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Comments of Doctors Without Borders on the Joint Review of the Canada-United States-Mexico Agreement (CUSMA)

1. Background

Médecins Sans Frontières/Doctors Without Borders (MSF) is an independent international medical humanitarian organization that provides medical care in over 70 countries. We operate on the principles of neutrality, impartiality, and independence, delivering assistance solely based on need, regardless of race, religion, gender, or political affiliation.

As a frontline medical treatment provider with more than 50 years of experience caring for vulnerable people around the world, MSF is well-positioned to speak about and has firsthand experience with the impact of international trade agreements, particularly intellectual property (IP) rules on access to health technologies. Across our operations, we routinely encounter barriers to accessing affordable, quality-assured medicines, vaccines, and diagnostics. These challenges are often linked to the consequences of monopoly protections, including intellectual property and regulatory exclusivities, which delay or block generic market entry. For example, patent and data exclusivity barriers have prevented access to affordable generic versions of lenacapavir for HIV,[1] delayed access to affordable generic versions of bedaquiline for drug-resistant tuberculosis,[2] constrained the scale-up of affordable diabetes medicines such as insulin analogues and pen devices,[3] and maintained high prices for rapid molecular tests like GeneXpert,[4] limiting their availability in low-resource settings, including MSF operations.

MSF's submission of comments in response to this Joint Review of the Canada-United States-Mexico Agreement (CUSMA) reflects our continued concern over the impact of market exclusivity on access to medicines, particularly standards higher than those required by the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) which further negatively impacts access to medicines, the

[1] Mèdecins Sans Frontières (MSF) Access Campaign. *Gilead's Voluntary License on Lenacapavir: Key Limitations of the License and Recommendations to Improve Access.* July 3, 2025. Available at: https://msfaccess.org/gileads-voluntary-license-lenacapavir-key-limitations-license-and-recommendations-improve-access.

[2] Médecins Sans Frontières (MSF) Access Campaign. *MSF Demands J&J Give up Its Patent Monopoly on TB Drug to Put Lives over Profits.* April 26, 2023. Available at: https://msfaccess.org/msf-demands-jj-give-its-patent-monopoly-tb-drug-put-lives-over-profits.

[3] Médecins Sans Frontières (MSF) Access Campaign. *Open Letter to Eli Lilly on Barriers to Accessing Diabetes Medicines.* September 23, 2024. Available at: https://msfaccess.org/open-letter-eli-lilly-barriers-accessing-diabetes-medicines.

[4] Médecins Sans Frontières (MSF) Access Campaign. *Time for $5.* March 21, 2024. Available at: https://msfaccess.org/time-for-5.

right to health, and biomedical innovation[5].

For the past 25 years, MSF has consistently raised objections to the implementation of TRIPS-plus provisions, including but not limited to extended patent terms, patent linkage, data exclusivity, expanded patentability criteria, restrictions on public participation in pre- and post-grant patent oppositions, and weakened powers to issue compulsory licenses. In the context of access to health technologies, TRIPS-plus provisions have a detrimental effect by providing more extended and exclusive protection over originator products, keeping life-saving products out of reach for many. As a treatment provider, MSF relies on the availability of affordable health technologies to provide care for its patients. TRIPS-plus barriers directly affect our ability to deliver treatment. Even when we procure products from countries where such barriers do not exist, we are still unable to bring them into countries where extended intellectual property protections exist.

Such provisions also interfere with countries' ability to improve the health and well-being of their populations by blocking or delaying the entry of generics, resulting in higher treatment costs. Higher treatment costs are devastating to low-income individuals, and they undermine the sustainability of public health programs – particularly in developing countries, where public finance for healthcare is limited. Because MSF often relies on medicines, vaccines, and diagnostics procured through national government supply chains, barriers to availability and affordability directly affect our ability to deliver care and respond effectively to medical needs in our operations.

2. Intellectual property provisions in CUSMA

We focus our submission on the following issues in CUSMA that relate to intellectual property and pharmaceuticals: patent term extension for patent application examination and regulatory approval, pharmaceutical data protection, patent linkage, and enforcement provisions. Our comments are confined to these topics, which align with MSF's expertise in pharmaceutical law and policy and our institutional mandate as a humanitarian healthcare provider.

2.1. Patent Term Extensions

CUSMA requires each Party to process patent applications in an efficient and timely manner and to "adjust the term of the patent" in case of "unreasonable delays" (Article 20.44). It also requires "patent term adjustment" due to "unreasonable or unnecessary delays" in the marketing approval process (Article 20.46). The time required to process a patent application or to obtain regulatory approval is viewed as important because of perceived losses to the effective patent term. The WTO TRIPS

[5] Médecins Sans Frontières (MSF). *Lives on the Edge: Time to Align Medical Research and Development with People's Health Needs.* April 28, 2016. Available at: https://msfaccess.org/lives-edge-time-align-medical-research-anddevelopment-peoples-health-needs.

Agreement states that “the term of protection available shall not end before the expiration of a period of twenty years counted from the filing date” (Article 33). There is no obligation under TRIPS or any other multilateral agreement to extend patent terms beyond this 20-year period. Proposals to introduce such extensions were explicitly discussed and rejected during the TRIPS negotiations, reflecting the deliberate choice of WTO Members to set a fixed and predictable term of protection.[6]

A key responsibility of a patent office is to determine whether a patent application should be granted or rejected, in accordance with national laws and patentability criteria that comply with international rules. The relevant international legal frameworks – the Paris Convention for the Protection of Industrial Property and the WTO TRIPS Agreement – grant Member States considerable flexibility in determining how their patent office conducts examinations.

Unlike countries that apply only a formality review, the United States, Canada, and Mexico conduct substantive search and examination of all patent applications to verify compliance with patentability criteria before granting protection. The key challenge today is not the duration of examination, but the growing volume of low-quality and evergreening applications that overwhelm patent offices and seek to unjustifiably extend monopolies beyond the 20-year term mandated by TRIPS. Rigorous examination is therefore essential to prevent unmerited secondary patents from being granted. If such patents are approved and later become eligible for patent term extensions, they perpetuate a cycle of monopoly renewals that further delay generic entry and restrict access to affordable medicines.

Regulatory agencies have the obligation to ensure that medicines are safe, effective, and of quality before they reach the market — this review process protects patients and serves the public interest. Drug regulation and patent examination are distinct and independent functions, and delays in one should have no bearing on the other. Moreover, nothing prevents pharmaceutical corporations from filing for regulatory approval while their patent applications are still under examination, which already allows them to avoid unnecessary delays. The time required for regulatory review is therefore part of a legitimate and essential public-health function — not a burden to be “compensated” through longer monopolies.

"Adjustments" to the patent term lead to a situation where the term of a patent is effectively extended beyond its normal expiry, creating extra monopoly time beyond the 20-year term under TRIPS Agreement. Extending patent terms to offset regulatory review/examination time effectively penalizes regulators/patent offices for doing their job and rewards companies with additional years of exclusivity, delaying generic entry and raising prices without delivering any added social or therapeutic benefit. From policy and public-health perspectives, such extensions raise access-to-medicines concerns since delayed generic entry is further postponed.

Before the WTO TRIPS Agreement, national patent terms varied widely across countries and product

[6] UNCTAD–ICTSD, *Resource Book on TRIPS and Development*, 2005.

categories. TRIPS introduced a uniform 20-year minimum term — the longest of any country at the time — to account for the time needed for patent examination and regulatory review. Extending protection beyond this period would therefore amount to a double reward for patent holders, strengthening private monopolies at the expense of the public domain and access to health technologies.

Proponents of patent term extensions argue that they are necessary to "compensate" for the time invested in research, development, and regulatory approval before a medicine reaches the market. However, evidence shows that this justification is unfounded. As highlighted in MSF's analysis of the European Supplementary Protection Certificate (SPC)[7] system, such extensions rarely serve to recoup genuine R&D investments; rather, they primarily prolong monopoly protection and delay generic competition, imposing significant costs on health systems and patients. The 20-year patent term already provides ample time for cost recovery under prevailing business models, particularly given the substantial public funding and risk-sharing that support pharmaceutical innovation. Extending patent terms beyond this period offers no additional incentive for innovation — only further barriers to timely and affordable access to medicines.

Globally, these measures have faced growing opposition. Proposals for patent term extensions were put on hold during the CPTPP (Comprehensive and Progressive Agreement for Trans-Pacific Partnership) negotiations and explicitly rejected in the EU-Mercosur and RCEP (Regional Comprehensive Economic Partnership) agreements. In Brazil, the Supreme Court (STF) issued a landmark 2021 ruling striking down automatic patent term extensions, recognizing that they violate constitutional principles of legal certainty and the right to health[8]. This decision reaffirmed that extending patent terms beyond 20 years undermines the balance intended under TRIPS and directly harms timely access to affordable medicines.

2.1.1. Impact of Patent Term Extensions

Several impact studies have assessed the effects of patent-term extensions (PTE) on access to medicines across the Americas. These provisions, which prolong pharmaceutical monopolies beyond the 20-year TRIPS standard to compensate for regulatory or administrative delays, have been repeatedly shown to delay generic entry, increase public and household health expenditures, and provide no measurable benefit in innovation, technology transfer, or local production.

- Brazil – The Universidade Federal do Rio de Janeiro (2016)[9] quantified the impact of Article 40 of Brazil's Patent Law, which automatically extends patent terms pending examination. Analyzing nine high-cost medicines, the study found that extensions of up to ten years beyond the 20-year

[7] MSF, "*Extending monopoly protection on medicines: How the Supplementary Protection Certificate system delays generic competition and access in Europe*," *PLoS Med* 2020, PMC6958714

[8] https://msf-access.medium.com/brazils-supreme-court-delivers-a-groundbreaking-decision-in-favour-of-access-to-medicines-348be69a08ac

[9] Universidade Federal do Rio de Janeiro – Instituto de Economia, Grupo de Economia da Inovação. *Extensão das patentes e custos para o SUS.* Rio de Janeiro, 2016.

term generated an additional BRL 6.8 billion (≈ USD 1.3 billion, 2020 values) in costs to the public health system. The Fiocruz (2017)[10] assessment of the EU–Mercosur Free Trade Agreement projected that adopting PTE to offset regulatory-approval delays would extend monopoly protection for HIV and hepatitis C medicines by approximately 4–6 years, resulting in about BRL 17 billion in additional public expenditure over 35 years.

- Colombia – The IFARMA/PAHO (2004)[11] and IFARMA & Misión Salud (2006)[12] analyses of the U.S.–Colombia FTA estimated that patent-term extensions would postpone generic entry by up to five years, increasing annual public spending by USD 80–280 million. While compounded by data exclusivity and patent linkage, PTE was identified as a distinct driver of prolonged monopolies and higher costs.

- Dominican Republic – The Fundación Plenitud/ICTSD/PAHO (2009)[13] modelling of the DR-CAFTA intellectual-property chapter projected that PTE would delay generic market entry by 2–5 years and raise institutional medicine prices, particularly for chronic-disease treatments procured by the public insurer.

- Costa Rica – The CINPE/ICTSD/PAHO/UNDP (2009)[14] study found that extending patent duration beyond 20 years could raise public procurement costs by up to 17 percent, mainly due to delayed competition in high-expenditure therapeutic classes.

- Peru – The Ministry of Health (2005)[15] assessment of the Peru–U.S. FTA estimated that PTE provisions would prolong exclusivity by about two years, delaying generic entry and increasing costs for essential medicines.

- Guatemala – Analyses by MSF (2005)[16] and Correa (2006)[17] of the CAFTA-DR agreement similarly warned that PTE and other TRIPS-plus obligations would extend monopolies by at least two years, postponing access to affordable generics.

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[10] Fundação Oswaldo Cruz (Fiocruz). *EU–Mercosur Free Trade Agreement: An Impact Assessment Study of TRIPS-plus Provisions on Public Procurement of Medicines in Brazil.* Rio de Janeiro, Mar 2017. DOI 10.13140/RG.2.2.10410.84161.

[11] Fundación IFARMA / OPS. *Impacto de las medidas ADPIC-plus en Colombia (escenario FTA EE. UU.–Colombia).* Bogotá, 2004.

[12] Fundación IFARMA / Misión Salud. *Impacto del Tratado de Libre Comercio Colombia–EE. UU. en el acceso a medicamentos.* Bogotá, 2006.

[13] Fundación Plenitud / ICTSD / OPS. *Impacto del CAFTA-DR en el acceso a medicamentos en República Dominicana.* Santo Domingo, 2009.

[14] CINPE / ICTSD / OPS / PNUD. *Impacto del CAFTA-DR en el acceso a medicamentos en Costa Rica.* San José, 2009.

[15] Ministerio de Salud (MINSA). *Evaluación de impacto en salud del TLC Perú–EE. UU.* Lima, 2005.

[16] Médecins Sans Frontières (MSF). *Analysis of the Central America Free Trade Agreement (CAFTA-DR) and its Impact on Access to Medicines.* Geneva: MSF Access Campaign, 2005.

[17] Correa, C. *Impacto del CAFTA-DR en el acceso a medicamentos en Centroamérica.* ICTSD / Fundación Friedrich Ebert, 2006.

Across all cases, the evidence demonstrates that patent-term extensions systematically prolong monopoly protection, impose significant fiscal burdens on health systems, and fail to deliver any public-health or innovation benefit—confirming that PTE provisions are contrary to public-health objectives and incompatible with the right to timely access to medicines.

2.2. Data Exclusivity

In the protection of undisclosed test or other data submitted to obtaining regulatory approval, CUSMA also goes beyond what is required by the WTO TRIPS Agreement. Article 39.3 of TRIPS requires Members that mandate the submission of undisclosed test or other data for the marketing approval of pharmaceutical products to protect such data against unfair commercial use and disclosure, which is fundamentally different than providing exclusive protection over such data. CUSMA requires that when a company submits clinical or pre-clinical data to obtain marketing approval, national drug regulators cannot rely on those data—or on the approval granted based on them—to authorize a generic or similar product for at least five years, unless the originator company consents – establishing a data exclusivity mechanism (Article 20.48).

Data exclusivity prevents drug regulatory authorities from relying on existing clinical trial data to approve equivalent generic or biosimilar products for a set period. It grants originator companies exclusive protection over clinical trial and other data for that set period. Even without a patent in force, regulators are legally barred from referring to or relying on the originator's safety and efficacy data, effectively blocking generic registration.

Introducing such exclusive protections has been proven detrimental to access to medicines. In 2016, US pharmaceutical corporation Gilead Sciences sued the Ukrainian government and blocked the entry of generics by claiming data exclusivity on sofosbuvir, a key hepatitis C medicine. Gilead did not hold patents on sofosbuvir in Ukraine, but data exclusivity provisions enabled the company to hinder generic entry and competition in the market that would have driven prices down. That delayed the ability for MSF to provide sofosbuvir in its operations in Ukraine by at least a year, when the barrier to generics was removed and MSF could procure the drug from more affordable sources.

This forces generic manufacturers to either repeat all pre-clinical and clinical studies—an unethical and unnecessary duplication of human trials prohibited by the Declaration of Helsinki—or wait until the exclusivity period expires. Such duplication raises development costs, discourages generic market entry, and leaves patients, treatment providers, and health systems without affordable alternatives. Introducing separate exclusivity period through regulatory mechanism could potentially extend monopolies beyond 20 years for those protected by patents or secure exclusivity on non-patented medicines, as in practice, data exclusivity creates a market monopoly independent of patents, delaying competition and keeping medicine prices high.

Regulatory agencies have the duty to ensure safety and efficacy, not to grant additional monopolies. Data exclusivity forces duplication of clinical trials that are unethical and unnecessary, while denying timely access to affordable versions of life-saving medicines. MSF opposes the inclusion of data exclusivity in trade agreements and national laws because it is a TRIPS-plus measure that directly undermines generic entry and public-health objectives.

2.2.1. Impact of Data Exclusivity

Several studies have evaluated the impact of data exclusivity (DE) on access to medicines in the Americas. Across all assessments, DE provisions are consistently found to delay generic and biosimilar entry, raise medicine prices and public-sector expenditures, and provide no measurable incentive for innovation, technology transfer, local production, or faster originator registration.

- Argentina – The FGEP (2018)[18] study estimated that a 10-year DE period proposed under the EU–Mercosur Agreement would cause cumulative overspending in Argentina's HIV and hepatitis C programs, rising from the first year and reaching +26.5 percent by 2050.

- Brazil – The Fiocruz (2017)[19] assessment of the EU–Mercosur Agreement projected that introducing DE would increase medicine prices by 15–25 percent and add BRL 34 billion (five-year DE) or BRL 51 billion (eight-year DE) in cumulative public expenditure for HIV and hepatitis C treatments over 35 years, while also reducing domestic production capacity.

- Chile, Peru and Colombia – The AIS–IFARMA (2013)[20] regional study of the Trans-Pacific Partnership (TPP) found that DE obligations would extend exclusivity for new chemical entities and biologics by 5–8 years, delay generic and biosimilar entry, and raise prices by 20–100 percent compared with baseline scenarios. The analysis further confirmed that DE does not accelerate drug approval or improve timeliness of registration.

- Colombia – The IFARMA/PAHO (2004)[21] and IFARMA & Misión Salud (2006)[22] evaluations of the U.S.–Colombia FTA projected that a five-year DE period would delay generics by up to five years and increase annual public spending by USD 80–280 million. The subsequent IFARMA (2012)[23] assessment of ten years of DE in force confirmed empirically that exclusivity postponed

[18] FGEP (Fundación Grupo Efecto Positivo). *EU–Mercosur Bi-Regional Association Agreement: Impact of the Intellectual Property Chapter on Public Procurement of Medicines in Argentina.* Buenos Aires, 2018.
[19] Fundação Oswaldo Cruz (Fiocruz). *EU–Mercosur Free Trade Agreement: An Impact Assessment Study of TRIPS-plus Provisions on Public Procurement of Medicines in Brazil.* Rio de Janeiro, 2017.
[20] AIS & IFARMA. *El impacto del TPP en el acceso a los medicamentos en Chile, Perú y Colombia.* Bogotá, 2013.
[21] Fundación IFARMA / OPS. *Impacto de las medidas ADPIC-plus en Colombia (escenario FTA EE. UU.–Colombia).* Bogotá, 2004.
[22] Fundación IFARMA / Misión Salud. *Impacto del Tratado de Libre Comercio Colombia–EE. UU. en el acceso a medicamentos.* Bogotá, 2006.
[23] Fundación IFARMA. *Impacto de 10 años de protección de datos en medicamentos en Colombia.* Bogotá, 2012.

competition by three to seven years and imposed additional costs on the national insurance system.

- Costa Rica – The CINPE/ICTSD/PAHO/UNDP (2009)[24] study estimated that a five-year DE period under CAFTA-DR would raise procurement costs by 17 percent by 2030 and force the public insurance system to reduce medicine consumption by 14–17 percent.

- Dominican Republic – The Fundación Plenitud/ICTSD/PAHO (2009)[25] modelling projected that a five-year DE period would delay generic entry by 2–5 years and increase institutional medicine prices, especially for chronic-disease treatments procured by SENASA.

- Ecuador – The Fundación IFARMA/PAHO (2010)[26] analysis of Ecuador's 2006 IP reform found that data exclusivity led to delays and refusals of generic registration and higher procurement prices, particularly for antiretroviral and oncology medicines.

- Peru – The Ministry of Health (2005)[27] assessment of the Peru–U.S. FTA estimated that a five-year DE period would postpone generic entry by about two years and raise public procurement costs for essential medicines, noting that originator products were already registered promptly after approval in the U.S. or EU.

- Guatemala – Analyses by MSF (2005)[28] and Correa (2006)[29] of CAFTA-DR warned that the DE clause would block registration of generics for at least five years, even when no patent existed, effectively creating new monopolies and excluding domestic producers from the market.

Across all these studies, evidence shows that data exclusivity prolongs market exclusivity, delays competition, and imposes heavy fiscal burdens on health systems. None of the assessments identify improvements in registration timeliness or availability of new medicines. Instead, DE systematically blocks or postpones generic and biosimilar registration, creating additional monopoly years beyond patent protection and generating significant increases in public health expenditure.

[24] CINPE / ICTSD / OPS / PNUD. *Impacto del CAFTA-DR en el acceso a medicamentos en Costa Rica.* San José, 2009.
[25] Fundación Plenitud / ICTSD / OPS. *Impacto del CAFTA-DR en el acceso a medicamentos en República Dominicana.* Santo Domingo, 2009.
[26] Fundación IFARMA / OPS. *Impacto de los derechos de propiedad intelectual en el acceso a medicamentos en Ecuador.* Quito, 2010.
[27] Ministerio de Salud (MINSA). *Evaluación de impacto en salud del TLC Perú–EE. UU.* Lima, 2005.
[28] Médecins Sans Frontières (MSF). *Analysis of the Central America Free Trade Agreement (CAFTA-DR) and its Impact on Access to Medicines.* Geneva: MSF Access Campaign, 2005.
[29] Correa, C. *Impacto del CAFTA-DR en el acceso a medicamentos en Centroamérica.* ICTSD / Fundación Friedrich Ebert, 2006.

2.3. Patent-Registration Linkage

CUSMA requires countries to link the drug regulatory approval process to patent status, establishing a patent-registration linkage system (Article 20.50), requiring health authorities to notify patent holders when a generic manufacturer seeks marketing approval for a product covered by an active patent. It also obliges countries to give patent owners time to sue or seek injunctions and to provide rapid enforcement measures—such as preliminary injunctions—to block the marketing of allegedly infringing products. These provisions go beyond TRIPS, which do not require any connection between drug registration and patent status.

In practice, this links drug regulatory approval to patent enforcement as the health authority cannot approve a generic medicine until patent issues are resolved, effectively turning health regulators into patent enforcers. The mechanism delays the approval and marketing of generics, giving patent holders an early warning and a procedural tool to delay generic entry through litigation or injunctions. It prolongs monopoly periods, and increases medicine prices, even when patents are invalid, expired, or under dispute. It has been widely criticized as a TRIPS-plus barrier that undermines timely access to affordable medicines and misdirects public-health authorities toward private patent protection.

2.3.1. Impact of Patent-Registration Linkage

Several studies have evaluated the impact of patent linkage on health. Across all assessments, linkage is consistently identified as a mechanism that delays generic entry by conditioning marketing authorization on patent status or disputes. It extends monopoly periods, increases public pharmaceutical expenditure, and creates legal uncertainty for regulators and domestic producers. None of the studies identify any innovation or access benefit—its only demonstrated effect is to impose an additional regulatory barrier to timely generic entry.

- Costa Rica – The CAFTA-DR impact study by CINPE/ICTSD/PAHO/UNDP (2009)[30] projected average delays of about two years for generic approvals, extended exclusivity for originator products, and higher procurement costs for the social-security system, resulting from the new requirement for the Ministry of Health to verify patent status before registration.

- Dominican Republic – The Fundación Plenitud/ICTSD/PAHO (2009)[31] study found that linkage would expose regulators to patent disputes, delay the market entry of generics, and raise medicine prices under CAFTA-DR, with no compensating innovation or registration benefits.

[30] CINPE / ICTSD / OPS / PNUD. *Impacto del CAFTA-DR en el acceso a medicamentos en Costa Rica.* San José, 2009.

[31] Fundación Plenitud / ICTSD / OPS. *Impacto del CAFTA-DR en el acceso a medicamentos en República Dominicana.* Santo Domingo, 2009.

- Peru – The Ministry of Health (MINSA, 2005)[32] warned that patent linkage would oblige DIGEMID to resolve patent disputes prior to marketing authorization, effectively postponing generic entry and increasing public-sector spending on essential medicines—contrary to Peru's public-health priorities and TRIPS flexibilities.

- Colombia – The IFARMA/PAHO (2004)[33] and IFARMA & Misión Salud (2006)[34] studies concluded that the proposed U.S.–Colombia FTA linkage clause would tie INVIMA's regulatory decisions to private patent claims, generating litigation, legal uncertainty, and delayed approvals for domestic producers. The authors found no evidence of faster originator registration or innovation gains and warned that linkage would "convert a public-health procedure into a patent-enforcement mechanism."

Empirical evidence from Mexico, where patent linkage has been in force since 2003, confirms these predicted effects. Analyses by COFECE[35], PAHO[36], and independent researchers[3738] document systematic delays of one to three years—and up to four years for products such as efavirenz, losartan, and atorvastatin—due to repeated patent listings and injunctions. During these delays, IMSS and Seguro Popular continued purchasing originator products at prices 20–40 percent higher than in neighboring countries where generics were already available. None of the analyses found any improvement in originator approval times or innovation outcomes.

The Federal Competition Commission (COFECE, 2022)[39] and the Auditor-General (ASF, 2012–2015)[40] likewise identified inefficiencies and lost savings for IMSS and Seguro Popular resulting from postponed generic entry after the introduction of linkage. COFECE reported that the first generic enters the market on average more than two years after patent expiry, and that generics capture only around 21 percent of market share two years after entry. The Commission attributed these to the complexities and litigation created by the Gaceta de Patentes and recommended its elimination to restore timely competition. ASF's audits reached similar conclusions, citing missed procurement savings for high-

[32] Ministerio de Salud (MINSA). *Evaluación de impacto en salud del TLC Perú–EE.UU.* Lima, 2005.
[33] Fundación IFARMA / OPS. *Impacto de las medidas ADPIC-plus en Colombia (escenario FTA EE.UU.–Colombia).* Bogotá, 2004.
[34] Fundación IFARMA / Misión Salud. *Impacto del Tratado de Libre Comercio Colombia–EE.UU. en el acceso a medicamentos.* Bogotá, 2006.
[35] COFECE (Comisión Federal de Competencia Económica). *Estudio sobre condiciones de competencia en el mercado de medicamentos genéricos en México.* Mexico City, 2022.
[36] Organización Panamericana de la Salud (PAHO). *Health Systems and Access to Medicines in Latin America: Regulatory Challenges.* Washington D.C., 2019.
[37] Correa, C. *Implications of the U.S.–Mexico Patent Linkage System for Access to Medicines.* ICTSD, Geneva, 2007.
[38] Ravinet, P. *La vinculación de patentes y registros sanitarios en México: efectos sobre la competencia.* Universidad Nacional Autónoma de México (UNAM), 2015.
[39] COFECE (Comisión Federal de Competencia Económica). *Estudio sobre condiciones de competencia en el mercado de medicamentos genéricos en México.* Mexico City, 2022.
[40] Auditoría Superior de la Federación (ASF). *Informes del Resultado de la Fiscalización Superior de la Cuenta Pública.* Mexico City, 2012–2015.

expenditure medicines such as losartan, atorvastatin, and efavirenz.

Together, these findings make Mexico the clearest empirical example that patent linkage functions as a regulatory barrier: it prolongs market exclusivity, triggers costly litigation, and increases medicine prices, while offering no measurable gain in innovation, registration timeliness, or access. Both COFECE and PAHO have recommended limiting or eliminating the Gaceta de Patentes mechanism to restore the independence of the health regulator and accelerate generic competition.

2.4. Enforcement Provisions – Border Measures

CUSMA obliges each Party to establish procedures allowing customs authorities to suspend or detain goods suspected of infringing intellectual property rights, including through ex officio actions initiated by customs on their own initiative (Article 20.83). Customs officials are empowered to share shipment information with right holders and to determine infringement through administrative or judicial procedures that may result in fines, seizure, or destruction of the goods.

Unlike the WTO TRIPS Agreement—which limits mandatory border measures to counterfeit trademark and pirated copyright goods upon a right holder's request and leaves ex officio actions as optional (Article 58)—CUSMA makes such actions mandatory and extends them to goods in transit, destined for export, or located in free-trade zones or bonded warehouses. This broad scope goes well beyond TRIPS standards, expanding enforcement powers in ways that risk capturing legitimate generic medicines moving through a Party's territory. By enabling customs seizures based on mere suspicion of infringement, the CUSMA provisions introduce legal uncertainty and potential disruption to global medicine supply chains, creating chilling effects on the trade and timely delivery of affordable generic medicines.

2.4.1. Historic abuse of counterfeit legislation in relation to medicines

MSF has long warned that overly broad anti-counterfeiting rules increase the risk of wrongful seizures of legitimate generic medicines by customs authorities. The wrongful seizure and detention of generic medicines – including in transit – can lead to harmful delays for people who need access to life-saving medicines. These concerns are not theoretical: between 2008 and 2009, at least 19 shipments of generic drugs were seized while in transit through the Netherlands alone.[41]

MSF's *Hands Off Our Medicine* report details further seizures, whose delays or failure to arrive harmed

[41] World Trade Organization (WTO). *European Union and a Member State – Seizure of Generic Drugs in Transit.* Dispute Nos. 10–2836. Geneva, 2010. Available at: https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=Q:/IP/D/28.pdf&Open=True.

patients:[42]

- Dutch customs authorities detained a shipment of an active pharmaceutical ingredient (losartan potassium) necessary to make a generic medicine to treat high blood pressure. The medicine was transiting from its producers in India to Brazil via the Netherlands in December 2008. The drug is neither patented in India nor Brazil, but the customs raids were carried out nonetheless, on the basis that the drugs were under patent in the country of transit – the Netherlands. The shipment was eventually returned to India, and according to the Brazilian government, 300,000 patients in Brazil were awaiting treatment with the detained medicines.
- In November 2008, a shipment of an AIDS medicines purchased by UNITAID for use in Nigeria was seized in transit through the Netherlands.
- The Dutch government further revealed in April 2009 that customs authorities had conducted 17 seizures in 2008 of medicines bound for Brazil, Peru, Colombia, Ecuador, Mexico, Portugal, Spain and Nigeria. The drugs were for the treatment of diseases such as cardiac ailments, AIDS, dementia and schizophrenia.
- In 2009, generic antibiotics were seized at the Frankfurt airport by German authorities on the misguided assumption of trademark infringement.

The detention and potential destruction of medicines wrongly classified as counterfeit can create a chilling effect on the international trade of generic medicines. Faced with the risk of seizure, generic manufacturers and suppliers may be compelled to implement costly logistical adjustments, such as rerouting shipments, altering packaging, or engaging in additional costly legal disputes, to pre-empt and respond to overzealous IP enforcement actions. These defensive measures increase supply-chain costs, which are ultimately passed on to health systems and patients, reducing affordability and access. For these reasons, MSF believes the term counterfeit should not be used in relation to medicine and instead more accurate and precise terms, such as ‘fake’ or ‘substandard’, should be used where concerns are related to the quality of medicines.

3. Conclusion

The WTO TRIPS Agreement establishes a minimum standard of intellectual property protection, explicitly confirming that countries “shall not be obliged to implement in their law more extensive protection than is required by this Agreement” (Article 1.1). Yet, CUSMA introduces several TRIPS-plus obligations—including patent-term extensions, data exclusivity, patent linkage, and strengthened enforcement provisions—that go beyond these standards. These measures collectively narrow the policy space available to governments to protect public health and to ensure timely access to affordable

[42] Médecins Sans Frontières (MSF) Access Campaign. *Europe! Hands Off Our Medicine – Campaign Briefing Document.* 2010. Available at: https://50years.msfaccess.org/europe-hands-our-medicine-campaign-briefing-document.

medicines.

Empirical evidence from across the Americas demonstrates that these TRIPS-plus rules delay generic competition, prolong monopolies, and increase medicine prices and public-sector expenditures, without delivering any measurable gains in innovation, technology transfer, or local production. They also create additional administrative burdens for health and regulatory authorities, diverting them from their core public-health mandates. All studies reach the same conclusion: higher levels of IP protection translate into delayed access and higher costs for health systems and patients, with no benefits.

MSF therefore urges the Parties to CUSMA to remove or amend all pharmaceutical IP and enforcement provisions that exceed TRIPS obligations. Doing so would restore critical policy space for governments to safeguard public health, facilitate generic and biosimilar competition, and uphold the right to health for people across the region. MSF calls on the Parties to reaffirm their commitment to the 2001 Doha Declaration on TRIPS and Public Health and to ensure that trade agreements never undermine access to affordable, quality-assured medicines and medical technologies.