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## NOTE FOR GUIDANCE ON PATIENT SUPPORT PROGRAMS AND MEDICAL PRACTICE ACTIVITIES

### INTRODUCTION

The purpose of this document is to provide additional guidance related to the interpretation of Section 15, Patient Support Programs and Medical Practice Activities, of Innovative Medicines Canada (“IMC”)’s Code of Ethical Practices (“Code”).

This Note for Guidance must be read with the spirit of the Code in mind and in conjunction with applicable laws and regulations. Member companies are strongly encouraged to consider the points outlined in this document when organizing their Patient Support Programs (“PSPs”) and Medical Practice Activities (“MPAs”).

### POINTS FOR CONSIDERATION

The intent of PSPs and MPAs is to provide support to patients and medical practices to:

- increase or facilitate patients’ understanding of a disease and/or treatment;
- better patients’ health outcomes; or
- improve patients’ adherence to treatment.

The changes to Section 15 are meant to provide additional clarity and guidance to help mitigate against real or perceived conflicts of interest between the pharmaceutical industry and Health Care Professionals (HCPs)/Medical Practices. They do so by:

1. Prohibiting Members’ direct and indirect payments or other benefits to a patient’s prescribing HCP or a person who is not at arm’s length from the patient’s prescribing HCP;
2. Prohibiting third-party service providers from providing payments or other benefits to a patient’s prescribing HCP or a person who is not at arm’s length from the patient’s prescribing HCP; and
3. Prohibiting payments or other benefits to an HCP for services reimbursable by the healthcare system.

In order to ensure compliance with Section 15 of the Code, Member companies should consider the following:

- 1. Prohibiting Members’ direct and indirect payments or other benefits to the patient’s prescribing HCP or a person who is not at arm’s length from the patient’s prescribing HCP.**

In the context of a PSP/MPA, Member companies are not permitted to provide any payment or other benefit, directly or indirectly, to a patient’s prescribing HCP or a person who is not at arm’s length with the patient’s prescribing HCP. Any support provided to a patient or medical practice through a PSP/MPA



should exclusively benefit the patient and not the patient's prescribing HCP or a person who is not at arm's length from the patient's prescribing HCP.

The following is an example of a prohibited "other benefit": A third-party provider of PSP/MPA hires a nurse to provide services related to the PSP/MPA at a medical practice and the nurse does additional work for the medical practice or the patient's prescribing HCP (i.e. other work outside of the PSP/MPA responsibilities). The additional work would be considered an inappropriate "other benefit" to the medical practice or the patient's prescribing HCP and would be prohibited.

PSPs encompass a broad scope of activities, ranging from patient support calls to the administration of drug products. Member companies may be permitted to pay for certain procedures (such as genetic or diagnostic testing), products or vaccines that are required for the diagnosis of a disease and/or the potential prescription or the administration of a product. Payment for these types of procedures/products/vaccines benefit patient care and would not be prohibited by the Code, provided that no payment for these procedures or administration of products/vaccines is provided to the patient's prescribing HCP or a person who is not at arm's length from the patient's prescribing HCP.

**2. Prohibiting third party service providers from providing payments or other benefits to a patient's prescribing HCP or a person who is not at arm's length from the patient's prescribing HCP.**

The Code provides for a general prohibition against a patient's prescribing HCP, or a person who is not at arm's length from the patient's prescribing HCP, receiving a payment or other benefit directly or indirectly, for services provided under a PSP to his/her patient. This means that no payment or other benefit should be transferred to an HCP for services he/she provides to his/her own patient under the PSP, even when such transfer is taking place through a third party service provider.

That said, the Code provides an exception to this general prohibition for a patient residing in a remote community and being enrolled in a PSP requiring the assistance of an HCP, where the only access to an HCP in the remote community is to the patient's prescribing HCP. Absent the exception, the patient would not be able to receive the PSP services or benefit from the treatment. In such exceptional situations, compensating the patient's prescribing HCP or a person who is not at arm's length from the patient's prescribing HCP would be acceptable at the appropriate fair market value. A remote community refers to a community where there is no access to a non-prescribing HCP qualified to perform the services under the PSP or the PSP provider cannot provide the service due to the location of the patient.

**3. Prohibiting payments or other benefits to an HCP for services reimbursable by the healthcare system.**

It is the intention that PSPs/MPAs funded by a Member will not involve payments to an HCP for services that are reimbursable to the HCP by the publicly-funded healthcare system.

A Member company and/or its third party vendor may not compensate an HCP in circumstances where it could result in the duplication of compensation received from the public healthcare system (i.e. no double dipping is permitted).