# Analysing the impact of trade and investment agreements on pharmaceutical policy and access to medicines:
## *provisions, pathways, methods and challenges*

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# Overview

- Provisions in contemporary trade agreements with implications for pharmaceutical policy and access to medicines
- Pathways through which trade agreements can affect pharmaceutical policy and access to medicines
- Methods for analysing impact
- Methodological challenges
- Concluding points and recommendations

# Contemporary trade agreements with wide-ranging implications for pharmaceuticals – examples

- Trans Pacific Partnership Agreement (TPP)
  - 12 countries
  - Concluded but not in force - US withdrew Jan 2017
- Comprehensive and Progressive Agreement for Trans-Pacific Partnership (CPTPP or TPP-11)
  - Incorporates majority of TPP rules; certain provisions suspended
  - Comes into force 30 Dec 2018 for first 6 countries to ratify
- Comprehensive Economic and Trade Agreement (CETA)
  - EU and Canada
  - Provisionally entered into force Sept 2017
- United States-Mexico-Canada Agreement (USMCA)
  - Negotiations completed 30 Sept 2018

# Pathways through which trade agreements can affect pharmaceutical policy and access to medicines

1. **Intellectual property** protection
2. **Investment** protection
3. Procedural requirements for **pharmaceutical pricing and reimbursement** programs
4. Restrictions on regulation of **pharmaceutical marketing**
5. Regulatory requirements for **assessment of safety and efficacy**
6. Reduction/elimination of **tariffs** on pharmaceuticals
7. Disciplines applying to **government procurement** of pharmaceuticals
8. Disciplines applying to **state-owned enterprises and designated monopolies**

| Type of provision | TPP | CPTPP (TPP-11) | CETA | USMCA |
|---|---|---|---|---|
| TRIPS-Plus intellectual property provisions | Chapter 18 | Chapter 18 (some provisions suspended) | Chapter 20 | Chapter 20 |
| Investment protection – ISDS, IP covered in definition of investment | Chapter 9 | Incorporates TPP Chapter 9, slightly narrowed scope | Chapter 8 | Annex 14-D (only between Mexico and US, scaled back) |
| Procedural requirements for pharmaceutical pricing and reimbursement programs | Annex 26-A, Art 3 | Suspended by CPTPP Article 2 | - | Chapter 29, Section B, Art 29.12 |
| Restrictions on regulation of pharmaceutical marketing | Annex 26-A, Art 4 | Incorporates TPP Annex 26-A, Art 4 | - | Art 29.13 |
| Regulatory requirements for assessment of safety and efficacy | Annex 8-C | Incorporates TPP Annex 8-C | - | Annex 12-F |
| Compliance with standards for pharmaceutical manufacturing practices | - | - | Protocol on the mutual recognition of the compliance and enforcement programme | - |
| Reduction/elimination of tariffs on pharmaceuticals | Eliminates tariffs on some medicines | Eliminates tariffs on some medicines | - | Eliminates tariffs on some medicines |
| Disciplines applying to government procurement | Chapter 15 | Incorporates TPP Chapter 15 with minor changes | Chapter 19 | Chapter 13 |
| Disciplines applying to state-owned enterprises | Chapter 17 | Incorporates TPP Chapter 17 | Chapter 18 | Chapter 22 |

# 1. Intellectual property protection - provisions

- Patents for new uses/methods/processes
- Patent term adjustments
- Data protection for new pharmaceutical products
- Additional data protection for new indications/formulations/methods of administration or for combination products
- Biologics – special longer period of data/market protection
- Patent linkage
- Trade secrets protection
- TRIPS-Plus enforcement

| Provision | TPP Ch. 18 | CPTPP (TPP-11) | CETA Ch. 20 | USMCA Ch. 20 |
|---|---|---|---|---|
| Patents for new uses/methods/processes | Art 18.37 | Suspended by CPTPP Article 2 | - | Art 20.F.1 para 2 |
| Patent term adjustments for delays in granting patents | Art 18.46 | Suspended by CPTPP Article 2 | Article 20.27 (2-5 years based on period from patent application filing to marketing approval) | Art 20.F.9 |
| Patent term adjustments for delays in marketing approval process | Art 18.48 | Suspended by CPTPP Article 2 | | Art 20.F.11 |
| Data/market protection for new pharmaceutical products | Art 18.50 para 1 – at least 5 years | Suspended by CPTPP Article 2 | Art 20.29 (6 years data protection + 2 years market protection) | Art 20.F.13 para 1 |
| Data/ market protection – additional 3 years for new indications/ formulations /methods of administration or 5 years for combination products | Art 18.50 para 2 | Suspended by CPTPP Article 2 | - | Art 20.F.13 para 2 (not required for parties providing at least 8 years of protection) |
| Longer period of data and/or market protection for biologics | Art 18.51 – at least 8 years or least 5 years + other measures | Suspended by CPTPP Article 2 | - | Art 20.F.14 – 10 years effective market protection |
| Patent linkage | Art 18.53 | Incorporates TPP Art 18.53 | N/A, (Art 20.28 - right for originator manufacturers to appeal decisions under Notice of Compliance linkage regulations) | Art 20.F.16 |
| Trade secrets protection | Art 18.78 | Incorporates TPP Art 18.78 | - | Art 20.1 |
| TRIPS-Plus enforcement | Section I, incl. Art 18.76 | Section I, including Art | Article 20.43 | Section J, including |

# 1. Intellectual property protection - pathways

- Delayed market entry of generics and biosimilars
- Prices/costs remain high for longer periods – impact on government expenditure and/or out of pocket costs
- Potential for reduced access where pharmaceutical coverage is not universal or where extra costs cannot be absorbed
- Limited empirical evidence
  - Large number of commentaries and legal/policy analyses exploring how the mechanisms work to cause delays
  - Handful of quantitative studies demonstrating/predicting impact: delay in generic competition, increases in price/expenditure, contraction of generic medicines industries, reduced access for patients

# 2. Investor-state dispute settlement (TPP, TPP-11, CETA)

- Allows foreign investors to sue governments if they perceive their investments are harmed by a change in policy or law
- Investments include intangibles such as intellectual property
- Average cost of defending a case: $8 million USD
- Awards often hundreds of millions
- Small number of cases involving pharmaceutical companies to date
  - E.g. Eli Lilly claim against Canada for $500 million CAD after patents on 2 drugs revoked
- Chilling effect on health policy
  - E.g. Colombia dissuaded from issuing a compulsory license for imatinib (Glivec) after Novartis filed a notice of dispute in 2016

Baker, B.K. & Geddes, K. (2017) The incredible shrinking victory: Eli Lilly v. Canada, success, judicial reversal, and continuing threats from pharmaceutical ISDS. *Northeastern Public Law and Theory Faculty Research Paper Series No. 296*.

# 3. Pharmaceutical pricing and reimbursement (TPP, USMCA)

- Industry-favourable procedural requirements for listing medicines on national formularies & setting prices for reimbursement
  - Requirements to disclose information (e.g. rules used to assess applications)
  - Timeframes for considering applications
  - Review process for negative listing decisions
  - Obligation to consult with other parties if requested in writing
- Consequences for New Zealand (if implemented)
  - New timeframes for decision making; new review process
  - NZ $4.5 million in initial costs; $2.2 million per year ongoing costs
- Procedural requirements suspended in TPP-11; reappeared in USMCA

# 4. Restrictions on regulation of pharmaceutical marketing (TPP, TPP-11, USMCA)

*"As is permitted to be disseminated under the Party's laws, regulations and procedures,* each Party shall permit a pharmaceutical product manufacturer to disseminate to health professionals and consumers through the manufacturer's website registered in the territory of the Party, and on other websites registered in the territory of the Party linked to that site, truthful and not misleading information regarding its pharmaceutical products that are approved for marketing in the Party's territory..."

(TPP Annex 26-A, Art 4)

# 5. Regulatory requirements for assessment of safety and efficacy (TPP,  TPP-11, USMCA)

- Harmonisation and streamlining of regulations for marketing approval processes
- Opportunity for “persons from another Party” to be involved in developing technical regulations and standards
- Prescribes criteria that can be used to make marketing approval decisions (safety, efficacy, quality)
- Marketing approval processes must be administered in a “timely, reasonable, objective, transparent, and impartial manner”
- Requirements for pharmaceutical inspections

# 6. Reduction/elimination of tariffs on medicines (TPP, TPP-11, USMCA)

- Trade agreements may reduce the cost of medicines if tariffs on medicines are reduced or removed
- Few countries still have tariffs on medicines
- These can be removed unilaterally
- ? Effects on domestic generic pharmaceutical sector

# 7. Government procurement (TPP, TPP-11, CETA, USMCA)

- Purpose: to ensure governments do not discriminate against foreign suppliers when purchasing goods and services (ie. favour local firms)
- Pharmaceutical purchasing by central/sub-central governments and hospitals opened to foreign competition
- Subsidies or other preferential arrangements would need to be removed
- May affect viability of domestic generic medicines industry

# 8. State-owned enterprises and designated monopolies (TPP, TPP-11, CETA, USMCA)

- TPP/USMCA: State-owned pharmaceutical companies cannot be given advantages that discriminate against foreign investors (and must not discriminate against foreign goods/services in the purchase or sale of goods and services)
  - E.g. subsidies/assistance from governments may need to be eliminated if it affects the interests of another Party
- Under some agreements, state-owned pharmaceutical companies may be exposed to investor-state disputes
- Potential implications for viability of generic medicines industries in some countries

# Methods

- Quantitative studies
  - Single country / comparative
  - Cross-sectional / longitudinal
- Qualitative studies
  - Policy analyses
  - Legal analysis
  - Interview studies
- Health and human rights impact assessments
  - Generally ex ante
  - Often integrate/synthesise evidence from a range of sources

# Methodological challenges

- Establishing causality, e.g.
  - Legislation/administrative changes can be introduced in order to meet multiple objectives
  - Ambiguities in the legal text of trade agreements may give rise to different outcomes in different contexts;
- Data and design issues, e.g.
  - Obtaining data
  - Choosing the right assumptions
- Generalisability of methods and findings
  - Country contexts are very different
  - Complexities in trade agreement texts – every text is different

# Concluding points

- Expanding array of provisions in trade and investment agreements with implications for pharmaceutical policy and access to medicines – both IP and non-IP
- Range of methods available for research, but limited empirical research to date, particularly for newer provisions and pathways
- Formidable challenges: establishing causality, data and design issues, generalisability of methods and findings
- Recommendations:
  - Inter-disciplinary research;
  - Triangulating different methods - using quantitative measures along with qualitative methods to understand the context;
  - Careful consideration of timing and study design;
  - Choosing appropriate data types and outcome measures.

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