



June 28, 2017

Amgen Canada's submission

"Health Canada Consultations on the proposed Amendments to the Patented Medicines Regulations"

Amgen applies science and innovation to help fight serious illness and dramatically improve people's lives. With Canadian headquarters located in Mississauga's vibrant biomedical cluster, and a research facility in Burnaby, British Columbia, Amgen's Canadian affiliate has been an important contributor to Canada's biotechnology sector since 1991.

Amgen Canada serves patients throughout Canada by delivering vital medicines to them. In addition, Amgen contributes to the development of new therapies or new uses for existing medicines in partnership with many of Canada's leading healthcare, academic, research, government and patient organizations. Today, tens of thousands of Canadians use Amgen medicines every year, and thousands more are enrolling in Amgen clinical studies that deliver the next generation of innovation.

Biologic medicines have the ability to change the practice of medicine like never before. As a global leader in developing and delivering breakthrough biologic medicines that improve the health and well-being of patients dealing with serious illnesses, Amgen is committed to working with Canada's federal and provincial governments and other stakeholders to develop practical, cost-effective ways to sustain and improve Canada's healthcare system over the long term. Amgen would like to offer some commentaries on the possible impact of the proposed changes outlined in Health Canada's consultation document entitled "*Protecting Canadians from Excessive Drug Prices*". At the outset, it should be noted that the lack of detail as to how the proposed changes will be implemented, makes it difficult to assess the specific impact to our business. The public statements made by the government that the proposed changes could deliver savings of \$3.5 billion dollars over \$15.2 billion dollars of revenue for patentees in 2015 would represent a 23 % decrease in industry revenues. Such magnitude would have a serious impact on our operations. Finally, at a policy level, we believe that many of the changes contemplated are not aligned with the PMPRB's mandate of protecting Canadians from excessive drug prices.

The Use of Pharmacoeconomic Evaluations

The consultation document indicates a willingness to use of pharmacoeconomic (P/E) evaluations to determine if the price is excessive. The use of P/E assessments for this purpose presents many challenges, not the least of which is that it assumes that a single P/E assessment can be universally applied. The results of any given P/E assessment are inextricably linked to the perspective from which the evaluation is conducted. Rarely do two independent P/E evaluations arrive at the same conclusion. The most appropriate example is the difference between Quebec's INESSS and CADTH's evaluations. CADTH conducts its reviews from a strict health system perspective, ignoring the impact of a given health technology on broader societal factors like family caregivers, individual productivity or economic contribution to society. Quebec on the other hand takes a societal perspective incorporating factors outside of the health system. Private Health Insurers have also begun to look at using health technology assessment (HTA) and have noted that CADTH or INESSS' evaluations may be too narrow for the goals of its private plans which are looking to keep employees healthy, productive and away from disability. It is difficult to see how the PMPRB could use a unique evaluation that would be appropriate for all Canadians. It is likely for this reason that, to our knowledge, no other country utilizes P/E evaluations for any purpose other than reimbursement decisions.

While we commend the Minister's initiative in aligning NOC, HTA and PMPRB pricing decisions, it has been noted by Health Canada officials that not all drug candidates will be privy to parallel, timely and in sequence approvals. A system in which PMPRB would have access to only a subset of HTA evaluations at the time of decision making would potentially further delay decision making and limit access.

To conclude on this proposed change, for all of the reasons outlined above, Amgen strongly feels that P/E evaluations are not the appropriate tool for a regulator to apply in ensuring non-excessive pricing and we urge the government not to adopt this approach

Market Size

The consultation document also proposes amending the regulations to include the size of the market in Canada and also in countries outside of Canada. Market size can be dynamic in the life of a drug as new indications are studied and its usage evolves. It can also be static as many of the agreements negotiated with Canadian payers have a component of budget management that is often correlated with usage and capitation clauses. This would be true in Canada and abroad.

This means that PMPRB's ability to track market size over the life of a drug both at home and internationally would be highly problematic. In theory, the inclusion of this factor is consistent with the view that higher volumes should lead to lower per unit price. However this view is overly simplistic as the value of a drug or health technology can vary dramatically depending on

its application. While the relationship between price and volume is an important consideration, we believe that the underlying value of a health technology should be an equally important consideration in establishing its price. Both of these factors are already a basis for arriving at pricing agreements with payers. The inclusion of this factor in PMPRB's determination of non-excessive pricing is therefore redundant and unnecessary. Payers already make that assessment and extract price concessions on this basis from manufacturers today.

Gross Domestic Product

How GDP would factor into price regulation is not clear. To the extent that PMPRB will rely in future on reference pricing, the use of per capita GDP as a basis for informing the choice of reference markets seems appropriate. The use of GDP and/or GDP growth as a factor in price regulation is more complex and it is unclear how it would intersect with PMPRB's current use of the Consumer Price Index (CPI).

Changes to the List of Comparator Countries

We fundamentally believe that to the extent that reference pricing remains a part of PMPRB's price regulatory methodology, the basket of reference countries needs to reflect countries with similar levels of economic development and similar levels of investment in health systems. The OECD membership does not achieve this as it includes countries with very disparate levels of overall wealth, economic development and health system expenditure.

While we understand the political appeal of removing the United States from the basket, we would note that its proximity and the similarities of our two markets in terms of public-private split and our economic interconnectedness makes it a good comparator country.

The selection of a new basket should also be reflective of Canada's vision for a new industrial policy for our sector that includes the support for innovation, signals that the nation open for investments and that the government is committed to bringing breakthrough technologies to Canadians.

Patented Generic Drugs reduced Burden

The proposed changes to simplify and remove some obligations of patented generics to report pricing information to the PMPRB given their low market power is a welcome signal from the regulator. Amgen would encourage PMPRB to examine other drug classes where the market dynamics are at play and the regulator's resources could be better employed.

While we are supportive of the technical changes on generic filing, we are surprised that the Minister's objectives to reduce drug prices in Canada in no way touch on the generic class of drugs. Dollars spent on drugs account for 15.7% of the health budget. Of that 6.4% is patented drugs and 9.3% is generics. PMPRB stated last year that Canadian generic prices "still continue to be about 19 per cent higher than the international prices". Canadians spend \$5 billion dollars

on generic drugs a year. We encourage the Minister to ensure that all participants in the drug industry are contributing to achieving her objective of making drugs more affordable for Canadians.

Modernizing Reporting Requirements

These proposed changes for new reporting requirements are problematic. First, *the cost utility analysis by approved indication of the medicine, where that information is available to the patentee*, as stated in the first section of our submission does not account for the variety of perspectives of different payers and hence is not appropriate for usage in determining whether or not a price is non-excessive.

On the second requirement: *the estimated uptake of the medicine, by approved indication, in Canada without restraint on utilization (e.g. market/budget impact analysis in any relevant market)*, where that information is available to the patentee, while this information can be provided for the Canadian market, providing this information for comparator countries would be difficult and highly burdensome. Amgen believes that market size and budget impact assessment should remain the responsibility of the payers.

Third Party Price Reduction Reporting

The consultation document calls for the disclosure of confidential rebate information and asks *“Are there any reasons why patentees should not be required to disclose to the PMPRB information on indirect discounts and rebates provided to third party payers?”*

Amgen questions the necessity of this information for the purpose of setting a price that is non-excessive. If it is PMPRB’s goal to ensure Canadian are not paying excessive prices, regulation based on the current level of disclosure is sufficient as the effects of further non-transparent price reductions only serve to improve net price. Furthermore, the absence of details of how this information would subsequently be used is highly problematic.

The Pan Canadian Pharmaceutical Alliance (pCPA) has also acknowledged that the ability to extract more savings from manufacturer and address the affordability issues around their own drug plans is dependent on non-transparent pricing arrangements and provisions for this are incorporated into agreements. The reporting of discounts risks undermining the system which has evolved for public plans to manage their drug expenditures. In addition, the reporting of these rebates would increase the burden of compliance on patentees..

The global pricing regime of international referencing makes confidential pricing one of the few tools where manufacturers can provide significant reduction in price to governments serving low income and vulnerable populations.

Furthermore, many of the pricing agreements being negotiated with payers today include risk sharing provisions through which a net price can only be determined retrospectively which

makes it difficult and in some cases impossible to report accurately on annual net prices. Listing agreements with confidential pricing have also evolved in the private market where the performance of the drug is also being measured and rewarded for agreed upon health outcomes. These market dynamics should be left to unfold without government interference.

Amgen cautions the government not to put at risk the system that exists with payers in Canada where savings can be extracted.

Perhaps a better understanding of the need for the PMPRB to have access to this data may trigger a different reaction on our part.

Conclusion

While Amgen supports the vision communicated by the government around access, affordability, appropriate prescribing, the changes proposed by Health Canada will not necessarily achieve those goals. Adding pharmacoeconomics (P/E) to the PMPRB evaluation could delay access to new therapies as not all new drug candidates are likely to receive a Notice of Compliance (NOC) and a Health Technology Assessment (HTA) recommendation at the same time: creating a two tier system. More importantly, P/E evaluations are specific to a payer's needs and given Canada's system with its public and private components, it is unlikely that PMPRB would provide an assessment that would be appropriate for all Canadian payers.

The lack of information around the utilization of Canada's GDP and Market Size as new economic factors makes it difficult to assess its impact. It should be reiterated that many payers, both public and private, currently use capitation and utilization in their negotiations with manufacturers. Market size is a better tool for the payer than the regulator establishing a maximum allowable price threshold.

And finally, the disclosure of non-transparent rebates poses a serious risk to the pCPA system which is still evolving. Disclosure of this information could impact the benefits currently enjoyed by public plans that serve low income and at risk populations and transfer those benefits to the private insurers who have no obligations to fully pass along those savings to their plan sponsors.

The market dynamics currently at play in Canada are regularly bringing payers and industry to the negotiation table. While the government may want to see transparent list prices decrease in the future, many of the consideration outline above should be considered as policy decisions are implemented.