INNOVATIVE MEDICINES CANADA | MÉDICAMENTS NOVATEURS CANADA

INNOVATIVE MEDICINES CANADA COMMENTS ON THE PROPOSED NEW GENERAL REGULATION MADE UNDER THE HEALTH SECTOR PAYMENT TRANSPARENCY ACT, 2017

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I. 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 Ministry of Health and Long-Term Care (Ministry) for the opportunity to comment on the proposed new General Regulation (Regulation) made under the *Health Sector Payment Transparency Act* (Act). In addition to this submission, IMC has also submitted a letter to the Minister on March 22, 2018 specifically related to our serious concern that trade associations could be considered to be "recipients" under the Act and Regulations.

The principle of transparency is one that our association and membership support not only in principle but also through our shared standards incorporated within the IMC Code of Ethical Practices. While our members are committed to complying with the Regulation, as currently drafted, there are numerous and serious concerns with the Regulation that we would like to raise in this submission. The primary areas of concern are summarized in Section II of this submission, and other comments and questions regarding various elements of the Regulation follow in Section III.

We would also like to take this opportunity to highlight that the reporting requirements under the draft Regulation will result in a material increase in corporate compliance expenditures, and represent yet another additional regulatory issue for our industry in Canada. When considered cumulatively with other issues, such as the proposed changes to the mandate of the Patented Medicine Prices Review Board, the regulatory burden may have the effect of delaying or preventing the launch of new medicines in Canada. In other words, the impact of the proposed Regulation needs to be placed in the context of other negative impending changes to the business environment in Canada.

II. Primary Areas of Concern:

1. **Timelines.** There is a lack of clarity with many elements of the Regulation that will impact our members' ability to begin to prepare for implementation. In addition, the scope of what is categorized as "recipients" and "transfer of value" (ToV) is so extensive that it will require significant additional time for our members to make the costly changes required to be able to capture such extensive data. In most – if not all – instances, members will be required to create new processes and implement new systems. The changes required will have both material financial and human resource impacts on our members. The current proposal provides our members with only five to six months to prepare for the new reporting requirements. **Accordingly, IMC respectfully requests that the Ministry reconsider the implementation timelines to allow payors a minimum of 12 months from the time the Regulation is finalized to the start of the first reportable period to prepare, test systems and make modifications necessary to comply (i.e. either collecting July to December 2019 to report half-a-year in 2020, or collecting January to December 2020 for a full year of reporting in 2021).**

2. **Re-prints.** The objective of disseminating article re-prints is to provide fair and balanced medical/scientific information to healthcare professionals. While the information is of professional value, the actual re-print has no material monetary value to its recipients, and therefore should not

be classified as a ToV. Tracking re-prints would require a significant change to our members' tracking systems and practices as payors, and yet would contribute nothing towards efforts to increase transparency. **Accordingly, IMC respectfully requests that the Ministry remove article re-prints from the list of ToVs [s. 2(1)(n)], and add them under section 6 ("Exceptions to reporting requirement").**

3. **Intermediaries.** Due to the extensive scope of the proposed reporting requirements by payors, the additional requirement of accounting for a ToV provided through an intermediary is overly burdensome, risky and impractical. Based on our experience within the context of medical/educational grants, for example, the additional task of obtaining information from intermediary third parties would require significant additional resources to be made by many companies, while also creating the risk that our submissions and publications would be inaccurate, incomplete, and untimely. We firmly believe that collecting intermediary ToV information at the source would ensure accuracy and completeness of reported information, exposing therefore the payors to liabilities that are not possible to efficiently manage. Payors could therefore be facing substantial fines that are disproportionate to payor's capacity of requiring and ensuring intermediaries to comply with the Regulation. Moreover, we are concerned that the proposed regulatory treatment of intermediaries under section 4 exceeds the Act's definition of "intermediary". **Accordingly, IMC respectfully requests that the Ministry reconsider its treatment of "intermediaries" for reporting purposes while remaining consistent with the definition established by the Act.**

4. **Exceptions to Reporting Threshold.** IMC's membership has carefully considered the proposal that payors would not be required to report transactions that have a dollar value of less than $10.00. In so doing, we determined that a higher minimum threshold of $25.00 would maintain the volume of data and transaction to be published at a manageable and realistic level while still ensuring that meaningful and material ToVs are reported. **Accordingly, the Ministry is asked to consider increasing the dollar threshold to at least $25.00.**

5. **Technical Considerations.** In order for members to begin modifying reporting systems and processes in light of the new transparency regime, we will at minimum need unique identifiers for each recipient – particularly those that are not healthcare professionals and therefore do not have a licence number. We also ask for a simplification of the proposed categories of ToVs and alignment with lists employed elsewhere, such as under the *Physician Payments Sunshine Ac*t (Sunshine Act) in the US, as well as examples to assist our understanding of the proposed categories of ToV. In addition, members will require detailed technical specifications regarding how the data is to be submitted to the Ministry. **Accordingly, IMC respectfully requests that the Ministry provide details regarding the manner by which data will be received by the Government.**

Each of these areas of primary concern and several other areas of material concern are further described in Section III below.

III. Comments and Questions

1. Transfer of value (Section 2)

1.1. IMC requests clarification regarding jurisdictional realities that would impact the reporting of many ToVs given the nature of members' operations throughout Canada. Members are seeking clarity with respect to their obligations as proposed in the Regulation pertaining to the province in which the ToV is made or intended to be spent. Assume that a ToV is made to an eligible recipient whose head office or business address is in Ontario, and that the ToV is intended for an activity that takes place outside of Ontario – for example, a national medical association with a head office in Ontario receives funding for a conference taking place in another province. It is unclear to our members whether this ToV must be reported under this Ontario legislation. Clarification regarding scope is also required for individuals. For instance, if a healthcare professional licenced to practice in Ontario is engaged by a payor to be a speaker at an event taking place outside of Ontario, it is unclear whether or not that ToV must be reported.

Similarly, if an eligible recipient, with a national scope of activity and a business address outside of Ontario receives a payment/ToV for an activity taking place in Ontario, it is unclear if this ToV must be reported. By way of example, a patient advocacy group with a national scope of activity and offices outside of Ontario that uses a ToV received from a payor to assist patients in Ontario.

Similar questions arise within the context of the requirements under subparagraph 2(1)(r) "travel and accommodation". It is unclear whether a payor is required to report travel and accommodation expenses incurred by an eligible recipient regardless of where the travel or accommodation takes place. For instance, if a healthcare professional licenced to practice in Ontario is engaged by a payor as a speaker at an event taking place outside of Ontario, it is unclear whether or not the healthcare professional's extra-provincial travel to the event and stay in a hotel would be reportable.

IMC members require greater clarity around these reporting requirements so as to be in a position to comply with the reporting regime. Should the Ministry suggest that Ontario-specific ToVs must be reported separately, we ask that the Ministry clarify how shared costs and budget items, such as administrative or legal fees, are to be divided to account for – as per the stated purpose of the regime – the true "financial relationships that exist within Ontario's health care system".

1.2. IMC also asks the Ministry to clearly define the following terms used in the subparagraphs of section 2(1), for the reasons identified below:

- "honoraria" (e) versus "compensation for services" (d):
    - These terms are frequently used interchangeably in our industry.

- "items that are provided on a value-added basis in connection with a procurement process" (k):
    - Members would like a clear definition and examples of such items.
- "grants and donations" (f):
    - We note that "event sponsorships" (g) may in fact be provided in the form of a grant. This may lead to misreporting.
    - Likewise, we question whether a donation would be considered as a charitable/philanthropic ToV. If so, it is unclear if the recipient would be required to be a registered charity or if the nature of the ToV would dictate whether or not the funding was a "donation". Furthermore, if a donation is charitable/philanthropic, how does this relate to subparagraph (x) "charitable contributions made in the name of a recipient within the meaning of the Act"?
- "supplies and equipment, including information technology" (l):
    - Members would like clarity as to whether "supplies" includes medical items required to administer and dispense their products.
- "licences and copyright fees including, but not limited to, software licences and article re-prints" (n):
    - Consistent with our previous comments (page 2, item 2), IMC respectfully requests that the Minister reconsider the inclusion of article re-prints. Re-prints are often sourced from peer reviewed medical journals and help healthcare professionals learn up-to-date and relevant information so they may better treat their patients. This allows healthcare professionals to critically assess the source of our claims and decide if their conclusions are sound based on the data and methodology. Compelling the reporting of a ToV for accepting a reprint would reduce the likelihood of HCPs retaining a copy, thus reducing transparency of the basis for our claims to them. Members also question how different payors will consistently attribute a dollar value to such items. Further, a current practice is to send re-prints by mail or email, which would raise issues around determination on whether the healthcare professional accepted the reprint.
- "payments to cover marketing and advertising costs" (v):
    - Members request clarity regarding the scope of this provision, as we believe it is overly broad as currently stated.

2. **Intermediary (Section 4)**

IMC members would like to better understand what is intended by section 4(2) of the Regulation ("Intermediary"). As described during discussions between IMC and Ministry staff, our members provide funding to many medical/scientific initiatives – always in accordance with the principles and

standards set out in the IMC Code of Ethical Practices[1]. As a condition of membership, IMC members agree to ensure that the provision of funding is for worthwhile initiatives and that under no circumstances will such funding be used as – or be perceived as being used as – an incentive to prescribe, recommend, purchase, supply or administer a product, or interfere with the independence of a healthcare professional's prescribing or dispensing practices. To maintain the independence of the recipient organization and its members, funding is frequently provided at arm's length and often well in advance of the actual event or initiative being supported. Within the context of such funding, the independence of the recipient is in fact critical to maintaining the integrity of the activity being funded.

Consequently, IMC members may never learn the identity of an eligible recipient that may have benefited indirectly from a contribution. Likewise, in many circumstances members may not come to know the amount that was paid to an eligible recipient, and inquiring may be perceived as an intention to inappropriately influence or undermine the independence of the recipient in question. Moreover, in situations where members do come to know how individuals have benefited from their funding, this may occur after the timeframe for reporting prescribed by subsection 10(1) of the Regulation.

Adding to the level of complexity involved in this type of funding relationship, it is often the case that the contribution is used to the benefit of several individuals (e.g. if a portion of the contribution is used to fund a meal during a conference, there would be multiple recipients, some of whom may not be from Ontario, and in any case, members would rarely have access to conference participant lists).

IMC would also note the complexity of fulfilling the "Corrections" requirements imposed by section 12 of the Regulation when dealing with intermediaries. In the example above, a payor could be required to notify the participants of the conference about the funding and ask them to validate that they did indeed received the said ToV (e.g. contribution to the lunch budget) during the course of the conference, notwithstanding that the same recipient would receive similar notices from other conference sponsors that may have provided funding (e.g. for breakfast instead of lunch). The recipient could then have to contest several ToV transactions with several payors, who would have to decide if the correction was founded without having ready access to the source data, all of this within the short timeframe imposed by the Regulation. This example highlights some of the practical implications of the proposed Regulation for payors.

In view of the above practical considerations – and more so as a matter of statutory interpretation – we believe that the Ministry is treating a "recipient" as an intermediary under subsection 4(1) of the Regulation by requiring the payor to report back on the subsequent dispersion of all or part of the ToV by this recipient to further recipients when the source funding is from a payor (i.e. manufacturer). This presents two issues:

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[1] *See Innovative Medicines Canada, Code of Ethical Practices (2016), at section 12 ("Provision of Funding"), available online at http://innovativemedicines.ca/wp-content/uploads/2015/06/IMC_Code_EN.pdf.*

a) The wording of subsection 4 (4) of the Act explicitly states that a recipient that is a party to a transaction has no obligation to provide the information needed by a payor to report this transaction, confirming that the intent of the Act was to stop the reporting obligation at the first party that qualifies as a recipient instead of the last party to receive the ToV. Payors thus have no legal basis under the Act to compel recipients considered as intermediaries under the Regulation to provide them with the information needed to report the ToV, making them unable to comply with the Regulation's requirements.

   In view of the Act's definition of "intermediary" – that is, "a person or entity who provides or facilitates a ToV to a recipient on behalf of a payor" – we believe that the Regulation's intermediary reporting requirement goes beyond what the Act contemplates and will result in interpretations that such payments ought not to be reported.

b) It is our view that while perhaps paragraph 4(1)(2) of the Act can stand in cases where an intermediary is working for or facilitating such payments *on behalf* of a payor (i.e. a company provides a ToV without knowing the recipient, but the payment and related work/activities are on that company's behalf), it however fall short when it extends the reporting requirement to include ToVs provided to recipients by another recipient who is not doing so on a payor's behalf. For example, funding for grand rounds, fellowships, academic/research chairs or large multi-sponsor conferences is given to the initial recipient, and not for an eventual transfer to another recipient on a company's behalf.

If the Ministry wants to ensure comprehensive and traceable disclosure, the Regulation ought to contemplate cases in which a beneficiary (or other person or entity) provides a ToV where the source funding originates from a payor. We propose that this can be accomplished by way of section 3(6) of the Act and section 5 ("Additional payors") of the Regulation. An alternative suggestion for simplifying and improving reporting where intermediaries are involved would be to draft an additional clause in the Regulation that would account for situations in which intermediaries should be considered as payors for reporting purposes while allowing the Ministry to stay true to the statutory definition of "intermediary". This would overcome the concerns raised by IMC about administrative burden and workload, including a payors' limited ability to audit/verify the recipient(s) data, and would simplify any dispute resolution in this regard.

We provide examples of what the above proposal would look like in practice: If a payor provides funding to a scientific group as a sponsor of a congress, the payor would be obligated to report the total amount provided to the group, and the scientific group would be required to report the ToV provided to the congress participants. A similar situation would arise, for example, in a situation where a third-party entity is asked to engage healthcare professionals on our members' behalf to provide patient counseling or support to patients enrolled in a patient assistance program. Under this proposal, it would be the third party that would report all payments to eligible recipients, rather than the member who had commissioned that third party. We believe that this proposed revised scope of payors would result in more accurate reporting of ToVs, while limiting duplicate reporting and related resources.

In addition, as currently drafted, the requirement of having an intermediary providing the payors with reportable information places the payors at high risk of being in breach of the Regulation and facing hefty fines that are disproportionate to payor's capacity of requiring intermediaries to comply with the Regulation.

3. Exceptions to reporting requirement (Section 6)

We refer once again to our discussions with the Ministry's representatives, and reiterate that IMC strongly recommends that the proposed $10.00 threshold be reconsidered. We do not believe that it was the intent of the proposed transparency regime to capture immaterial amounts, such as those paid for a reasonable meal (e.g. a sandwich or salad during a lunchtime learning program). After careful consideration of both the objectives of the Act and the common practices of our membership, we recommend that the threshold be raised, modestly, to at least $25.00. Not only would this increase the materiality of reportable transactions, it would also significantly reduce the administrative burden of reporting smaller amounts. IMC has canvassed its membership and has concluded that an increase in the threshold from $10.00 to $25.00 would translate into a 20-30% reduction in the financial resources that would be attributable to reporting ToVs under the proposed regime. IMC is aware that other associations may be requesting a higher minimum threshold and, for the reasons cited above regarding the need to avoid excessive data collection, has no objection to such requests.

It is important to note that our position regarding the minimum threshold is advanced within the context that our members must comply with the IMC Code of Ethical Practices, which prohibits excessive meals and refreshments, and requires that any expenditures be ancillary to a legitimate business purpose. Our members are further regulated by their own internal standards, which set reasonable dollar limits on meals.

4. Information re parties to transactions (Section 7)

Contrary to what is implied by section 7(2), many of the individuals who would fall under the proposed category of "recipients" would not have a designation as a healthcare professional, be regulated by a health college, or have a licence number. In these circumstances, the only prescribed identifying information available for us to report on would be the individual's name, employer and job title.

As demonstrated in other jurisdictions with legislated transparency requirements, a unique identifier being assigned to each recipient is essential to the consistency and accuracy with which data is reported on individuals. If different reporting payors submit a slight variation of the same individual's name without information that is unique to that individual, it will become very difficult for the Government to verify and discern recipients with accuracy. For instance, a Mr. John Harold Smith may be a recipient; Payor A may list him as John H Smith, Payor B may list him as John Smith, Payor C may list him as JH Smith, etc.

In addition, the Ministry must be mindful of payors' obligations under Canadian privacy legislation. IMC members require and collect information from payees to deliver payments linked to a specific activity or event. Any additional information collected on the payees would only be done for the

purpose of meeting the requirements of the Regulation. It is therefore imperative that the Ministry specifically prescribe the unique and identifiable information to be collected for each individual recipient.

IMC members therefore request greater clarity regarding the reporting requirements as prescribed under section 7 for situations where the recipient is an individual other than a licenced healthcare professional with a unique license number. The Ministry should consider assigning a unique identifier for individual recipients that do not have a license number or similar designation.

Many questions also remain regarding the format and technical elements of reporting, and IMC requests greater detail in this regard. IMC members will have great difficulty in implementing or modifying existing reporting systems until the details and formatting required of their data handling is clearly outlined. Members wish to avoid making changes to reporting systems that may not be consistent with the format ultimately required by the Government.

5. Transfer of value, description (Section 8)

IMC is very concerned by the numerous categorizations of ToVs proposed in section 8 of the Regulation. As stated on previous occasions, the Regulation's wide scope of inclusion of the categories of recipients and ToVs will require a significant number of modifications to members' reporting systems and processes, especially given the fact that the proposed categories of ToVs are not ones that IMC members report or track for regular business purposes. Furthermore, the categories are inconsistent with those used in other jurisdictions for disclosure purposes, thereby preventing IMC members from leveraging existing reporting mechanisms. IMC respectfully requests that the Ministry reconsider the proposed list of categories to align them with categories already in use elsewhere, such as those already established under the US Sunshine Act.

6. Manner and frequency of reporting (Section 10)

IMC members respectfully request that the Ministry reconsider the effective implementation date. Given the numerous items requiring clarification, as set out in this submission and including the extensive scope of both recipients and ToVs, complying with the Act and Regulation as currently drafted would divert a substantial amount of time and resources from ongoing major projects on very short notice. As such, our members cannot implement these changes within the five- to six-month period expected between the coming into force of the Regulation and the first reporting deadline.

IMC therefore respectfully requests a full year from the time the Regulation is passed before the first reporting cycle is begun (i.e. either collecting July to December 2019 to report half-a-year in 2020, or alternatively collecting January to December 2020 for a full year reporting in 2021). While still challenging, IMC members believe that a one-year period to prepare and update reporting systems would help to ensure more complete and accurate reporting.

7. Corrections (Section 12)

As touched upon briefly above, IMC would like to raise an important concern regarding the proposed corrections process. The reality is that multiple payors interact with the same recipients, and these

recipients will therefore receive requests for data validation from multiple payors during the same reporting period. Take, for example, a healthcare organization such as a hospital that may receive requests to validate ToVs received in the form of grants, sponsorships and donations from multiple payors. Under the Regulation as drafted, that institution would likely need to validate ToVs such as modest meals and refreshments that their employees had received during the course of medical or educational presentations.

In this way, the proposed Regulation will impose a significant administrative burden on our members and a potentially even more onerous burden on other stakeholders (e.g. eligible recipients). The burden to the recipients may have negative consequences on patient care since resources in the healthcare system are already limited. Creating a regime that requires institutions – such as a hospital, in our example above – to invest their limited resources towards validating data related to ToVs may result in criticism of the transparency regime and discourage compliance.

Furthermore, subsection 12(9) proposes a maximum 12-month period to report corrections. IMC believes that this period is too short and notes that the US Sunshine Act allows for corrections up to three years after the data has been reported. IMC therefore encourages the Ministry to consider a three-year correction period.

IV. Conclusion

In conclusion, IMC members remain very concerned about their ability to efficiently and effectively comply with the proposed Regulation. The lack of clarity, combined with the extensive scope of recipients and ToVs being proposed, make the January 2019 collection start date unfeasible. IMC members require a minimum of twelve months to be ready to collect data given that implementation will require significant time and resources. The data required by the Act and Regulation is not reported in a like fashion in other jurisdictions. Accordingly, existing systems cannot simply be imported and easily adapted to meet the new requirements proposed in Ontario.

IMC and its members are also concerned with the limited knowledge of the Act of many of the recipients who are likely to be impacted by the proposed regime. Recipients will be required to track their activities in order to be in a position to confirm a ToV once prompted by payors (including our members). We are aware of situations where healthcare professionals have incorrectly interpreted the requirements being advanced under the new regime. While IMC does not itself require an extension to the consultation period, we are aware that other groups may have requested an extension to allow them to provide a more comprehensive response, and consequently IMC has no objection to the granting of an extension. Irrespective of whether an extension is granted, we request that the Ministry increase its communication efforts to include notices to impacted recipient groups and conduct information sessions for all parties that have the potential to be impacted by the Act and Regulation.

We respectfully request that the Ministry meaningfully address the concerns set out above before finalizing the Regulation in order to help ensure effective and efficient compliance. If there are any questions regarding our submission, please do not hesitate to contact IMC at your earliest convenience.