

October 2019

QUESTIONS & ANSWERS

CODE OF ETHICAL PRACTICES – 2020

1. Why did Innovative Medicines Canada (IMC) update its Code of Ethical Practices (Code)?

The IMC Code is a living document and it has been five years since its last major update in 2014. The changes seek to clarify the language of certain sections and to address areas of potential or actual conflict of interest to ensure that the Code continues to reflect robust ethical practices.

Following 18 months of due diligence by the IMC Ethics Operational Team and touch points with over 80% of our membership and our stakeholders, IMC recommended amendments to the Code which were then approved by the IMC Board of Directors.

2. What is new in the updated Code?

There are five (5) major updates to the Code.

Guiding principles – Section 1: Clarity provided regarding the fact that the guiding principles apply throughout the Code and should be read into all sections of the Code.

Meeting locations and venues – Sections 6 and 10: Clarity and guidance provided to assess the appropriateness of locations and venues when conducting business meetings and discussions initiated by Member companies. Guidance related to venues for such meetings was already included in the Code but additional clarity has been provided as to the appropriateness of a venue.

With respect to meetings and events sponsored by Member companies, additional clarity and guidance has been provided. When considering whether or not to sponsor a conference or congress, Member companies should be guided by the same criteria and standards that apply when they themselves initiate a meeting or event. The criteria to be considered before committing to sponsor an event have been included.

Compensation for services provided by stakeholders – Section 7: the standards related to the compensation of stakeholders must apply to both direct and indirect (i.e. through a third party) hiring of stakeholders. This is not a new concept since it is already reflected in the guiding principles and certain annotations, but it was important nonetheless to clarify the language in this section.

Funding – Section 12 and NEW Section 13: Member companies provide various types of funding in the form of grants, donations, sponsorships, collaborations and partnerships. The changes define and more clearly distinguish the various types of funding and provide standards that apply to each.

Patient Support Programs (PSPs) and Medical Practices Activities (MPAs)– Section 14 (Section 15 in new Code): greater clarity has been provided on the provision of payments or other benefits to prescribing Healthcare Professionals (HCPs) in the context of the delivery of PSPs/MPAs. Briefly, the changes will limit the ability of Member companies to provide direct or indirect (through a third party) payments or



other benefits to prescribing HCPs. Third parties or internal qualified Member employees can be hired to deliver PSPs/MPAs; however, third parties cannot pay or provide a financial benefit to the prescribing HCP. The only potential exception is where a patient resides in a remote community and would not otherwise be able to reasonably obtain the PSP/MPA service but for the hiring and payment or provision of a financial benefit to a prescribing HCP.

3. What is the purpose of the Notes for Guidance?

Notes for Guidance have been prepared on the following topics:

- Meeting locations and venues – Section 6 and 10
- Compensation for services- Section 6, 7 and 8
- Patient Support Programs (PSPs) and Medical Practices Activities (MPAs)– Section 14 – Section 15 in new Code.

The purpose of these documents is to provide additional guidance related to the interpretation of certain provisions of the Code as well as clarify the intent and the scope of application of the changes.

These Notes for Guidance are non-binding but provide guidance on topics that often raise questions.

4. When will the new IMC Code be implemented?

The new IMC Code will come into effect on January 1st, 2020. However, the section related to Patient Support Programs and Medical Practices Activities (currently Section 14 – in new Code Section 15) will become effective on July 1, 2020 and Section 10, which relates to sponsored conferences and congresses, will come into effect on January 1, 2021.

5. Why the different implementation periods?

With respect to two of the changes, additional time has been provided to allow companies and their stakeholders to transition to compliance with the updated Code. The different timelines were needed to allow sufficient time for the implementation of changes required by the new Code, in particular to existing PSPs (currently Section 14, - in new Code Section 15). Furthermore, in order to ensure that pre-existing sponsorship commitments could be respected and in order to allow for a reasonable transition period, it was necessary to have a later implementation date for the changes to Section 10.