SERVIER CANADA

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ATTENTION: 2020 Revised Draft Guidelines Consultation
Patented Medicine Prices Review Board
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As part of the current consultation process, Servier Canada Inc. (**Servier**) would like to provide comments on the Patented Medicine Prices Review Board (**PMPRB**) revised draft Guidelines released on June 19, 2020 (**2020 Guidelines**).

Servier understands that the PMPRB intends to update its Guidelines within the framework of the amendments to the Patented Medicines Regulations, which are not yet in force. While Servier is committed to constructive engagement with the PMPRB on the draft Guidelines, Servier's response to this consultation is not intended and should not be interpreted as supporting the amendments to the Regulations.

Servier continues to have grave concerns about the practicality and legality of the amended Regulations, which are the subject of ongoing legal challenge. Servier reserves the right to oppose any aspect of the Guidelines that exceeds the jurisdiction of the federal government under the relevant legislation.

Servier, as a member of both Innovative Medicines Canada (**IMC**) and BIOTECanada, is in agreement with, and fully supports, the comments submitted by these associations.

Servier is the Canadian affiliate of Servier Group, an international pharmaceutical company governed by a non-profit foundation headquartered in France. With a strong international presence in 149 countries and a worldwide headcount of 22 000 people, the Group reinvests on average 25% of its global turn-over in Research & Development (**R&D**). Servier has been present in Canada since 1978 with a mission to provide the Canadian medical community and its patients with innovative therapeutic solutions in treating cancer, diabetes, heart disease, and high blood pressure.

Servier strongly believes that all Canadians should have timely and optimal access to innovative medicines and is of the view that the 2020 Guidelines will have the unintended consequence of decreasing access to innovative medicines for Canadian patients and deterring companies from launching new drugs in Canada.

2020 Guidelines do not provide transparency and predictability to patentees

The mandate of the PMPRB, as established by the Patent Act (**Act**), is to ensure that prices charged by patentees for patented medicines sold in Canada are not excessive. The Guidelines, which are issued pursuant to subsection 96(4) of the Act, are intended to provide transparency and predictability to patentees in determining whether a patented medicine appears to be priced excessively in Canada. When compared to the 2019 PMPRB Draft Guidelines, the 2020 Guidelines are more complex and unpredictable with respect to setting ceiling prices in Canada, given that these prices rely on variables that are unknown to patentees until well after product launch.

After careful analysis of the 2020 Guidelines, Servier would like to highlight the following main areas of concern:

Pharmacoeconomics

The 2020 Guidelines continue to rely on Cost-Utility Analysis (**CUAs**) prepared by publicly funded Canadian organizations assessing Pharmacoeconomic value to establish net price ceilings for the most innovative new medicines. The objective of pharmacoeconomic analysis is to relate improved health outcomes with new drugs compared to established or so-called standard treatments to the costs associated with their use, and not to make pricing decisions for new patented medicines. CUAs are based on estimates and assumptions, and involve a high degree of subjectivity, such that assessments often vary substantially between Health Technology Assessment (**HTA**) agencies. Furthermore, these assessments may be made available to patentees after a medicine has been launched on the Canadian market. Consequently, patentees would not be able to reasonably predict allowable ceiling prices at product launch and obtain required launch approvals ahead of countries that reference Canadian prices. Moreover, the 2020 Guidelines penalize medicines with no pharmacoeconomic assessment by imposing a 50% reduction on the median price if annual sales exceed $12 million. These significant disincentives will result in further delays in patient access and

prevent new innovative medicines from launching in Canada. The latter would defeat the government's stated policy objective of increasing accessibility to medicines for Canadians.

Market Size

Innovation should be recognized and incentivized, and not penalized as will be the case under the 2020 Guidelines given the de facto revenue control mechanism resulting from the application of the market size factor and the compounding price reduction approach (e.g. MRP, MRP(A)). Market size is difficult to predict and using this factor in the MRP assessment and as a reason for reassessment is unwarranted in an ever-changing pricing and reimbursement environment. The 2020 Guidelines further mandate that once a price ceiling is determined based on market size or high cost, it cannot be increased based on reduced revenues. This revenue control mechanism goes far beyond PMPRB's stated mandate under the Act. Furthermore, market size, as a factor, is relevant for payers when negotiating listings but is not relevant in setting regulated price ceilings.

GDP/GDP per capita

The calculation of the annual treatment cost using the maximum number of courses of treatment over a period of 12 months does not always reflect a medicine's actual average or median duration of treatment, and could overestimate the cost of a medicine. This is particularly true for some oncology products used to treat aggressive cancers for which life expectancy is expressed in months, or even in weeks (e.g. pancreatic cancer). In many instances, this approach would need revisiting in order for the annual treatment cost to accurately reflect the actual average or median treatment duration and not a theoretical extension of it over a period of 12 months.

Scientific Review Process

The 2020 Guidelines create further uncertainty and unpredictability by allowing the PMPRB Staff to determine Therapeutic Criteria Level, comparator medicines for the domestic and international Therapeutic Class Comparison (**dTCC & iTCC**), and the relevant indication. Without expert scientific advice, this assessment is inherently biased and subjective. These functions should continue to be performed by the Human Drug Advisory Panel (**HDAP**) expert committee whose mandate under the current Guidelines is to provide credible, independent, and expert scientific advice to PMPRB Staff independent of the price review. This would ensure that the scientific review of a new patented medicine is an entirely distinct process, not influenced by the price review. Also, by selecting the

lowest price for a comparator medicine with multiple sellers in the dTCC test, the 2020 Guidelines further penalize innovative medicines which already face increasing generic competition.

PMPRB Staff not bound or limited by Guidelines

The 2020 Guidelines provide the PMPRB Staff with Board-like powers and inappropriately broad discretion such that they can use any methods or tests deemed appropriate and consistent with the Act and Regulations, regardless of whether they are in scope of the Guidelines. Furthermore, the tests and ceilings used during an investigation may differ from the test and ceilings used to establish the initial thresholds that led to the triggering of the investigation, resulting in the new investigation ceiling being used to calculate excess revenues. This will create considerable uncertainty and unpredictably for patentees who rely on the Guidelines for evaluating potential ceiling prices and excess revenues. If the PMPRB Staff is responsible for ensuring that the price review of patented medicines is carried out in accordance with the Guidelines, how can they not be bound or limited by the boundaries of the Guidelines they are committed to uphold?

Reassessment Criteria

Under the 2020 Guidelines, the reassessment of new innovative products will cause considerable uncertainty for patentees in forecasting pricing. Patentees will not be able to make long-term business decisions nationally and globally when the pricing of their patented medicines can be negatively impacted by a reassessment at any time during their lifecycle and for multiple reasons, many of which are beyond the foreseeability or control of the patentee. Servier believes in investing in R&D in order to bring innovative medicines to all Canadians, but this approach will be challenged given the constant uncertainty created by continual reassessment.

Recent Federal Court Decision on Calculation of Net Prices

The Federal Court has found that subsection 3(4) of the Amended Regulations relating to the calculation of net prices is outside the scope of the Act and subsection 4(4) of the Patented Medicines Regulations in their current form will remain in effect following the implementation of the Patented Regulations on January 1st, 2021. The PMPRB has indicated that it does not believe any substantive changes to the proposed Guidelines are required as a result of this court decision. How is this possible when the maximum rebated price (MRP) ceiling, as calculated in the 2020 Guidelines, is determined based on the knowledge that the Amended Regulations required patentees to include

the quantum of confidential third-party rebates provided by patentees? Moreover, the MRP ceiling is based on an already discounted maximum list price (**MLP**) set at the median of the PMPRB11, followed by additional discounts based on Pharmacoeconomic thresholds (for high cost drugs), dTCC (for high market size drugs), reduction floors of up to 50% off MLP and market size adjustments. Without changes to the proposed MRP approach, the 2020 Guidelines are inoperable and must be revised. Furthermore, pending any appeals of the Federal Court decision, the uncertainty regarding the adequate protection of confidential net pricing information poses international pricing risk.

In light of the court decision and based on the many concerns mentioned above, Servier believes that the MRP concept should be abandoned altogether and the price ceiling of a new patented medicine should be set at the international median. Consequently, the PMPRB will need to reset the Guidelines process and engage in extensive and meaningful discussions with stakeholders to ensure that the concerns outlined above are adequately addressed. Moreover, many operational feasibility issues have yet to be addressed by the PMPRB, and with the new Online Help Tool yet to be released, assessing the full potential impact is nearly impossible.

Servier believes that there is a simpler path to achieving the PMPRB's objectives via more predictable and less complex regulatory tools and would welcome the opportunity to work alongside the PMPRB and other stakeholders to develop them.

As an important stakeholder in the healthcare system, we appreciate the opportunity to participate in the 2020 Guidelines consultation process. We look forward to working collaboratively with the PMPRB and other stakeholders to address these serious concerns that will ultimately affect Canada's access to the newest and most significant innovations to treat and cure diseases.

Yours sincerely,
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