



European Federation of Pharmaceutical
Industries and Associations



Five years of the Trade Facilitation Agreement – a view from the pharmaceutical industry

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The Trade Facilitation Agreement is relevant for industry

The primary goal of trade facilitation is **to help make trade across borders (imports, exports, incl. transit) faster, and cheaper and more predictable, whilst ensuring its safety and security.**

Tariffs come with customs checks – the costs from red tape and time lost are higher than the tariff costs imposed. For pharma: WTO 0-4-0 agreement – but not updated since 2010.

And let's keep it in mind that **countries do not export or import: companies do** (80% of world trade is intermediate trade of which the bulk is intra-company trade). On COVID-19:

- Pfizer/BioNTech COVID-19 vaccine: **280 components from 87 factories in 19 countries;**
- Monoclonal antibody treatments against COVID-19 have sometimes up to **550 ingredients from all over the world.**
- TF facilitates cross-border trade, without compromising on safety and security;
- TF increases the size of the market by decreasing barriers and market fragmentation;
- TF increases flexibility and resilience in case of (pandemic) emergencies.

Let's look at COVID-19... Five steps to advance vaccine equity

- Who saw the COVID-19 crisis come in Nov 2019 or the war in Ukraine in Feb 2022? – These events disrupt(ed) global supply chains, so TFA measures are key to help.
- About crises: **good or bad crisis**? A crisis is always bad – but:
 - Level of preparation and starting position matter (which need to be created in advance!);
 - Learning from crisis and applying lessons learnt key to future preparedness.

On COVID-19, the [IFPMA 'Five steps to urgently advance vaccine equity'](#) were industry's guiding principles – **let's focus on the real issues**:

- Step up dose sharing of vaccines
- Continue to optimise production
- **Call out trade barriers to be eliminated**
- Supply country readiness
- Drive further innovation

Urge governments, in coordination with the *World Trade Organization (WTO)*, to eliminate all trade and regulatory barriers to export and to adopt policies that facilitate and expedite the cross-border supply of key raw materials, essential manufacturing materials, vaccines along with the prioritized movement of skilled workforce needed for COVID-19 vaccine manufacturing.

Example: COVID-19 and digitalization of customs

WCO (2020): *The COVID-19 pandemic has shown the importance of ... the WTO Trade Facilitation Agreement (TFA), including major concepts supported by these instruments: an all-digital clearance process, and efficient risk management.*

- April 2020: during the first lockdowns, **shipments of medicines from the EU to Africa were halted by customs** because necessary customs papers were not in order due to closed embassies.
- **COVID-19 has sped up the digitalisation of customs procedures** around the world.
- For industry, the **advantages of digital customs are many**: back-traceability is ensured; reduction physical archives; simplification of audits; cost efficiency; reduction of paper loss during transport; increased flexibility; easier harmonisation of data for export authorisations; more opportunities to simplify customs procedures; barrierless border crossing via risk assessment procedures.
- Information that some customs organisations want to **return to paper-based procedures** are a step back and concerning.
- Industry is keen to **collaborate with authorities to continue to advance digitalisation in customs** (e.g. DaziT project).

Let's look at COVID-19 and lessons learnt

IFPMA and EFPIA lessons learnt from COVID-19:

- IP has not been a bottleneck but a driver to get COVID-19 vaccines approved and partnerships accelerated R&D and manufacturing. IP is key for future pandemic preparedness.
- Shortages of raw materials and intermediate products, **made worse by trade restrictions and competition for and among vendors**, resulted in inefficient allocation of available supply.
- Regulatory agility and convergence guard safety and speed of access.
- **Vaccine nationalism imperils everyone** (**export restrictions** and vaccine hoarding have intensified and likely prolonged the COVID-19 pandemic).
- Lack of access and vaccine equity did not come from IP or lack of production, but from **export restrictions**, limited absorptive capacities of healthcare systems, and vaccine hesitancy.
- Industry actively engages with the EU and stakeholders to build manufacturing capacities in Africa: **trade**, IP, **regulatory**, skills, **and customs**, are key for a sustainable business case.
- **Demand is key** – and therefore the **size of the market** (= less fragmentation).
- **Key: gap** between formal frameworks and implementation in practice (largest for LICs).

Way forward

- Industry a **strong supporter of the Trade Facilitation Agreement** because TFA matters for exports (and imports) and welcomes progress made over the past 5 years.
- Industry also hopes the next 5 years will see **further steps beyond monitoring and transparency** into:
 - Building best practices at technical levels regarding commitments to building best practices in National TF committees and regarding – for example – conformity assessments
 - Furthering digitalisation of customs to facilitate trade crossing borders (pre-shipment inspections)
 - Sharing of customs data to enhance risk-based approaches to customs, facilitate pathogen sharing.
- In this regard, industry, while congratulating the TFA and all progress made, hopes this is the first step towards **more ambitious Trade and Health commitments in line with the Ottawa Group proposal (tariffs, export restrictions, regulatory collaboration, TFA) and WTO own research work** as this is a **real way to support future pandemic preparedness** (unlike TRIPS waiver compromise).
- Industry also asks to **update the WTO zero-for-zero agreement** (last updated in 2010).
- Business is **keen to participate, engage and provide inputs from the ground as part of a government-industry platform** to make real progress to facilitate trade and enhance future pandemic preparedness.



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Thank you

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