Accelerating development and global access to oral therapeutics during a public health emergency: Early insights for consideration

July 2024

COVID TREATMENT QuickStart CONSORTIUM

Working Document for Feedback

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COVID Treatment QuickStart Consortium

- Catalytic public-private partnership with 10 national governments across Africa and Asia to rapidly introduce and scale access to COVID-19 oral antiviral therapies and build test-and-treat capabilities for future needs.
- Supported by the Open Society Foundations, Conrad N. Hilton Foundation, and Pfizer, Inc. (including donation of up to 100,000 courses of nirmatrelvir/ritonavir).
- QuickStart combines implementation support with operational research and policy analysis, and will continue throughout 2024 to collaborate with countries as they transition to sustainability and establishment of “always on” emergency response capabilities.

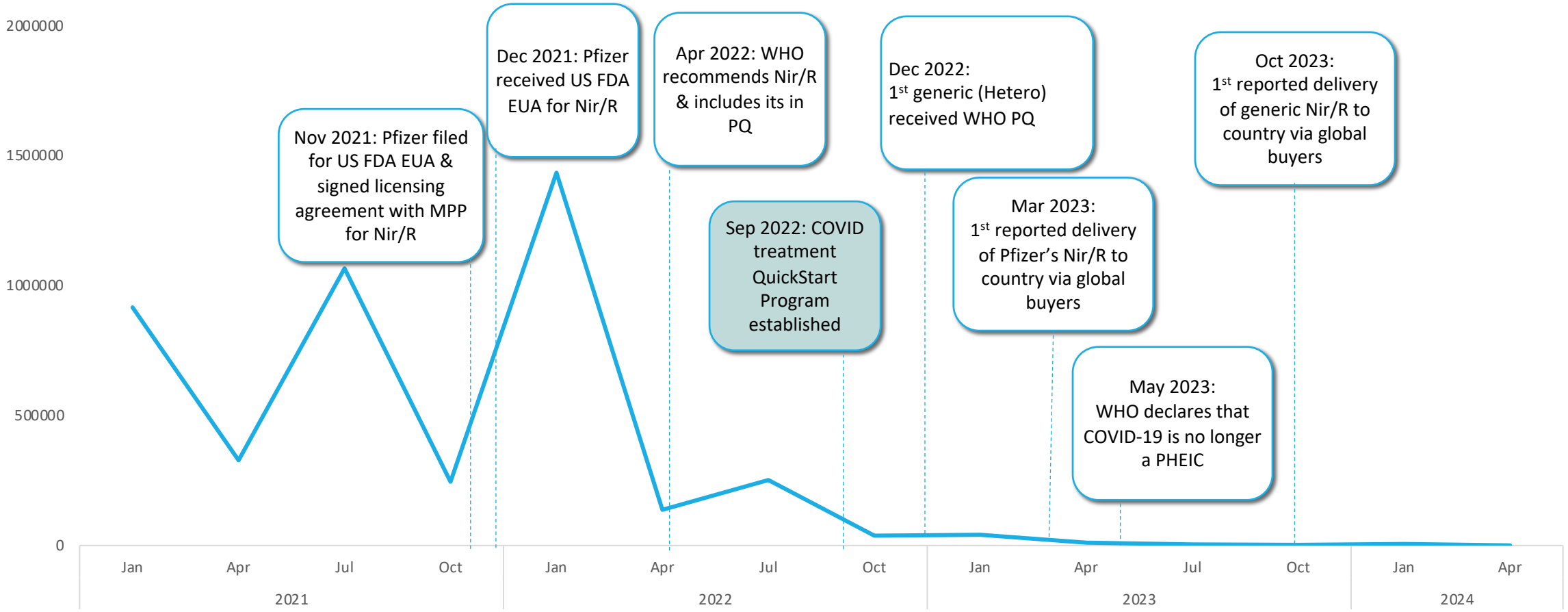
Progress to date

- > 700 sites activated across 8 countries offering COVID-19 test and treat services
- More than 685,000 people tested for COVID-19 in activated test and treat sites
- 5,900 people tested positive
- > 2,400 patients initiated into care

Partner countries: Ghana, Kenya, Laos, Malawi, Nigeria, Rwanda, South Africa, Uganda, Zambia, and Zimbabwe

Nirmatrelvir /Ritonavir (Nir/R) only became available in LMICs in 2023 after the major COVID-19 waves had passed

Monthly new confirmed COVID-19 cases in Africa



Sources: COVID-19 Data Explorer by Our World in Data; Assessed May 16, 2024

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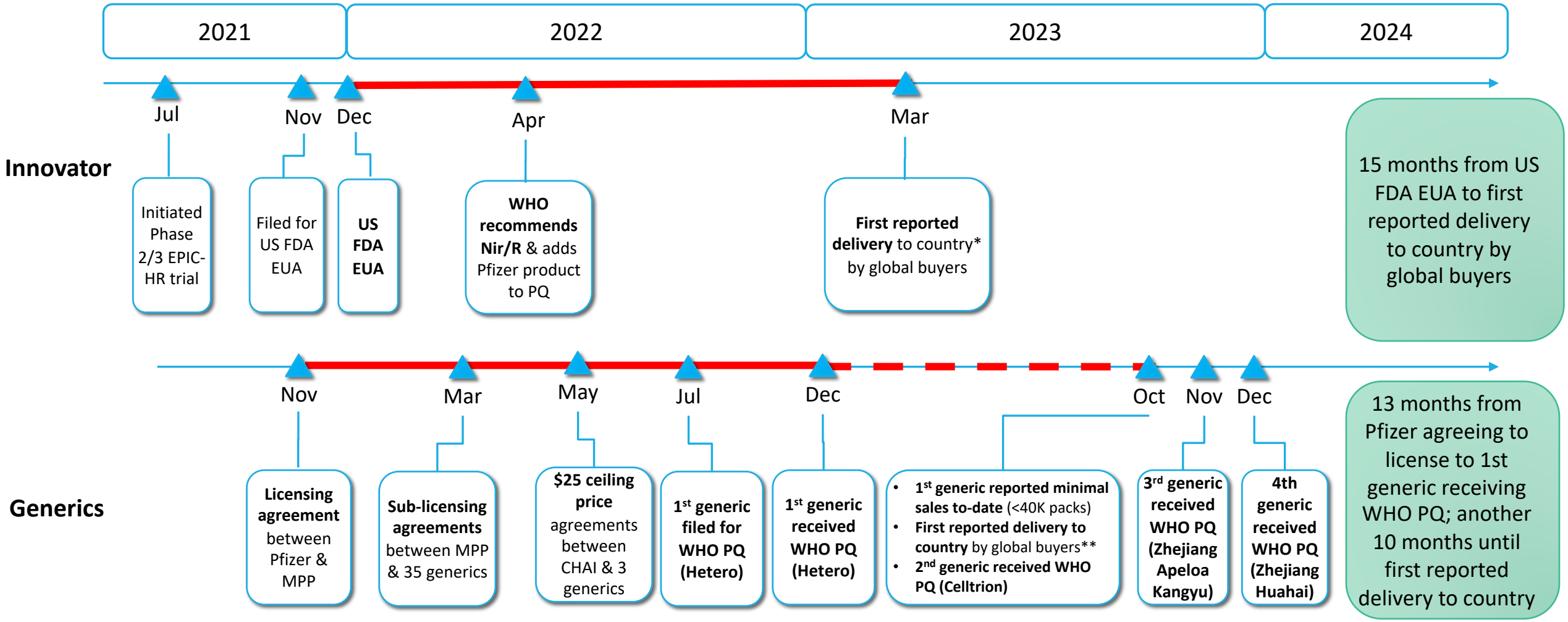
Detailed timelines of key events for the introduction of nirmatrelvir/ritonavir

Summary of as of April 2024



*As reported by UNICEF COVID-19 Market Dashboard; Nir/R not listed on GFATM reference pricing prior to Q4 2023

** UNICEF reported first country delivery of generic Nir/R in October 2023

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Key insights and findings

QuickStart's public-private partnership model proved catalytic, as partner countries demonstrated the ability to establish – and rapidly decentralize – test and treat programs, including access to novel oral antivirals and self-testing.

However, significant – but solvable – challenges slowed the timing and scope of getting pills to people:

1. Global stakeholders failed to effectively prioritize, coordinate, and accelerate end-to-end treatment R&D, product access, and delivery as part of the global COVID-19 response.
2. Addressable bottlenecks slowed access to innovator product and quality-assured generic oral antivirals, including approach and slow pace of generic licensing, procurement challenges, limited market shaping interventions, and lack of robust demand signaling and demand generation.
3. Implementation timelines were highly variable country to country, highlighting the critical importance of leadership at the national and subnational levels, community engagement, and "always on" emergency response capabilities for expediting both new product entry and delivery implementation.

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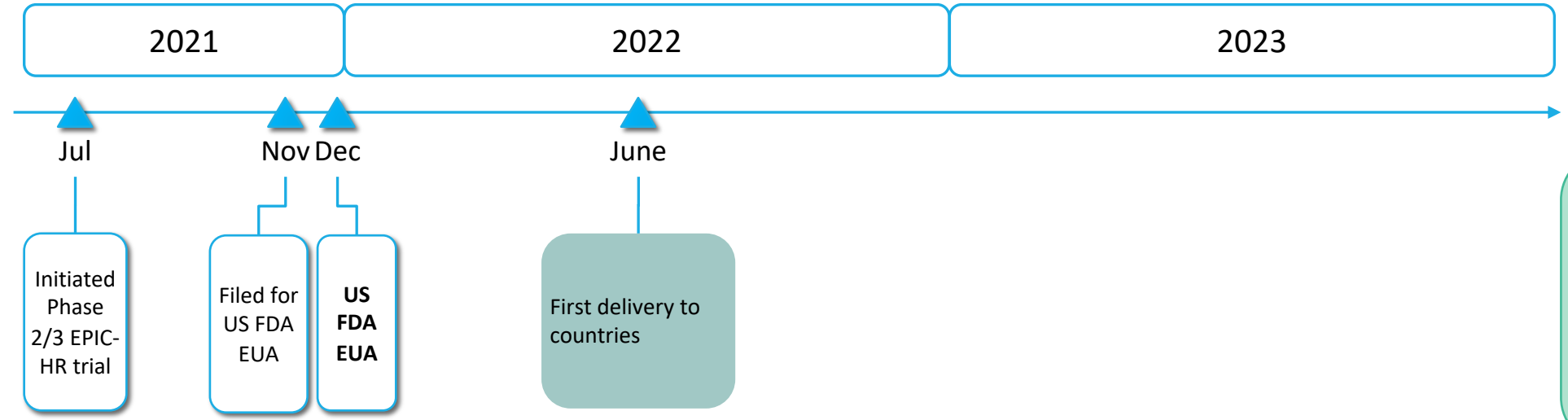
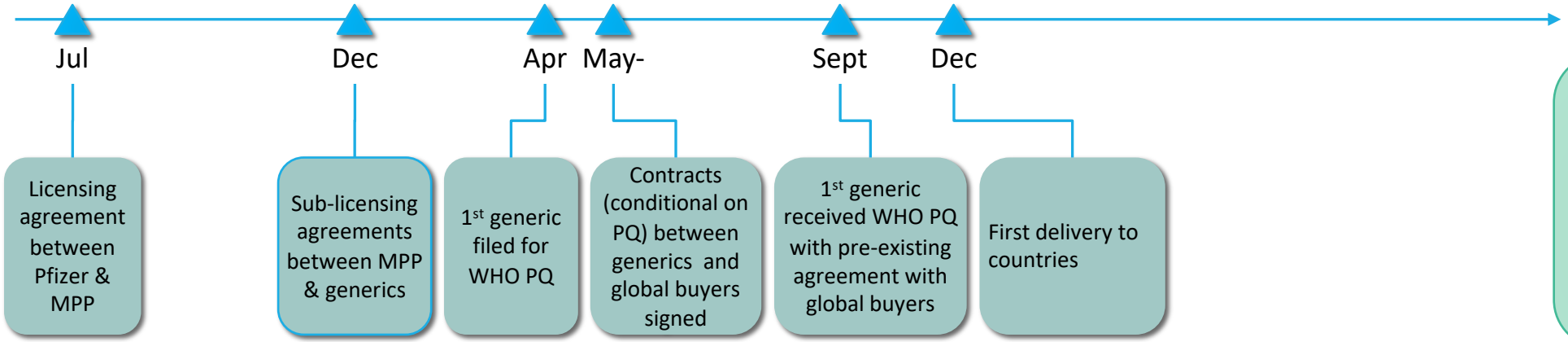
Solving these bottlenecks could have significantly accelerated product availability and enabled greater utilization of products when needed

Potential acceleration from actual timelines



Innovator: Pfizer

First procurement & delivery to countries in June 2022 instead of March 2023, i.e., 9 months faster



Generics

Generics becoming available in December 2022 instead of October 2023, i.e., 10 months faster

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Global stakeholders failed to effectively prioritize, coordinate, and accelerate end-to-end treatment R&D, product access, and delivery as part of the global COVID-19 response.

High-priority recommendations

1. **Multilateral organizations and HICs should further prioritize funding and coordination for therapeutics** (and diagnostics) R&D, manufacturing, introduction, and last-mile delivery, including the establishment of a CEPI-like entity or consortium for LMIC-suitable therapeutics and more effective platforms for industry engagement.
2. **Country-level stakeholders should be more actively engaged in "upstream" decisions** on R&D and market shaping, while **global and regional stakeholders need to more actively support "downstream" delivery** implementation and demand generation.
3. **Global and regional stakeholders should support national governments to stand up delivery and demand generation efforts in parallel** with, not subsequent to, expediting new product entry in country.
4. **Bilateral and multilateral agencies and foundations should support nimble, catalytic public-private partnerships** for emergency response that can be first movers, generating early insights and paving the way for scale-up and sustainability.

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High-priority recommendations

1. **HICs should incorporate provisions supporting accelerated global access into their domestic procurement contracts,** including timing and quantity of products available for procurement by LMICs, rather than relying on product donations.

2. **Liability and indemnification issues should be addressed in advance of emergencies** through adoption of no-fault compensation schemes akin to that employed by COVAX for vaccines.

3. **Innovator companies should accelerate generic development by targeting a small group of pre-qualified generic manufacturers for direct voluntary licensing** during Phase 3 clinical trials, including the provision of technical assistance and reference product.

4. **Multilateral organizations and HICs should move aggressively to put in place market shaping interventions**, such as AMCs, volume guarantees, and ceiling price commitments, to incentivize and accelerate development, manufacturing, and LMIC access of quality-assured generics.

5. **More coordinated and efficient regulatory authorization pathways** for therapeutics and diagnostics at national, regional, and global levels are needed to ensure timely access to safe and effective products.

6. **Regional stockpiles and pooled procurement agreements should be established** to send critical demand signals and ensure earlier LMIC access to innovator and generic products alike.

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Implementation timelines were highly variable country to country, highlighting the critical importance of leadership at the national and subnational levels, community engagement, and “always on” emergency response capabilities for expediting both new product entry and delivery implementation.

High-priority recommendations

1. **National governments should appoint or empower a key senior official** to spearhead whole-of-government, highly-coordinated emergency response efforts, including access to therapeutics.
2. **Access to testing, including self-testing, and treatments should be prioritized** and implemented in scalable and decentralized manner in coordination with community engagement and demand generation activities.
3. **National governments should prioritize strengthening of core emergency response capabilities**, including well-resourced, “always on” emergency response systems, with sustainable financing mechanisms such as ring-fenced budgets.
4. **Bilateral and multilateral agencies should accelerate funding and technical assistance for county-led efforts to strengthen data systems and surveillance capabilities** that can provide early warnings of new outbreaks and help monitor progress during emergencies.