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USTR-2025-0004

Mr. Daniel Watson
Assistant USTR for the Western Hemisphere
Office of the U.S. Trade Representative
600 17th Street, N.W.
Washington, DC 20508

**Re: Request for Comments on the Operation of the Agreement between the United States of America, the United Mexican States, and Canada, 90 Fed. Reg. 44869 (September 17, 2025)**

Dear Mr. Watson:

The Pharmaceutical Research and Manufacturers of America (PhRMA) appreciates this opportunity to provide the following submission in response to the request for comments regarding the operation of the U.S.-Mexico-Canada Agreement (USMCA or Agreement) ahead of the Joint Review of the Agreement on July 1, 2026. Despite making multiple commitments in USMCA to provide an innovation ecosystem that is akin to that afforded to companies operating in the United States, both Canada and Mexico have failed to faithfully implement those commitments within the generous transition periods provided, denying American manufacturers and their workers of reciprocal access to those markets. As such, it is critical for USTR to engage with its Canadian and Mexican counterparts to ensure full implementation of these commitments *ahead of* the Joint Review to be held next year, and then to leverage the Joint Review to achieve additional commitments as outlined below.

PhRMA member companies are devoted to inventing, manufacturing and distributing valuable therapeutics and vaccines that enable people to live longer, healthier and more productive lives. The U.S. biopharmaceutical industry is the world leader in medical research – producing more than half the world's new molecules in the last decade. Pioneering work by biopharmaceutical innovators in the United States contributes significantly to economic growth and supports high-paying, high-standard and diverse jobs in all 50 states. The U.S. biopharmaceutical industry supports over 4.9 million jobs across the economy, including more than one million direct jobs, and contributes more than $1.65 trillion in economic output on an annual basis.[1] Our sector also continues to be one of the most research-intensive, manufacturing-intensive and export-intensive in America, annually investing an estimated $122.2 billion in researching and developing new

[1] TEConomy Partners, "The Economic Impact of the U.S. Biopharmaceutical Industry: 2022 National and State Estimates," May 2024, available at https://phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Refresh/Report-PDFs/D-F/The-Econ-Impact-of-US-Biopharma-Industry-2024-Report.pdf.

medicines.[2] In 2023, U.S. biopharmaceutical goods exports exceeded $101 billion,[3] making the sector the largest exporter of goods among the most R&D-intensive industries.[4]

Innovators and investors in this critical sector depend on strong intellectual property (IP) protection and enforcement, health care systems that reward the value of innovation and fair and transparent access to global markets. With the right policies in place at home and abroad, our member companies can continue to bring valuable new therapeutics and vaccines to patients around the world.

Facilitating North American trade, innovation and investment in the biopharmaceutical sector are key objectives of the USMCA. To further these objectives, the Parties committed to strengthen and enforce IP rights, ensure timely marketing authorizations for pharmaceutical products and revise their government pricing, reimbursement and procurement processes so that they operate in a fair and transparent manner. The upcoming Joint Review is an important opportunity to: (i) secure full implementation of these commitments; (ii) further strengthen the USMCA's IP provisions so that the Agreement reaches its full potential to promote North American innovation, supply chains and reciprocal trade in the pharmaceutical sector; and (iii) advance President Trump's goal to ensure that other high-income countries pay their fair share of the cost of biopharmaceutical research and development. The innovative biopharmaceutical industry urges the U.S. government to prioritize the following objectives for the Joint Review:

- **Ensure Canada and Mexico fulfill outstanding USMCA obligations**: The United States should insist that Canada and Mexico fully implement their USMCA obligations related to the biopharmaceutical sector prior to the Joint Review. As detailed below, Mexico must take additional actions to comply with IP reforms due in 2020 (e.g., effective patent enforcement) and 2025 (e.g., patent term extension (PTE) and regulatory data protection (RDP)), and to implement timely, transparent and fair regulatory and procurement procedures. Canada must also take action to bring its patent term adjustment (PTA) and PTE measures into compliance with the USMCA, and to ensure that its pricing and reimbursement policies are fair, transparent and appropriately value innovative medicines as required by the Agreement. USTR has raised several of these issues in its annual National Trade Estimate and Special 301 reports.[5]

- **Strengthen IP protections to promote North American innovation, supply chains and reciprocal trade**: The United States should leverage the Joint Review to strengthen the USMCA's IP provisions consistent with President Trump's original vision for the Agreement. The original USMCA text signed in 2018 would have required Canada and Mexico to provide ten years of RDP for biologic medicines – a significant improvement that

[2] Research!America, "U.S. Investments in Medical and Health Research and Development, 2016-2020," January 2022, available at https://www.researchamerica.org/wp-content/uploads/2022/09/ResearchAmerica-Investment-Report.Final_.January-2022-1.pdf.

[3] U.S. Bureau of Economic Analysis, International Accounts Products for Detailed Goods Trade Data, available at https://www.bea.gov/international/detailed-trade-data.

[4] ndp analytics analysis of National Science Foundation and Business Research and Development Survey data, 2024.

[5] *See*, *e.g.*, USTR 2025 National Trade Estimate Report at pp. 262-63 and 265; USTR 2025 Special 301 Report at pp. 6, 59 and 72.

would bring them closer to the U.S. standard of 12 years, incentivizing American innovation and addressing the failure of these countries to afford reciprocal IP protections to U.S. innovators. Regrettably, this provision and other pro-innovation provisions designed to ensure reciprocal protection of U.S. IP in Canada and Mexico were removed during congressional debate over the USMCA in 2019, despite the fact that the United States already satisfied these commitments in its domestic laws. Realizing that Canada and Mexico previously agreed to these commitments, the United States should ensure that these critical IP provisions are restored as an outcome of the Joint Review. Doing so would incentivize stronger North American supply chains and fulfill President Trump's original objective for the USMCA to "reflect a standard of [IP] protection similar to that found in U.S. law."[6]

- **Ensure foreign nations pay their fair share for American innovation:** The United States should leverage the Joint Review to fulfill the objective set forth in Section 3 of President Trump's May 12, 2025, Executive Order, which directed USTR and DOC to address foreign acts, policies or practices that have "the effect of forcing American patients to pay for a disproportionate amount of global pharmaceutical research and development, including by suppressing the price of pharmaceutical products below fair market value in foreign countries."[7] Despite being one of the world's most developed economies, Canada employs a range of measures that artificially devalue medical innovations developed in the United States and limit and delay patient access to American-made innovative medicines. As a result, Canada spends only 0.32 percent of its GDP per capita on new innovative medicines, compared to 0.78 percent in the United States.[8] USTR should require Canada to adopt binding and enforceable trade commitments to achieve an appropriate level of spending on new innovative medicines.

The innovative biopharmaceutical industry firmly supports the USMCA and encourages a successful Joint Review that preserves and strengthens the benefits of the Agreement. Securing full and prompt implementation of existing commitments and reinstating high-standard IP provisions, as detailed below, are important steps to ensure that the Agreement promotes reciprocal treatment of U.S. firms and IP and incentivizes biopharmaceutical innovation.

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[6] Summary of Objectives for the NAFTA Renegotiation, Office of the U.S. Trade Representative, July 17, 2017, available at https://ustr.gov/sites/default/files/files/Press/Releases/NAFTAObjectives.pdf.

[7] Trump, Donald J., *Delivering Most-Favored-Nation Prescription Drug Pricing to American Patients*, 90 Fed. Reg. 20749 (May 15, 2025), Executive Order 14297, available at https://www.federalregister.gov/documents/2025/05/15/2025-08876/delivering-most-favored-nation-prescription-drug-pricing-to-american-patients.

[8] Pharmaceutical Research and Manufacturers of America, *Comment on Request for Comments Regarding Foreign Nations Freeloading on American-Financed Innovation*, Office of the U.S. Trade Representative, 90 Fed. Reg. 23105 (May 30, 2025), available at https://comments.ustr.gov/s/commentdetails?rid=VB9V88JYC6.

## I. Key USMCA Commitments Requiring Full Implementation by Mexico

### A. Intellectual Property Commitments

Implement Effective Patent Enforcement Mechanisms

USMCA requires Mexico to implement effective patent enforcement mechanisms to ensure that patent-infringing follow-on products (i.e., generics or biosimilars) are not approved for marketing prior to the expiration of patents on the relevant innovative product. Annex 20-A of USMCA preserves Mexico's ability to maintain its existing framework based on coordination between the patent office (IMPI) and the marketing approval authority (COFEPRIS) to prevent the authorization of patent-infringing pharmaceutical products. Nonetheless, Mexico has not implemented a patent enforcement mechanism that satisfies its USMCA commitments. Mexico's patent enforcement system fails to: consider all relevant patents related to an innovator product, provide adequate notice to a patent holder when a third party seeks marketing approval for a follow-on product, and afford the patent holder a reasonable opportunity to present facts and arguments to IMPI related to the relevant patents before the follow-on product is authorized for marketing. Further, obtaining effective preliminary injunctions or final decisions on cases regarding IP infringement within a reasonable time (as well as collecting adequate damages when appropriate) remains the exception rather than the norm. Even when preliminary injunctions are granted, they have in some cases been lifted or stayed before full adjudication, raising concerns about their practical efficacy.

Earlier this year COFEPRIS announced a collaboration scheme with IMPI that requires applications for follow-on products to be published on its website and that patent holders would be able to submit information to determine possible infringement. However, this action does not satisfy USMCA because it does not enable a patent holder to present facts and arguments to IMPI related to all relevant patents before the follow-on product is authorized due to the limited information available on generic and biosimilar applications. Moreover, it does not explicitly require inclusion in the Gazette of all relevant patents related to an innovative product, including use patents (a situation exasperated by a January 2025 court decision finding that use patents should not be published in the Gazette).

To operationalize a patent enforcement mechanism that is effective and consistent with USMCA, Mexico must issue secondary regulations that:

(i) confirm that all relevant patents, including use patents, are subject to such mechanism;[9]
(ii) require IMPI to inform (i.e., provide proper notice to) a patent holder when IMPI has received a request from COFEPRIS and to provide the patent holder with IMPI's preliminary determination;

[9] A Bill was recently introduced in Mexico that seeks to revise language in Article 162 of the Mexican Federal Law for the Protection of Industrial Property in an attempt to facilitate the listing of use patents in Mexico's Linkage Gazette. In addition, COFEPRIS has released a special edition of the IMPI Medicines Gazette which includes use patents. While these are welcome steps, secondary regulations are necessary to formalize the procedure for listing use patents and to provide a durable legal framework supporting their listing.

(iii) if IMPI has made a preliminary determination that there is no infringement, provide the patent holder with an opportunity to demonstrate to IMPI that the follow-on product would infringe an existing patent before IMPI responds to COFEPRIS;
(iv) provide the patent holder with the relevant, necessary and sufficient information to determine whether patent infringement exists, including confidential access to the marketing authorization dossier solely for that purpose; and
(v) ensure that a preliminary injunction cannot be lifted absent compelling evidence of changed circumstances, lack of irreparable harm or invalidity of the underlying claim.

Provide Comprehensive Regulatory Data Protection (RDP) for Biopharmaceuticals

To comply with USMCA, Mexico must issue federal legislation and secondary regulations to provide RDP that covers all pharmaceutical products, including small molecules and biologics. Article 20.48 of the Agreement requires Mexico to protect, for at least five years, the comprehensive test data that pharmaceutical innovators submit to regulatory authorities to demonstrate the safety and efficacy of a medicine as part of the marketing authorization process. After the RDP term has ended, third parties are allowed to references and/or rely on the data submitted by innovative companies to obtain marketing authorizations for follow-on products. Currently, RDP is subject solely to internal guidelines at COFEPRIS, is not automatically granted and routinely requires litigation against COFEPRIS in order to secure protection and/or an appropriate term, adding unnecessary uncertainty, complexity and costs for U.S. innovators. Moreover, the internal guidelines apply only to new chemical entities, thereby excluding key biopharmaceutical innovations such as biologics, new therapeutic uses, new dosage forms, new routes of administration and new formulations.

Implement Adequate PTA Mechanism and Provide PTE

Article 20.44 of USMCA requires Mexico to provide PTA to compensate for unreasonable patent office delays. Although Mexico has adopted legislation to provide for PTA, it has yet to issue secondary regulations to provide a mechanism for securing that protection without relying on judicial intervention.

Similarly, Article 20.46 requires Mexico to implement PTE to restore a portion of the patent term lost during the lengthy development and regulatory approval process for new medicines. Despite committing to implement PTE by the end of 2024, Mexico has yet to approve federal legislation and secondary regulations to comply with this commitment. While a bill has recently been introduced that would establish a PTE mechanism in Mexico, the draft text is highly general with several substantive and procedural details requiring further clarification, making it difficult to assess whether the proposed mechanism would meet Mexico's USMCA commitments.

Clarify Bolar Exemption

Article 20.47 of USMCA requires Mexico to ensure that its Bolar Exemption to patent rights is "solely for purposes related to generating information to meet requirements for marketing approval for the product." To comply with this commitment, Mexico should issue secondary

regulations that ensure the exemption is limited to this sole purpose of securing marketing approval of a follow-on product so that it can be launched in Mexico after all relevant patents on the innovative product have expired.

## B. Regulatory and Government Procurement Commitments

Address Market Access Delays

Article 12.F.6.4 of the Agreement requires Mexico to administer marketing authorizations "reasonably, including by … providing an applicant that requests marketing authorization for a pharmaceutical product with a determination within a reasonable period of time." Article 29.7 also requires Mexico to ensure that its pricing and reimbursement procedures for pharmaceuticals are fair and transparent, and Article 29.6 affirms the need for Mexico to appropriately value pharmaceuticals through relevant procedures or the operation of competitive markets.

Despite these commitments, biopharmaceutical innovators continue to face significant regulatory approval delays at COFEPRIS that inhibit timely patient access to innovative medicines. Once COFEPRIS has approved a medicine, the National Health Council (NHC) evaluates and recommends which medicines should be included in the National Compendium, the formulary defining which medicines may be procured and reimbursed. This process further delays patient access to innovative medicines. Only 23 percent of new medicines launched globally since 2014 have launched in Mexico, with patients waiting an average of 30 months from global first launch of those new medicines to become available.[10] During the past five years, the share of new medicines launched globally over the prior five years that are available in Mexico declined from 20 to 11 percent – a worse decline than in any other OECD or Latin American country.[11] It is critical that COFEPRIS and the NHC address these delays and provide transparent and fair pricing, reimbursement and procurement processes to reverse this troubling trend and improve patient access to innovative medicines.

Finally, on September 26, 2025, amendments were proposed to Mexico's General Health Law as published in the *Gaceta Parlamentaria* seeking to grant preferential and expedited market authorization for pharmaceutical products manufactured locally, thereby discriminating against U.S. manufacturers. Prioritizing such applications threatens to exacerbate the lengthy delays currently experienced by U.S. biopharmaceutical manufacturers navigating the Mexican marketing approval process.

Implement Timely, Fair and Transparent Procurement Processes

Mexico committed in Chapter 13 of USMCA to open, fair and transparent government procurement procedures. Since 2018, Mexico has made frequent and nontransparent changes to its public procurement system, resulting in supply chain challenges and product shortages for

[10] PhRMA analysis of regulatory, launch and reimbursement data for new medicines launched globally between January 1, 2014, and December 31, 2023.

[11] PhRMA, "Global Access to New Medicines Report," 2023, available at https://phrma.org/en/resource-center/Topics/Access-to-Medicines/Global-Access-to-New-Medicines-Report.

Mexican patients. These modifications could also lead to increased use of procurements with limited tenders, in violation of Mexico's commitment to open tendering procedures in Article 13.4.4. These procurement challenges in Mexico are compounded by the lack of effective patent enforcement mechanisms, as described above.

On June 2, 2025, the Mexican Government introduced a Presidential Decree "to promote investment within the national territory to strengthen the development of the pharmaceutical industry, health supplies manufacturing, and national scientific research" by granting advantages in the public procurement process for manufacturers having investments in Mexico, including manufacturing plants, laboratories and warehouses. Such requirements are inconsistent with Mexico's obligations under Article 13.4 of the USMCA, which explicitly prohibits discrimination against U.S.-supplied goods and the use of "offsets" – including local content requirements, investment or technology transfer – as a condition for public procurement. It is critical that Mexico honor its commitment to open tendering and procurement under USMCA.

## II. Key USMCA Commitments Requiring Full Implementation by Canada

### A. Intellectual Property Commitments

Implement a Compliant PTA System

Canada committed in Article 20.44 of USMCA to implement a PTA system to compensate patentees for "unreasonable" delays in the patent examination process by January 1, 2025. While Canada has implemented a PTA mechanism, it is riddled with deficiencies, including that the PTA term runs concurrently with Canada's equivalent of PTE (discussed further below) rather than as an independent adjustment. This approach results in the term of one vitiating the other term, such that biopharmaceutical patentees are not receiving the full benefit to which they are entitled under USMCA. As a result, Canada is failing to fulfill two independent trade obligations (Articles 20.44 and 20.46), which each serve important purposes and compensate for distinct delays.

In addition, Canada's PTA system imposes significant and inequitable barriers that prevent innovators from receiving the intended relief for patent office delays. Specifically, Canada's PTA system includes a number of elements that undermine an effective PTA system, including the manner in which Canada proposes to calculate the PTA term, the discretion afforded to the Commissioner of Patents to subtract unspecified days from a PTA calculation and inadequate processes for applicants to seek redetermination of the PTA term. Consistent with the intent of Article 20.44 of USMCA and the PTA mechanism available in the United States, Canada must revise its PTA system to address these deficiencies.

Implement a Compliant PTE Mechanism

PTE seeks to compensate for a portion of the crucial effective patent life lost due to clinical trials and the regulatory approval process. Most of Canada's major trading partners, including the United States, the European Union and Japan, offer forms of PTE which generally allow patent holders to recoup a valuable portion of a patent term where time spent in clinical development

and the regulatory approval process has kept the patentee off the market. In these countries, up to five years of lost time can be recouped.

By way of implementing the Comprehensive Economic and Trade Agreement (CETA), Canada promulgated the Certificate of Supplemental Protection (CSP) Regulations,[12] which provide a "*sui generis* protection" of no more than two years to restore a portion of the patent life lost during the lengthy development and regulatory approval process for pharmaceuticals in Canada. As noted above, this is significantly shorter than the maximum term of five years that may be restored in the United States. Consistent with the Administration's intent to ensure that its trading partners are providing reciprocal access and protections, the Joint Review of the Agreement offers a critical opportunity to remedy this deficiency in Canada's CSP system, including eliminating the language in footnote 40 to Chapter 20 of the USMCA that permits Canada to provide no more than two years of *sui generis* protection (see *infra* Section III). Canada should provide five years of PTE that runs consecutively with patent term adjustment instead of concurrently.

Moreover, the *sui generis* protection provided by the CSP does not grant the full patent protections that PTE is intended to provide and instead appears to be implemented subject to an exception for "manufacture for export." This exception is not consistent with Article 20.46 of the USMCA or with PTE in most other jurisdictions. Implementing PTE so that it does not confer the same level of protection as the underlying patent, e.g., providing an exception for "manufacturing for export" or other infringing activities, is not consistent with the fundamental purpose of restoring patent term lost due to the lengthy marketing approval process. Moreover, restricting the availability of CSPs to new drugs submissions filed within one year of seeking approval in Australia, the European Union, Japan, Switzerland, United Kingdom or United States is unprecedented among PTE regimes and further diminishes Canada's commitment to provide reciprocal protections to its trading partners.

## B. Regulatory Commitments

Address Market Access Delays

Article 12.F.6 requires Canada to provide "an applicant that requests marketing authorization for a pharmaceutical product with a determination within a reasonable period of time." Obtaining market authorization is only the first hurdle in launching a pharmaceutical product in the Canadian market. Once the regulator determines that a product is safe and effective, it is subsequently reviewed by a health technology assessment (HTA) body (of which there are two in Canada, INESSS (Quebec), and CDA (rest of Canada)), which informs the reimbursement negotiations led by the pan-Canadian Pharmaceutical Alliance (pCPA). Following pCPA negotiations, interested public payers enter into a common agreement known as a Letter of Intent (LOI) with manufacturers detailing the preliminary terms and conditions for public reimbursement. Following the LOI, manufacturers must then negotiate with each individual jurisdiction to finalize product listing agreements to ultimately list a drug on a public formulary. These processes have become increasingly time-consuming and complex in nature, and on

[12] Available at https://gazette.gc.ca/rp-pr/p2/2017/2017-09-07-x1/html/sor-dors165-eng.html.

average they take 25 months to complete, which is double the amount of time it takes in most other OECD countries.[13] During that time period, patients are unable to access these medicines and patentees are unable to fully benefit from market exclusivity, and the rights and benefits associated with their patents are eroded as a result. Canada should reduce the burdensome and unnecessary regulatory steps between national assessments and inclusion on public formularies of provinces and territories, in line with their obligations under Article 12.F.6.

Ensure Innovative Medicines are Appropriately Valued

Articles 29.6 and 29.7 further require Canada to appropriately value pharmaceuticals through relevant procedures or the operation of competitive markets and ensure that its pricing and reimbursement procedures for pharmaceuticals are fair and transparent. However, under Canada's Patented Medicine Prices Review Board (PMPRB), which regulates the maximum allowable price that a manufacturer can charge for all patented medicines in Canada, these commitments are not satisfied. Canada amended the PMPRB's basket of reference countries with the goal of lowering the ceiling prices of patented medicines in Canada at the OECD median price. Through this amendment, the PMPRB removed the United States and Switzerland – two countries that take a more holistic view of the value of medicines – and added six jurisdictions with lower drug prices and more onerous price controls to the reference basket of countries. International reference pricing is a deeply flawed methodology that undermines continued R&D in medicines that patients need most. It is particularly egregious for Canada not to reference the United States and other countries with pro-innovation pharmaceutical policies. The United States is Canada's largest trading partner and the pharmaceutical markets in both countries share many common features, including important supply chains for the biopharmaceutical industry.

In addition, when assessing new medicines, Canada's Drug Agency uses low and outdated monetary thresholds per life year gained for clinically proven treatments to make coverage recommendations that are contingent on price cuts of 70-90 percent for some new cancer and rare disease products.[14] Public insurance plans run by each province require further price cuts and, as noted above, impose bureaucratic requirements that considerably delay patient access.[15] As a result, only 20 percent of new medicines launched globally since 2014 are reimbursed by Canada's public plans, compared to 87 percent in the United States.[16] As discussed in Section IV below, the United States should use all available trade tools, including the Joint Review of the USMCA, to ensure that developed economies like Canada increase their spending on innovative

[13] *See* The Conference Board of Canada, Access and Time to Patient: Prescription Drugs in Canada (Jan. 4, 2024), available at https://www.conferenceboard.ca/product/access-and-time-to-patient-jan2024.

[14] Balijepalli, Chakrapani et al., "The Impact of Willingness-to-Pay Threshold on Price Reduction Recommendations for Oncology Drugs: A Review of Assessments Conducted by the Canadian Agency for Drugs and Technologies in Health," *Journal of Comparative Effectiveness Research* 13(5), 2024, available at https://becarispublishing.com/doi/10.57264/cer-2023-0178.

[15] Rawson, Nigel, "Health Technology Assessment and Price Negotiation Alignment for Rare Disorder Drugs in Canada: Who Benefits?," *Orphanet Journal of Rare Diseases* 17(218), 2022, available at https://ojrd.biomedcentral.com/articles/10.1186/s13023-022-02390-x.

[16] PhRMA analysis of regulatory, launch and reimbursement data for new medicines launched globally between January 1, 2014, and December 31, 2023. In Canada, public reimbursement for medicines is determined at the province level. For this analysis, a medicine is counted as publicly reimbursed if at least half of the national population lives in a province that reimburses the medicine.

medicines, reevaluate their use of outdated thresholds to appropriately value innovative medicines and thereby contribute their fair share to the research and development of new treatments and cures.

## III. Strengthen IP Protections to Promote North American Innovation, Supply Chains and Reciprocal Trade

When the Trump Administration negotiated the USMCA, it set an objective to secure IP commitments that "reflect a standard of protection similar to that found in U.S. law."[17] The resulting agreement signed on November 30, 2018 contained the highest-standard IP protections ever achieved in a U.S. trade agreement. Importantly, Canada and Mexico agreed to provide at least ten years of RDP for biologic medicines, bringing them closer to the 12-year period provided by the United States.[18] This was a major achievement that would have created important incentives and protections for U.S. innovation of biologic medicines, which due to their complexity may not be adequately protected by patents alone. Indeed, President Trump correctly observed that this provision would "make North America a haven for medical innovation and development[.]"[19] In addition, the 2018 agreement included strong provisions addressing RDP for new clinical information and patents for new uses, methods and processes, in order to ensure robust and reciprocal protection of U.S. IP in Canada and Mexico.

Regrettably, after the 2018 agreement was signed, certain Members of the minority in Congress demanded the removal of many pro-innovation provisions from the IP chapter, even though these provisions did not require changes to U.S. law and in fact did not fully reflect the United States' own high standards. The subsequent Protocol of Amendment to the USMCA signed on December 10, 2019, eliminated the obligation for Parties to provide at least ten years of RDP for new biologics.[20] As a result, the USMCA currently requires Canada and Mexico to provide only five years of RDP for new biologics, falling far short of the objective to establish reciprocal levels of IP protection by U.S. trading partners. The Protocol similarly removed or weakened other important IP provisions concerning RDP for new clinical information and patents for new uses, methods and processes.[21]

The upcoming Joint Review is a critical opportunity to ensure that the USMCA promotes robust and reciprocal protection of U.S. IP throughout North America, consistent with President Trump's original objective for the Agreement. To achieve this, the United States should insist that all IP protections removed or weakened by the 2019 Protocol of Amendment are restored to the original form agreed by Canada and Mexico in the 2018 agreement, including Articles 20.48

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[17] Summary of Objectives for the NAFTA Renegotiation, Office of the U.S. Trade Representative, July 17, 2017, available at https://ustr.gov/sites/default/files/files/Press/Releases/NAFTAObjectives.pdf.

[18] Article 20.49 (Biologics), November 30, 2018 signed version.

[19] Remarks by President Trump on the United States-Mexico-Canada Agreement, October 1, 2018, available at https://trumpwhitehouse.archives.gov/briefings-statements/remarks-president-trump-united-states-mexico-canada-agreement/.

[20] Protocol of Amendment to the USMCA at Article 3.E, available at https://ustr.gov/sites/default/files/files/agreements/FTA/USMCA/Protocol-of-Amendments-to-the-United-States-Mexico-Canada-Agreement.pdf.

[21] *Id.*, Articles 3.D(iii) and 3.A.

and 20.49 (related to RDP) and Article 20.36 (Patentable Subject Matter). In addition, the United States should assess all of the USMCA IP commitments to ensure that they require a level of protection that is reciprocal to that provided in the United States. To this end, Article 20.46 (related to PTE) should be revised to require Canada and Mexico to restore up to five years of patent life lost during due to clinical trials and the regulatory approval process, as is the practice in the United States.[22] These revisions to USMCA would not require changes to U.S law and are necessary to ensure that Canada and Mexico, whose industries enjoy robust protection of their IP in the U.S. market, provide reciprocal protection of U.S. IP in their own markets. Raising the level of IP protection required by the USMCA is necessary for the Agreement to reach its full potential to promote American innovation, job creation and exports and incentivize further development of pharmaceutical supply chains within the region, consistent with the Administration's objective to locate key supply chains "as close to the U.S. as possible, in North America preferably."[23]

## IV. Ensure Canada Pays its Fair Share for American Innovation

Ensuring that Canada reforms pricing and reimbursement policies that deny fair market value and access to innovative medicines is of particular importance given President Trump's May 12, 2025, Executive Order directing USTR to address foreign government policies that have "the effect of forcing American patients to pay for a disproportionate amount of global pharmaceutical research and development, including by suppressing the price of pharmaceutical products below fair market value in foreign countries."[24] As described above, these measures are trade barriers that allow Canada to benefit from U.S. biopharmaceutical development without paying its fair share for these innovations. USTR should require Canada to adopt binding and enforceable trade commitments to achieve an appropriate level of spending on new innovative medicines, including through the implementation of specific reforms to the policies described above. USTR also should establish mechanisms for bilateral consultation with Canada to ensure implementation and sustained compliance with these obligations.

* * *

[22] By definition, this would include removing subpart (iv) of Footnote 40 to Chapter 20 of USMCA, as added per Article 3.B of the Protocol of Amendment to the USMCA, that explicitly permits Parties to limit *sui generis* protection to two years.

[23] Public Remarks by Ambassador Jamieson Greer at the Economic Club of New York, September 30, 2025, available at https://www.youtube.com/watch?v=WaPY0g41RTE.

[24] Trump, Donald J., *Delivering Most-Favored-Nation Prescription Drug Pricing to American Patients*, 90 Fed. Reg. 20749 (May 15, 2025), Executive Order 14297, available at https://www.federalregister.gov/documents/2025/05/15/2025-08876/delivering-most-favored-nation-prescription-drug-pricing-to-american-patients.

PhRMA appreciates this opportunity to highlight the deficiencies in Mexico's and Canada's implementation of their USMCA commitments and supports the Administration's ongoing efforts to ensure that U.S. companies and workers are treated fairly and that U.S. innovation and IP is not devalued overseas. We look forward to working with the three governments to ensure that these issues are resolved ahead of and during next year's Joint Review of the Agreement.

Sincerely,

/s/ Douglas Petersen

Douglas Petersen
Deputy Vice President, International