Unitaid
SAVE LIVES FASTER

ACCESS IS NOT AN AFTERTHOUGHT

Equitable access to therapeutics during pandemics

October 2023

Access is not an afterthought

- **Equitable access to a lifesaving product requires that the product is developed in the first place.**
- **Start early and start now.**
  - Set strategic priorities for Tx from the outset, to develop access-oriented products that are:
  - Designed for use in LMICs;
  - Priced affordably and transparently;
  - Distributed fairly.
- **Secure access-focused financing.**
  - Fund early-stage R&D in the years before the next pandemic to develop a healthy pipeline.
  - Secure at-risk financing to manufacture and rapidly secure access to promising candidates for LMICs.
- **Fill in capacity gaps now to avoid delays.**
  - Establish sustainable capacity for clinical trials, regulatory processes and manufacturing.
  - Improve and sustain capacity in LMICs to rapidly integrate Tx at scale, including communities.
- **Coordinated strategies across all MCMs (Dx, Vx, Tx) based on clinical evidence and market availability.**
  - Dynamic scenario planning of need for the different emerging health products, combining data for all MCMs, from evidence on use-case and supply

Key for success: inclusive coordination, innovative approaches, and embedding access end-to-end

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Unitaid applies an access lens to **spotlight action needed now** to enable **equitable access** to therapeutics during pandemics

Equitable access to therapeutics during pandemics requires systemic end-to-end change – and action now, before the next one

Example of challenges during C-19

A lack of Tx Candidates.

Delayed integration into programmes.

Limited product volumes, high prices.

Delayed uptake of product.

Root causes

Lack of pre-pandemic funding into R&D

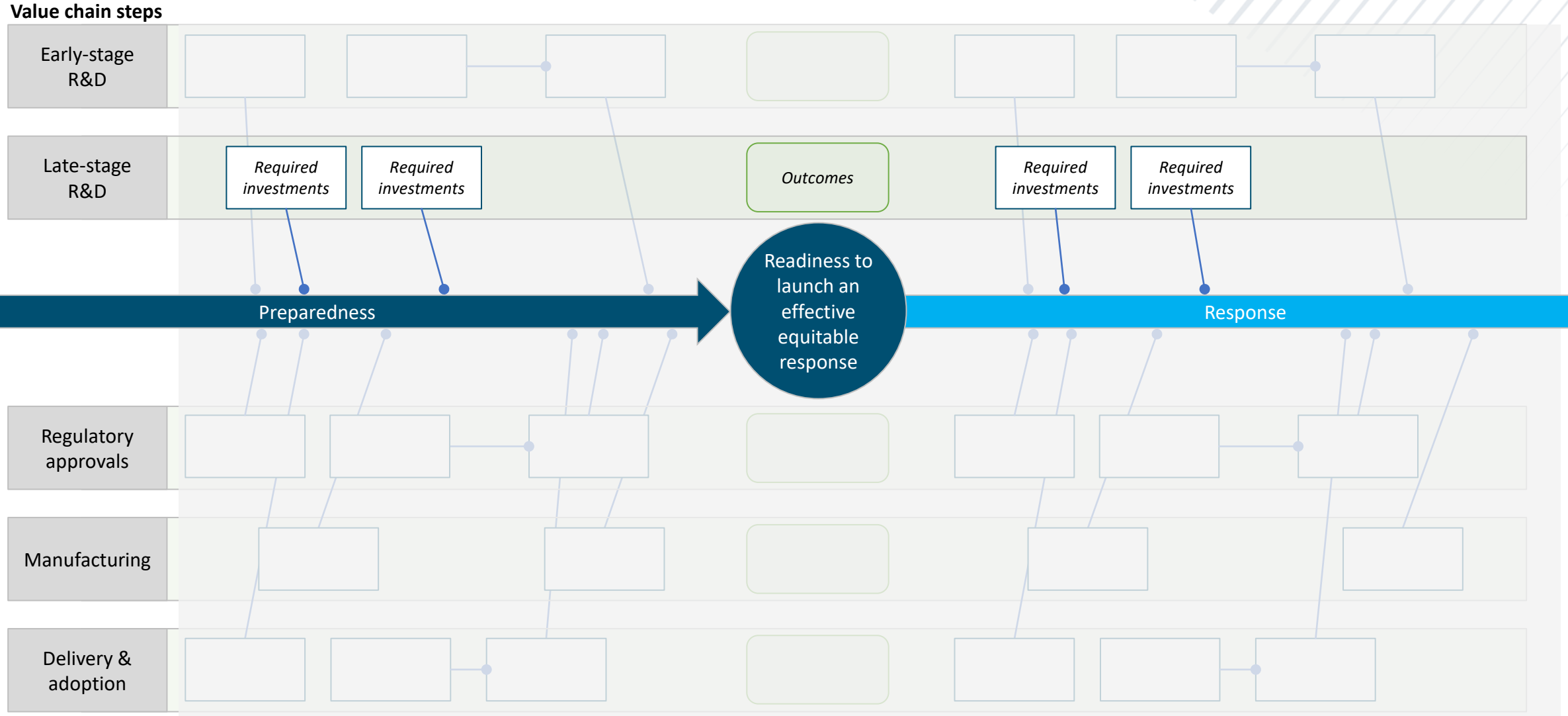
Slow approval processes

Lack of production capacity; lack of at-risk financing; inadequate access terms

Limited in-country readiness; lack of coordinated strategies across tools

Summary of Unitaid's vision for equitable access to Tx in the next pandemic

A roadmap to define prerequisites (and investments) for equitable response would need to systematically apply an access lens



Pre-pandemic preparedness is key for a rapid response, with therapeutics that can be scaled fast

	Preparedness	Response
Research & development	*A healthy pipeline of LMIC-suited Tx candidates, sustained investment, and sufficient clinical trial capacity …*	*…to respond with coordinated evaluations for priority health products.*
Regulatory approvals	*Efficient emergency use regulatory processes…*	*…to enable rapid evaluations and approvals.*
Manufacturing & supply	*Strengthened scalable production capacity and pre-agreed access terms,* ***and rapidly deployable financing*** *… …*	*…for fast and sufficient supply in the response.*
Delivery & adoption	*Country readiness for fast adoption...*	*…to enable an efficient, well-planned equitable roll-out of safe and scalable care.*

R&D in preparedness

Goal: A healthy advanced pipeline of LMICs-suited Tx candidates

Essential access-focused interventions:

- Develop access-oriented target product profiles (TPPs) guiding R&D from the outset – and informing strategic priorities
- Ensure capacity, including coordinated pre-clinical models, to develop sufficient Phase II-ready LMICs-suited antiviral candidates*
- Support coordinated global and regional clinical evaluation capacity

Access commitments:

- Access terms built-in to facilitate further R&D and scalable production of affordable Tx
- Enable data-sharing

Financing considerations:

- Timely and adequate pre-pandemic R&D funding for small molecules and monoclonal antibodies

(*) See 100 Days Mission.

Not exhaustive overview. Intended as a standalone perspective, focused on equitable access, and input for broader roadmap.

Regulatory in preparedness

Goal: Streamlined emergency-use processes and collaboration for LMICs access

- Research & development
- **Regulatory approvals**
- Manufacturing & supply
- Delivery & adoption

Essential access-focused interventions:

- Establish channels for regulator-regulator & regulator-industry collaboration to anticipate expedited regulatory pathways for priority products
- Ensure support for efficient clinical trials, e.g., 80% pre-approved protocols for expedited trial authorization
- Pre-positioned and trained surge regulatory workforce capacity, including for monoclonal antibodies
- Coordinated expedited regulatory reviews, in parallel when possible
- Expedited/parallel regulatory reviews, with clear guidance for generics/biosimilars
- Data-sharing to enable fast review of originators and generics

Note: Not exhaustive. Intended as a standalone perspective, focused on equitable access, and input for broader roadmap.

Manufacturing & supply in preparedness

Goal: Scalable capacity, affordable and accessible Tx products

- Research & development
- Regulatory approvals
- **Manufacturing & supply**
- Delivery & adoption

Essential access-focused interventions:

- Sustainable and scalable regional manufacturing capacity with business models that can flex to pandemic-relevant products
- Sufficient supply base and optimized manufacturing for both small molecules and monoclonal antibodies
- Effective and expedited channels for distribution and procurement

Access commitments:

- Pre-established access commitments including pricing and volume, transparency, voluntary licensing, and tech transfer for pipeline priority candidates
- Supply agreements for LMICs to secure product volumes early and at-risk

Financing considerations:

- Pre-positioned financing channels to produce promising candidates for evaluation in trials and production in LMICs
- Pre-positioned at-risk financing and agreements to secure product early to increase rapid uptake in LMICs

Note: Not exhaustive. Intended as a standalone perspective, focused on equitable access, and input for broader roadmap

Delivery & adoption in preparedness

Goal: Country readiness for Tx uptake and integration

- Research & development
- Regulatory approvals
- Manufacturing & supply
- **Delivery & adoption**

Essential access-focused interventions:

- Coherent strategies and targets within and across health tools – Tx, Vx, Dx – on how they will be collectively deployed and integrated within the health system
- Pre-agreed accelerated product-introduction country roadmaps including for outpatient care

Access commitments:

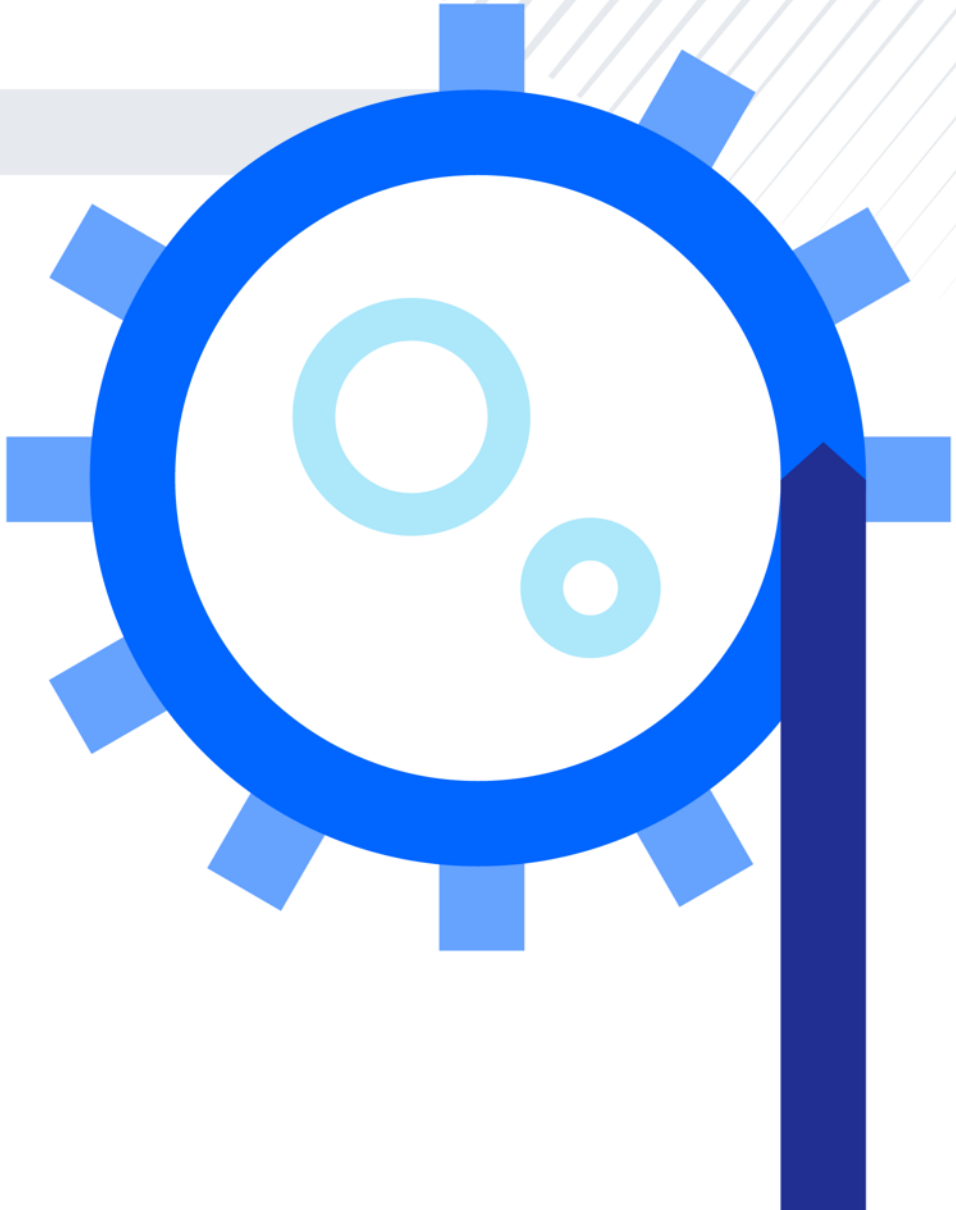
- Equitable distribution agreements in line with public health priorities
- Community-centric delivery models with a lens of vulnerability, human rights, gender, and equity

Financing considerations:

- Pre-positioned financing mechanisms to account for rapid delivery, adoption, and integration in case of a pandemic response
- Ongoing support for the maintenance of country readiness in LMICs

Note: Not exhaustive. Intended as a standalone perspective, focused on equitable access, and input for broader roadmap.

Annexes



Annex (1/3): Detailed pre-requisites within the broader Tx roadmap to enable an equitable response

Preparedness → **Response**

Healthy pipeline of LMIC-suited Tx candidates, and sufficient clinical trial capacity …

- Fund and track discovery and development of antivirals for WHO-priority pathogens families ready for Phase II*
- Establish access-oriented TPPs through a consultative process, including LMICs' stakeholders and communities, covering all potential use cases, including use cases at the peripheral level (ease-of-use)
- Establish dose/safety data for antivirals targeting all populations
- Develop pre-clinical models and platform technologies
- Ensure access terms on affordability and equity, including IP, know-how, and data sharing/TT, and equitable allocation) and are built into R&D funding contracts
- At-risk funding for manufacturing and stockpiling for Phase II trials of priority candidates and to establish ready-to-scale manufacturing processes
- Set up "80% ready" and coordinated clinical trial platforms, including in LMICs.
- Ensure sustainability by working with LMICs' public health priorities in inter-pandemic periods

…to respond with coordinated, prioritized therapeutics development

- Support product optimization of pre-developed priority candidates for better adoption in LMICs
- Reactive pipeline for pandemic pathogen

- Launch strategic globally coordinated clinical trial evaluations for WHO priority medicines meeting TPPs in pre-established platforms' sites with coordinated expedited trial approval
- Coordinate and course-correct pipeline in consideration of advances across all medical countermeasures (including Vx, Tx, Dx)

Notes: (*) See 100 days Mission report. "80% readiness" for clinical trials including operational preparedness (such as protocol templates, data collection system, regulatory preparation, and SOPs), legal, financial, and training activities, adapted from Pantherhealth.org

Annex (2/3): Detailed pre-requisites within the broader Tx roadmap to enable an equitable response

Preparedness → **Response**

Regulatory approvals

Efficient emergency-use regulatory processes…

- Establish a coordinated & expedited review process for trials that ensure lack of duplication, efficiencies and fast start of trials for priority candidates
- Establish coordinated & expedited products' review process including for generics and biosimilars
- Strengthen and streamline regulatory capacity and processes at the regional level

…to enable rapid approvals

- Expedited review of clinical trials by authorities
- Emergency use authorization channels, or interim authorization for priority products
- Coordinated review of product dossiers by champion regulatory authorities (across regions) and WHO; mutual reliance
- Post marketing authorization data-sharing

Manufacturing & supply

Strengthen manufacturing capacities in preparedness…

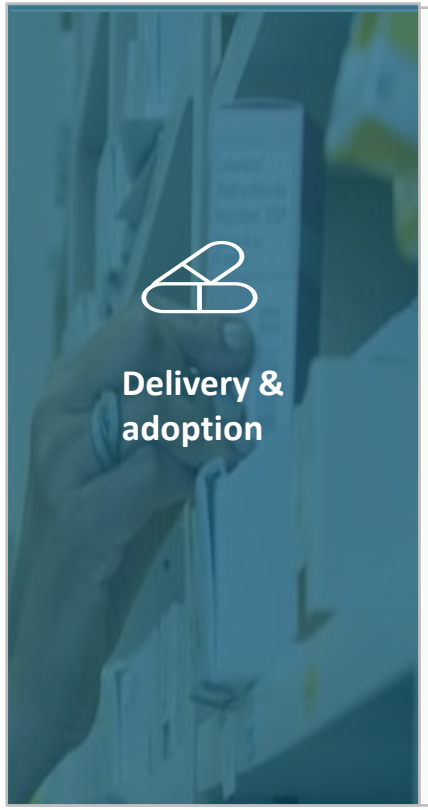
- Promote pro-access IP management, including public health-voluntary licensing for priority candidates since R&D stage
- Prepare regional sustainable scaled-manufacturing GMP capacities for small molecules and biologics with surge capacity that can be sustained in inter-crisis periods with production of public health priorities outside pandemics
- Ensure regional capacity to conduct bioequivalence/ pharmacokinetic/ pharmacodynamic studies for faster regulatory approval and market entry of generics and biosimilars
- Preestablished contracts and commitments to access: pricing and volumes

…towards equitable and sustainable supply-demand dynamics in response

- Pivot production capacity for priority pandemic products
- Support expanded production for priority products in Phase II & III, including technology transfer as relevant
- At-risk funding for push-pull mechanism (through production and conditional pooled procurement contracts for supply in LMICs) for priority pandemic products

Annex (3/3): Detailed pre-requisites within the broader Tx roadmap to enable an equitable response

Preparedness → **Response**



Strengthened country readiness for fast adoption...

- *Support country-led development of* **accelerated country-product introduction and adoption roadmaps** in each region (including regulation and normative procedures, quantification and procurement, within-country delivery channels, information sharing across all stakeholders, including treatment literacy and community engagement, coordinated deployment with other countermeasures)
- Prepare for integrated models across MCMs (including T&T when possible), and plan for access by all populations in need (e.g. high-risk)
- Work with country stakeholders to develop community-centric delivery models with a lens of vulnerability, human rights, gender, and equity

…to enable an efficient, well-planned roll-out of safe and scalable care

- Establish coordinated strategies across all MCMs based on dynamic evidence and use cases
- Constant tracking/monitoring projections of need for the different emerging health products (scenario planning combining data for all MCMs, from evidence and market availability)
- Secure firm procurement agreements for global LMIC supply in consideration of potential volumes needed
- Ensure coordinated equitable allocation mechanisms in periods of scarce supply
- Publish and update information on sources and prices for all priority products
- Support all stakeholders' updated information and literacy (including communities) and demand generation in consideration of all available medical health tools against the given pathogen

Thank you

Acknowledgments: The perspectives reflected in this document are informed by Unitaid's experience, with contributions from a wide range of stakeholders.