AVIR PHARMA INC.

January 26th, 2021

Dr. Mitchell Levine
Chair, Patented Medicine Prices Review Board (PMPRB)
333 Laurier Avenue West, Suite 1400
Ottawa, Ontario K1P 1C1

Subject: Comment on the proposed amendments to the new PMPRB Guidelines

Dear Dr. Levine,

On behalf of Avir Pharma Inc. ("Avir"), I am writing in response to the PMPRB's request for consultation regarding further amendments to the October 2020 PMPRB Guidelines ("Published Guidelines"). In particular, Avir wishes to advocate that manufacturers who have received their DIN post August 21, 2019, and make a first sale at any time during the period of January 1, 2021 to July 1, 2021, retain the right to self-categorize as Gap medicine or New Patented medicine.

Presently, Gap medicines are classified as drugs for which a DIN was assigned on or after August 21, 2019 and first sold in Canada prior to January 1, 2021. However, the proposed amendment extends the date of first sale to the new coming-into-force date of July 1, 2021. This proposed amendment could prove problematic on many levels.

First, it is Avir's understanding, that the decision to delay the coming-into-force date of the *Regulations Amending the Patented Medicines Regulations* ("Regulations") was prompted by the need to give industry further time to familiarize themselves with the reporting instruments in the Published Guidelines. By changing the definition to Gap medicine at this juncture, the PMPRB is not providing 'further' time to industry to understand the Regulations, but is in fact further complicating and confusing the landscape.

Based on the clarity that came from the Regulations being promulgated in the first place, manufacturers were finally able to plan and finalize product launch timelines in Canada. Not to mention, these Canadian launches may have a knock-on impact on other international launches as well. A manufacturer that made a first sale after January 1, 2021 would have done so based on the understanding that the medicine would be categorized as a New Patented medicine and would have to comply with the pricing rules of the Published Guidelines. Any change at this point may result in a retroactive application of the Guidelines, depriving manufacturers of the opportunity to be governed by the

Published Guidelines, and creating a prejudice in the case of certain medicines. Asking industry to take a step back and to reassess commercial models and product launch plans *again* would effectively put industry back where it started at the beginning of this process – in a land of unpredictability. Manufacturers need the ability to develop clear pricing structures, to prepare for product launches, and to set timelines. These vital processes are essential to remaining commercially viable in the industry and to be able to continue to offer Canadian patients much needed medicines. Although industry may have been able to improvise thus far, many manufacturers are at their risk threshold – some of which have had to initiate product launches despite not having reasonable certainty with respect to the Regulations and underlying Guidelines that are constantly in flux.

Moreover, a change to the definition of a Gap medicine could more than likely result in some manufacturers further delaying launches until July 1, 2021, in particular for Category II products. Small to medium-size manufacturers do not have the same risk-threshold (and frankly, product margins) that larger corporations do. This seemingly trivial amendment may prove to be the decisive point in delaying launches. In some cases, manufacturers may even be forced to abandon launches entirely, as changing a medicine's categorization may result in the product becoming unviable from a commercial perspective.

Avir's own experience during this PMPRB reform process has resulted in launch delays of over eight (8) months - a setback almost certainly not unique to Avir. As a small, emerging Canadian pharmaceutical company, Avir falls squarely within a sub-set of manufacturers to whom the constant modifications to Regulations and Guidelines, creating ambiguity and uncertainty in the PMPRB processes, has had a negative impact. Avir in-licenses niche, rare molecules, that have an unmet need in Canadian practice; however, Avir is unable to launch these niche products if it cannot reasonably predict at what prices it will be able to sell them. Avir's own experience is that it has been challenging to launch products in Canada, even critical ones, amidst the continually shifting PMPRB Guidelines, Regulations, complex pricing instruments and shifting dates. Avir has used its best-efforts to follow the evolving Guidelines and changing dates, and to engage in good-faith negotiations with the PMPRB throughout the process in order to manage its launch of a product called Jorveza™ (NOC was issued in November 2019 under Priority Review); nevertheless, because of evolving Guidelines and implementation delays, Avir was compelled to delay Jorveza's launch in an effort to seek clarity on pricing. During this delay, it faced many daily challenges, including physician requests for clarity on delays to launch, pharmacies unable to fulfill patient prescriptions, and patients with prescription in hand but with no access to an approved medicine. As such, Avir made the decision to launch Jorveza in January 2021 - a critical decision that was made relying on the

AVIR PHARMA INC.

categorization of Jorveza as a New Patented Medicine in accordance with the Regulations and Guidelines in effect at that time.

Based on the above, and considering not only the challenges facing Avir, but more importantly the industry as a whole, Avir strongly urges the PMPRB to reconsider changing the definition of a Gap medicine. Moving significant dates at this critical juncture would have a major impact on many manufacturers' ability to bring medicines to market before July 1, 2021, and on their commercial viability as a whole. By giving industry the right to self-categorize as a Gap medicine or New Patented medicine during this interim period, the PMPRB would grant manufacturers the opportunity to preserve their current product launch plans, avoid any prejudices that may result from retroactive application, and above all ensure the supply of much-need medicines to the Canadian population.

Respectfully,

Kaled Kadri
Vice President Business Development
Avir Pharma