DEVELOPING & DELIVERING COVID-19 VACCINES AROUND THE WORLD

1. Vaccine development

Universities & Institutes | Private sector | Governments | NGOs (e.g. corporate foundations)

- Patents
- Trademarks
- Industrial designs
- Trade secrets & test data
- Copyright

IP status

Vaccine

Medical devices

Intellectual Property (IP*)

IP sharing (including licensing)

2. Domestic approval (Manufacture)

Pharmaceutical quality
small scale studies

Non-clinical
in vitro

Clinical trials phase
I II III

Evaluation & decision
safety efficacy

WHO (including UN procurement)

Approval by regulator

Emergency use listing
Pre-qualification

Emergency use authorization
Standard approval

3. Vaccine manufacture

Export procedures

Raw materials

Vaccine

Packaging materials

Packaging and labelling

Approval by domestic authority (Exporter)

Lot release

Import procedures

COVID-19 TRADE CONTROLS

Quality control representing up to 70% of manufacturing time

Several hundred quality control tests

Inspection by regulatory authority (exporter + importer)

Good manufacturing practice
A vaccine typically travels through several different sites before being ready for shipment.

**Domestic approval**
- **Repeat step 2** OR **Use step 2 approval (WHO or foreign regulator)**
  - Approved by regulator
  - Approval of manufacture facility
  - Approved for market (labelling, packaging)

**International distribution**
- Procurement
  - Public
  - COVAX
  - Private
- Transit
- Cold chain integrity
- A vaccine typically travels through several different sites before being ready for shipment

**Border clearance**
- Customs & other border agency approval
- Tariffs, other duties & charges, internal taxes
- Inspections & controls
- Customs release decision
- Good distribution practice

**Domestic distribution & surveillance**
- Last-mile delivery
- Action by health and regulatory surveillance authorities
- Action by market surveillance & enforcement authorities
- Waste management

Source: WTO, based on EMEA, IFPMA. 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.