



WORLD TRADE
ORGANIZATION

DEVELOPING AND DELIVERING **COVID-19 VACCINES** AROUND THE WORLD



An information note
about issues with trade impact

This information note explores how trade policy can play its part in ensuring the rapid roll-out of vaccine against COVID-19.

This document has been prepared under the WTO Secretariat's own responsibility as a factual overview and is without prejudice to the positions of WTO members or to their rights and obligations under the WTO.

Section A

Section A provides background information on immunization and the urgent search for vaccines against COVID-19.

Section B

Section B provides an overview of the development and delivery of vaccines in the form of an infographic.

Section C

Section C identifies where key decisions with trade impact may need to be made along the vaccine value chain and provides a non-exhaustive list of useful resources to help inform decision-making.

This information note was published on 22 December 2020.

SECTION A:

Background information



Immunization is a key component of primary health care



VACCINE

Vaccines are critical to the prevention and control of outbreaks of infectious diseases (World Health Organization [WHO](#))



IMMUNIZATION

Immunization averts 2-3 million deaths every year ([WHO](#)).



REDUCING MORTALITY

[Vaccination](#) is indispensable to end preventable deaths of newborns and children under 5 years of age by [2030](#).



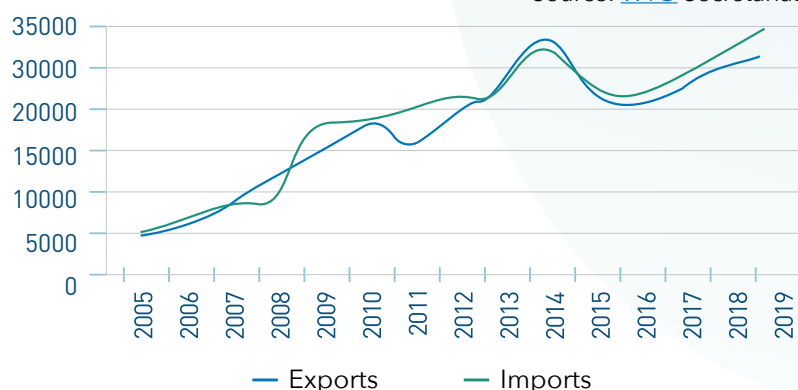
GLOBAL IMMUNIZATION

The [G20 Leaders' Declaration](#), issued on 21-22 November 2020, states: "We recognize the role of extensive immunization as a global public good".

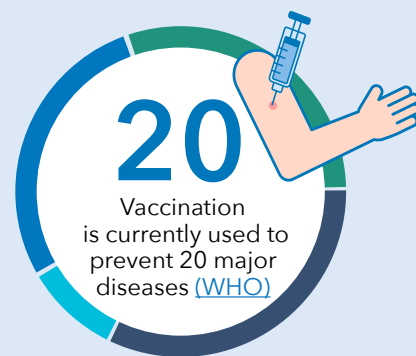
World trade of vaccines for human medicine (HS 300220), 2005-19

(Million dollars)

Source: [WTO](#) Secretariat



New vaccines typically take more than 10 years to be developed and approved. COVID-19 vaccines had already been approved for [emergency use](#) and [registered](#) domestically some eight months after this new disease was notified to the [WHO](#). The development of COVID-19 vaccines is following a "pandemic paradigm", i.e. a compressed timeframe and with many steps executed in parallel rather than sequentially, according to the Coalition for Epidemic Preparedness Innovation ([CEPI](#)). A first vaccine candidate was in clinical testing just two months after the publication of the genetic sequence of SARS-CoV-2, the virus that causes COVID-19 ([Nature](#)). To increase the likelihood of finding and approving a safe, effective vaccine a "[portfolio approach](#)" is being used, i.e. investing in multiple vaccine candidates for testing. To ensure swift roll-out of an approved vaccine, manufacturing capacity is being scaled up and production had commenced even before regulatory approvals were received. According to CEPI's [manufacturing survey](#), published in August 2020, there is capacity to manufacture at least 2-4 billion doses of COVID-19 vaccines before the end of 2021. ([CEPI manufacturing survey](#))



Trade in vaccines for human medicines has increased five-fold since 2005, according to the [WTO](#). The [WHO](#) estimated global demand for vaccines at 3.5 billion doses in 2018. This figure excludes the oral polio vaccine, seasonal influenza and vaccines for the travel and military markets.

Shortages occur regularly. Sixty-nine countries reported vaccine [stockouts](#) (i.e. a shortage of at least a one-month duration) in 2018. Vaccines particularly affected were those for yellow fever, measles and polio.

12 JANUARY 2020

On 12 January 2020, the genetic sequence of SARS-CoV-2, the coronavirus that causes COVID-19, was published. ([WHO](#))

Ambitious national and global targets have been set for **COVID-19 vaccines**. These include, amongst others:

1 BILLION doses

Annual COVID-19 vaccine production capacity is expected to reach 610 million doses by end 2020 and top 1 billion doses in 2021, as per reports from China's State Council and [Xinhua News](#).

300 MILLION doses

The goal of the US Government's [Operation Warp Speed](#) is to produce and deliver 300 million doses of safe and effective vaccines with the initial doses available by January 2021, as part of a broader strategy to accelerate the development, manufacturing, and distribution of COVID-19 vaccines, therapeutics, and diagnostics.

An [evaluation by the WHO](#) of the distribution of the vaccine against the 2009 pandemic influenza A(H1N1) virus (also known as swine flu) highlighted that "specific challenges included managing high volumes with limited transportation options, addressing trade restrictions and dealing with the impact of national registration processes". This evaluation also highlighted difficulties due to a lack of handling facilities to repackage large volumes of cold-chain deliveries at transit points, such as regional cargo hubs.

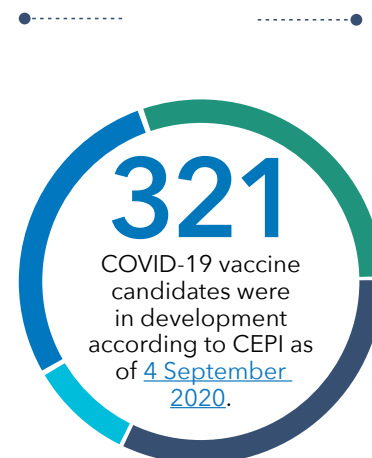
Vaccines are biological products that are sensitive to environmental conditions. They can be damaged by conditions such as high or freezing temperatures or by excessive light, and are effective only for a limited time period at room temperature. Inappropriate transportation or improper storage reduces their effectiveness. Any break in the chain of quality would result in weakened or ineffective vaccine and a reduction in the impact of immunization efforts and of health services as a whole ([WHO Vaccine and Biologicals Guidance](#)).

5 MILLION doses

COVID-19 vaccine production capacity is to reach 5 million doses per month by January 2021, according to the [Ministry of Health of the Russian Federation](#) (August 2020).

2 BILLION doses

According to the [WHO](#) and [Gavi](#), the Vaccine Alliance, 2 billion COVID-19 vaccine doses are to be distributed by the end of 2021, with an allocation for every country equal to 20 per cent of the population so as to cover prioritized target groups.



"rights" of vaccine supply-chain management, according to the [\(WHO\)](#)

- ✓ Right product
- ✓ Right quantity
- ✓ Right condition
- ✓ Right place
- ✓ Right time
- ✓ Right cost

“Vaccines are in development, but their ability to end this pandemic depends on an effective supply chain that can connect diverse production locations to the public”.

Frank Appel, CEO, Deutsche Post DHL Group

Successful immunization programmes are built on functional, end-to-end supply chain and logistics systems. The role of the supply chain is to ensure effective vaccine development, manufacturing, storage, handling, and stock management; rigorous temperature control in the supply chain; and maintenance of adequate logistics management information systems. The goal is to ensure the uninterrupted availability of quality vaccines from manufacture to delivery, so that opportunities to vaccinate are not missed due to the unavailability of vaccines (see [WHO](#)).



APPROXIMATELY

15k

FLIGHTS, AND



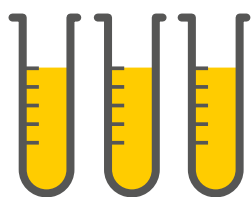
200k

MOVEMENTS BY PALLET SHIPPERS, AND



15m

DELIVERIES IN COOLING BOXES WOULD BE REQUIRED TO SHIP



10 billion

DOSES IN THE STRINGENT AND CONVENTIONAL SCENARIO.

Declarations and statements made by a wide range of [WTO members](#) have, among other things, underscored the importance of well-functioning supply chains and the need to facilitate cross-border flows of vital medical supplies and services. [According to the WHO, the World Intellectual Property Organization \(WIPO\) and the WTO](#), the cross-dimensional coverage of various declarations and statements indicates the importance of a coherent approach to measures to address the pandemic.

While recognizing that governments may take emergency measures to address public health challenges, including shortages of COVID-19 technologies, G20 [trade ministers](#) have called upon countries to ensure that any trade-restrictive measure taken to promote public health be “**targeted, proportionate, transparent, [and] temporary**”.



export prohibitions and restrictions enacted by 43 WTO members and six non-WTO members on COVID-19-related medical goods or devices remained in force in early December 2020.

Source: DHL, McKinsey

Source: [DHL White Paper](#), September 2020.

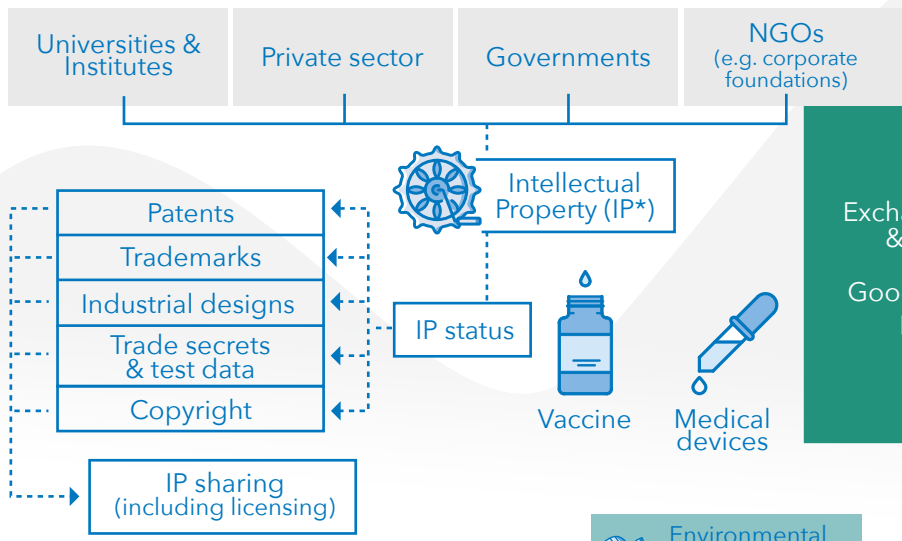
SECTION B:

Overview of the vaccine chain Infographic

DEVELOPING & DELIVERING COVID-19 VACCINES AROUND THE WORLD

1 Vaccine development

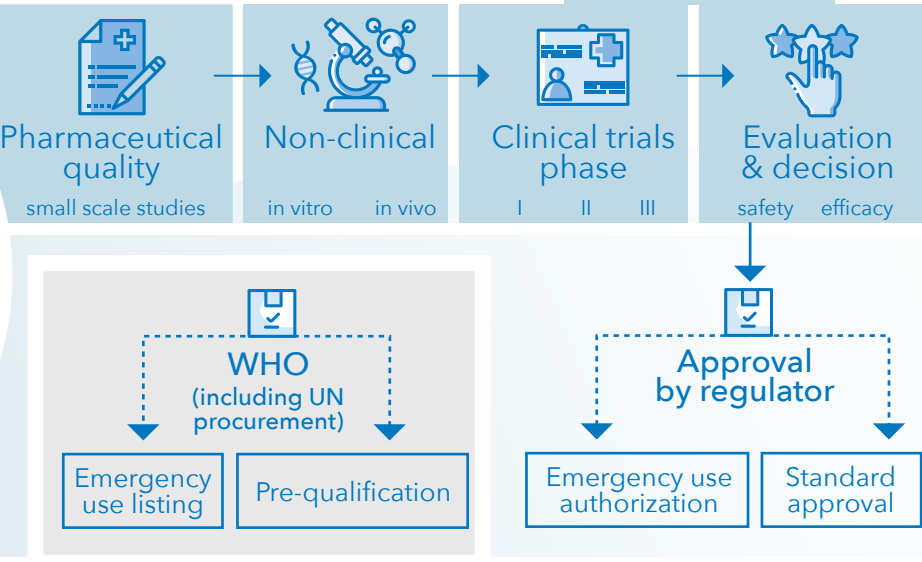
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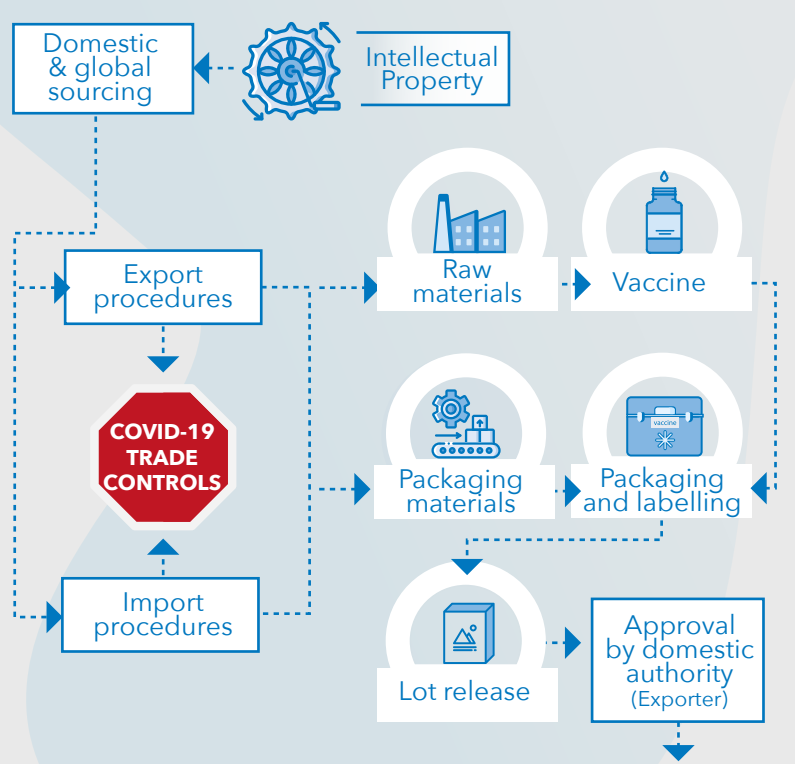
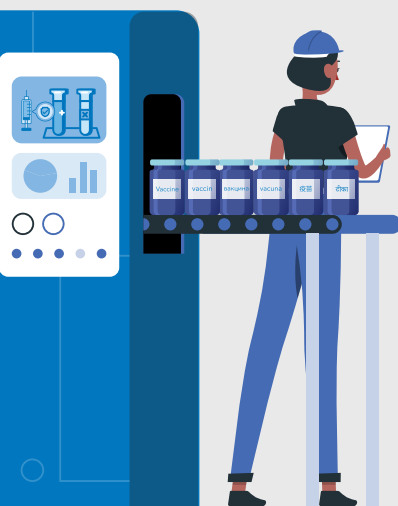
Exchange of data & samples

Good laboratory practice

2 Domestic approval (Manufacture)



3 Vaccine manufacture



Quality control representing up to **70%** of manufacturing time

Several hundred quality control tests

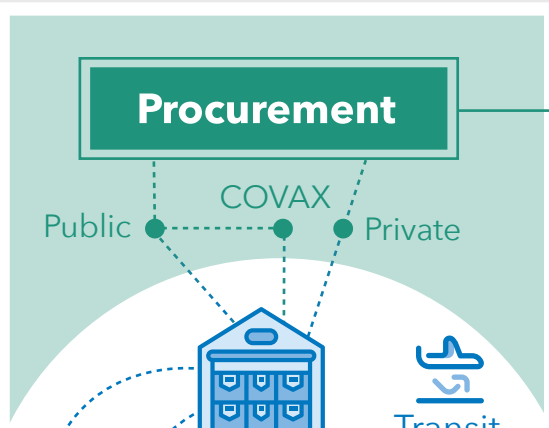
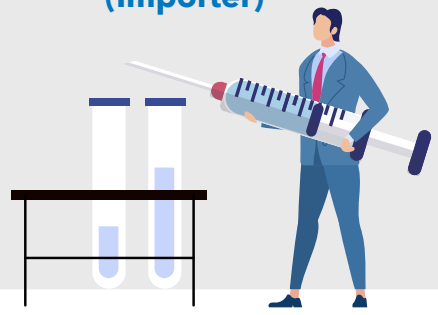
Inspection by regulatory authority (exporter + importer)

Good manufacturing practice

QUALITY ASSURANCE

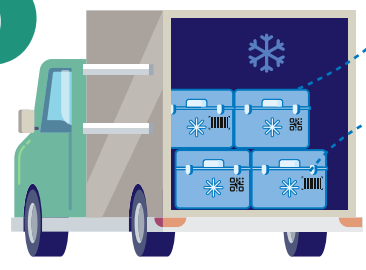
4 Domestic approval (Importer)

Domestic approval (repeat step 2) **OR** Use step 2 approval (WHO or foreign regulator)



- APPROVED** ✓
- Approved by regulator
- Approval of manufacture facility
- Approved for market (labelling, packaging)

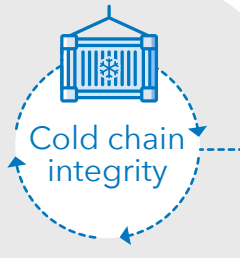
5 International distribution



A vaccine typically travels through several different sites before being ready for shipment

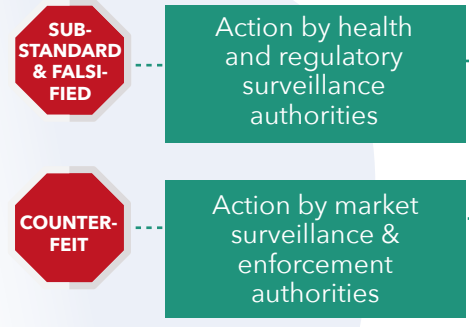
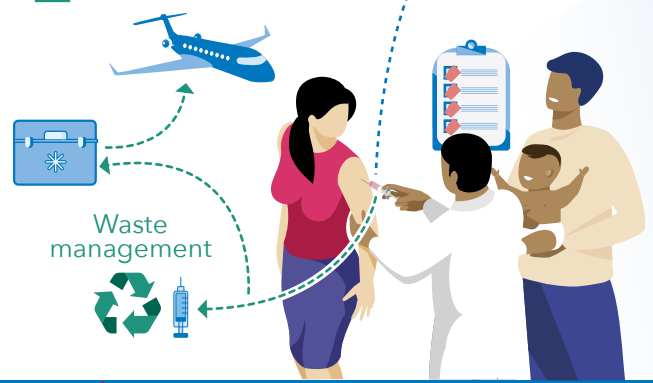
Good distribution practice

6 Border clearance



Metrology

7 Domestic distribution & surveillance



Testing

TRANSPARENCY ESSENTIAL AT EVERY STEP

Source: WTO, based on EMEA, IEPMA. For clarity of presentation, the different steps in the vaccine value chain are presented sequentially. To expedite access, in practice, different steps are being undertaken in parallel. *IP may be generated at multiple steps in the vaccine trade value chain.

SECTION C:

A checklist of trade issues to consider
along the COVID-19 vaccine value chain

STEP 1

Vaccine development

COVID-19 vaccine candidates are emerging from a global web of research and development (R&D) partnerships that bring together universities and research institutes, non-government organizations, governments, the private sector and international organizations. The diversity and geographic spread of parties engaged in R&D is a defining feature of the supply chains that support each step in the vaccine value chain. International standards and guidelines support R&D and reflect the current state of medical technology and scientific knowledge.

The [International Chamber of Commerce \(ICC\)](#) emphasized in April 2020 that the COVID-19 pandemic demonstrated the importance of cross-border scientific collaborations within and between the public and private sector, and of the effective and timely global exchange of scientific information, samples and materials.

Also in April 2020, the WHO issued a [public statement](#) calling for collaboration on the development of a COVID-19 vaccine. An [R&D blueprint](#) was issued by WHO with the objective of accelerating COVID-19 diagnostics, vaccines and therapeutics by improving coordination and accelerating the R&D process. The WHO also released a [concept paper](#) in October 2020 titled "Operationalising the COVID-19 Technology Access Pool (C-TAP)".

Gavi, the vaccine alliance, is using a so-called "[market-shaping](#)" approach that seeks to secure a sufficient and uninterrupted [vaccine supply](#), minimize vaccine costs, and ensure appropriate and quality products. Also noteworthy is the portfolio approach being taken to vaccine development ([WHO](#)). Public procurement can also be used strategically to foster innovation in vaccine development.

[Intellectual property](#) (IP) is created through R&D activities and may also be generated at multiple steps in the vaccine trade value chain. Well-functioning and balanced IP systems give effect to the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights' (TRIPS) objective that the protection and enforcement of intellectual property rights should be "conducive to social and economic welfare".

Enabling these welfare outcomes entails taking into account public policy concerns, including the interests of a wide range of stakeholders, such as start-ups, R&D institutions (both public and private), universities and corporations, as well as the interests of funders, whether public or private, and of the public at large, including, in the case of public health, those of patients, who benefit from equitable access to innovation that meets their needs. Each country can tailor its domestic IP system to its particular needs and circumstances with a view to the public interest, using the TRIPS Agreement and the flexibilities that it provides ([WHO, WIPO and WTO](#)). Some [WTO members and groups of members](#) have made proposals regarding the role of the TRIPS Agreement to address the pandemic.

Public and private actors have launched collaborative global efforts to develop and manufacture therapeutics, vaccines and diagnostics with the aim of guaranteeing equitable access. Actions include committing to non-exclusive and royalty-free licensing, or issuing non-enforcement declarations of patent rights in some or all jurisdictions, publishing scientific data on a free-to-use basis, publishing technical specifications of vital equipment (e.g. ventilators) and sharing knowledge.



More than
6,000 registered scientific studies on COVID-19



2,262 clinical trials of COVID-19 treatments

Source: [COVID-19 - living NMA initiative \(9 December 2020\)](#)



42 candidate vaccines in clinical evaluation



162 candidate vaccines in preclinical evaluation

WHO [landscape](#) of COVID-19 candidate vaccines (10 December 2020).

STEP 1

Vaccine development

Possible issues with trade impact to consider

- Are there policies and regulations in place that promote an effective, timely cross-border exchange of scientific information, data and physical samples both at the research and development stage and at other steps of the vaccine trade value chain?
- What actions can be taken to encourage the exchange of data about COVID-19 vaccines (e.g. studies, clinical trial data, database access) in order to facilitate international R&D collaboration? For example, do domestic laws include public interest clauses that allow clinical trial data to be disclosed? How are “legitimate commercial interests” protected with respect to any confidential information submitted to regulators?
- How can access to investigational products (e.g. drugs, plasma and other medical supplies) needed in COVID-19 vaccine research be facilitated, and how can the quality and safety of these products be assessed promptly?
- How can access to the technical know-how (including as embodied in international standards) needed in COVID-19 research be facilitated?
- What information exists about the IP, data and knowledge relative to the development of vaccines, and how can this information be accessed? What mechanisms are available to incentivize development and support IP-sharing? Do IP laws provide for research exceptions? What policies apply to IP ensuing from publicly funded research? What forms of intervention may be needed to curb or limit IP rights to ensure necessary access and use? What, if any, access and benefit-sharing regimes for pathogen materials apply?
- Is there a focal point within the national administration that can answer requests in relation to establishments licensed to conduct COVID-19-related vaccine R&D?
- Are the results of inspections for quality assurance (e.g. good laboratory practices/good clinical practices and other relevant standards or guidelines) shared?
- How can joint ventures and cross-border cooperation in R&D best be facilitated so as to contribute to effective vaccine development? What measures can be taken to promote further investment in vaccine development, particularly in developing and least-developed countries?
- How can government procurement best be used as a tool to stimulate innovation in health care systems, including in the development and supply of new or improved vaccines?

Non-exhaustive list of WTO resources¹

Agreement on Trade-Related Aspects of Intellectual Property Rights ([TRIPS Agreement](#))

Technical Barriers to Trade ([TBT](#)) Agreement

WHO, WIPO and WTO (2020), *Promoting access to medical technologies and Geneva: Intersections between public health, intellectual property and trade* (second edition), [WHO, WIPO and WTO](#). See in particular Chapters [II](#) and [III](#)

WTO information note: [“The TRIPS Agreement and COVID-19”](#)

Non-exhaustive list of other resources

[WHO Solidarity Call to Action](#)

WIPO COVID-19 [Policy Tracker](#)

World Health Assembly [resolution WHA73.1](#)

WHO [Access to COVID-19 Tools \(ACT\) Accelerator](#)

[Medicines Patent Pool](#)

[Nagoya Protocol on Access and Benefit-Sharing](#)

[WHO PIP Framework](#)



1: This document has been prepared under the Secretariat's own responsibility and the non-exhaustive list of resources is reproduced without prejudice to the positions of Members or to their rights and obligations under the WTO or any of the institutions, agreements or mechanisms cited.

STEP 2

Domestic approval (Manufacture)

A vaccine usually takes more than
10 years to come to market.
(World Economic Forum)



Vaccines are given to healthy individuals, notably infants, as a prophylaxis against a subsequent infection. The quality, safety and efficacy of the vaccine are paramount. According to the COVID-19 Vaccine Global Access Facility ([COVAX](#)), a global pooled procurement mechanism for COVID-19 vaccines, managed by Gavi, the Vaccine Alliance, CEPI and WHO, new vaccines have an approximately 7 per cent chance of succeeding at the preclinical trial stage. Vaccines are assessed for harmful effects not only on humans, but also on the environment.

Vaccines are a diverse class of medical products, so quality/safety evaluation and approval are typically needed on a product-specific basis. Regulatory requirements vary depending on the type of vaccine, the manufacturing process, its mechanism of action and the nature of the disease to be prevented, as well as the target population. In addition to the preparation itself, for some of the potential COVID-19 vaccine candidates, approval may also be required for the medical devices used to store and deliver the vaccine (e.g. needle-free jet injectors, vials, vaccine storage units, etc.).

Vaccines are approved by the relevant [national regulatory authority](#) in charge of assuring the quality, safety, and efficacy of medical products. Due to the complexity of biotherapeutic products, their authorization in general requires more and larger clinical studies as compared with “small-molecule products”. The WHO has developed specific guidelines for biotherapeutic products and some regulatory authorities also apply specific rules (see [WHO, WIPO and WTO](#)). These rules have been further supplemented with technical guidance for COVID-19 vaccine developers (e.g. that provided by the [WHO](#)). Once approved for quality, safety, efficacy and the appropriateness of the product information (e.g. instructions for storage and usage), COVID-19 vaccines may also require a separate [marketing authorization](#) distinct from regulatory approval. The national or regional vaccine approval process will in turn be guided by relevant international standards and guidelines, including those of the WHO. The TBT Committee’s [Indicative List of Approaches to Facilitate the Acceptance of the Results of Conformity Assessment](#) may also be helpful in this regard.

Two main forms of COVID-19 vaccine regulatory approval are available to developers: authorizations for emergency use, and standard approval by national regulatory authorities. Emergency use is an accelerated process to grant approval for a limited time period (e.g. the duration of the public health emergency), based on available scientific information. Examples include the authorization for temporary supply granted by the UK Medicines and Healthcare Products

Regulatory Agency on [2 December 2020](#), the emergency use authorization decisions of the US Food and Drug Administration taken on [11](#) and [18](#) December 2020 and the conditional marketing authorisation given by European Medicines Agency on [21 December 2020](#). Emergency approvals are subject to specific conditions applying to the manufacturer and product (e.g. labelling, provision of testing data, lot release procedures) as determined by the national regulatory authority to ensure quality, safety and efficacy. An example of a standard approval decision is the [official registration](#) by the UAE Ministry of Health and Prevention of an inactivated COVID-19 vaccine.

Vaccine developers may also apply to the [WHO Emergency Use Listing Procedure](#) (EUL). The EUL is a risk-based procedure for assessing and listing unlicensed vaccines. The process aims to assist UN procurement agencies to evaluate available data on the quality, safety, efficacy and performance of vaccines. The EUL provides a time-limited listing for unlicensed products in an emergency context when limited data are available and products are not yet ready to apply for the WHO [Vaccine Prequalification Programme](#).

Regulatory measures to limit liability for unexplained adverse reactions may also provide confidence to commercialize R&D discoveries. A [report](#) by the UK’s National Audit Office explains how protection against liabilities and legal action that could arise from any adverse events have been used in procurement contracts. Similar protections have been agreed in other procurement contracts (see [WEF article](#))

Transparency of approval data and decisions is an important consideration. It is fundamental to ensuring the safety of patients and to ensuring that no product with an unacceptable benefit-to-risk balance will be made available to the public. As described in more detail at Step 4, the national regulatory authority of an importing country may decide to base its approval decision on evaluation reports prepared by other national or regional authorities, or on those of the WHO through the EUL or Prequalification Programme.

Clinical trial data is generally protected against unfair commercial use and unauthorised disclosure, and WTO members have used policy space within the TRIPS Agreement to apply diverse approaches to data protection. For example, some allow a period of data exclusivity, while others allow regulatory authorities to refer to such data when approving follow-on products. Members have in certain cases required the disclosure of clinical trial data in the public interest.

STEP 2

Domestic approval (Manufacture)

Possible issues with trade impact to consider

- What national legislation is applicable for vaccine approval? Is there a focal point within the national administration that can answer requests in relation to relevant legislation?
- Can emergency-use authorizations be issued? If so, under what circumstances and conditions? What is the duration of emergency-use approvals? What liability does the supplier incur?
- Can emergency-use authorizations be issued for medical devices used in conjunction with the COVID-19 vaccine? To the extent necessary, are liability and compensation schemes in place?
- Does the regulatory authority conduct its own assessment (e.g. health and environmental assessments)? If so, does national law provide for the possibility of sharing assessments and approval decisions? What, if any, domestic confidentiality rules apply? Can information from foreign regulators be used to accelerate the process?
- Does the regulatory authority conduct its own assessment (e.g. health and environmental assessments)? If so, does national law provide for the possibility of expediting assessments, and sharing both assessments and approval decisions with regulators in other jurisdictions? What, if any, domestic confidentiality rules apply? Can information from foreign regulators be used to accelerate the process?
- What IP access rules apply to clinical trial data? Do IP access rules for clinical trial data include an exception that allows for the disclosure of such data if this is in the public interest? What arrangements are in place for regulatory approval of follow-on or similar biotherapeutic products manufacturers?



WTO resources (non-exhaustive)

Agreement on Trade-Related Aspects of Intellectual Property Rights ([TRIPS Agreement](#))

Technical Barriers to Trade ([TBT](#)) Agreement

WHO, WIPO and WTO (2020), *Promoting access to medical technologies and innovation: Intersections between public health, intellectual property and trade* (second edition), Geneva: [WHO, WIPO and WTO](#). See in particular [Chapter II](#).

WTO information note: "[The TRIPS Agreement and COVID-19](#)"

Other resources (non-exhaustive)

WHO (2020), "Use of Emergency Use Listing procedure for vaccines against Covid-19 [Q&A](#)".

Gavi, the Vaccine Alliance (2020), "[How emergency use authorisations could accelerate access to COVID-19 vaccines](#)".

Gavi, the Vaccine Alliance (2020), "[The Gavi COVAX AMC: An investment opportunity](#)".

STEP 3

Vaccine manufacture

Vaccine manufacture is supported by complex upstream raw material and component value chains. A typical vaccine manufacturing plant will use in the region of 9,000 different materials sourced from some 300 suppliers across approximately 30 different countries (estimate from the International Federation of Pharmaceutical Manufacturers and Associations). WTO trade statistics suggest that global exports of some particularly critical raw materials for vaccine production (including nucleic acids, amino acid phenols, acyclic amides, lecithins and sterols) grew by 49 per cent in the first six months of 2020 to reach some US\$ 15.5 billion in value.

Pharmaceutical companies increasingly rely on third parties for the timely supply of goods, such as components of medical equipment (e.g. vials, syringes, stoppers) and raw materials (e.g. active pharmaceutical ingredients), machinery and equipment, formulated drugs and packaging materials, critical product components and services. As discussed in [AstraZeneca's 2019 Annual Report](#), all of these raw material inputs are key to operations and are difficult to substitute in a timely manner, or at all, and biologics drug substance production (i.e. drugs made from a living organism or its products) represents a particular constraint. Some raw materials are also subject to seasonal availability (see the 2015 [GlaxoSmithKline plc. article "Turbocharging the effect of vaccines"](#)) or to other ecological supply constraints (e.g. [tachypleus amebocyte lysate](#)).

In view of the complexity of upstream raw material and component value chains, export controls, border clearance and transit issues affecting the sourcing of imported raw materials and other essential components could pose difficulties for scaling up vaccine manufacturing operations (see Step 5). Components, raw materials and technology required to manufacture vaccines may also be subject to intellectual property rights (IPRs). Easy access to information about the IPR status is essential for manufacturers. It is rare that a single entity owns all of the IPRs for the components, raw materials and technology required to manufacture vaccines. Therefore, licensing is key to accessing the supplies and technologies needed for local production and export. Voluntary licensing may facilitate collaboration, partnership arrangements and technology transfer. Compulsory licensing also remains a policy option, (see [WHO, WIPO and WTO](#) for more information).

The vaccine market is not a free and open market and is, in fact, very different from typical pharmaceutical markets, according to a [2017 UNIDO and WHO white paper](#). Vaccines are biological products made from living organisms; their development cycle is quite different from that of a chemical product. Another 2017 report by [UNIDO, AVMI and WHO](#) highlights that the risk of failure in vaccine product development and production is high. Each stage of the vaccine manufacturing process requires significant investment and know-how, with packaging and distribution needing the least and bulk antigen production the most. In general, the manufacturing process for vaccines is much more complex than for pharmaceuticals and necessitates the use of highly specialized facilities and equipment ([UNIDO and WHO](#)).

The complexity of biotherapeutic products means that it takes time for similar biotherapeutic products (SBPs) of approved vaccines to emerge. A further delaying factor is that proving the safety and efficacy of a vaccine, even if it is a "copy" (i.e. an SBP) of an existing one, requires a full regulatory dossier containing data on pre-clinical and clinical trials. This adds time and complexity to the process of making and copying existing vaccines. As explained by [WHO, WIPO and WTO](#), the biotherapeutic market is dominated by originator products (i.e. the product that was first authorized - see [WHO glossary of terms](#)).

In 2018, 17 vaccine manufacturers produced vaccines for [Gavi, the Vaccine Alliance](#), with 11 based in Africa, Asia and Latin America. Sixteen (38 per cent) of the 42 candidate vaccines in clinical evaluation identified in WHO's draft landscape of COVID-19 candidate vaccine in [mid-October 2020](#) involved (sole or partnered) contributions from non-Organisation for Economic Co-operation and Development (OECD)-based entities (i.e. China, Cuba, India, Kazakhstan and the Russian Federation). Forty-five (29 per cent) of the 156 candidate vaccines in pre-clinical evaluation involve non-OECD entity participation (i.e. Argentina, Bangladesh, Brazil, China, Egypt, India, Kazakhstan, Nigeria, Peru, Romania, Russia, Slovenia, Thailand and Viet Nam). The Asian Development Bank (ADB)'s supply chain map for vaccine manufacturing lists 112 suppliers in 24 countries. ([ADB](#)). [CEPI's](#) June 2020 survey of COVID-19 vaccine manufacturing capacity identifies capacity in 41 countries.

Since the outbreak of the COVID-19 pandemic, a broad range of other national and regional measures has been taken to support investment in COVID-19 relevant production capacity. Measures taken are beginning to appear among the [COVID-19 support measures](#) communicated by WTO members as part of reporting on trade-related developments.

Licensing agreements between companies seeking regulatory approval for originator products seek to scale up production for vaccines when they are approved. Market-shaping actions by the Gavi's COVAX Advance Market Commitment (AMC) have facilitated licensing agreements by providing upfront capital to increase manufacturing capacity (see [Gavi's article of 29 September 2020](#))

Advance market commitments (AMCs) are a commonly used measure. These are legally binding contracts whereby one party, such as a national government or Gavi, the Vaccine Alliance, commits to purchasing from a vaccine manufacturer a specific number or percentage of doses of a potential vaccine at a negotiated price, on condition that this vaccine is developed and licensed and proceeds to manufacture. These bilateral agreements often secure priority access to vaccine and manufacturing capacity. AMCs negotiated by national governments have been criticized on ethical and medical effectiveness grounds for skewing distribution of vaccines on the basis of the ability to pay, rather than medical need. It has also been argued that AMCs support a vaccine portfolio development approach since governments that enter into AMCs for candidate vaccines that do not demonstrate evidence of safety and efficacy also risk not getting immediate or sufficient access to successful vaccine candidates. These concerns have been reflected in declarations and statements made by some [WTO members and groups of members](#).

A series of initiatives to address local supply-side constraints in pharmaceutical production have also been given new impetus by the COVID-19 pandemic. These include the African Union's [Pharmaceutical Manufacturing Plan](#) which, through the [Africa Medical Supplies Platform](#), seeks to ensure equitable and efficient access to critical supplies for African governments and expand COVID-19-related medical supplies from local manufacturers. The platform uses pooled procurement - an approach pioneered by the [Pan-American Health Organization](#) (PAHO) [Revolving Fund](#) (RF) in vaccination procurement. Since 1977, the 41 countries and territories participating in the PAHO RF have pooled their resources to procure high-quality vaccines, syringes and related supplies for their populations at the lowest price. The PAHO RF is one of the procurement channels for the [COVAX Facility](#), which applies the lessons learned from the PAHO RF by pooling the purchasing power of its more than 180 participating countries and territories to leverage access to safe and effective vaccines as soon as they receive regulatory approval.

Public procurement plays an essential role in achieving immunization and other public health objectives. The inputs needed for immunization programmes are limited in range (e.g. vaccines, injection devices, safe disposal containers, cold chain equipment), but have specific characteristics that make their procurement challenging, as already outlined by [UNICEF](#) in 2019. Ensuring that financing and regulatory processes and procurement activities work together to secure timely access to products requires the close coordination of stakeholders' efforts. The choice of procurement approach can have an important influence on market development.



In 2017, low and middle-income countries represented 20 per cent of the global vaccine market by value, but 79 per cent by volume.

[WHO, WIPO, WTO](#)

STEP 3 Vaccine manufacture

Possible issues with trade impact to consider

- How can access to raw materials, components and other inputs needed to manufacture COVID-19 vaccines be expedited and costs reduced? Where might export, import and transit controls hamper the timely sourcing of such inputs and the operation of vaccine manufacturing?
- What vaccine-related IP rights exist domestically and in export markets? If local capacity exists to manufacture vaccines or other essential products, how can information about relevant IP be accessed? What actions or interventions may be needed to facilitate or enable access to and use of necessary IP-protected technologies?
- How can governments facilitate technology transfer and local production capacity? How can governments support firms that seek to enter into licensing agreements?
- Is public sector investment in manufacturing taking place/ needed? Is the sourcing of raw materials in inputs by public sector manufacturers covered by public procurement rules?
- How can investment be drawn into vaccine manufacturing, particularly in developing and least-developed countries?

WTO resources (non-exhaustive)

[Trade Facilitation Agreement \(TFA\)](#)

Agreement on Trade-Related Aspects of Intellectual Property Rights ([TRIPS Agreement](#))

Technical Barriers to Trade ([TBT Agreement](#))

WTO information note: "[Export prohibitions and restrictions](#)"

[Import Licensing Agreement](#)

WHO, WIPO and WTO (2020), *Promoting access to medical technologies and innovation: Intersections between public health, intellectual property and trade* (second edition), Geneva [WHO, WIPO and WTO](#). See in particular Chapter [IV](#).

WTO information note: "[The TRIPS Agreement and COVID-19](#)"

Other resources (non-exhaustive)

Coalition for Epidemic Preparedness Innovations ([CEPI](#))

CEPI manufacturing survey ([June 2020](#))

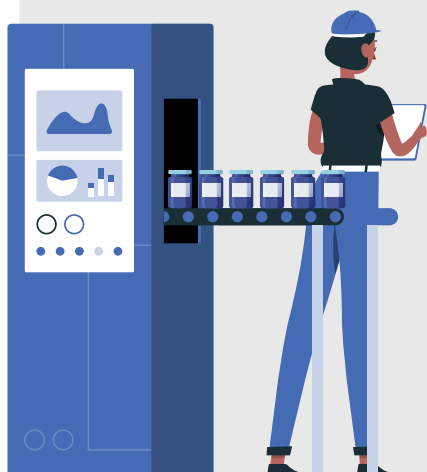
COVAX [Facility](#)

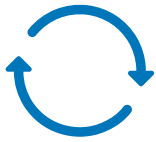
Gavi, the Vaccine Alliance: Financing [mechanisms](#)

World Bank: "[World Bank Approves \\$12 Billion for COVID-19 Vaccines](#)"

UNCTAD [Tool Box](#) for Policy Coherence in Access to Medicines and Local Pharmaceutical Production

[WHO](#): Increasing access to vaccines through technology transfer and local production





Quality assurance - a continuous step

Quality assurance is integral to producing safe, efficacious vaccines. Quality is a broad concept referring to the extent to which a vaccine fulfils requirements, and safety and efficacy are attributes of quality.

According to the Innovation Partnership for a Roadmap on Vaccines in Europe ([IPROVE](#)), some 70 per cent of manufacturing time is consumed by control testing. Quality infrastructure processes (i.e. accreditation, metrology, standards and conformity assessment procedures – see technical [explanation of terms](#)) underpin trade in medical products, providing the confidence needed between trading partners for commerce to happen. Quality assurance and its supporting processes are based upon relevant international standards and guidelines.

The vaccine trade value chain is highly regulated. Manufacturers, distributors, wholesalers, importers, exporters and other entities are licensed by the relevant national (and regional) authority (or authorities). The issuance of a licence is based on compliance with national (and regional) quality and safety regulations (e.g. technical regulations and standards). These national requirements, in turn, are based upon international standards and guidance. On-going operational compliance is ensured through inspections, testing protocols, certification and approval process. Quality assurance extends upstream to the raw materials and components needed for vaccine production and downstream to post-market surveillance. Quality assurance and testing of vaccines starts before, and continues well after, the factory gate.

Vaccines are varied in their production processes and the technology they use, e.g. whether they are protein-based, non-replicating viral vectors or DNA vaccines. Hence the equipment and processes to produce each vaccine differs. Approval of manufacturing facilities is an essential part of the regulatory approval process, notwithstanding the fact that a manufacturing facility may already be approved for (other) vaccine production. Regulatory agencies periodically inspect manufacturing facilities to evaluate compliance with applicable regulations and identify potential deficiencies.

Vaccine manufacturers meet quality assurance regulations not only in the “domestic market” (i.e. one in which a regulatory approval has been given) but also in other countries in which these vaccines are licensed, manufactured or sold. Quality assurance rules and the processes required to demonstrate compliance can differ from one WTO member to another. Promoting coherence and compatibility of regulations on vaccines, including by aligning with international standards and guidelines, is therefore important. For example, more than 100 countries have incorporated [WHO good manufacturing practice \(GMP\) guidelines](#) into their national laws, but both the specific provisions of GMP requirements and the compliance procedures are often country-specific. GMP approval in one country does not confer automatic recognition in another. Regulatory divergence further extends across other elements of conformity assessment, such as sampling methods, inspection protocols, testing results, etc. An additional challenge in the current COVID-19 pandemic is that sanitary restrictions have reduced the ability of regulatory authorities to conduct inspections, both in-country and in manufacturing facilities in other countries.

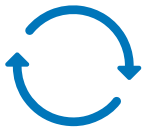
With multiple COVID-19 vaccines on track to secure regulatory approval in various WTO members, but at different times, quality assurance approval processes merit consideration if prompt distribution is to be ensured. As per a recent [information note](#) published by the WTO on standards and regulations, various measures to enhance regulatory approval and cooperation on standards for COVID-19-related medical goods have been notified to the WTO. These include measures to expedite regulatory assessments, accept (unilaterally or bilaterally as a result of a mutual recognition agreement) certification and approval already given by other members, and allow for certain flexibilities, such as remote or electronic conformity assessment procedures. A range of options are elaborated in the TBT Committee’s [Indicative List of Approaches to Facilitate the Acceptance of the Results of Conformity Assessment](#).

Metrology (i.e. the science of weights and measures), together with others pillars of quality infrastructure, is indispensable for the integrity of the “cold chain”. According to the United States [Center for Disease Control](#), “assuring vaccine quality and maintaining the cold chain is a shared responsibility among manufacturers, distributors, public health staff, and health-care providers”. Among the key elements of an effective cold chain is reliable storage and temperature monitoring equipment. Vaccine potency is reduced by exposure to improper conditions, such as to heat, cold or light. Reliable temperature measurements are therefore essential. Calibration testing is done to ensure the accuracy of a temperature monitoring device’s readings against nationally accepted standards.

Labelling provides vital information related to quality assurance of the vaccine. For instance, labelling traditionally conveys information about product usage, expiry, storage recommendations, formulation and warnings. For COVID-19 vaccines which require ultra-cold conditions, “smart labels” are expected to play an essential role in monitoring quality in real time. A vaccine vial monitor is a special type of smart label which is described by the [WHO](#) as a “label containing a heat-sensitive material which is placed on a vaccine vial to register cumulative heat exposure over time”. According to Gavi, the Vaccine Alliance, developing high-performance vaccine vial monitors will be essential for monitoring and ensuring the efficacy of COVID-19 vaccines that rely on cold chain conditions.

**SEVERAL
HUNDRED**
quality control tests are
performed on a vaccine
during its manufacturing
journey.

(International Federation of Pharmaceutical
Manufacturers & Associations - [IFPMA](#))



Quality assurance

Possible issues with trade impact to consider

- How can processes to demonstrate compliance with quality/safety requirements, such as good manufacturing practice, be expedited without compromising vaccine safety, quality and efficacy?
- How can cooperation between regulatory authorities on the inspection of COVID-19 vaccine production sites be promoted?
- How can test results, certification and vaccine lot release systems be operated to meet both international standards and the requirements of importing countries?
- What measures can be taken by exporting countries to promote quality assurance?
- Can standard labelling and packaging be accepted by the importing country?
- How will technical specifications for government procurement systems be formulated? How can the agencies that will approve the vaccine be involved in their formulation to avoid unexpected difficulties at the approval stage? Which procurement methods will be used?
- Will customs and other border officials accept suppliers' declarations of conformity? If not, what other type of certification (e.g. third-party certification) must be produced for border clearance?
- What measures need to be taken to ensure that local testing results and quality/safety assurance samples can be transmitted back through the vaccine trade value chain to relevant actors (e.g. regulators and vaccine developers or manufacturers)?
- Does the national quality infrastructure ensure accurate and reliable measurements (and other services) to ensure the integrity of the cold chain?

WTO resources (non-exhaustive)

Technical Barriers to Trade (TBT) Agreement

WTO information note: "[Standards, regulations and COVID-19 - What actions taken by WTO members?](#)"

WTO TBT Committee discussions on [Quality infrastructure](#)

Other resources (non-exhaustive)

CEPI centralized laboratory [network](#) to standardize COVID vaccine assessment

Gavi, the Vaccine Alliance - [Smart labels](#)

International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) guidelines on terminology and electronic standards for the transfer of regulatory information.

International Network on Quality Infrastructure ([INetQI](#))

[ISO](#) list of national resources to support the fight against COVID-19

The Medical Device Single Audit Program (MDSAP) run by the [International Medical Device Regulators Forum](#) allows an MDSAP recognized Auditing Organization to conduct a single regulatory audit of a medical device manufacturer that satisfies the relevant requirements of the regulatory authorities participating in this international forum.

[OECD](#) regulatory quality and COVID-19

The [Pharmaceutical Inspection Co-operation Scheme](#) is a non-binding, informal cooperative arrangement that shares the results of good manufacturing practice inspections among its [53 participating authorities](#).

[WHO](#) quality assurance of essential medicines and health products

[WHO](#) Expert Committee on Biological Standardization

[WHO](#) documents for SARS-CoV-2 vaccines and other biologicals

[WHO](#) regulatory authority lot release system

[WHO](#) guidance for SARS-CoV-2 COVID-19 treatment - medicines (on quality assurance in general)

[WHO](#) vaccine vial monitor

STEP 4

Domestic approval (Importer)

Proper regulatory decision-making in a time-efficient manner could have an important impact on saving lives and mitigating the COVID-19 pandemic, according to the [WHO and UNICEF](#). Regulatory alignment, collaboration and information-sharing will help to facilitate equitable access to safe and efficacious vaccines that meet international quality and manufacturing standards. A high degree of cooperation will be required due to the large number of vaccines under development and countries which could benefit from such vaccines.

The list of official documents that vaccine manufacturers must provide the regulatory authorities of importing countries when seeking approval for a new vaccine, or related medical products, can be long and includes clinical trial data, registration dossiers, operating licences, product marketing authorizations, quality assurance certification and environmental risk assessments. In addition, requirements are not uniform from one country to another. Formats differ (e.g. electronic, paper and also the way in which clinical trial data must be presented), translations can take time (e.g. documents will normally need to be completed in the official language(s)), registration timeframes may vary in duration, and the governmental entities from which approvals are required can differ significantly (e.g. the approval of sub-national authorities may be necessary). Information about regulatory requirements may be unavailable, or out of date.

Regulatory adaptation is critical during public health emergencies, and thus the [WHO and UNICEF](#) are encouraging national regulatory authorities to modify traditional, reactive control systems and to take a proactive, risk-based approach in order to speed up public access to life-saving medical products. To facilitate regulatory alignment and cooperation, the WHO has developed product-specific roadmaps to assess the safety, efficacy and quality of candidate vaccines (e.g. that of [Astra-Zeneca](#)). A variety of options exist to speed up the approval process, including:

- Recognition of and/or reliance on the approval granted by [stringent regulatory authorities](#) or [WHO-listed authorities](#) is among the regulatory options available for national regulatory authorities. The TBT Committee's [Indicative List of Approaches to Facilitate the Acceptance of the Results of Conformity Assessment](#) may also be relevant in this regard.

1 BILLION

UNICEF plans to procure 1 billion syringes by the end of 2021 to guarantee a supply of COVID-19 vaccines. UNICEF and the PAHO Revolving Fund are coordinating procurement and supply of vaccine for the [COVAX](#) Facility.

35%

The WHO's global vaccine report identified procurement delays as being responsible for 35 per cent of vaccine stockout incidents among middle-income countries in 2018.

- Emergency use approval. A regulatory authority can use discretionary powers to waive certain product authorization requirements to allow importation and marketing on a temporary basis (see further discussion of this in Step 2).
- Recognition and/or reliance on the WHO prequalification/ Emergency Use Listing ([EUL](#)) decisions. WHO determines the acceptability, in principle, of vaccines for [UNICEF](#) and other UN agencies through its [prequalification programme](#). UNICEF procures more than 2 billion doses of vaccines annually and is coordinating the procurement and supply of COVID-19 vaccines for the [COVAX](#) Facility.

Vaccine procurement decisions by public and private entities are entwined with approval processes. Decisions on vaccine selection, the establishment of immunization schedules, demand quantification, the preparation of procurement specifications, contract awards and other functions depend on approval procedures. With multiple COVID-19 vaccines potentially becoming available on the market, care may need to be exercised to ensure that best international practices on government procurement, notably as embodied in the WTO Government Procurement Agreement ([GPA](#)), are followed. The GPA sets binding minimum standards for transparent, fair and open public procurement procedures. The GPA also includes procedural flexibilities (e.g. shorter time periods to accelerate procurement and limited tendering) as well as general exceptions that can be used to protect human life. E-procurement and the [publication of procurement decisions](#) can be helpful in accelerating procurement and enhancing transparency. They are among the steps already taken by WTO members according to information [shared with the WTO](#). Patent databases may help to inform the procurement of COVID-19 vaccine and vaccine-related health products.

Knowledge about what intellectual property rights apply in the importing member, including as determined by its intellectual property [exhaustion](#) regime, can help to inform the importer about whether voluntary or compulsory licences are needed to ensure the smooth flow of vaccines across borders.

STEP 4 Domestic approval (Importer)

Possible issues with trade impact to consider

- What measures can be taken by importing countries to expedite the domestic approval of COVID-19 vaccines while ensuring safety and efficacy? Are domestic approval procedures published and available, e.g. on the internet?
- Can the results of a domestic approval decision taken at Step 2 be accepted and used by the importing country's regulatory authority to approve COVID-19 vaccines and other related products?
- Can import approval be based on WHO decisions, including vaccine pre-qualification? If the importing country's regulatory authority requires foreign-approved COVID-19 vaccines to pass through a domestic approval process, can information from foreign regulators be used to accelerate this process? Can the assessment and decision be shared with other countries? Can emergency-use authorizations be issued for COVID-19 vaccines and related medical devices?
- How can intellectual property information related to the vaccine be accessed? What intellectual property, if any, applies to the vaccine in the importing country? For least-developed countries, has the temporary exemption from the requirement to protect and enforce patents and clinical trial data for pharmaceutical products been implemented domestically? Has a tailored regime for the exhaustion of intellectual property rights been implemented?
- Which entity/entities (both public and private) will take procurement decisions and how will they be coordinated, including with regard to contract management and the distribution of vaccines? How will contract management and the distribution of vaccines be organized? How can domestic approval and procurement decisions be synchronized so as to avoid delays?
- Are appropriate procurement procedures and mechanisms in place to ensure efficient public purchasing of vaccines? How can procurement flexibilities in domestic legislation and trade agreements be used to promote rapid access to an approved COVID-19 vaccine? Which obligations in the WTO trade agreements (e.g. the Government Procurement Agreement or in regional trade agreements) continue to apply, if any?
- Which procurement methods will be used? Is safety and efficacy ensured through use of appropriate technical specifications/supplier qualification requirements? How is quality control ensured?

WTO resources (non-exhaustive)

General Agreement on Tariffs and Trade ([GATT](#)) 1994

Agreement on Trade-Related Aspects of Intellectual Property Rights ([TRIPS](#) Agreement)

Government Procurement Agreement ([GPA](#))

Technical Barriers to Trade ([TBT](#)) Agreement

The TBT Committee's [Indicative List of Approaches to Facilitate the Acceptance of the Results of Conformity Assessment](#) (see page 60).

WHO, WIPO and WTO (2020), Promoting Access to Medical Technologies and Innovation: Intersections between public health, intellectual property and trade (second edition), Geneva: [WHO, WIPO and WTO](#). See in particular Chapters II and IV

Other resources (non-exhaustive)

The COVID-19 Vaccine Global Access Facility ([COVAX Facility](#))

International Coalition of Medicines Regulatory Authorities ([ICMRA](#)) acts as a forum to support strategic coordination and international cooperation among global medicine regulatory authorities during the COVID-19 pandemic.

The Open Contracting [Partnership Guide](#) collects, publishes and visualizes COVID-19 procurement data.

The Open Contracting Partnership [findings and recommendations](#) for better emergency procurement from 12 countries

Pan-American Health Organization (PAHO) [Revolving Fund](#)

UNICEF vaccine procurement [toolbox](#)

[UNICEF](#) procurement and shipment information for COVID-19 related goods and services

- How is transparency ensured when determining procurement needs, publishing procurement opportunities and decisions, and enabling governments and other interested stakeholders to review procurement outcomes after the fact?
- How can national authorities make use of initiatives such as the [COVID Technology Access Pool](#), [COVAX](#) and the [Medicines Patents and Licenses Database](#) in their public procurement processes?

WHO guidelines on [import](#) procedures for medicinal products

[WHO regulation](#) of vaccines: building on existing drug regulatory authorities

WHO system for the [prequalification](#) of vaccines for UN supply

[WHO](#) vaccine procurement mechanisms and systems

World Bank (2020), "[World Bank Approves \\$12 Billion for COVID-19 Vaccines](#)", press release, 13 October 2020.



STEP 5

International distribution

Time is of the essence for global vaccine distribution, so the speed and reach of aviation will be a critical factor in prompt COVID-19 vaccine distribution and to enable economies, regardless of their geographical locations, to access vaccines and related supply chains. Air transport plays a pivotal role for many developing countries, allowing them to overcome infrequent shipping services or poor infrastructure for ground transportation, according to the [International Civil Aviation Organization \(ICAO\) and the World Customs Organization \(WCO\)](#). However, widespread COVID-19-related travel restrictions and weak passenger demand have constrained the frequency of international flights since the beginning of the pandemic, with a knock-on effect on air cargo, as a large portion of air cargo is carried in the hold of passenger planes. In September 2020, available international cargo capacity remained down 28 per cent year-on-year according to the International Air Transport Association ([IATA](#)), and the WHO, UNICEF and Gavi, the Vaccine Alliance are reporting difficulties in regular planned vaccine programmes due to limited air connectivity ([UNICEF](#)).

Quarantine measures and related health controls are another limiting factor for air cargo operations. In response, the ICAO has instituted a [public health corridor](#) concept for air cargo crews and relief operations which, unless individuals exhibit COVID-19 symptoms, exempts them from quarantine, travel bans and pre-departure and on-arrival testing.

Vaccines must be handled and transported in line with international regulatory requirements, at controlled temperatures and without delay to ensure the quality of the product. While the distribution of COVID-19 vaccines needs very stringent temperature requirements (which in some cases may be as low as -80°C), structural challenges, such as the enabling of high-performance cold chain logistics, can only be overcome through technological advances and policy intervention, as outlined by a recent [DHL white paper](#). According to the Global Express Association ([GEA](#)), guidance may be needed for vaccine shippers and manufacturers so that operators are not forced to reject shipments for non-compliance with dangerous goods shipping requirements (e.g. dry ice for vaccine refrigeration or other dangerous goods). If specialized reusable cold storage containers and equipment are required, it will then be essential to ensure that their rapid reutilization for distribution in other countries is not unnecessarily delayed.

Poor transportation and storage, including breaks in cold chain integrity, can lead to patients receiving substandard, unsafe or impotent vaccines. Ensuring consistent temperature management throughout the last-mile network is complex. ([DHL](#)). One regulatory consideration that governments may need to consider is how to allow, prioritize and facilitate temperature-sensitive end-to-end delivery by international logistics suppliers, including through multi-modal transport. Governments may wish to consider whether fast-track approval for entry and operations of such suppliers may be needed and whether certain requirements (e.g. local partnerships and foreign equity limits) may be relaxed or waived so as to facilitate distribution of the vaccine.

To help prioritize and facilitate end-to-end delivery of temperature-sensitive products, [UNICEF](#) has been mapping cold chain equipment and storage capacity for some time and preparing guidance for countries to receive vaccines. With support from Gavi, the Vaccine Alliance, and in partnership with WHO, UNICEF is upgrading cold chain equipment. Since 2017, over 40,000 solar-powered cold-chain fridges have been installed, mostly in Africa.

As per [ICAO and WCO](#), air cargo is handled by several entities with varying responsibilities along the trade value chain, including aircraft operators, express carriers, postal operators, regulated agents, consignors, consignees, hauliers and ground handlers. Time will be needed to train staff in appropriate handling techniques and to make relevant equipment available. A [report](#) by the UK's National Audit Office highlights the estimate of NHS England and NHS Improvement that it may need up to 46,000 staff to deliver the COVID-19 vaccination programme (based on a 75 per cent take-up rate). An [evaluation by the WHO](#) of the deployment of vaccines to treat the pandemic influenza A(H1N1) virus highlighted difficulties due to a lack of handling facilities to repackage large volumes of cold-chain deliveries at transit points.

Another consideration is transit. Cargo may transfer between several different flights before it reaches its final destination and consignments may be subjected to a variety of procedures and documentary requirements ([ICAO and WCO](#)). The disciplines of the WTO Trade Facilitation Agreement on [freedom of transit](#) are relevant in this regard. Vaccines should be able to transit through a WTO member's territory without the intellectual property rights (IPRs) which exist in the country of transit creating a barrier to legitimate trade.

In the absence of sufficient local manufacturing capacities, many developing countries are heavily dependent on imports of vaccines which are either donated or sold at reduced prices. This may significantly increase the economic interest of diverting these vaccines into higher-priced markets. In order to ensure that vaccines reach and stay in a destination country, appropriate measures, including but not limited to those required under the Agreement on Trade-Related Aspects of Intellectual Property Rights, need to be taken by the importing country against unlawful diversion to prevent re-exportation of the vaccines, and by all WTO members to prevent the importation and sale of diverted vaccines in their territories.

Of the export prohibitions and restrictions (see the related [WTO information note](#)) on COVID-19-related medical goods or devices reported to the WTO, some 58 measures enacted by 43 WTO members and six non-WTO members remained in force in early December 2020. From a logistical standpoint, such measures can greatly complicate an already mammoth and complex task. Furthermore, vaccines can only be administered if appropriate injection equipment is also available. County-specific labelling and packaging requirements add a further challenge for entities involved in the international distribution of COVID-19 vaccines.

Transparency and clarity as to regulatory requirements is critical. Timely WTO notifications (including on an emergency basis) of proposed changes to technical regulations and conformity assessment procedures are important to keep stakeholders abreast of latest information on trade-facilitating measures, and to provide opportunities for comments (on this subject, see the [WTO information note on standards, regulations and COVID-19](#)). In addition, the [ePing](#) alert system provides email alerts about notified changes to technical barriers to trade measures, and these alerts can be tailored to COVID-19-related notifications.



8,000

747 CARGO
PLANES

would be needed to provide a single-dose COVID-19 vaccine to 7.8 billion people, according to [IATA](#)

“If borders remain closed, travel curtailed, fleets grounded and employees furloughed, the capacity to deliver life-saving vaccines will be very much compromised”

Alexandre de Juniac, Director General and CEO, [IATA](#)

STEP 5 International distribution

Possible issues with trade impact to consider

- What measures can governments take to support the airline industry to expand air cargo capacity for vaccine distribution? How might governments use ICAO health protocols to facilitate air cargo operations?
- What measures can governments take to ensure that export restrictions and prohibitions do not affect access to the raw materials and components needed to manufacture COVID-19 vaccines and do not further complicate the task of COVID-19 vaccine distribution?
- What can a country of transit do to expedite the passage of COVID-19 vaccines through its territory? How can transit be assured if the vaccine is not approved, or is subject to intellectual property rights or export controls?
- How can governments ensure that relevant WTO Trade Facilitation Agreement disciplines on transit are respected? (These disciplines cover exempting transit goods from the technical regulations and conformity assessment procedures of the transit member and allowing for advance processing of transit documentation prior to arrival.) Measures could be envisaged to speed up transit consignments, together with provisions on guarantees (if applicable).
- What measures can governments take to facilitate time-sensitive cold chain distribution, notably by air cargo and other logistics service providers (e.g. pre-arrival processing, transit, and other WTO Trade Facilitation Agreement provisions)?
- What measures can border agencies take to facilitate the entry of transport crews linked to vaccine distribution?
- What can governments do to prevent the unlawful diversion of vaccines to other markets?

WTO resources (non-exhaustive)

WTO information note: "[Export restrictions and prohibitions](#)"

General Agreement on Tariffs and Trade ([GATT 1994](#))

General Agreement on Trade in Services ([GATS](#))

Agreement on Trade-Related Aspects of Intellectual Property Rights ([TRIPS Agreement](#))

[Trade Facilitation Agreement \(TFA\)](#)

Trade Facilitation Agreement Facility ([TFAF](#)) COVID-19 Trade Facilitation Resource Repository

Trade Facilitation Agreement Database ([TFAD](#))

WHO, WIPO and WTO (2020), *Promoting Access to Medical Technologies and Innovation: Intersections between public health, intellectual property and trade* (second edition), Geneva: [WHO, WIPO and WTO](#). See in particular Chapter [IV](#).

WTO information note: "[Standards, regulations and COVID-19](#)"

Technical Barriers to Trade ([TBT](#)) Agreement

List of TBT [enquiry points](#)

[ePing](#) alert for TBT notifications

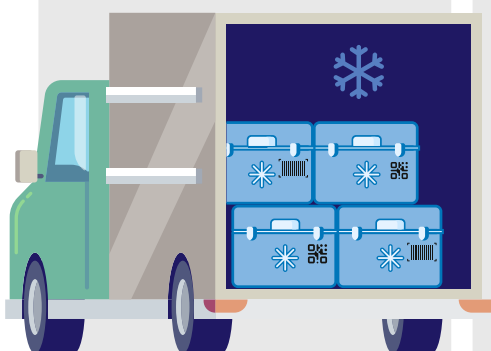
Other resources (non-exhaustive)

[Global Express Association](#) (2020), "COVID-19 Vaccine Distribution: Getting Ready", October 2020.

International Civil Aviation Organization ([ICAO](#)) COVID-19 Health Protocols

[International Civil Aviation Organization \(ICAO\) and the World Customs Organization \(WCO\)](#) (2020), "Moving Air Cargo Globally Air Cargo and Mail Secure Supply Chain and Facilitation Guidelines", second edition.

WHO [Guidelines](#) on the international packaging and shipping of vaccines



STEP 6

Border clearance

Measures taken by customs and other border agencies to expedite border clearance procedures at the onset of the pandemic have provided a solid basis for further border agency cooperation and actions to facilitate the entry of COVID-19 vaccines (see also the recent [WTO information note](#) on this subject). Actions taken have included:

- prioritization of customs clearance for “COVID-19-related” goods (e.g. medical goods);
- establishing special procedures to expedite consignments of medical equipment to authorized operators;
- temporary suspension or simplification of import licensing procedures;
- accepting the electronic submission of documents for pre-arrival processing;
- temporary suspension or simplification of origin requirements;
- simplification of import and export forms; and
- implementation of green lanes under the guidelines for border management measures (see for example the European Commission [communication](#) on upgrading the transport Green Lanes during the COVID-19 pandemic resurgence).

Many of these measures were time-limited and sought to expedite access to certain critical COVID-19 supplies during the first phase of the pandemic, notably personal protection equipment, sanitizers, disinfectants, medical equipment and medicines/drugs. These measures were tracked by WTO [trade monitoring](#) and WTO members’ notifications, many of which were summarized in September 2020 in a [WTO information note](#). In addition, some [WTO members and groups of members](#) have made proposals and statements on COVID-19 and world trade.

Additional measures may be needed to ensure smooth distribution of vaccines. Applicable procedures and formalities within and among the relevant authorities should facilitate rather than obstruct access to COVID-19 vaccines (see [WHO and UNICEF](#)). For example, the International Air Transport Association ([IATA](#)) has suggested that border agencies work with private sector partners to examine where further opportunities exist to implement trade-facilitating measures, standards, tools and guidance that would support the fast

processing of vaccines and of pharmaceutical, life science and medical products. National Trade Facilitation [Committees](#), which already group key stakeholders at the national level, could provide a forum for this cooperation and coordination. The World Customs Organization ([WCO](#)) agreed in December 2020 on a resolution on the role of customs in facilitating the cross-border movement of situationally critical medicines and vaccines; this resolution lists 12 measures that customs authorities can take to facilitate the clearance of these goods.

Timely implementation of applicable procedures should be ensured authorities, and the national regulatory authority should be able to grant import permits expediently (see [WHO and UNICEF](#)). Intermittent storage of the vaccine at the port(s) of entry is discouraged and immediate customs clearance should be facilitated where possible. All entities relevant to import controls, including the national regulatory authority, the customs control authority, the national control laboratory and the port control authority, should coordinate their activities with the objective of enhancing and speeding up the importation and clearance of COVID-19-related medical products, including by highlighting administrative processes that could delay customs clearance processes and addressing these bottlenecks ahead of time (see [WHO and UNICEF](#)).

One noteworthy concern is that the scarcity of specialized cold chain equipment, including reusable cold storage containers, could inadvertently be exacerbated by slow or inefficient border clearance processes. Requirements to post financial guarantees or bonds for cold chain equipment could delay the re-export of such items and their timely reuse in the transport of additional vaccines, thereby slowing down global distribution. Temporary admission procedures allow the entry of goods “conditionally relieved, totally or partially from payment of import duties and taxes”, when the goods enter “for a specific purpose, are intended for re-exportation within a specific period, and have not undergone any change except normal depreciation and wastage” ([Article 10.9 of the WTO Trade Facilitation Agreement](#)). The international standards set out in the World Customs Organization’s [Convention on Temporary Admission \(Istanbul Convention\)](#) and [Customs Convention on Containers 1972](#) are also germane. These standards provide for temporary admission of containers, pallets and packings without the requirement of a customs document or security.

Another source of concern is that COVID-19 control measures may have slowed border clearance processing times. Custom clearance can be a lengthy process, exacerbated by insufficient personnel or a lack of coordinated fast-track processes ([DHL](#)). Expedited [procedures](#) for vaccines arriving as air cargo, such as [pre-arrival processing](#) (including clearance at the importer's premises - a practice that could relieve pressure on cold storage at the port of entry), priority clearance (including outside standard business hours) and electronic payments could be envisaged, together with enhanced coordination between health and customs officials, notably in risk-based cargo inspection so as to respect cold chain integrity.

The WHO advises that vaccines procured from assured sources - i.e. WHO prequalified vaccines, vaccines given WHO Emergency Use Listing ([EUL](#)), or vaccines approved by [stringent regulatory authorities](#) - need not be tested again by receiving countries, as they have been tested and released already by national regulatory authorities with stable, formal approaches for vaccine approval. If countries are required by law to review the summary lot protocols, vaccine release should be done quickly and on the basis of the review of the minimum of necessary documents, as advised by WHO. Countries may also wish to explore whether there can be any law or exception granted in the case of emergency use of a vaccine with existing stringent regulatory authority approval (see [WHO and UNICEF](#)).

Inclusion of COVID-19 vaccines and related products in [national lists](#) of essential goods to combat COVID-19 for priority clearance may be helpful in reducing or avoiding clearance delays. Special procedures to expedite consignments of medical equipment shipped by approved operators are a further possibility. Where scope exists, the waiving or deferral of customs duties, internal taxes, fees and charges could also be envisaged (see [UNICEF](#)). However, care may need to be exercised to ensure that such measures are implemented on a most-favoured-nation basis (i.e. treating other economies in an equal manner, without discrimination) and do not discriminate arbitrarily between different suppliers. Publication through different channels, including online, of information about accelerated procedures for import, export and transit, together with the required forms and documents, is an important step toward transparency, together with ensuring that enquiry points can provide accurate and up-to-date information.

Since the outbreak of the COVID-19 pandemic, the threat posed by fake medicines and medical products has increased dramatically. Organized crime groups have been taking advantage of the high market demand for medicines, personal protection equipment and hygiene products, and have been making lucrative profits from the sale of fake items, according to the International Criminal Police Organization ([Interpol](#)). During a public health crisis such as the current COVID-19 pandemic, tackling this global problem becomes even more acute and urgent. With the arrival of COVID-19 vaccines on the market, according to the United Nations Office on Drugs

and Crime ([UNODC](#)), it can be expected that criminal acts will extend to those products.

Trademark counterfeiting is another potential concern. In international trade, a trademark plays an important role as a trade identifier and indicates a trade source, which helps to identify fake products. Counterfeiters use a sign identical to or confusingly similar to the registered trademark without authorization by the right-holder, thus falsely representing its identity and source in order to pass it off as the genuine product. Intellectual property enforcement measures to combat trademark counterfeiting both at the border and on the domestic market can thus have positive side effects, potentially supporting efforts to keep dangerous products out of the market (see [WHO, WIPO and WTO, 2020](#)). To support the real-time exchange of relevant information to fight the trafficking of counterfeit medical supplies, the WCO and its members are exchanging intelligence information through regional intelligence liaison offices ([RILO](#)). This information includes messages and alerts via the secure channels developed under the Customs Enforcement Network Communication Platform ([CENcomm](#)) and the Customs Enforcement Network ([CEN](#)), which is a database of seizures and offences, as well as pictures required for the analysis of illicit trafficking in the various areas under the competence of customs ([WCO](#)).

153 WTO members

have ratified the Trade Facilitation Agreement (TFA).

Implementation of scheduled commitments stands at

66.5 per cent.

([TFA Database](#))

139 WTO members

have implemented temporary admission [provisions](#) in the TFA, while a further 21 members have indicated that they need more time or technical assistance to comply.

([TFA Database](#))

STEP 6 Border clearance

Possible issues with trade impact to consider

- What procedures are needed to ensure timely, appropriate communication between border agencies and health regulatory authorities? What role can the National Committee on Trade Facilitation, or another entity, play in the coordination of the different stakeholders? How can the National Committee on Trade Facilitation, or another entity, ensure interaction between government agencies and the private sector actors involved in the manufacture, transport and distribution of vaccines and related equipment?
- What measures (e.g. pre-arrival processing, electronic payment and other TFA disciplines) can border agencies take to expedite clearance for approved COVID-19 vaccines and other materials needed for immunization campaigns? Can electronic documentation be submitted?
- Can special procedures be used to expedite consignments of medical equipment to authorized operators? Do COVID-19 vaccines and related equipment appear in national lists of essential goods?
- Will the importation of vaccines and related materials be subject to import licensing, rules of origin and other requirements? Will import tariffs, internal taxes or other fees and charges be waived, eliminated or reduced? If so, how and for what duration?
- What measures can border agencies take to ensure cold chain integrity (i.e. that vaccines are kept at the right temperature to remain potent) throughout the border clearance process and by border clearance service providers? What measures can be taken to minimize or eliminate the need for physical inspections? If physical inspections must be applied, how can these be undertaken jointly between health and customs officials on the basis of risk-based assessments?
- How can border agencies enhance cooperation to facilitate cross-border trade by ensuring that delays do not occur at border crossings?
- What measures can border agencies take to simplify the formalities for the temporary admission of cold chain equipment, including reusable cold storage containers and boxes?
- What border control measures can be taken to prevent the import of substandard and falsified vaccines? How can border agencies prevent the entry of counterfeit vaccines?

WTO resources (non-exhaustive)

[ePing](#) alert for technical barriers to trade/sanitary and phytosanitary notifications

WTO information note: "[Export restrictions and prohibitions](#)"

General Agreement on Tariffs and Trade ([GATT 1994](#))

General Agreement on Trade in Services ([GATS](#))

Agreement on Trade-Related Aspects of Intellectual Property Rights ([TRIPS Agreement](#))

[Trade Facilitation Agreement \(TFA\)](#)

Technical Barriers to Trade ([TBT](#)) Agreement

WTO information note: "[The treatment of medical products in regional trade agreements](#)"

List of national trade facilitation [committees](#)

List of TFA [enquiry points](#)

WTO information note: "[Standards, regulations and COVID-19](#)"

List of TBT [enquiry points](#)

Trade Facilitation Agreement Facility ([TFAF](#)) COVID-19 Trade Facilitation Resource Repository

WHO, WIPO and WTO (2020), Promoting Access to Medical Technologies and Innovation: Intersections between public health, intellectual property and trade (second edition), Geneva: [WHO, WIPO and WTO](#).

Other resources (non-exhaustive)

- How can changes to import, export and transit procedures be published promptly in a non-discriminatory and easily accessible manner in order to enable governments, traders, and other interested parties to become acquainted with them? Will they be published on the internet? Will [enquiry points](#) (i.e. officials or offices designated to deal with enquiries from other WTO members and the public on specific trade-related subjects) be trained to be able to answer reasonable enquiries about them?

Global Alliance for Trade Facilitation
COVID-19 [resource hub](#)

International Civil Aviation Organization
[COVID-19 Response and Recovery Platform](#)

International Air Transport Association
(IATA) - [Action Cargo COVID-19](#)

International Road Transport Union (IRU)
- [COVID-19 information hub](#)

International Maritime Organization
(IMO) - [COVID-19](#)

World Customs Organization-
[COVID-19 updates](#)



STEP 7

Domestic distribution & surveillance

Keeping substandard and falsified COVID-19 vaccine products out of the supply chain is a big challenge. A [WHO review](#) of access to medicines published in 2017 found that products which enjoy lucrative commercial markets are particularly susceptible to falsification, as are badly needed medicines and vaccines that are in short supply. As per [WHO, WIPO and WTO](#), both originator and generic medical products that do not meet quality standards or contain either none or the wrong dose of active ingredients or different substances, can lead to treatment failure, exacerbation of disease, resistance to medicines and even death.

Market surveillance and control plays a crucial role in assuring consumer safety of medical products. According to a [WHO global benchmarking tool](#) published in 2018, such activities cover control of import activities, prevention and detection of and responses to substandard and falsified medical products, market surveillance programmes (e.g. spot checks) for monitoring the quality of medical products throughout the supply chain, and control of promotional, marketing, labelling/packaging and advertising activities. Quality infrastructure and metrology systems underpin market surveillance and enforcement. [Vigilance](#) activities should be established in countries based on a risk management approach. A vigilance system, in general, monitors all kinds of patient harm potentially related to medical products, whether due to inadequate product quality, inappropriate use (e.g. medication errors) or intrinsic adverse effects. It is important to establish such a system because serious effects can erode confidence in medical products.

A further consideration is national laboratory testing capacity and calibration. Collaboration with other regulatory authorities on lot release and cooperation in laboratory testing for quality assurance are options recognized by WHO [laboratory](#) testing benchmarking. Quality infrastructure, such as metrology systems, is also indispensable for the integrity of the cold chain. Reliable storage and temperature monitoring equipment is necessary to protect vaccine potency from exposure to improper conditions. The use of smart labels (e.g. vaccine vial monitors, designed to measure heat exposure) monitor vaccines that must be maintained in low temperatures.

Management of waste related to COVID-19 vaccination requires special attention, due to the infectious nature of the virus. If COVID-19 vaccines are delivered in a mass vaccination campaign strategy, the generation of healthcare waste will be amplified, due to the mandatory use of disposable and reusable materials and hazardous wastes, such as personal protection equipment, used by the vaccination teams (see [WHO and UNICEF](#)). The WHO and UNICEF have published a

[guidance note](#) on waste management for SARS-CoV-2 (i.e. the virus that causes COVID-19).

“In the past two years, alerts were issued for falsified yellow fever vaccines, hepatitis C medicine, meningitis vaccines, anti-malaria medicines, and treatments for epilepsy.”

WHO

Pharmaceutical waste includes expired, unused, spilt and contaminated pharmaceutical products, prescribed and proprietary drugs, vaccines and serums that are no longer required, and, due to their chemical or biological nature, need to be disposed of carefully, using safe waste management practices (see WHO [handbook](#)). Inadequate and inappropriate handling of healthcare waste may have serious public health consequences and a significant impact on the environment (see United Nations Environment Programme [report](#) on waste management during the pandemic). The disposal of sharp waste (such as syringe needles) is a particular challenge since it can cause injuries that leave people vulnerable to infection, or indeed spread infection directly. [WHO](#) has developed performance specifications for puncture-proof and impermeable containers to dispose of used syringes.

As [UNEP](#) has noted, the COVID-19 pandemic creates new waste management challenges. Some medical waste could cross borders. Differences in waste treatment and disposal costs drive trade in waste products, as well as the recycling of valuable secondary raw materials. There is also a significant [illegal trade](#) in waste, marked by black-market transport, falsely declaring hazardous waste to be non-hazardous, or classifying waste as second-hand goods. Trade in waste is regulated by different multilateral environmental agreements (MEAs), including the Basel Convention on the Control of Transboundary Movements of Hazardous Waste and their Disposal. WTO members are free to adopt environmental policies, such as waste management requirements, at the level they choose, even if they significantly restrict trade, provided they do not introduce unjustifiable measures or arbitrarily discriminate against trading partners. Joint studies by WTO with [UNEP](#), and with [CITES](#), demonstrate the mutual supportiveness between WTO rules and MEAs.

STEP 7 Domestic distribution & surveillance

Possible issues with trade impact to consider

- What regulatory measures can be taken to prevent the marketing of substandard and falsified vaccines? What actions can be taken by market surveillance and enforcement authorities against counterfeit vaccines?
- What measures can be taken to help ensure cold chain integrity through the last mile of distribution, to the end-user, and to facilitate the operations of logistics and other relevant service suppliers? What measures may be required to rapidly expand cold or ultra-cold chain capacity? Are measures in place to support the accelerated construction and licensing of cold chain storage?
- Do the measures in place allow for the entry and operation of the transport and logistics services suppliers best equipped to ensure cold-chain integrity, without requirements to enter into partnerships with local suppliers and without foreign equity ceilings?
- What measures might be taken to enable and facilitate efficient and transparent inventory management for vaccine distribution, e.g., digital platforms that allow data-sharing, as well as track-and-tracing?
- What measures are available in domestic competition law to deal with the abuse of intellectual property rights?
- What measures need to be taken to ensure that local testing results and quality assurance samples can be transmitted back through the vaccine value chain to relevant actors (e.g. vaccine developers, regulators or manufacturers)?
- How can regulatory cooperation be promoted so as to overcome limited laboratory and other quality assurance infrastructure capacity in developing and, in particular, in least-developed countries?
- How will the management of government procurement contracts be organized in these regards?
- Are there strategies and measures in place to manage the growing volume of healthcare waste associated with the COVID-19 pandemic, including waste generated by vaccination? What policies and guidance should be adopted in handling waste, given the sanitary restrictions and limitations imposed by the ongoing pandemic? What measures can be taken to prevent illicit trade in medical waste?



WTO resources (non-exhaustive)

Agreement on Trade-Related Aspects of Intellectual Property Rights ([TRIPS Agreement](#))

General Agreement on Trade in Services ([GATS](#))

Technical Barriers to Trade ([TBT](#)) Agreement

WHO, WIPO and WTO (2020), *Promoting Access to Medical Technologies and Innovation: Intersections between public health, intellectual property and trade* (second edition), Geneva: [WHO, WIPO and WTO](#). See in particular Chapter [IV](#).

Other resources (non-exhaustive)

[WCO IPR CENcomm Group](#) for data exchange on counterfeit medical supplies and fake medicines

[WHO](#) Global Surveillance and Monitoring System for Substandard and Falsified Medicines

WHO [Good distribution practice](#)

[UNEP](#) (2020), *Waste Management during the COVID-19 Pandemic: From Response to Recovery*, Nairobi: UNEP.

[Bamako Convention](#) (1998)

[Basel Convention](#) on the Control of Transboundary Movements of Hazardous Wastes and Their Disposal (1992)

[Stockholm Convention](#) on Persistent Organic Pollutants (2004)

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