

July 31, 2020

Dear PMPRB,

Thank you for the opportunity to provide feedback on the updated PMPRB Guidelines.

Overall, it is important to note that AHS is supportive of an updated PMPRB process that improves the value received from new drug therapies. The opportunity cost of new drug therapies in our Health Authority are compared against other new or additional services AHS can provide to Albertans. The ability to derive good value from new drug therapies allows AHS to continue to serve all Albertans in the best possible manner.

There are five main areas that we would like to highlight in the changes that should require reconsideration:

1) Previous feedback

Your presentation frequently highlighted feedback contrary to your previous proposal. AHS, along with others, provided feedback that the model originally proposed would be a good framework to ensure value to Canadians from new drug entries, which does not appear to be reflected in your feedback summary.

We are concerned that the previous feedback Alberta Health Services provided is not reflected in the proposed update and the significant changes made to this proposal and permits the entry of drugs to the Canadian market without offering sufficient value.

2) Complexity of the model

In terms of ability to understand the thresholds and pricing limits, PMPRB has taken a significant step backwards in this manner. The proposed changes are difficult to understand and follow. With different categories, levels and pricing structures based on sales, it is challenging to understand what an appropriate drug price will be.

3) Value to Canadians

The value for Canadians has been greatly reduced with the proposed changes. We acknowledge a higher QALY threshold for rare and hard to treat conditions can be warranted, however this appears to raise the QALY threshold for low value drugs as well, which will be expensive to the Canadian system.

While timely access of medications is important to Canadians, not all new medications represent an advancement in care. Value is found in directing additional resources to those new medications that provide patients with improved outcomes that are meaningful to the patient, as demonstrated in the published literature. Where a new drug provides an advancement in care, it also needs to be at a price that is reflective of its benefit and be affordable to the Canadian health care system

4) Therapeutic Levels

The Therapeutic Criteria Level concept does allow for considerations for new treatments and significant improvements. It also provides an indication of the overall value a drug may have to Canadians.

The main concern however is that Level III provides limited value to Canadians and Level IV offers next to no value to Canadians. However the Pharmacoeconomic Value Threshold (PVT) continues to be \$150K/QALY, and the discount does not get to a pricing that is suggestive of the target QALY we would expect. The presentation cites the NICE threshold of €30,000/QALY (approximately \$50,000/QALY (CAD)), which we believe all drugs in Level III would fit, given the limited value. We would also suggest that Level IV drugs, offering next to no value to Canadians, should use a lower threshold than \$50,000/QALY.

Our opinion is:

- Level III should be at an initial target of \$50,000 QALY (CAD)
- Level IV drugs should have no more than an initial target of \$25,000 QALY (CAD)

Our rationale is if Canada did not list a Level III or IV drug, it appears not to negatively impact the health of Canadians. Therefore introduction of limited value treatments should only be introduced if they provide a cost advantage to our health systems. The improved value driven by a lower QALY from Level III and IV treatments would help offset the higher costs PMPRB has conceded on Level I and II from the previous draft.

5) Price Reductions

It is unclear to us whether, once a price is set, it will be straightforward to lower the price in a timely manner, if it passes the key thresholds. We would want three key things assured if the pricing tiers are implemented:

- a. That the sales reflect the entire national sales (government plans, private insurance, cash patients and hospital sales) and not just the billing that would go to governmental drug plans
- b. There be frequent (at least quarterly) evaluation of sales and once thresholds are met, new costs are set and implemented quickly so savings can be realized
- c. That a model like this is feasible and that manufacturers are willing/able to comply with the reduced prices as thresholds are met. If the manufacturer were to appeal a price reduction, it would need to be clear that the lower price is implemented immediately and no access issues would occur while the appeal is underway

In summary, AHS would like to note that the previous model proposed would achieve much greater value for Canadians than what is contained in the current proposal. As well, the complexity of the proposed model makes it difficult to understand what the price point of a drug will be. From the proposed model, we recommend a model that provides better value for Canadians and is easier to understand what price PMPRB would be applying.

Sincerely,



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