— we help people achieve healthy skin

October 24, 2016

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Patented Medicine Prices Review Board (PMPRB)
Box L40, 333 Laurier Avenue West, Suite 1400
Ottawa, Ontario K1P 1C1
Submitted via e-mail to: PMPRB.Consultations.CEPMB@pmprb-cepmb.gc.ca

Re: LEO Pharma Inc. submission to consultation on PMPRB Guidelines Modernization Discussion Paper.

About LEO Pharma Inc.:

LEO Pharma Inc. Canada (LEO) is a subsidiary of LEO Pharma A/S. LEO Pharma helps people achieve healthy skin. By offering care solutions to patients in more than 100 countries globally, LEO Pharma supports people in managing their skin conditions. Founded in 1908 and owned by the LEO Foundation, the healthcare company has devoted decades of research and development to delivering products and solutions to people with skin conditions. LEO Pharma is headquartered in Denmark and employs approximately 5,000 people worldwide.

LEO Pharma Inc. Response to Consultation:

LEO is pleased to provide a submission in response to the PMPRB's consultation on the PMPRB Guidelines Modernization Discussion Paper. LEO feels that it continues to be necessary to have mechanisms in place to ensure non-excessive pricing of patented medications as part of the drug reimbursement process in Canada. This is critical to all stakeholders, most importantly to patients. In addition, we believe that it is paramount for Canada to maintain an environment which facilitates innovation, investment and research in medications for patients.

Firstly, LEO would like to convey our support for the views brought forth by Innovative Medicines Canada (IMC) in their submission. Secondly, LEO would like to provide feedback on specific themes which we believe are important topics to address as part of the consultative process. Given the broad nature of the Discussion Paper, specific comments and suggestions are not possible at this juncture.

<u>The role of the PMPRB in the greater Canadian health care system</u>

- The PMPRB is an integral part of a multi-stakeholder system which governs the pricing and availability of medications in Canada.
  - As directed by Parliament in 1987, the role of the PMPRB is to ensure non excessive prices for patented medicines. A departure from this mandate to

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determine affordability is outside of its scope of prescribed governance.
- Other groups, such as public and private payers, The Canadian Agency for Drugs and Technologies in Health (CADTH), Institut national d'excellence en santé et en services sociaux (INESSS), and the Pan-Canadian Pharmaceutical Alliance (pCPA) also have an integral role as agencies which work on behalf of Canadian patients to ensure affordability and value to both the patient and the healthcare system.

- As such, the role of the PMPRB and any change therein to the Guidelines cannot be considered in isolation of other stakeholders or other aspects of the healthcare system.
  - Of note, the Discussion Paper provides no guidance on how PMPRB would interact with other agencies in order to support its intended goal of protecting consumers from excessively priced patented medicines. Any proposal for change made by the PMPRB should complement the work done by other agencies- not duplicate it.
  - It is important to note that both public and private payers have different directives and tools available to help facilitate affordable drug pricing. This should be considered by the PMPRB prior to making any policy changes. Public payers are funded through tax payer dollars and cover segments of vulnerable populations. Private plans, composed of several different groups, are for profit and design benefit plans to attract and retain employees. Currently available tools to manage affordability include formulary review mechanisms, plan design, and product listing agreements.

<u>Defining affordability and value of medications for Canadian patients</u>
- The Discussion Paper addresses affordability from a conceptual perspective. No adequate definition of affordability has been provided by the PMRPB within the construct of the proposed framework.

- Affordability cannot be limited solely to the price of a medication but must also consider ability to pay (for example, total payer drug budget), and budget impact (utilization of a given medication multiplied by its price).
  - The PMRPB is not a payer, and does not have visibility to prices paid by drug plans or have accountability for drug budgets and as such cannot determine or regulate medications as being affordable.
  - Pharmaceutical pricing policies cannot be made in the absence of decisions within the greater context of the drug pricing and reimbursement system.

- LEO believes that a discussion of value must accompany those on affordability.
  - Patented medications are not consumer goods. They are highly regulated and bring benefits to patients and to the healthcare system as a whole. These benefits could include improvements in morbidity/ mortality to patients and downstream savings to the healthcare system.
  - An entire system is in place to provide accountability and the PMPRB already has a role within this system. PMPRB references to the need to end medication monopolies and unilateral market power have no basis.

The opportunity to create a sustainable future

- The PMPRB cites its motivation for policy change based on the current environment. LEO agrees that the Canadian drug and reimbursement environment has changed from the time when the PMPRB was created. However, many of the proposed changes to the Guidelines are reactionary to the current environment.
  - It is paramount to consider today's environment and the future, including both short-term and long-term trends.
  - LEO strongly urges PMPRB not to develop a framework policy based solely on today's environment; but to consider how, within the construct of the current PMPRB Guidelines, to best regulate prices today and in the future.
  - As an example of possible policy change, consider the perceived failure of IMC member companies to deliver on R&D investments. This also could be re-examined in today's environment and consider future trends to include innovative investments and partnerships made by companies as opposed to the previous definition determined by the PMPRB Guidelines.

- The broad nature of the Discussion Paper allows for varied stakeholder input into the proposed framework. However it is not detailed enough for stakeholders to provide meaningful feedback on specific rules.
  - More analysis needs to be conducted on the therapeutic and cost impact of changing the approach to the factors governing patented medicine pricing prior to making a decision.
  - It is important to work with involved stakeholders to understand and interpret not only retrospective data but conduct prospective analysis in order to do achieve robust decisions.
  - The proposed working groups should be utilized earlier in the process to allow for more meaningful conversation about any changes to the Guidelines.

LEO would like to thank the PMPRB for the opportunity to provide feedback on this initiative. Given the broad scope of the proposed framework, we strongly urge the PMPRB to provide greater clarity and direction on the themes addressed above prior to making any changes to the current Guidelines. Ultimately, this approach will help ensure that Canadian patients continue to have access to innovative and value based medicines.

Sincerely,

Xavier Bertin
Xavier Bertin
President and CEO
LEO Pharma Inc., Canada

CC: Sukaina Noormohamed, Senior Manager Market Access and Public Relations, LEO Pharma Inc.