Equitable access and fair allocation of COVID-19 vaccines

Mariângela Simão – 23 July 2020
# The COVID-19 pandemic: Facts at a glance

<table>
<thead>
<tr>
<th><strong>COVID-19 is the biggest threat to global health security in a century</strong></th>
<th><strong>COVID-19 vaccine development is advancing at an unprecedented pace</strong></th>
<th><strong>But development and manufacturing are complex, long and risky</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>13.1M</td>
<td>160+</td>
<td>7% / 17%</td>
</tr>
<tr>
<td>Confirmed COVID-19 cases globally¹</td>
<td>COVID-19 vaccines in development³</td>
<td>Probability of success for preclinical/clinical vaccine programs⁴</td>
</tr>
<tr>
<td>573k</td>
<td>23</td>
<td>$137M - 1.1B</td>
</tr>
<tr>
<td>COVID-19 related deaths globally¹</td>
<td>COVID-19 vaccines in clinical trials³</td>
<td>Average R&amp;D costs to develop a vaccine⁵</td>
</tr>
<tr>
<td>189</td>
<td>12-18 months</td>
<td>expected supply constraints after approval of the first COVID-19 vaccine</td>
</tr>
<tr>
<td>Affected countries and territories globally¹</td>
<td></td>
<td></td>
</tr>
<tr>
<td>$9T</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Global economic cumulative losses in 2020 and 2021²</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

---


---

**Speed, Scale, Access**
ACT-A leverages the best of international health in coordination with WHO

**Vaccines**
- Development & manufacturing
- Policy & allocation
- Procurement & delivery at scale

**Therapeutics**
- Rapid assessment of candidates
- Market preparedness
- Deployment in all countries
- Costing & financing

**Diagnostics**
- R&D
- Market readiness tools
- Supply
- Country preparedness

**Health Systems Connector**
- Country systems
- Protect frontline workers
- Clinical care
- Integrated data mgmt
- Financing
- Community-led responses
- Private sector
- Key supply elements
- Supply chain

**Coordination & Support**

**Cross-cutting Access & Allocation**

**All Pillars**
- Norms & Standards
- Regulatory/PQ
- Policy & Technical guidance

**In discussion**
- Support Hub
  - Coordination & Support
  - Cross-cutting Access & Allocation
  - All Pillars
    - Norms & Standards
    - Regulatory/PQ
    - Policy & Technical guidance

**Co-convener**
Why we need a collaborative platform – “COVAX”

With a fast-moving pandemic, no one is safe, unless everyone is safe

- Today, historic scientific collaboration, with currently over 200 vaccine candidates in varying stages of development
- Unprecedented commitment from industry to work together in the interest of the global public good
- Under a business as usual approach, it could take years to develop effective vaccines and decades to ensure they reach everyone that needs them
- US$375 billion lost to the global economy each month

Bilateral deals leave many countries behind

High risk of failure in vaccine development

Over 500,000 deaths and counting
Different vaccine technologies are under development

<table>
<thead>
<tr>
<th>Technology</th>
<th>Description</th>
<th>Example candidates</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Protein</strong></td>
<td>Purified or recombinant proteinaceous antigens from a pathogen to elicit immune response</td>
<td><a href="#">Clover Biopharmaceuticals</a>, <a href="#">NOVAVAX</a>, <a href="#">The University Of Queensland</a>, <a href="#">CSL</a></td>
</tr>
<tr>
<td><strong>Nucleic Acid</strong></td>
<td>Genetically engineered plasmid containing the DNA sequence containing sequence for disease-specific antigen&lt;br&gt;<strong>Messenger RNA</strong> containing sequence for a disease-specific antigen</td>
<td><a href="#">inovio</a>, <a href="#">CureVac</a>, <a href="#">moderna</a>, <a href="#">Biontech</a></td>
</tr>
<tr>
<td><strong>Viral vector</strong></td>
<td>Chemically weakened viruses to carry DNA, containing sequence for disease-specific antigen, into human cells</td>
<td><a href="#">MERCK</a>, <a href="#">Themis</a>, <a href="#">UNIVERSITY Of OXFORD AstraZeneca</a></td>
</tr>
<tr>
<td><strong>Inactivated</strong></td>
<td>Chemically “killed” virus or subunits of the virus grown under controlled conditions</td>
<td><a href="#">sinovac</a>, <a href="#">SINO PHARM</a></td>
</tr>
</tbody>
</table>
Why we need to build manufacturing capacity now

To deliver 2 billion doses by the end of 2021, 2-3 successful programmes are needed to:

- Produce early doses to support clinical studies
- Scale up processes to industrial scale before clinical trials begin
- Scale-out products in different countries to expand capacity
- Stockpile vaccines in bulk in anticipation of dose level definition
- Anticipate projects failing during clinical development
- Repurpose facilities for successful products, if needed
# The situation is unique from a regulatory approval and safety & monitoring perspective

**Regulatory approval**

<table>
<thead>
<tr>
<th>What makes this situation unique</th>
<th>Need for global regulatory alignment at <strong>high speed</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td><strong>Need to manage massive workloads</strong> before and after regulatory approval processes</td>
</tr>
<tr>
<td></td>
<td><strong>Need for simultaneous regulatory approval in high number of countries</strong> with different regulatory contexts</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Safety &amp; Monitoring</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>High number of novel platforms</strong> in the race (e.g. mRNA)</td>
</tr>
<tr>
<td><strong>High speed from development to scaled mass vaccine delivery</strong> (e.g., tens of thousands subject in clinic and tens to hundreds of millions of vaccinations in few months)</td>
</tr>
</tbody>
</table>

**What COVAX is doing to address these issues**

<table>
<thead>
<tr>
<th></th>
<th>We are working with regulators, including FDA and EMA, on several topics and specific products</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>We are working with a number of organisations and advisory committees on how best to define and prepare for safety and monitoring for adverse events to inform vaccine delivery</td>
</tr>
</tbody>
</table>

*Speed, Scale, Access*
The Allocation Framework and Allocation Mechanism

Goal
Protect public health and minimize societal and economic impact by reducing COVID-19 mortality
Equal allocation between LICs, LMICs, UMICs and HICs as we seek to reach 20% of the population

Priorities

1. **Health and social care workers**
   - All countries receive doses to cover 3% of their population

2. **High-risk adults**
   - All countries receive additional doses to cover a total of 20% of their population (in tranches)

3. **Further priority groups**
   - Countries receive doses to cover more than 20% of their population

Timing

- Countries receive doses proportionally to their total population
- Timing is based on country need, vulnerability and COVID-19 threat

*A buffer will also be set aside for emergency deployment based on immediate needs*
Addressing uncertainties – pooled mechanisms for access – the “COVAX Facility”

Three options

A **National access mechanism**
Countries negotiate deals with manufacturers individually (e.g., lock into supply agreements locally)

B **Grouped access mechanism**
Countries form regional groups or blocks to negotiate supply agreements

C **Global access mechanism**
Countries participate in a global mechanism to procure and access products – the COVAX Facility, managed by GAVI

Implications

Global access offers:
Opportunity to have fair access and allocation across countries
Access to a large number of manufacturers, offering ‘risk-pooling’ (e.g., less risk of having no supply if certain vaccine candidates fail, or do not cover all populations)
COVAX Facility – expressions of interest

76 EOIs received from fully self-financing countries (to date)

HIC: 40 countries, 0.5+ B people
UMIC: 37 countries, 1.0+ B people

COVAX AMC countries with ODA donor-support

90 countries, 3.8+ B people
Next steps
“a cautious optimism”…