all stages in the research, development and use of medicines, to ensure patient safety, efficacy of therapy, and to accelerate the spread of knowledge about new clinical science.

These collaborations are bound by local and international laws and regulated by the ethical codes of provincial regulatory bodies as well as IMC's Code of Ethical Practices (the **Code**). Adherence to the Code is a precondition for membership in IMC, and member companies are required to confirm their ongoing compliance with the Code on an annual basis (Code s.19.1.2). IMC recognizes the importance of transparency in transfers of value between the private sector (including, but not limited to, IMC members) and HCPs. Transparency can facilitate public trust, assist patients in making informed decisions, and enhance the credibility of the innovative pharmaceutical sector as a partner in the Canadian health care system. IMC has embedded several transparency requirements in the Code. For example, when member companies sponsor learning programs, acknowledgement of sponsorship is required to appear on all program related materials (Code s. 9.2.3), and member involvement in patient support programs and medical practice activities must be transparent (Code s. 14.3.2).

The stated purpose of the Act (s. 1) is "to require the reporting of information about financial relationships that exist within Ontario's health care system, including within health care research and education, and to enable the collection, analysis and publication of that information in order to,

> (a) strengthen transparency in order to sustain and enhance the trust that patients have in their health care providers and in the health care system;
>
> (b) provide patients with access to information that may assist them in making informed decisions about their health care;
>
> (c) provide the Minister and others with information for the purposes of health system research and evaluation, planning and policy analysis; and
>
> (d) provide for the collection, use and disclosure of personal information for these purposes."

For the Act's purpose to be met, the reporting of financial relationships must be accurate and meaningful to ensure that the information analysed and published by the Minister is itself accurate and meaningful, and therefore meets the objective of this transparency initiative. IMC advocates for a measured approach to the mandatory reporting of information about financial relationships within this new transparency regime whereby details are developed by way of a working group that includes government, industry and other stakeholders. This approach would best ensure that the information collected supports the government's objectives for this legislation, to ensure that the drivers of innovation are not stifled, and to allow industry to take the required steps to ensure accurate and meaningful disclosure. By taking a measured approach based in dialogue, industry and other stakeholders can work with the government to build a solution that meets the government's requirements while respecting the implementation concerns of stakeholders.

IMC has identified the following six key concerns with the Act:

1. **The number of details left to regulation:** The Act leaves many significant issues to be addressed by subsequent regulations. By leaving so much of the new regime to the regulations, there may not be a meaningful opportunity for consultation on crucial aspects of the new regime, and companies cannot properly prepare at present for the new regime without additional information that will only be included in the regulations.

2. **The scope of the Act:** The Act appears to provide powers to Ontario inspectors that extend beyond Ontario and Canada, and may lead to unequal enforcement resulting in inaccurate and therefore, meaningless disclosures that will frustrate the transparency initiative.

3. **Reporting issues:** Ambiguities in the Act could result in both over and under reporting of transfers of value, and in this regard, could frustrate the intent of the transparency initiative because of inaccurate reporting.

4. **Privacy:** The Act provides exemptions from privacy legislation allowing disclosure of personal information that may be far broader than is necessary to accomplish the purpose of the Act.

5. **Records:** The Act may place record keeping requirements on individuals who are unaware or unable to maintain such records.

6. **Liability and Enforcement:** The Act provides overly broad inspection powers and penalties that are not proportionate to the stated purpose of the Act.

1. SIGNIFICANT DETAILS LEFT TO REGULATION

IMC notes that many details of the newly proposed regime are left to regulation, including information which will be crucial in determining the impact and scope of the Act and how our members will comply with the regime. Given the importance of the issues that have been left to regulation, IMC respectfully submits that the government should engage stakeholders in the development of such regulations, including before such regulations are drafted and circulated for comment. Some examples of the important details which have been left to regulation are as follows:

- **"Recipient":** the definition of "recipient" has been left to be prescribed by regulation (s. 2). The way that recipient is defined will directly impact the reach of the Act. IMC considers this definition to be of crucial importance to the transparency regime and would welcome the opportunity to further consult with the Ontario Government and other stakeholders on this point.

  In so far as HCPs (irrespective of HCP designation) are included as part of the definition of recipient, it is important that the definition of recipient be limited to those HCPs that are engaged directly in the care of patients. Manufacturers engage consultants who are registered HCPs but who do not provide care directly to patients. Reporting of their remuneration is beyond the intended scope of the Act and should therefore not be included.

  Also of importance to our members is that the Act captures transfers of value by generic pharmaceutical manufacturers, who typically make payments and/or provide other benefits to wholesalers, operators of pharmacies, or companies that own, operate or franchise pharmacies, or to their directors, officers, employees or agents in Ontario. IMC submits that such transfers of value must be included in the definition of "recipient".

  In addition to pharmaceutical companies, the government should ensure that medical device companies and others who participate in transfers of value in the healthcare space should be included in the transparency regime.

  The definition of recipient may also result in the need for reporting that is not necessary to achieve the stated purpose of the Act. For example, the definition of recipient may inadvertently capture employees, non-arm's length family members and/or organizations owned or controlled by HCPs and could implicate transfers of value that are unrelated to a physician acting in his/her capacity as an HCP.

- **Threshold**: Another important detail left to regulation is the threshold payment below which transfers of value need not be reported. The proposed Ontario Act identifies in s. 4(2) that a threshold will exist, but does not include the dollar amount.

  The threshold will have a significant impact on the cost to implement any reporting system, affecting both payors, HCPs, and the government. If a very low threshold is chosen, particularly if qualified by an aggregate amount as it is in the US Sunshine Act, minor payments, such as coffee purchases, will have to be tracked and reported at great time and expense to the manufacturer, government, and recipients. The low aggregate amount in the US has resulted in a complex, resource intensive, and costly system with unclear and unproven public policy value.

  Further, given the significant penalties provided for in the Act, a low threshold could result in disproportionate consequences for minor or inadvertent misreporting. The lower the threshold, the more difficult it will be to track payments, and the higher the chances of reporting errors resulting in potentially inaccurate and less meaningful disclosure to Ontarians about the transfers of value in the healthcare

system. IMC members consider the threshold to be of crucial importance to the transparency regime and would welcome the opportunity to further consult with the government and other stakeholders on this point.

- **Exempted Transactions**: Subsection 4(2) of the Act further exempts "transactions that are otherwise prescribed by regulation" without any indication of what such exemptions might be. These exemptions could become important. For example, payments to an employee's HCP (to the extent that the healthcare provider is included in the definition of "recipient") could engage the reporting obligation. If a pharmaceutical manufacturer (for example) funded an employee's drug therapy, and recipient is defined to include a pharmacist, the employer's payment for the employee's drug therapy could be reportable if it is not exempt by regulation. Likewise, if physician services for employees not covered by OHIP are funded, these could also be reportable.

  Reasonable exemptions will also be required to ensure that other transfers of value not intended to be included in the regime are not captured. For example, if a registered physician is directly employed by a manufacturer, he/she should be excluded. Salaries of employees are highly confidential and such disclosure would be unrelated to the stated purpose of the Act. Likewise, manufacturers often hire experts in the context of litigation, some of whom are HCPs. Reporting of such payments is also unrelated to the stated purpose of the Act and therefore should be exempted.

  As discussed above, IMC believes that a measured approach to implementing transparency initiatives involving cooperation among government, industry and other stakeholders is in the public interest. IMC submits that the goals of the transparency regime would be better accomplished by clearly defining the types of transfers that are reportable in the Act itself and adding when necessary, rather than broadly defining transfer of value and then exempting certain transfers afterwards.

- **Frequency and Method of Reporting:** Other details remain to be determined by regulation including the frequency and method of reporting. As an example, s. 4(5) states (number 6) that the payor will have to report "a description of the transfer of value, including the reasons for it". Providing a list that enumerates categories of payments would facilitate consistency in reporting and provide certainty as to the types of payments that need to be reported. If the Ontario regime leaves it to the payor to provide a "description" of the transfer of value, the level of discretion could result in inconsistencies in reporting, ultimately resulting in inaccurate and potentially meaningless end-data, which would frustrate the intention of the Act. Additionally, IMC recommends that the frequency of reporting be not more than once per year, since more frequent reporting would be more burdensome without any clear additional benefits.

These examples of the substantive content that has been left to regulation also raise potential concerns about the opportunity to participate in a reasonable and timely manner in the consultation process. IMC respectfully submits that there must be additional consultation on any draft regulations made under the Act to ensure ample consultation with, and resulting procedural fairness for, stakeholders on the above-noted (and other) important elements of the proposed regime that have been left to regulation. As set out above, IMC submits that the government should engage stakeholders in the regulation-making process, i.e. before regulations are drafted and circulated for comment, including by establishing a working group or committee that includes stakeholders, for the purpose of considering these important practical issues that need to be resolved in order to ensure a meaningful and operational transparency regime.

Furthermore, without a better understanding of the specifics of the regime, it is difficult to begin the process of modifications in the systems which will be required for the collection and disclosure of the required information. IMC submits that the government must ensure that all material details of the proposed regime are disclosed well

in advance of it taking effect to ensure ample time for stakeholders to be prepared to comply. In its current state, the Act does not include the level of detail needed for businesses to prepare for implementation.

It also would be advisable to establish a first reporting period that provides all stakeholders with reasonable lead time of at least six months prior to any initial reporting period to revise their internal systems to comply with the new reporting regime. This transitional period should not commence until all details of the transparency regime are known (i.e., after regulations are published).

2. SCOPE OF THE ACT

The definition of "payor" in the Act (s. 3) is broad and, as such, appears to give broad jurisdiction to the Ontario government, including over companies and individuals outside of Ontario and Canada that are involved in a transfer of value in Ontario. The Act also provides considerable inspection powers as well as the ability to issue compliance orders.

Given that many pharmaceutical companies are multinational corporations, IMC questions how the Ontario government can effectively enforce the Act in the case of foreign manufacturers or foreign affiliates of Canadian manufacturers. For example, if ABC Canada Inc. is the Canadian subsidiary of ABC Co, and ABC Co. makes a reportable transfer of value to an Ontario physician but does not report it, the Ontario Government may not be able to enforce the Act against ABC Co. for several reasons. The jurisdiction in which ABC Co. operates may not be amenable to assisting or enforcing the Act, or, from a practical perspective, it may be difficult for the government to send inspectors to investigate foreign companies.

The Act also holds every director and officer of a company responsible for ensuring compliance with the Act (s. 16). It is difficult to understand how this provision could be enforced, but IMC notes that it could result in significant personal liability to both Canadian and foreign directors and officers. While IMC understands that this is not the first proposed regime to hold foreign directors and officers liable for activities occurring (or not occurring) in Ontario/Canada, IMC is concerned that difficulties in enforcement will result in a system that does not facilitate accurate and meaningful reporting, resulting in inconsistencies in disclosure and frustration of the intent of the transparency regime.

Additionally, it is not clear from the Act what transfers of value will be captured. For example, is the Act only triggered by a transfer of value to an Ontario-based recipient for services rendered in Ontario? Or is the Act also triggered by a transfer of value to an Ontario-based recipient if that transfer was made for services rendered in another province (for example, if an Ontario physician provides continuing education at an event in Alberta)?

It is very important to the IMC membership that there be no incentives or opportunities for companies to avoid compliance with the Act. While the IMC membership believes in the importance of transparency, we are concerned that not all participants in the healthcare system who make transfers of value will necessarily feel the same way. Therefore, depending on the scope of the Act, there may be additional consequences for the collaboration between industry and HCPs in Ontario. For example, it could lead to the structuring of payments outside of Ontario, the sponsoring of continuing education events outside of Ontario, or the exclusive use of non-Ontario consultants. IMC members are aware that the introduction of Bill 102 in Ontario[1] resulted in generic drug companies structuring the making of rebate payments in the rest of Canada to avoid triggering the Ontario

[1] Bill 102 introduced caps on the rebates that manufacturers could pay to wholesalers, operators of pharmacies, or companies that own, operate or franchise pharmacies, or to their directors, officers, employees or agents in Ontario. Such rebates are now prohibited under the *Ontario Drug Benefit Act* and the *Drug Interchangeability and Dispensing Fee Act*.

regime. It is foreseeable that commercial entities who are not members of IMC could structure their activities to either avoid or limit their reporting requirements under Bill 160.

3. REPORTING ISSUES

At a high level, the Act speaks to the following reporting obligations:

1. A payor must report all transfers of value made directly by itself or indirectly through an intermediary (s. 4(1)); and

2. An intermediary, affiliate of an intermediary and affiliate of a payor may be asked to report with respect to a specific transaction, at the request of the Minister (s. 4(3)).

IMC is concerned that this reporting structure creates both the potential for double reporting, and the potential for unreported transfers of value. The lack of clarity around what must be reported could also lead to the collection and disclosure of inaccurate information, which would frustrate the purpose of the transparency regime.

A. *Potential Double-Reporting*

There is a potential for double reporting under the Act in the case where the Minister requests reporting of a specific transaction from an intermediary or affiliate of an intermediary, and where the transfer of value was already reported by the payor.

"**Intermediary**" is defined in the Act (s. 2) as a person or entity who provides or facilitates a transfer of value to a recipient on behalf of a payor. Payments made indirectly by a payor through an intermediary must be reported by the payor. In addition, as set out above, intermediaries must report directly when the Minister makes a request with respect to a transaction. It appears from the language that this reporting is transaction-specific.

Therefore, where a transfer of value is made by a payor through an intermediary, the payor would have to report that transfer. Additionally, the Minister could request that the intermediary report, in which case the transfer of value would be double reported. For example, if ABC Canada Inc. pays physicians through an intermediary company XYZ Co., ABC Canada Inc. would report such payments as required. If the Minister asks XYZ Co. to report as well, these transfers of value would be double reported. To the extent that the ability to require an intermediary to report is intended for verification purposes only, i.e. to confirm a source of funding, IMC suggests that this should be clearly articulated in the Act to avoid concerns around potential double-reporting.

Additionally, an intermediary can itself meet the definition of a payor and, accordingly, indirect transfers of value made from a manufacturer to a healthcare provider through an intermediary that is itself a "payor" would be double reported. Using the example above, if XYZ Co. is a marketing firm, it will meet the definition of "payor" and both ABC Canada Inc. and XYZ Co. will have to report the same payments.

The example above also demonstrates a further potential complication: ABC Canada Inc. may not be aware of the payments that are made to HCPs by XYZ Co., and the HCPs may not be aware of ABC Canada Inc.'s identity. One or more parties may therefore be unable to accurately record the payment and ABC Canada Inc. may be unable to accurately report such payments. This may occur, for example, when the nature of the service the intermediary is providing requires that the identity of one or more party is not known to the other party (e.g. during market research where the recipients are blinded as to the manufacturer's identity).

By way of comparison, the Sunshine Act accounts for this by exempting payments where the manufacturer is unaware of the identity of the recipient. While it is possible that such payments will also be exempted by regulation, this is not clear from the Act as currently drafted. If these payments are not exempt, payors will need

to structure contractual relationships in a way that would require the third party, if it is not itself a payor, to report any payments to recipients back to the manufacturer which may, depending on the intermediary's role and purpose, be problematic. IMC submits that such payments should be exempted by the Act itself to prevent confusion and unnecessary liability.

It is unclear from the Act how the Minister will take potential double reporting into account. IMC is concerned that the end result could be a misrepresentation to the public as to the extent of transfers of value made within the healthcare system generally. Depending upon how the Minister ultimately reports to the public, this potential double reporting issue could also have implications for individual HCPs, who may be seen to have accepted multiple payments when, in reality, only a single transfer of value was made.

Although not a true "double reporting" issue, these definitions also create ambiguities and potentially onerous reporting requirements for manufacturers given the corporate structures of pharmaceutical companies. For example, in a multinational company, each corporation could be considered a separate "payor", each with its own, overlapping reporting obligations. The government could therefore receive reports of some transfers of value from ABC Co. and reports of other transfers from ABC Canada Inc. Depending on the complexity of corporate structures, this uncoordinated reporting could result in significant difficulty in tracking payments and potential under or over reporting.

B. Potential Missed Reporting

"**Affiliate**" is defined (s. 2) by reference to the definition in the *Business Corporations Act*. Essentially it includes parent companies, sister companies, and subsidiaries. Affiliates must report transfers of values in situations where they meet the definition of "payor", and also upon request of the Minister (i.e. even where it does not meet the definition of "payor"). There is no requirement that anyone report payments facilitated by an affiliate, if the affiliate does not meet the definition of "payor" and no request is made by the Minister. Presumably, if no request is made by the Minister, a transfer of value made by a non-"payor" affiliate may not be reported. For example, if ABC Canada Inc. and ABC Co. structure their activities such that ABC Co. does not meet the definition of "payor", and all payments made to HCPs are made from ABC Co., these payments could go unreported.

IMC notes that the affiliate in this scenario may nonetheless be considered an "intermediary". If these definitions are considered mutually exclusive, however, the potential for missed reporting exists.

C. Description of transfers of value unclear

As discussed above, the Act provides in s. 4(5) that the information to be reported shall include "a description of the transfer of value, including the reasons for it". Much discretion is therefore left to payors to report the purpose of the transfer of value. IMC is concerned that the lack of standards in reporting obligations could result in inaccurate and potentially meaningless data being reported to the Minister, and then subsequently disclosed to Ontarians.

The Act could instead provide categories within which payors report. This approach has two advantages: first, it provides clear data that is easily interpreted and analyzed; and second, it has the advantage of making clear which types of transfers are reportable and ensures that some of the unintended transfers discussed above are not inadvertently captured by the reporting requirement. Additionally, and as set out above, if a very low threshold is chosen, minor payments will have to be tracked and reported by way of potentially-trivial descriptions.

Although we understand that the regulation-making power provided in the Act extends to defining or clarifying words or expressions used in the Act, IMC submits that the descriptions are better defined in the Act itself. This would allow for greater certainty to payors and ensure that the aims of the Act are achieved.

4. PRIVACY

The Act provides broad exemptions allowing the Minister to collect and disclose personal information. While certain information (e.g., physician name and address) will likely be necessary to fulfill the purpose of the Act, IMC submits that limits should be included such that only that personal information that is strictly necessary will be collected. IMC submits that this can be accomplished by identifying specific types of information, rather than granting the Minister the broad power to collect and disclose unqualified "personal information" (s. 6(1)). The Act does provide that if the Minister intends to collect information it must give notice as required by the *Freedom of Information and Protection of Privacy Act* and can do so by posting notice in accordance with s. 4(6) of the Act (either on a government website or by other prescribed method). Personal information should, therefore, be limited to the type for which notice is given.

Given the mandatory nature of reporting of this information, IMC submits that an explicit provision exempting payors from liability for sharing the personal information required should be included in the Act.

5. RECORDS

The Act imposes record retention requirements on both parties to the transaction (s. 4(9)). It is therefore necessary that both the payor and the recipient (and the intermediary or affiliate if applicable) retain records of any transfers of value. This requirement may not be clear to recipients and may create onerous record keeping requirements for individual HCPs. For example, a healthcare professional may be required to keep track of every coffee purchased by a sales representative and when the purchase is made, and may be unaware of the value. This requirement would be even more difficult in the case of a company-sponsored learning event where a meal is served to participants and the value to each recipient is difficult to ascertain.

6. LIABILITY AND ENFORCEMENT

Section 15 of the Act provides an exemption of liability for the Minister when acting in good faith. In contrast, s. 17(3) states that it is not a defence that a payor has taken all reasonable steps to prevent a contravention.

IMC respectfully submits that this unbalanced approach places significant potential liability on payors, particularly given the uncertainties and ambiguities that exist within the regime, and the potential difficulties associated with collecting all the necessary information. This could be exacerbated by the multinational nature of many companies and the duplicative and overlapping reporting obligations required under the Act. For example, if the threshold for payments is low, a sales representative could easily lose a receipt and forget to report it. Provided the manufacturer has taken reasonable steps to ensure such errors do not happen, the manufacturer should not be liable for this type of oversight on the part of its employee. This strict approach to liability is inconsistent with the goal of the Act.

The Act also provides broad and potentially excessive inspection powers, as well as the ability to issue compliance orders. For example, an inspector may without notice, on reasonable belief that a record relating to a reportable transaction is located there, enter and inspect for the purpose of determining compliance (s. 9(2)). Given that reference is made to a "reportable transaction", it appears that an inspector will be able to conduct an inspection relating to any transaction that has a value greater than the minimum amount. Invasive inspections are completely inappropriate in relation to minor payments or *de minimis* reporting errors.

In addition to examining records, an inspector may question any person on matters the inspector determines relevant to the inspection (s. 9(6)) and audit accounts and financial transactions (s. 9(7)). While this may not be

used frequently in practice, it does provide inspectors with considerable power and may be unnecessarily disruptive to payors.

These enforcement powers appear to be over-reaching and provide too much discretion given the purpose of the Act. Additionally, in comparison to other federal legislation with similar inspection provisions, the overall impact of non-compliance with the Act should be considered. That is, there are no risks to health or safety or consumers (as with the *Food and Drugs Act*), and no risk of non-payment of significant funds owing to the government (as with the *Income Tax Act*). IMC submits that the Act's inspection and enforcement powers should be proportional to the risks and implications of non-compliance. At a minimum, this should include reasonable notice and the ability to challenge a decision to inspect. Given that there are methods of inspection which are less costly to both the Minister and payors, IMC believes that the inspection provisions of the Act should be modified.

The Minister or an inspector may serve a compliance order that requires a person to do anything, or refrain from doing anything, in order to comply with the Act and regulations (s. 11(1)). Although the Act provides the opportunity for payors to make submissions before compliance orders are made public, there is no appeal provision. IMC submits that this broad provision is both unnecessarily harsh and unfair and that the Act should contain an appeal provision for payors.

The Act also provides offence provisions for any person who contravenes the Act or regulations. In IMC's submission, the monetary penalties provided for in the Act are unreasonably high, considering the goal of the transparency regime. Further, IMC notes that there is no limitation period. Given the practicalities of reporting and maintaining records, this creates an onerous and indefinite obligation. IMC submits that liability should be limited to a reasonable amount of time, and that reasonable limitation period should be included in the Act.

CONCLUSION

While IMC recognizes the importance of transparency in the healthcare system, it has numerous concerns with the Act as currently drafted as set out above. IMC and its members thank the Committee for the opportunity to submit these concerns, and would welcome the opportunity to further elaborate on these issues or to answer any questions upon request.