

Translating Technology Transfer in the WHO Pandemic Agreement into Reality Law, Politics, and the Path Ahead Kashish Aneja Visiting Scholar, Harvard Law School Consultant, O'Neill Institute, Georgetown University

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OVERVIEW

Why TT? Negotiating TT in the Agreement **Retrospective** Article 11 obligations Relationship with other Provisions mRNA TT Hub

Current Landscape

Translating into National Laws Lessons from existing TT initiatives TT without the US Prospective





Retrospective Reflections <u>What went wrong?</u>

Daily COVID-19 vaccine doses administered per million people, Dec 3, 2020

7-day rolling average. All doses, including boosters, are counted individually.



Daily COVID-19 vaccine doses administered per million people, Feb 10, 2021

7-day rolling average. All doses, including boosters, are counted individually.



Daily COVID-19 vaccine doses administered per million people, Mar 11, 2021

7-day rolling average. All doses, including boosters, are counted individually.



Daily COVID-19 vaccine doses administered per million people, Apr 11, 2021



7-day rolling average. All doses, including boosters, are counted individually.



Daily COVID-19 vaccine doses administered per million people, Apr 24, 2021

7-day rolling average. All doses, including boosters, are counted individually.

Share of people who received at least one dose of COVID-19 vaccine, Aug 12, 2024

Total number of people who received at least one vaccine dose, divided by the total population of the country.

Pharmaceutical

R&D Spending Growth (2022-2023)

Eli Lilly is a pior diabetes & weig drugs, including (2022) and Zepk (2023). As of Nov the world's most healthcare comp

Illy is a pioneer in the set of t	Lilly 2 29.5%
s, including Mounjaro 2) and Zepbound	U NOVARTIS 24.0%
3). As of Nov 2024, it is vorld's most valuable	• MERCK 21.7%
	Takeda 15.9%
	GILEAD 14.5%
	Boehringer 14.3%
	GSK 13.4%
	AstraZeneca 🔁 10.0%
	abbvie 8.5%
	3.3% Johnson&Johnson
0	0.3% sanofi
Roche -0.1%	+10% Industry Average
^{III} Bristol Myers Squibb -2.2%	Dinaria stock has dealined in recent years
-7.4% @Pfizer	due to waning demand for COVID-19 vaccines. The company will compete in the
3.3% BAYER	lucrative weight loss market with its upcoming once-daily pill, danuglipron.
VISUAL CAPITALIST	Source: WIPO Global Innovation Index 2024

Country	Company	R&D Spending Change (%)
🛤 US	Eli Lilly	29.5
Switzerland	Novartis	24.0
🛤 US	Merck	21.7
💽 Japan	Takeda Pharmaceutical	15.9
🛤 US	Gilead Sciences	14.5
💻 Germany	Boehringer Sohn	14.3
🛤 UK	GSK	13.4
🛤 UK	AstraZeneca	10.0
🛤 US	AbbVie	8.5
🗾 US	Johnson & Johnson	3.3
France	Sanofi	0.3
Switzerland	Roche	-0.1
🛤 US	Bristol-Myers Squibb	-2.2
🗾 US	Pfizer	-7.4
📁 Germany	Bayer	-18.3

-18.3%

(^{III}) Bristol Myers

- COVID-19 exposed inequities in access to vaccines, diagnostics, and therapeutics.
- LMICs demanded enforceable mechanisms for access
- Lack of (legal) structure (framework/blueprint)
- Part of a 'package'

TT are most essential for **Biologics** – eg. vaccines and monoclonal antibodies. For small molecule drugs, compulsory licensing may be sufficient. Manufacturing biologics requires both access to specific starting materials (cell lines, antigens) and to specialized know-how.

Retrospective Reflections Negotiating TT in the PA

Key Contentious Issues: Article 11

Global North Global South ► Voluntary vs. Mandatory tech transfer

'Know-how'

Peace Clause – Article 11(4)

Fn 8: For the purpose of the WHO Pandemic Agreement, "as mutually agreed" means willingly undertaken and on mutually agreed terms, without prejudice to the rights and obligations of the Parties under other international agreements

pandemic emergencies.

4. The Parties that are World Trade Organization (WTO) members reaffirm that they have the right to use, to the full, the TRIPS Agreement and the Doha Declaration on the TRIPS Agreement and Public Health of 2001, which provide flexibility to protect public health including in future pandemics. The Parties respect the use of these flexibilities that is consistent with the TRIPS Agreement and shall not exercise pressure in this regard.

Peace Clause [December, 2024]

Current Landscape

Article 11 obligations Relationship with other Provisions

mRNA TT Hub

- > Largely **aspirational**.
- Voluntary sharing 'on mutually agreed terms'.
- Transfer of relevant knowledge, skills, technical expertise, and cooperation on any other related know-how

ARTICLE 11

- Flexibility for states to implement TT through various mechanisms: licensing, capacity-building, relationship facilitating, incentives or conditions linked to R&D, procurement, and regulatory policy measures
- Technology Transfer Hubs Cooperation
- State-Owned Technology Transparency + Enhanced Availability + Non-Exclusive Licensing + Publishing Terms
- Pandemic-Specific Measures: forgo OR charge reasonable royalties and corporate with time-bound measures
- TRIPS flexibilities not compromised (footnote) but neither strengthened (peace clause!).

RELATIONSHIP WITH OTHER PROVISIONS

- Article 8: Regulatory Harmonization
- ➢ Article 9 and 14: Publicly Funded R&D (9.5) and Procurement (14.2)
- Article 10: Manufacturing Capacities (investments)
- ➢ Article 12: PABS Tech transfer as a non-monetary benefit (12.8)
- Article 13: Global Supply Chain network

mRNA TT Hub

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mRNA Technology Transfer Programme

The mRNA Technology Transfer Programme was set up to address the inequalities in access to vaccines in LMICs that emerged during the COVID-19 pandemic. The objectives of the Programme are to establish and enhance sustainable mRNA vaccine manufacturing capacity and to develop skilled human capital in the regions where mRNA vaccine manufacturing capacity is established or can be enhanced.

The key principles leading the Programme activities are:

Create value and share intellectual property through open access to innovation.

3

Promote sustainable capacity to produce mRNA vaccines with coherent policies and adequate investments. THE PROGRAMME OPERATING MODEL is a global collaborative network driven by multilateral technology transfers

> A centre for mRNA Technology Development and Transfer based at Afrigen in South Africa, will develop an effective mRNA vaccine technology by using COVID-19 vaccine as a proof-of-concept model.

The centre for Technology Development & Transfer will transfer the know-how, along with a comprehensive technical package and appropriate training to manufacturers in LMICs.

2

3

4

The first manufacturer to receive the technology is Biovac in Cape Town. Biovac will scale-up and industrialise the process and make this information available for tech transfer through the network.

A global collaborative network is established to explore and share improvements to the mRNA vaccine technology and its application to other disease targets relevant for the LMICs.

Sharing expertise across the global collaborative network

Sharing is an essential component of sustainability. The Programme will create an environment supporting joint research and development projects. The sharing of expertise and technology, and the co-development of new technologies and disease targets, including COVID-19 and beyond, will be shared across the network.

As new technologies emerge from the collaboration it will lead to decreased cost of goods and improved vaccine characteristics (e.g. thermostability) and products that are readily available and better suited to LMICs.

WHO has selected 15 manufacturers to join the mRNA Technology Transfer Programme to receive the mRNA technology platform

Prospective Reflections Translating into National Laws Lessons from existing TT initiatives TT without the US

Translating into National Laws

- > National statutory mandates required
 - Establishing legal authorities for Govt. agencies to facilitate/process or mandate TT
- Regulatory Framework Adaptation
 - Develop procedures for expedited review/approval
- ▶ IP laws must include know-how and capacity sharing (CL Laws)
- Emergency powers to trigger tech transfer?
- Public Procurement/Funding Reforms Agreements
- > Manufacturing infrastructure and supply chain network!
- Sustainable public financing
- Develop innovative demand aggregation mechanisms
- Stronger regional cooperation (e.g., AMA, ASEAN frameworks).

Lessons from existing TT Initiatives

- Lack of Direct Technology Transfer Support and Reliance on Public Domain Information
- Precarious Funding and Financial Sustainability
- Governance Issues: Centralized Control and Limited LMIC Representation
- Product Affordability and Constraints on Commercial Freedom
- Intellectual Property Landscape and Potential Litigation Threats

Four Critical Drivers for Success:1.Regulatory Capacities2.Trade Standards3.Manufacturing & R&D Capacity4.Demand Aggregation

Kolawole, O., Ncube, C., & de Beer, J. (2025). Challenges implementing technology transfer as a viable pathway for equitable vaccine production and access: A case study of the mRNA vaccine hub in South Africa. *Global Public Health*, 20(1). https://doi.org/10.1080/17441692.2025.2504698

Herder M, Benavides X (2024) 'Our project, your problem?' A case study of the WHO's mRNA technology transfer programme in South Africa. PLOS Glob Public Health 4(9): e0003173.

Campos N, Cortés MdlÁ, Pippo TA, Rius J, Fitzgerald J, Couve A. Multiple factors shape technology transfer for the development and manufacture of vaccines in Latin America and the Caribbean. *Biologicals*. 2025;90:101826.

In principle

In practice

Herder M, Benavides X (2024) 'Our project, your problem?' A case study of the WHO's mRNA technology transfer programme in South Africa. PLOS Glob Public Health 4(9): e0003173.

- ➢ U.S. exclusion weakens enforceability.
- U.S. pharma out of binding obligations limits scope of available technologies
- > Creates significant gap in global cooperation.
- Increased South-South Cooperation + Bilateral and Regional Engagements

What's Next?

"Technology transfer is the litmus test for whether this agreement is about equity—or just about optics."

Final Thoughts

- Pandemic Agreement = structure/blueprint/framework = canvas with policymakers as artists!
- Important precedent!
- > The year of PABS negotiations is crucial!
- > COPs role!

Thank you

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