



February 8, 2021

VIA EMAIL: PMPRB.Consultations.CEPMB@pmprb-cepmb.gc.ca

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This document represents Knight Therapeutics' submission to the consultation on the change to the definition of Gap medicines and the timeline for compliance (January 15, 2021). Knight has significant concerns with and is opposed to the January 15, 2021 proposal to reduce by half the Guidelines' transition period to six months.

Knight's position is aligned with the written submission presented by IMC with respect to the change to the definition of Gap medicines and the timeline for compliance. The IMC written submission provides clear feedback regarding the inadequacy of the proposed transition period for the industry, especially in light of a global pandemic. As highlighted by IMC, a reasonable timeline is needed for patentees to be fully aware of their compliance obligations and relevant national average prices and engage in transitional discussions envisioned under section 75 of the Guidelines, in order to minimize disruption to drug supply chains.

In conclusion, we strongly believe that a minimum twelve-month transition period from the date that the Regulations come into force is necessary for reasonable and feasible adherence to the new Guidelines.

Sincerely,

Jody Engel

A handwritten signature in black ink, appearing to read "Jody Engel".

Vice President Commercial Operations Canada