

CEPI Equitable Access Provisions



Workshop on
Accelerating the licensure of Lassa vaccines:
Generating robust evidence on vaccine efficacy and safety

Abuja, 25 – 26 October 2022



Key Equitable Access Provisions – 1/2

Commitments for vaccine availability and sustainable supply

- Presence of a manufacturing development plan
- Supply volumes and timing – (outbreak and non-outbreak scenarios)
- Technology transfer to LMICs as appropriate
- Pandemic preparedness provisions
- Enable a resilient supply chain for logistics, storage and administration of vaccines

Pricing and affordability

- Upfront agreement on pricing principles
- Price negotiated based on LMICs affordability and business sustainability (e.g. COGs +%, no. of years for investment to break even)
- Recognition that pricing must also be sustainable for business

Data Sharing and Transparency

- Open access to data, results and publications arising from CEPI funding
- Clinical trials must be registered in an easily discoverable existing public portal (e.g. clinicaltrials.gov)
- Sharing of Project Materials, Project Data, including animal models as the case may be

Key Equitable Access Provisions – 2/2

Registration and regulatory approval

- Regulatory submission strategy defined to ensure product licensure/commercialization in endemic countries
- Encourage use of WHO prequalification
- Support for 'Enabling Sciences'
- Development of a commercialization and partnering strategy, which includes LMIC manufacturers
- Advance planning of an Outbreak Protocol for diseases where efficacy studies may only be possible during an outbreak

Intellectual Property

- CEPI does not take ownership of Awardee IP rights
- CEPI requires access to Enabling Rights
- Ensuring project continuity through a Public Health License

Shared Benefits

- CEPI shares in profits obtained outside of LMICs
- Appropriate benefits sharing mechanism is negotiated between CEPI and Awardee

CEPI