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Honourable Ginette Petitpas-Taylor, Minister of Health
Patented Medicines Regulations Consultations
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via email: PMR-consultations-RMB@canada.ca and Minister_Ministre@hc-sc.gc.ca

re: Changes to the *Patented Medicine Regulations (the "Regulations")*, December 2, 2017

Dear Minister Petitpas-Taylor;

In May 2017, then Minister of Health Jane Philpott articulated her vision for updating the pharmaceutical regulations in Canada. She stated that the goals were to improve affordability, access and appropriate prescribing. Proposed changes to the *Patented Medicines Regulations* were announced at that time but focused solely on one narrow piece of these broad issues: the list price of innovative medicines regulated by the Patented Medicine Prices Review Board (PMPRB).

In the comments submitted by Janssen in response to the June 2017 consultation on these proposed changes, we clearly articulated why they will not result in meeting the Minister's stated goals. In fact, these regulatory changes will likely result in:

- *No change in affordability of medicines for the public healthcare system and preferential savings for the private insurance industry*
- *Decreased access to the most innovative medicines, and no meaningful improvement in access for Canadians who are uninsured or under-insured*
- *No impact on appropriate prescribing and utilization, which is the largest driver of the per capita cost of medicines in Canada, not the prices.*

In addition, these proposed changes will likely result in decreased investment in the Canadian life sciences innovative ecosystem, hindering your government's commitment to life sciences as part of the Innovation Agenda.

We were disappointed that the regulations presented in the December 2, 2017 Canada Gazette 1 did not differ in any material way from those announced in May, despite over 100 submissions having been received by Health Canada. We are aware that many of these submissions, including those from many patient organizations stated substantially similar concerns to those raised by Janssen.

We have therefore included our June 2017 submission as an important part of this current submission, as the points raised in that document are still relevant. Below is a summary of the main issues and potential solutions we would like to offer in lieu of proceeding with the current proposals.

The proposed regulations are not appropriate for regulating excessive prices of innovative medicines by the PMPRB.

The proposed schedule of countries does not reflect the economic standing of Canada nor the aspiration we, as Canadians, expect from our healthcare system.

Nowhere in the policy objectives of the PMPRB, nor in any other part of our healthcare system, is a stated objective that we emulate the median of the Organization for Economic Co-operation and Development (OECD). Despite use of assumptions to the contrary by Health Canada in its Cost-Benefit Analysis (CBA), pricing medicines at the median of the OECD will result in access to medicines at the median of the OECD. According to the PMPRB's own data, this means that less than 50% of new medicines will be accessible for Canadians if the proposed regulations are passed into law.¹

Recommendation 1: Utilize a group of countries with similar economic standing, healthcare goals and pharmaceutical markets as Canada. The G10 with or without the United States is a set of countries that makes sense to use in the context of assessing excessive prices for innovative medicines. This change alone would result in a decrease in prices of approximately 10-15%, thereby improving affordability without resulting in significant decreased access to medicines, decreased investments in the Canadian life sciences ecosystem, and job losses.

Pharmacoeconomic analyses are not appropriate for use in assessing excessive prices by the PMPRB.

Pharmacoeconomic analyses are used globally, and in Canada, to inform reimbursement decisions and negotiations, not as hard 'bright lines' to set 'non-excessive' prices. No other jurisdiction uses pharmacoeconomic analyses in this manner; Canada would be a global outlier.

Pharmacoeconomic analyses are based on models, which by their nature are based on assumptions. The choice of assumptions very much affects the results of the model, and whether a medicine is considered 'cost-effective'. There are many examples of large differences in results of these models between publicly-funded Health Technology Agencies, even within Canada. The PMPRB is a quasi-judicial federal body, separate from the public and private payer reimbursement decision-making system. Therefore, this type of modelling is inappropriate for use in the determination of 'excessive pricing'. Establishing a 'maximum non-excessive price' requires a precise calculation. As pharmacoeconomics is an inexact science, heavily dependent upon varying assumptions, using such a method to assess excessive pricing is very problematic as it is impossible to determine which set of assumptions are correct.

Please see the submission from Innovative Medicines Canada for a detailed analysis of the inappropriateness of using pharmacoeconomic analyses to determine excessive prices.

Recommendation 2: Remove pharmacoeconomic analyses as a factor in the regulations.

Market size, GDP growth and GDP per capita are not appropriate for use in assessing excessive prices by the PMPRB as they are measures of affordability that are more appropriately considered by public and private payers.

The PMPRB is a quasi-judicial federal body, whose mandate is to determine if the price of a patented medicine is *excessive*. Its mandate is not to set the price at which a manufacturer can sell a medicine, nor is its mandate to assess affordability. Affordability is a subjective analysis and will differ for each payer in Canada; public, private or individual Canadians. It is impossible for one federal agency to set one affordable price for each of these payers. Factors such as the

potential size of the market, and changes over time, are not relevant in excessive price for the purposes of the *Patent Act*.

The PMPRB assessment of affordability is duplicative to the work already done by payers across Canada. More specifically, the pan Canadian Pharmaceutical Alliance, private payers, and individual plan designs for employers already consider affordability factors when negotiating with innovative pharmaceutical manufacturers to have a product listed on the payer's drug formulary and provide access to patients. If the PMPRB becomes the sole arbiter of affordability of innovative medicines in Canada for all payers, does this mean that payers will lose their autonomy in decision-making regarding whether to provide a drug to their citizens or customers? For example, would each public payer list a drug immediately following the PMPRB's decision on an 'affordable' price? It seems unlikely that the provincial health systems and private payers would want to give up control over the healthcare for their citizens, resulting in additional layers and delays in access for patients, rather than improving access, as is the stated goal of your ministry.

Recommendation 3: Remove market size, GDP growth and GDP per capita as factors in the Regulations.

Reporting of confidential rebate information to the PMPRB is inappropriate and not needed to assess excessive prices.

The mandate of the PMPRB is to assess excessive prices of patented medicines as a safeguard to ensuring that patentees do not abuse their time-limited monopoly. Health Canada has not explained why they need to have confidential rebate information to assess excessive prices. Since, by definition, a rebate results in a price lower than the list price, it does not seem necessary or appropriate for the PMPRB to require this confidential information to determine excessive pricing.

The *Regulations* also state that if rebates are reported, the lower transparent price could then be used to set an Average Transaction Price for comparator medicines. It is unclear how this can be achieved without revealing confidential information between competing businesses, and without violating the patentee's right to privilege under section 87 of the *Patent Act*. If the PMPRB is using this information to effectively lower ceiling prices for competitive medicines, the PMPRB has moved away from assessing excessive prices, to effectively setting the retail price for these medicines. This is beyond the mandate of the PMPRB.

Revealing confidential rebates to the PMPRB may result in manufacturers being unable or unwilling to enter into product listing agreements with payers in Canada, and reduce the willingness of manufacturers to offer the same level of rebates currently available. Other countries such as Germany are realizing that there is value in allowing confidential rebates to occur in the market. Germany has found that lowering of list prices by significant amounts results in fewer medicines being available in the marketplace. In addition, regulators in these countries have realized that they can achieve greater savings through confidential rebates than by transparent reduction in prices.

Recommendation 4: Remove the requirement for patentees to submit third party confidential rebate and discount information.

The proposed regulations will result in negative consequences for Canadians.

Access:

Contrary to the minister's goal, the proposed changes will result in *decreased access to innovative medicines* for Canadian patients. As mentioned above, countries with prices at or below the median of the OECD have significantly fewer drugs available to them. Canada will become a third-tier country with respect to access to medicines, due to international price referencing. In addition, the level of price reductions that are being proposed could result in it being not financially viable to launch some medicines in Canada. Contrary to the Health Canada analysis, the proposed regulations will start with an average reduction in prices of approximately 20% due to the new basket of countries, and the additional factors will result in further reductions from there. No business can accept this level of reduction in revenue without impacts to their operating model.

Also concerning is the fact that these Regulations and the accompanying Guidelines proposal clearly state that the greatest scrutiny and greatest price pressure will be on the most innovative medicines. This will mean that many medicines, particularly those for rare diseases, will not be available in Canada if these Regulations are put in place.

Affordability:

Contrary to the minister's goal, most savings due to these proposals will benefit private payers. Public payers currently negotiate confidential rebates; therefore, the lowering of list prices by the PMPRB will not benefit the public healthcare system as they will continue to receive the same net price. The savings will preferentially be given to the private insurance industry, with no ability to ensure that this will result in lowered premiums for employers and individual patients. These proposals will reduce the negotiating room for rebates in the future and will not result in more budget being available to public payers to cover more medicines for more patients.

Innovation Agenda:

The large decrease in prices associated with these changes will make it difficult for the Canadian operations of multinational pharmaceutical companies to continue to attract global investment in the Canadian life sciences ecosystem. Contrary to what is stated in the Health Canada CBA, the pricing and reimbursement environment is a factor that companies consider when determining where to invest their R&D dollars.¹¹ J&J has invested over \$1 billion in the Canadian life sciences ecosystem since the signing of CETA in 2014. This level of investment will be difficult to maintain if we do not have a reasonable expectation that our medicines will be sold in Canada at a predictable price.

How did we get to this point?

The consultation on these proposals has been deficient to date. No significant feedback provided by more than 100 submissions in June 2017 has been incorporated into the Canada Gazette 1 Regulations. This lack of consultation is also apparent in the RIAS and CBA prepared by Health Canada, which include many errors and incorrect assumptions.

For example, the impact to the pharmaceutical industry is grossly underestimated. The median of the PMPRB12 is 20% lower on average than current prices in Canada, not a <10% impact on revenues as calculated by Health Canada in the CBA. In addition, the new factors will result in prices even lower than the median of the PMPRB12.

The CBA also assumes that the innovative pharmaceutical industry will continue 'business as usual' in the face of the "most significant suite of [proposed] changes to the country's drug-pricing regime in more than 20 years" (Minister Philpott, May 2017). Innovation investments will be impacted, and high-quality jobs will be lost.

The issues with the RIAS and CBA assumptions and data are articulated in the analysis completed by PDCI (appended), and in Innovative Medicines Canada and BIOTECanada's submissions in response to the Canada Gazette 1 consultation. Please see these documents for further details.

Fundamentally, this highlights the importance of truly meaningful consultation that goes well beyond the submission of written responses. Consultation needs to be with all stakeholders, including patient representatives and the full life sciences ecosystem, academics, life sciences incubators and startup companies, private payers, provincial ministries including Health and Economic Development and the federal Ministry of Innovation, Science and Economic Development.

Recommendation 5: Convene an immediate table of relevant stakeholders to develop a system to improve affordability for innovative medicines, while still allowing for the best medicines to come to Canada, and the pharmaceutical industry to continue to invest in Canadian life sciences.

It is also important to note that at the end of this process, appropriate time be allotted for the PMPRB and innovative pharmaceutical industry to work through the development and implementation of appropriate guidelines related to any new regulations. As per revisions in the past, working groups need to be convened to determine the best approach, and once regulations and guidelines are finalized, appropriate transition time needs to be allotted for manufacturers to come into alignment with the new process. Our industry establishes prices for our products at least two years in advance of launch, and investment decisions in R&D and jobs associated with a medicine are established years before the medicine comes to Canada. Therefore, it takes more than a few months to rework forecasts and bring a price into alignment with any new guidelines. Lowering prices for existing medicines that were in compliance with the current guidelines artificially penalizes investment decisions already made.

Recommendation 6: New regulations and guidelines should apply only to medicines with a first sale after implementation.

Recommendation 7: Allow a 'grace period' whereby medicines that launch in the first year after implementation of any new regulations and guidelines are given a subsequent reasonable period of time to bring their price into alignment.

Next steps and solutions

The innovative pharmaceutical industry recognizes our role in ensuring affordability and accessibility of medicines to all Canadians. However, the proposed changes to the Patented Medicines Regulations will not improve affordability for the healthcare system and will negatively impact accessibility.

To this end, IMC has proposed a wide-reaching plan designed to not only reduce the prices of innovative medicines, but also to increase access for all Canadians, improve appropriate prescribing and increase investments in Canadian life sciences research and development.

This proposal takes a much broader view of the issues impacting healthcare in Canada than the approach being proposed by the PMPRB. Ideas for discussion include:

Affordability:

- Changes to the PMPRB Regulations and Guidelines that will result in lowering of prices at a sustainable level of 10-15%; (e.g. A new basket of 10 countries, excluding the US; a price freeze on existing medicines)
- A risk-based approach to rare disease or very high cost drugs
- Value-based agreements, including data infrastructure to better track patient outcomes

Access:

- Collaborate to find solutions to address uninsured and underinsured patients
- Support for infrastructure to educate Canadians on the coverage they have but don't access

Appropriate Prescribing:

- Partnerships to create capacity for federal, provincial and territorial health data infrastructure to better track prescriptions

Research and Innovation:

- Modernize the definition of industry investment in R&D and establish a new threshold for the innovative pharmaceutical industry to commit to

We look forward to discussing this vision for the Canadian pricing and reimbursement environment in person with your ministry and colleagues at the Ministry of Innovation, Science and Economic Development.

Recommendation 8: Convene a table of stakeholders to develop a 21st Century approach to pricing and reimbursement that will allow timely access to the best medicines at affordable prices for all Canadians.

Conclusions

We are at a critical junction in the evolution of our healthcare system where we must decide if we are committed to finding multi-dimensional solutions for maintaining the high quality of healthcare we expect in Canada, or if we will let the issue of affordability hijack the need for a more comprehensive discussion about the complex challenges we face. If we limit ourselves and focus only on prices, we will miss out on the grander opportunities that the promise of science and innovation offer for a healthier, happier and more productive nation.

We are ready and willing to work with Canadian governments and health plan providers to build a healthcare system that not only values innovation, but is innovative itself, and provides a leading example to the world on how the current challenges can be overcome with a collective and collaborative approach.

Yours Sincerely,



Chris Halyk
President

cc.

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Geneviève Hinse, Chief of Staff, Health Canada

Kathryn Nowers, Senior Policy Advisor, Health Canada

Simon Kennedy, Deputy Minister, Health Canada

Honourable Navdeep Bains, Minister of Innovation, Science and Economic Development

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John Kubley, Deputy Minister, Ministry of Innovation, Science and Economic Development

Sheryl Groeneweg, Director General, Ministry of Innovation, Science and Economic Development

Maxime Dea, Policy Advisor to the Prime Minister

Doug Clark, Executive Director, Patented Medicine Prices Review Board

Mitchell Levine, Vice-Chairperson, Patented Medicine Prices Review Board

Encl.

- Submission from Janssen Canada to the June 2017 consultation
- Analysis completed by PDCI regarding the Health Canada CBA

ⁱ Patented Medicine Prices Review Board Meds Entry Watch 2015. http://www.pmprb-cepmb.gc.ca/CMFiles/NPDUIS/NPDUIS_MedsEntryWatch_2015_e.pdf

ⁱⁱ Ascending to the peak of biopharmaceutical innovation. Biopharmaceutical Competitiveness & Investment Survey, 4th Edition, 2017. Pugatch Consilium. http://www.pugatch-consilium.com/reports/BCI_2017_Report.pdf