INNOVATIVE MEDICINES CANADA / MÉDICAMENTS NOVATEURS CANADA

Submission

Consultation for the Renegotiation and Modernization of the North American Free Trade Agreement (NAFTA)

July 18, 2017

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1. IN YOUR VIEW, WHAT SHOULD BE A PRIORITY FOR THE GOVERNMENT OF CANADA IN THE RENEGOTIATION OF NAFTA (E.G. TRADE AREAS, PRACTICES, ISSUES)?

Innovative Medicines Canada (IMC) is the national voice of Canada's innovative pharmaceutical industry. We advocate for policies that enable the discovery, development and commercialization of innovative medicines and vaccines that improve the lives of all Canadians. We support our members' commitment to being valued partners in the Canadian health and regulatory system. IMC is grateful for this opportunity to submit comments to the Government of Canada in preparation of negotiations related to the North American Free Trade Agreement (NAFTA) with the United States and Mexico.

NAFTA has provided a framework for encouraging biopharmaceutical trade throughout North America. NAFTA helped to secure trade in Canadian pharmaceuticals while enabling Canada to compete on a more even playing field with international pharmaceutical firms. The U.S. and Mexico are top destinations for Canadian pharmaceutical exports in large part due to NAFTA's effect on the elimination of tariffs and duties. In 2016, the pharmaceutical industry exported approximately $8 billion worth of pharmaceutical products to the U.S. and another $72 million to Mexico[1] (Table 1). However, Canada is currently experiencing a $2.9 million trade deficit in pharmaceutical products with Mexico – a figure that fluctuates widely across years.

Table 1. Canadian Trade Balances with NAFTA Partners, in Thousands of Canadian dollars, 2012-2016

		2012	2013	2014	2015	2016
United States	**Total Exports**	3799519	3750488	4856451	7049686	8007297
	Total Imports	4182888	4068379	4582417	5467123	5434134
	Trade Balance	-383369	-317891	274033.8	1582563	2573163
Mexico	**Total Exports**	56184.77	68119.1	98606.31	132831.2	71656.56
	Total Imports	76810.67	69750.9	66675.53	73826.16	100924.5
	Trade Balance	-20625.9	-1631.8	31930.79	59005.09	-29267.9
Sub-total	**Total Exports**	3855703	3818607	4955057	7182517	8078954
	Total Imports	4259698	4138130	4649092	5540950	5535059
	Trade Balance	-403995	-319523	305964.6	1641568	2543895

Source: Government of Canada, Trade Data Online. Search Criteria: Products: HS 30 - Pharmaceutical Products; Origin: Canada; Destinations: Mexico, United States; Period: Latest 5 years.

IMC supports NAFTA and its stated objectives to "ensure a predictable commercial framework for business planning and investment"[2] and to "ensure that measures and procedures to enforce intellectual property (IP) rights do not themselves become barriers to legitimate trade"[3]. In particular, commitments made under NAFTA to better align Canadian IP policy with our competitor nations is a priority for our membership. Against the backdrop of the Comprehensive Economic and Trade Agreement (CETA) and Trans-Pacific Partnership (TPP) negotiations, the renegotiation of NAFTA provides state parties the opportunity to critically review whether these and other treaty commitments have been realized and are aligned with other international treaty objectives and the trading practices of our major competitors.

[1] Government of Canada, Trade Data Online, available at https://www.ic.gc.ca/app/scr/tdst/tdo/crtr.html.
[2] North American Free Trade Agreement, 32 I.L.M. 289 and 605 (1993) (NAFTA), at preamble.
[3] *Ibid*, at Article 1701.

In this document, IMC raises several concerns with regard to the implementation of the IP provisions of NAFTA – specifically with regard to regulatory data protection, the protection of confidential business information (CBI), patent term restoration (PTR), and IP enforcement mechanisms. We also highlight emerging areas of concern for our industry that could be mitigated by way of refinements under NAFTA – such as: recognizing the value of pharmaceutical innovation in pricing and reimbursement, and improving regulatory harmonization.

We encourage the federal government to continue to pursue legislative, regulatory and policy initiatives that demonstrate meaningful commitments to strong IP protection, innovation, and appropriate reward-for-value in Canada's biopharmaceutical industry. The proper renegotiation of these commitments will determine how effective these measures will be in both sending a positive signal to the international industry with respect to doing business in Canada, as well as supporting the development of innovative medicines in Canada.

2. ARE THERE ELEMENTS OF NAFTA THAT ARE WORKING WELL AND SHOULD BE PRESERVED OR IMPROVED UPON?

International trade negotiations have driven Canada's IP regime over several decades. The resulting changes have helped generate investment and progress in Canada's innovative pharmaceutical sector. Through trade agreements such as NAFTA and The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), and negotiations under CETA and the TPP, Canada gradually has brought its IP protections closer in line with those of its major trading partners. However, there are certain elements of NAFTA that could be improved upon, to enable Canadian innovators to compete on a more even playing field with international pharmaceutical firms.

We highlight priorities for our membership below that merit decisive government action under the NAFTA renegotiations. We do so within the context of NAFTA itself, commitments made under other trade deals, and the current IP climates in states party to NAFTA. In particular, we discuss the association's ongoing concerns related to regulatory data protection, the protection of CBI, PTR, and resolution mechanisms for patent disputes.

Regulatory Data Protection

- **Rationale:** The protection of undisclosed test data submitted for the approval of innovative drugs seeks to incentivize local and foreign pharmaceutical companies to make the enormous research and development (R&D) investments necessary for new medicines and vaccines while also inciting homegrown R&D.
- **Requirements under NAFTA:** Under NAFTA, parties agreed – should they require the submission of data to determine a product's safety and effectiveness – to "protect against disclosure of the data of persons making such submissions, where the origination of such data involves considerable effort, except where the disclosure is necessary to protect the public or unless steps are taken to ensure that the data is protected against unfair commercial use."[4] The period of data protection under NAFTA is "not less than five years".[5]

[4] *Ibid*, at art 1711(5).
[5] *Ibid*, at Article 1711(6).

- **Situation in Member States:** In Canada, data protection regulations were enacted in 2006 under the *Food and Drug Regulations*[6] in order to implement the data protection obligations under both NAFTA and TRIPS.[7] The *Food and Drug Regulations*, at section C.08.004.1, entitle innovative drugs to an eight-year term of data protection (plus a possible additional 6 months for submissions that include pediatric studies), and prevent a second-entry manufacturer from filing a submission for a copy of that innovative drug for the first six years of the eight-year period.

  IMC's membership has several concerns with respect to Canada's data protection regime. Firstly, Canada's eight-year base term of data protection applies to all drugs, including biologics. In addition, members have raised the concern that the regulatory provisions around pediatric extensions are unworkable given the design requirements of clinical trials in children (pediatric data must be filed in the original new drug submission, or any supplement thereto, within the first 5 years of the 8-year data protection period). This is in contrast to other jurisdictions, such as the U.S. and EU, where there are regulatory requirements for pediatric study plans and the timelines for completion of these are agreed upon between the regulator and sponsor. Moreover, we note that both Health Canada and Canadian courts have interpreted and upheld a strict interpretation of the "previously approved" and "variation" aspects of the definition of "innovative drug" – thereby diluting the benefits of the data protection to a certain extent.

  In the U.S., a period of five years of data protection is available for combination products containing at least one new active ingredient and three years are available for new clinical information submitted to secure marketing approval of a previously approved pharmaceutical product covering a new indication, new formulation or new method of administration. The result is a maximum term of 8.5 years in the U.S. for chemical products. The U.S. also provides 12 years for innovative biologic products.

  Mexican domestic law is silent about data protection for chemical drugs, biological medical products and new indications. However, in 2012, the Federal Commission for Protection against Sanitary Risks issued internal guidelines that provided a 5 year-term of data protection for new chemical entities. They do not provide protection regarding biotech products, new formulations and indications; nor do they set out specific proceedings and measures for observing and enforcing data protection. The guidelines are non-binding and may be rescinded at any time.

- **Canada's other trade agreements:** The TPP requires countries to provide five to eight years of data protection[8], and is therefore aligned with Canada's current term of data protection. Data protection under CETA requires: (a) prohibiting generic drug manufacturers from relying upon such data in its own market approval application for a period of six years; and (b) prohibiting the parties from issuing market approval within eight years of granting data protection, and is therefore consistent with the current Canadian regime. A maximum of 11 years of data protection is available in the EU.

- **Recommendations:** NAFTA should be updated to clearly provide five years of data protection for combination products and an additional three years of data protection for new clinical information submitted to secure marketing approval of a previously approved pharmaceutical product covering a new indication, new formulation or new method of administration. In view of the concerns noted with regard to pediatric extensions, the probability of success would be improved by extending the filing date requirement for which pediatric data must be filed, which is currently too short in many cases to gather

[6] *Food and Drug Regulations*, CRC, c 870.
[7] *Ibid*, at C.08.004.1 (2).
[8] See "Text of the Trans-Pacific Partnership" at Articles 18.50 and 18.52, online: New Zealand Department of Foreign Affairs and Trade http://tpp.mfat.govt.nz/text, last accessed 18 July, 2017.

the required data. Moreover, consideration should be given to adapting data protection regulations to reflect the rapid rise in new product development in biologics. To encourage research and investment in biologic drugs, consideration should be given to offering longer periods of data protection to help drug developers recover their R&D costs – for example, a 12-year period as provided in the U.S.

Protection of Confidential Business Information (CBI)

- **Rationale:** Health Canada is entrusted with substantial amounts of manufacturer-supplied confidential information required for the market authorization process for therapeutic products. This highly sensitive information includes chemistry, process, manufacturing, testing, and packaging specifications as well as extensive clinical data. For a single product, this data can encompass tens of thousands of pages. Appropriately addressing public expectations for regulatory transparency is an important component of Health Canada's mandate. This can be achieved while also respecting international obligations and ensuring alignment with the practices of other leading regulators.
- **Requirements under NAFTA:** NAFTA requires that CBI be protected against disclosure except where necessary to protect the public[9].
- **Situation in Member States:** The situation in Canada with regards to the protection of CBI is of particular concern. In November 2014, Canada enacted legislation to update *its Food and Drugs Act* (Bill C-17). Provisions in that law granted the Health Minister discretion to disclose a company's CBI without notice to the owner of the CBI and in accordance with a standard that is both inconsistent with other similar Canadian legislation and Canada's treaty obligations under NAFTA.

  More specifically, Canada has lowered this objective threshold by permitting the Ministry of Health to disclose CBI related to biopharmaceutical products if the Minister "believes" that the information "may" protect the public. There is no necessity requirement for disclosure to occur, only that it be related to protecting or promoting health[10].

  In July 2015, a final guidance document was issued by Health Canada with respect to the administration of its powers to require and disclose CBI. However, the document is a non-binding guidance as opposed to binding law or regulations, and as such Health Canada has the discretion not to follow its requirements, and it is also potentially vulnerable to future legal challenges.

  In September 2015, a pharmaceutical company was subjected to a disclosure by Health Canada of CBI related to its pharmaceutical product, representing the first known usage of the new legislative disclosure powers. Following a request made under the new mechanisms in the *Food and Drugs Act*, approximately 35,000 pages of raw trial data were released, demonstrating the potential prejudice to innovative biopharmaceutical companies that could result from future CBI disclosures.

  The amendments brought under Bill C-17 are inconsistent with the standards and practices of other national health regulators, including the U.S. Food and Drug Administration (FDA).
- **Canada's other trade agreements:** NAFTA and other international obligations do not refer to disclosure for the promotion of health, but rather disclosure needed to protect health of the public. The current situation in Canada results in inadequate protections to ensure that there is no unfair

[9] *Supra*, note 2, at Article 1711(5).
[10] *Food and Drugs Act*, RSC 1985, c F-27, at Section 21.1(2).

commercial use of the disclosed CBI as required by TRIPS[11]. The provisions of the TPP, as currently drafted, appear consistent with Canada's treaty obligations, given that they prohibit disclosure except where it is necessary to protect the public or unless steps are taken to ensure that the data are protected against unfair commercial use.

- **Recommendations:** IMC urges the Government of Canada to maintain and enforce NAFTA provisions regarding CBI to align its domestic legislation and regulations with its existing NAFTA and TRIPS obligations.

Patent Term Restoration (PTR)

- **Rationale:** As in other countries, Canada's market approval process significantly erodes the effective duration of the 20-year patent term for bio/pharmaceutical products of innovative companies. PTR is remedial time that can be added at the end of a patent's life to help compensate issues such as clinical trial time, unreasonable patent office delays, or delays due to marketing approvals. Since innovators and the patients that would benefit from their therapies are being penalized for regulatory and other delays beyond their control, these gaps make it harder for Canada to compete for investment internationally since all other developed nations have recognized that innovators should be entitled to recoup some of their R&D costs to encourage further innovative activity.

- **Requirements under NAFTA:** Under NAFTA, parties "may extend the term of patent protection, in appropriate cases, to compensate for delays caused by regulatory approval processes."[12] NAFTA goes on to specify that limited exceptions to patent rights must "not unreasonably prejudice the legitimate interests of the patent owner, taking into account the legitimate interests of other persons."[13]

- **Situation in Member States:** Patent term adjustment is already available in other countries. Even if the CETA "*sui generis*" protection provisions for a maximum period of two years are properly implemented (as below), Canada will remain the only nation among the G7 and other industrialized nations not to provide any supplementary IP protection to compensate for clinical development time and the time required to obtain approval from regulatory authorities. The U.S., in comparison, offers patent restoration terms of up to five years, depending upon the length of the clinical and/or regulatory delays (as does the EU and Japan, for example). Mexico's IP legislation, on the other hand, expressly states that the patent term is non-extendable[14].

- **Canada's other trade agreements:** TPP countries are given considerable leeway in the manner in which they must adjust patent terms to compensate for "unreasonable curtailment" of the effective patent term of pharmaceutical products, including through the provision of *sui generis* protection[15]. In CETA, Canada has agreed to implement a "*sui generis* protection" period of between 2 to 5 years.[16] IMC notes with concern, however, that the Government of Canada will implement the minimum level of 2 years required by CETA, will impose additional restrictive limitations on PTR eligibility, and will create an

[11] *Agreement on Trade-Related Aspects of Intellectual Property Rights*, 1869 UNTS 299; 33 ILM 1197 (1994), at Article 39.3.
[12] *Supra*, note 2, at Article 1709(12).
[13] *Supra*, note 2, at Article 1709(6).
[14] *Ley de la Propiedad Industrial - Cámara de Diputados*, at Article 23.
[15] *Supra*, note 8, at IP Chapter, Footnote 46.
[16] "Consolidated CETA Text" at c 22, at Article 20.27(6), online: Government of Canada http://www.international.gc.ca/trade-agreements-accords-commerciaux/agr-acc/ceta-aecg/text-texte/toc-tdm.aspx?lang=eng, last accessed 18 July, 2017.

export exemption whereby activities done for the purpose of producing drugs for export will not infringe a patent during its period of PTR[17].

- **Recommendations:** IMC encourages the Canadian Government to uphold commitments made under NAFTA, at a minimum, and to enhance PTR mechanisms for delays caused by both regulatory processes and by patent office delays. Moreover, any implementation of PTR that does not confer full patent rights, e.g., that would provide an exception for "manufacturing for export" or other infringing activities, is not consistent with the fundamental purpose of restoring a portion of the patent term lost during the marketing approval or reimbursement review processes and should not be permitted.

Resolution Mechanisms for Patent Disputes

- **Rationale:** The effective enforcement of patent rights strongly relies upon mechanisms such as patent linkage and effective preliminary injunctive relief, which provide for the early resolution of patent disputes before potentially infringing follow-on products enter a market. The premature launch of a product that is later found to infringe a patent may disrupt patient treatment, require governments to adjust and re-adjust national formularies and reimbursement policies, and cause commercial damages that are impossible to repair later.

- **Requirements under NAFTA:** NAFTA contains several provisions that seek to promote the enforcement of IP rights. Generally speaking, state parties have agreed that measures to enforce IP rights shall not themselves become barriers to legitimate trade[18]. NAFTA puts further requirements on parties to ensure, *inter alia*: expeditious remedies[19]; procedures that are not unnecessarily complicated or costly and do not entail unreasonable time limits or unwarranted delays[20]; and recourse to judicial review of decisions[21]. NAFTA contains the additional commitment to ensure that damages owing to the infringer of IP rights are compensatory in nature[22].

- **Situation in Member States:** Canada, Mexico and the U.S all have some form of patent linkage system. Canada's linkage proceedings are governed by the *Patented Medicines (Notice of Compliance) Regulations* [the *PM(NOC) Regulations*], which include several key deficiencies that weaken Canada's enforcement of patents, including the nature of patent dispute proceedings and a lack of an effective right of appeal for patent owners. Recent jurisprudence under the regulations has also resulted in a heightened level of liability for patent owners akin to punitive damages.

  As per the Canadian regime, Health Canada will deny regulatory approval for a generic drug until the patent is expired, invalidated or a patent holder consents. The *PM(NOC) Regulations* provide up to a maximum of 24 months for an expedited judicial process to test infringement and/or invalidity, and during this process the generic drug may not be introduced to the market. If an innovator fails in its application to uphold its NOC, a generic may be granted an NOC shortly thereafter and the Canadian Federal Court has held that it would not hear any appeal by an innovator company. Conversely, should a generic lose its NOC proceeding, it retained its right to appeal.

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[17] *Certificate of Supplementary Protection Regulations*, Canada Gazette, Part I, vol.151, no. 28, July 15, 2017.
[18] *Supra*, note 2, at Articles 1701(1), 1714(1).
[19] *Supra*, note 2, at Article 1714(1).
[20] *Supra*, note 2, at Article 1714(2).
[21] *Supra*, note 2, at Article 1714(4).
[22] *Supra*, note 2, at Article 1715(2)(d).

In the U.S., on the other hand, the FDA maintains a list of pharmaceutical patents and approved uses in its 'Orange Book' and will not provide marketing approval for a generic copy of innovative products that would infringe a patent listed therein. There is a notable absence of problematic inequalities (i.e. innovators have a right of appeal), provisional measures are available to rights holders, and the linkage stay period is set at 30 months.

As for Mexico, applicants seeking marketing approval for generic pharmaceutical products must certify that patent rights are not infringed. Health regulatory authorities then check with the patent office, which must respond within ten days to confirm whether a patent is involved. The USTR has expressed serious concerns over the state of patent enforcement in Mexico, noting in particular that government-wide budget cuts have negatively affected IP enforcement[23]. In addition, it has been noted that in Mexico the process for seeking and enforcing a preliminary injunction is especially onerous for the patent holders as preliminary injunctions may be lifted by simply via the filing of a counter-bond, while seeking damages for a patent infringement requires both civil and administrative decisions.

- **Canada's other trade agreements:** The TPP does not appear to require any changes to Canada's current patent linkage system, as parties to that agreement agreed to create measures to prevent the market approval of a generic drug until the relevant patent expires –unless the patent is invalidated or consent is given by the patent owner[24].

  Under the terms of CETA, both the patent holder and the generic challenger are entitled to equivalent and effective rights of appeal. It remains unclear how this will be implemented within Canadian IP legislation in an *effective* manner and in accordance with the NAFTA principles outlined above. This is particularly the case given that the draft amendments to the *PM(NOC) Regulations* that have been issued under CETA create even more complex post-CETA pharmaceutical actions that will still have to be negotiated during the current 24-month stay period that exists under the current regime[25]. Given that Canadian patent linkage cases presently take more than 24 months to complete under the present "paper process", it seems very unlikely that the more complex litigation process that is contemplated as part of the implementation of CETA can be accomplished within the same timeframe, even with more efficient court processes and increased judicial resources.

- **Recommendations:** Parties to NAFTA should agree to early and effective resolution mechanisms for patent disputes while seeking to address any asymmetry in legal rights that flows from the parties' linkage regimes. That which was agreed to under CETA, to provide all litigants an equivalent and effective right of appeal, should form the basis for this position. Given the more complex patent linkage regime that is included as part of the implementation of CETA, Canada should harmonize with the U.S. stay period of up to 30 months.

[23] Office of the United States Trade Representative, *2017 Special 301 Report on Intellectual Property Rights*, at Page 62, online: https://ustr.gov/sites/default/files/301/2017%20Special%20301%20Report%20FINAL.PDF, last accessed 18 July, 2017.
[24] *Supra*, note 8, at Article 18.51.
[25] *Regulations Amending the Patented Medicines (Notice of Compliance) Regulations, 2017*, Canada Gazette, Part I, vol.151, no. 28, July 15, 2017.

3. ARE YOU AWARE OF ANY TRADE PRACTICES, LAWS OR REGULATIONS IN THE UNITED STATES, AND/OR IN MEXICO, THAT UNDERMINE OR COULD UNDERMINE MEANINGFUL MARKET ACCESS FOR CANADIAN GOODS AND SERVICES?

In association with the above-noted elements of NAFTA that are either working well and should be preserved and those that should be improved upon, we here below provide a summary of issues of concern to Canadian pharmaceutical innovators across states party to NAFTA (as indicated in red). We also make note of positive trade practices and laws as opportunities for growth. CETA and TPP negotiated outcomes are also provided as reference.

Table 2. Summary of issues of concern in NAFTA countries, as compared to CETA and TPP provisions.

	Canada	Mexico	U.S.	CETA	TPP
Regulatory data protection	• **8 years** exclusivity. • No extension for new indications. • Restrictions on scope of products. • Applies to all drugs, including biologics.	• No legislated exclusivity. • **5 years** under guidelines. • Applies to all drugs, including biologics.	**Chemical Entities:** • **5 years** exclusivity + FDA approval time (1+ years). • **3 year** extension for new indications **Biologics:** • **12 years** exclusivity.	• **8 years** exclusivity. • Applies to all drugs, including biologics.	**Chemical Entities:** • **5 years** exclusivity. • **3 year** extension for new indications. **Biologics:** • **12 years** exclusivity.
Protection of CBI	Disclosure allowable if Minister of Health "believes" information "may" protect the public.	Absence of problematic exclusions.	Absence of problematic exclusions.	n/a	Disclosure allowable only where necessary to protect public or if steps taken to protect against unfair commercial use.
Patent Term Restoration	**0 years** (maximum of 2 years under CETA).	**0 years**.	Maximum **5 years***. *Max. combined post-approval market exclusivity 14 years.	Maximum **2-5 years**.	Restoration allowable, but term not defined.
Resolution Mech-anisms	• Links marketing approval to patent status. • Max. 24 months stay period. • Right of appeal for generics only. • Interlocutory injunctions discretionary.	• Links marketing approval to patent status. • Preliminary injunctions may be lifted by counter-bond.	• Links marketing approval to patent status • Max. 30 months stay period. • Any unsuccessful party may appeal. • Interlocutory injunctions discretionary.	Commitment to ensure equivalent and effective rights of appeal.	Links marketing approval to patent status (unless by consent or acquiescence of the patent holder).

4. ARE THERE ANY NEW ISSUES THAT YOU BELIEVE SHOULD BE INCORPORATED INTO NAFTA, OR ARE THERE ISSUES THAT YOU BELIEVE SHOULD BE EXPANDED UPON TO REFLECT ADVANCEMENTS SINCE NAFTA WAS ORIGINALLY NEGOTIATED?

A number of issues have recently emerged in Canada that pose concerns with regard to Canadian innovators' ability to compete with major trading partners. We raise several concerns below – with respect to pharmaceutical pricing and reimbursement decisions, and regulatory harmonization – that should be expanded upon to reflect advancements since NAFTA was originally negotiated.

Recognizing the Value of Pharmaceutical Innovation in Pricing and Reimbursement

The patented prescription medicines regulated by the Patented Medicines Prices Review Board (PMPRB) are a vital part of the Canadian health system, helping to prevent and cure disease as well as save lives. Developing and introducing new innovative treatments into Canadian health systems is critical. There is a demonstrable link between appropriate access to innovative medications and key health outcomes. IMC is of the view that Canada needs to establish clear policy objectives to set a pharmaceutical price ceiling mechanism that protects consumers while rewarding companies for introducing innovations.

The issue of pricing is of particular concern in view of the PMPRB's initiation, in 2015, of a stakeholder consultation on its Strategic Plan for 2015-2018 that contemplates an expansion of the Board's price regulation mandate. These concerns have been magnified by the spring 2016 Health Canada consultation with respect to proposed changes to the PMPRB's regulatory framework, including changes to the nations set out within the regulations used to determine whether or not patented medicines are priced excessively in Canada relative to international comparators[26].

As IMC has stated in its response to the Health Canada consultation, the proposed changes in the regulations and to the methodology employed by the PMPRB in its evaluation of "excessive" pricing may have a serious financial impact on biopharmaceutical companies operating in in Canada[27]. Moreover, there are far more efficient and effective partnership models that could address the cost concerns of Canadian public payers while also ensuring patient access to innovative medicines.

Policies that artificially lower the prices of medicines can hamper investment in R&D and delay or reduce the availability of new medicines for patients. The TPP offers a helpful example of principle-based promotion of high-quality health care and continued improvements in public health for parties' nationals. The U.S. proposed a chapter that would require countries with national drug pricing and reimbursement programs to establish a system of best practices covering such issues as decision-making processes, use of information, and appeal of pricing decisions. As a result, the TPP as currently drafted contains value-based provisions that could serve as the basis for greater procedural fairness and improved reimbursement decision-making[28].

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[26] Patented Medicine Prices Review Board, *PMPRB Guidelines Modernization – Discussion Paper – June 2016*, available online: http://www.pmprb-cepmb.gc.ca/en/news-and-events/consultations/current-major-consultations/rethinking-the-guidelines/discussion-paper, last accessed July 18, 2017.

[27] Innovative Medicines Canada, *Submission to the Patented Medicine Prices Review Board - June 2017*, online: http://innovativemedicines.ca/wp-content/uploads/2015/05/20170628_PMPRB_Submission_Final_EN_final.pdft, last accessed July 18, 2017.

[28] *Supra*, note 9, at Annex 26-A, Articles 2 and 3. However, Canada's national healthcare program explicitly falls outside the scope of this annex.

In order to address these concerns, government pricing policies should appropriately recognize the value of innovative pharmaceuticals, for example, by making determinations through competitive market-based mechanisms. As such, the NAFTA renegotiations provide an opportunity for NAFTA parties to agree to ensure that government regulatory reimbursement regimes provide greater procedural fairness and are non-discriminatory. The renegotiation of NAFTA likewise provides an opportunity for parties to sign onto a health agenda committed to patient access, quality and support for innovation, grounded in procedural fairness by public sector health regulators and agencies. Commitments to procedural fairness and improved reimbursement decision-making should apply to all public sector agencies and entities in the NAFTA nations, including at the sub-national level.

Regulatory Harmonization

A strong regulatory framework not only ensures that patients have better access to safe, high-quality, and effective medicines, but also encourages scientific research and innovative drug development. Technical regulations, standards, and conformity assessment procedures, including marketing authorization and notification procedures, should seek to adopt harmonized regulatory best practices and international, science-based regulatory standards. In addition, there is a need to harmonize timelines for approval and market access so that Canadian patients will have access to therapies available in the U.S. at a reasonable time.

Canada and the U.S. have recognized that closer regulatory cooperation and aligning regulatory systems can enhance economic competitiveness and maintain high levels of protection for health and safety. The two countries are already working together, formally, under the Regulatory Cooperation Council.

Anticipating that a revised NAFTA will include discussions about Trade in Services, we note Canada's strong capabilities, and our industry's strong demand for clinical trials. Provisions in NAFTA that would beneficially harmonize standards for Canadian clinical researchers would benefit our industry, Canadian scientists and researchers, and the Canadian Health system and patients. In particular, clinical trial approval and oversight, pre-market approval, post-market assessment, and compliance are all areas that would benefit from additional regulatory cooperation with the U.S.