DEVELOPING & DELIVERING **COVID-19 VACCINES** AROUND THE WORLD A CHECKLIST OF ISSUES WITH TRADE IMPACT

WTO OMC

Summary

Around the world, multiple vaccines against COVID-19 are on track for regulatory approval. Arriving at safe, efficacious vaccines of consistent quality will be a major scientific achievement. No less a feat will be manufacturing and delivering COVID-19 vaccines globally – a challenge of unparalleled scale, reach and complexity.

The COVID-19 vaccine trade value chain intersects with trade-related policies and WTO rules at multiple points. The aim of this non-exhaustive checklist is to foster dialogue and transparency, and to provide a tool for governments to help ensure that trade policy supports the development and prompt distribution of COVID-19 vaccines.

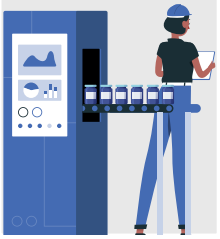
1 Vaccine development

- Are there policies and regulations in place that promote an effective and 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 information exists about intellectual property (IP), data and knowledge relative to the development of vaccines, and how can it 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 research?

2 Domestic approval (Manufacture)

- What national legislation applies to vaccine approval? Can emergency use authorizations be issued for COVID-19 vaccines and related medical devices?
- 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?
- What IP access rules apply to clinical trial data?

3 Vaccine manufacture



- 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 sourcing of such inputs?
- 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?
- How can the government facilitate technology transfer and local production capacity? How can the government support firms that seek to enter into licensing agreements?

Quality assurance: a continuous step

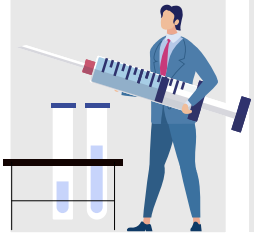
How can processes to demonstrate compliance with quality/safety requirements, such as good manufacturing practice, be expedited without compromising vaccine safety, quality and efficacy?

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?

4 Domestic approval (Importer)



- 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 World Health Organization 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 IP information related to the vaccine be accessed? What IP, if any, applies to the vaccine in the importing country? For LDCs, has the temporary exemption from the requirement to protect and enforce patents and clinical trial data for pharmaceutical products been implemented domestically?
- Which entity/entities will take procurement decisions and how will they be coordinated? Have appropriate procurement procedures and mechanisms been put in place? How is transparency in this regard ensured?

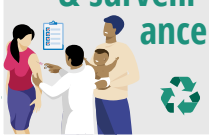
5 International distribution

- What can the 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 IP rights or export controls?
- 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 (TFA) 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?

6 Border clearance

- What procedures are needed to ensure timely, appropriate communication between border agencies and health regulatory authorities?
- 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?
- Will the importation of vaccines and related materials be subject to import licensing requirements, 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 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 sub-standard and falsified vaccines? How can border agencies prevent the entry of counterfeit vaccines?

7 Domestic distribution & surveillance



- What measures can be taken to ensure cold chain integrity through last mile delivery to the end user and to facilitate the operations of logistics and other relevant service suppliers? What measures may be required to rapidly expand (ultra) cold chain capacity?
- What regulatory measures can be taken to prevent the marketing of sub-standard and falsified vaccines? What actions can be taken by market surveillance and enforcement authorities against counterfeit vaccines?

Can standard labelling and packaging be accepted by the importing country?

How will technical specifications for government procurement systems be formulated? 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 though the vaccine trade value chain to relevant actors (e.g. regulators, and vaccine developers or manufacturers)?

TRANSPARENCY ESSENTIAL AT EVERY STEP