January 18, 2016

Guillaume Couillard
Director, Board Secretariat
Communications and Strategic Planning
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Ottawa, Ontario K1P 1C1

Dear M. Couillard:

Thank you for the opportunity to comment on proposed changes to the Patented Medicine Prices Review Board (PMPRB) Guidelines, as outlined in the Notice and Comment issued on December 4, 2015.

While we applaud the PMPRB's ongoing commitment to seeking stakeholder feedback on proposed changes to the Guidelines, we are concerned that the changes proposed in this particular Notice and Comment have already taken effect, as of January 1, 2016, 2 weeks prior to the deadline for responses. Also, the Notice and Comment states that "further consultation… may be undertaken on the proposed text in the Guidelines, as well as on operational/transitional details, prior to final adoption and implementation." This sentiment seems inconsistent with an implementation date of January 1, 2016. The implementation date does not provide manufacturers sufficient time to plan for any changes to the Guidelines, as global pricing strategies can take years of planning. Therefore, two weeks' notice for a change in the application of the PMPRB Guidelines is inadequate to allow manufacturers to adapt their pricing strategies, if required.

Roche recommends that any changes to the PMPRB Guidelines not be implemented prior to the completion of all stakeholder consultations and, once finalized, any changes to the Guidelines be published at least one year prior to their application to any new medicines.

Furthermore, given that both proposed changes relate to the application of the 6 PMPRB price sources, we also have issues with the inclusion of IMS CD&H as a PMPRB price source. When the IMS CD&H data sets the lowest price among the 6 sources, it is often net of significant benefits, provided to a subset of customers. Our position is that using this price source may create a disincentive for

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manufacturers to provide benefits, establish an un-level playing field between manufacturers, similar to the example later in this letter, and is inconsistent with the intentions of Parliament when they introduced the PMPRB.

Roche recommends that IMS CD&H be eliminated from the list of 6 price sources, and that the list include only the 5 remaining sources.

Initiative #1: Reasonable Relationship Test Amendment

In the following section we hope to demonstrate the limitations of both the current Reasonable Relationship (RR) Test and the proposed changes to the RR Test. These limitations include, but are not limited to, regional price disparity over time leading to a non-level playing field between manufacturers, discouraging manufacturers from providing benefits, and confidentiality issues.

The current method of using the lowest of the six publicly available price sources for the RR test, which is retained in cases where the new medicine and comparable medicine(s) are owned by different patentees, may be problematic for manufacturers, as illustrated in the example below.

Year	PMPRB Max Allowable Price Increase	OPDP price	RAMQ Price **(lowest of 6 sources)**	AB Price
1	n/a	$ 1.00	$ 1.00	$ 1.00
2	2%	$ 1.02	$ 1.00	$ 1.01
3	3%	$ 1.05	$ 1.00	$ 1.02

Table 1: The comparable medicine (Medicine A – a 5 mg tablet made by Manufacturer A)

The RAMQ price of Medicine A is the lowest of the 6 sources in the example. The province-specific prices for Medicine A have diverged, due to differences in the price increase policies in the provinces. In the example, the province-specific and national ATPs are within Guidelines in all time periods. Assume Medicine B, a new strength of Medicine A and owned by Manufacturer B, is introduced in Year 3. If Medicine B is a scored 10 mg tablet, based on the existing and proposed RR price test rules for this scenario, the MAPP would be: $ 1.00/5 mg x 10 mg = $ 2.00 per tablet.

This MAPP establishes a non-level playing field between manufacturers, as Manufacturer B is required, by PMPRB to sell Medicine B to Ontario and Alberta customers at a discount to the non-excessive price for the equivalent dosage of Medicine A. We believe un-levelling the playing field is an unintended, yet important impact of reliance on the lowest price among PMPRB's 6 published price sources in this circumstance.

The proposed changes to the application of the Reasonable Relationship (RR) test may eliminate potential investigations related to new strengths of existing medicines where the new drug and the

comparable drug product(s) are owned by the same patentee. However, it should be noted that the proposed method of using the ATP when the new drug and the comparable drug product(s) are owned by the same patentee does not eliminate regional parity issues and discourages benefits.

	RAMQ	AQPP	ODB	McKesson	PPS	CD&H	ATP
Existing DIN	$ 0.90	$ 0.90	$ 1.00	$ 1.02	$ 1.00	$ 1.02	$ 0.97
Proposed MAPP	$ 0.97						

Table 2: Existing DIN (Medicine C – a 5 mg tablet made by Manufacturer C)

By applying the proposed RR test rule on the above example, the MAPP for a new comparable DIN from Manufacturer C would correspond to the existing DIN ATP of $ 0.97. If Manufacturer C launches the new DIN at the MAPP, the existing DIN and new DIN would have inconsistent prices in each region. Although the regional price disparity is reduced compared to the existing RR Test method, it is not eliminated. Furthermore, benefits given for the existing DIN would lower the calculated ATP and thus establish a lower MAPP for the new DIN. This could result in a loss of incentive for the manufacturer to include benefits.

Since prices for a new product are public, the proposed rule for the RR test also poses confidentiality problems. Publication of the MAPP would not be possible as it uses confidential company ATP information and there is generally enough information in the public domain for manufacturers to infer the maximum list prices that would yield a non-excessive ATP. The inclusion of benefits may also be inferred.

The above examples highlight the flaws in both the current RR test and the proposed amendment. We propose a solution in which:

- The MAPP is set using the highest of the 5 sources (i.e., exclusion of IMS CD&H data), with the requirement that;
- The existing price from each individual source cannot be exceeded

The above would apply to all new drugs regardless of manufacturer. An example of the implementation of this proposal is shown in red in the following table:

	RAMQ	AQPP	ODB	McKesson	PPS	CD&H	ATP
Existing DIN	$ 0.90	$ 0.90	$ 1.00	$ 1.02	$ 1.00	$ 1.02	$ 0.97
Proposed MAPP	$ 1.02						
New DIN	$ 0.90	$ 0.90	$ 1.00	$ 1.02	$ 1.00	$ 1.02	$ 0.97

Table 3: Existing DIN (Medicine C – a 5 mg tablet made by Manufacturer C) using proposed solution

This would level the playing field between manufacturers because no manufacturer would be forced to sell medicines at a discount to the non-excessive price for the equivalent dosage of the same medicine. Using the highest of the 5 sources (i.e., exclusion of IMS CD&H data) will not discourage manufacturers from providing benefits, and stipulating that the price from each individual source cannot be exceeded solves regional parity issues.

Roche recommends that the PMPRB apply RR tests to new medicines in the same fashion, regardless of whether the manufacturers' of the comparable medicine(s) and the new medicine are the same. Roche also recommends using the highest of the 5 price sources (i.e., exclusion of IMS CD&H data) to set the MAPP in order to establish a level playing field between manufacturers, acknowledge regional parity issues, and so as to not discourage benefits.

Initiative #2: List Price Relative to Maximum Average Potential Price (MAPP) Verification (Section C.11) Amendment

This proposed change is a fundamental shift in the way the PMPRB executes its mandate. To date, the PMPRB has determined compliance with the Guidelines, based on average prices, net of benefits, as set forth in the Patented Medicines Regulations, as follows:
"*(4) (1)(f)(i),*

a. *(a) in calculating the **average price per package** of medicine, the **actual price after any reduction** given as a **promotion** or in the form of **rebates, discounts**, **refunds, free goods, free services, gifts** or **any other benefit** of a like nature and after the deduction of the federal sales tax shall be used; and*

b. *(b) in calculating the **net revenue from sales** of each dosage form, strength and package size in which the medicine was sold in final dosage form, the actual revenue after any reduction in the form of **rebates, discounts, refunds, free goods, free services, gifts** or **any other benefit** of a like nature and after the deduction of federal sales taxes shall be used."*

The rationale given for moving to a system of assuming list prices are excessive if they exceed the MAPP is that it is necessary to defend consumer interests. This rationale now presumes that excessive pricing exists if *any* Canadian payer is paying a price above the MAPP. This notion is contradictory to the above quote from the Regulations, and requires erroneous reasoning since, in some situations having calculated a MAPP based on an average, the price sources higher than the average are then deemed excessive. Secondly, the Regulations clearly accept and expect the provision of benefits, in many forms, including rebates and discounts. If rebates, discounts and other such reductions in price are to be considered "*benefits"* as defined in the Regulations, then they cannot accrue to all customers, and must be applied against some higher base price.

It appears the ultimate intent of such a change is to ensure that every individual medicine has only one price for all Canadian payers. While such a pricing system might appear desirable to some, it would undoubtedly have unintended negative consequences. For example, such a system would almost certainly eliminate all hospital price discounts. In many instances, manufacturers could not afford to offer current hospital prices to all customers, so hospital prices would rise, exposing hospitals to unexpected budget pressure.

Roche recommends rescinding the proposed Initiative #2, and maintaining the current practice of monitoring compliance with the PMPRB Guidelines based on the average transaction price.

Finally, we would like to express concern about the exceeding amount of uncertainty with regards to the application of the rules in each of the proposed initiatives. It is unknown whether benefits will be included in calculating the ATP to establish MAPP in Initiative #1. It is also unknown how the new initiatives will be enforced if the list price exceeds the MAPP, and how excess revenues will be calculated in situations where the N-ATP is in compliance.

Roche recommends that changes to the PMPRB Guidelines not be implemented prior to completing comprehensive stakeholder consultations regarding the application of the rules in both initiatives and, once finalized, any changes to the Guidelines be published at least one year prior to their application to any new medicines.

Once again, thank you for the opportunity to provide comments on the proposed changes to the PMPRB Guidelines. If you have questions or comment, please feel free to contact Patrick Douglas at (redacted).

Sincerely,

HOFFMANN-LA ROCHE LIMITED

Ilona Torontali
Vice-President, Regulatory Affairs and Market Access
(redacted)