International AIDS Society iasociety.org

Current access landscape for paediatric DTG formulations in southern Africa

Perspectives from the Medicines Patent Pool

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19 October 2026 – Lilongwe, Malawi

Working towards an equitable world

*MPP negotiates with pharmaceutical companies to **accelerate access** to new, essential health products **for the people** who need them*



Conflict of Interest Disclosure

- I have no relevant financial relationships with pharmaceutical companies or other conflict of interest to disclose.

Thanks to the entire MPP team!



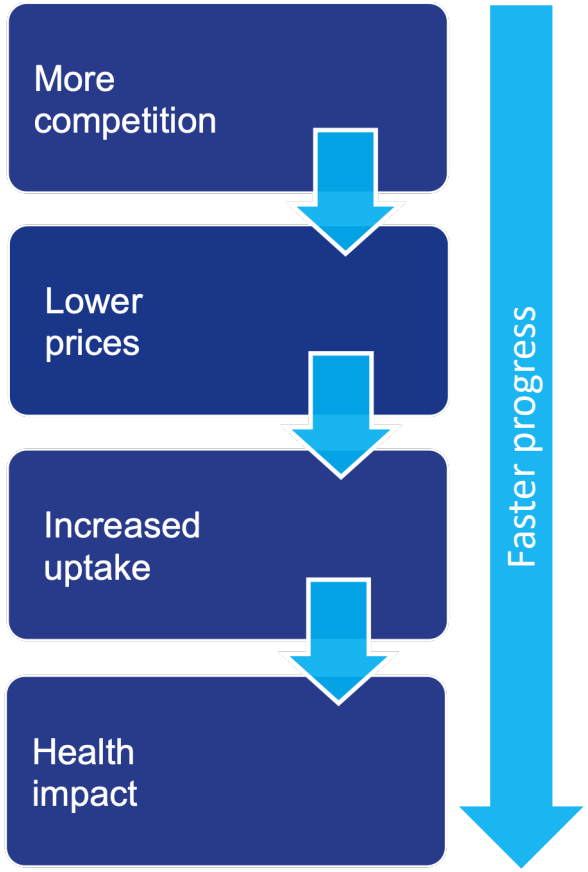
Acknowledgments

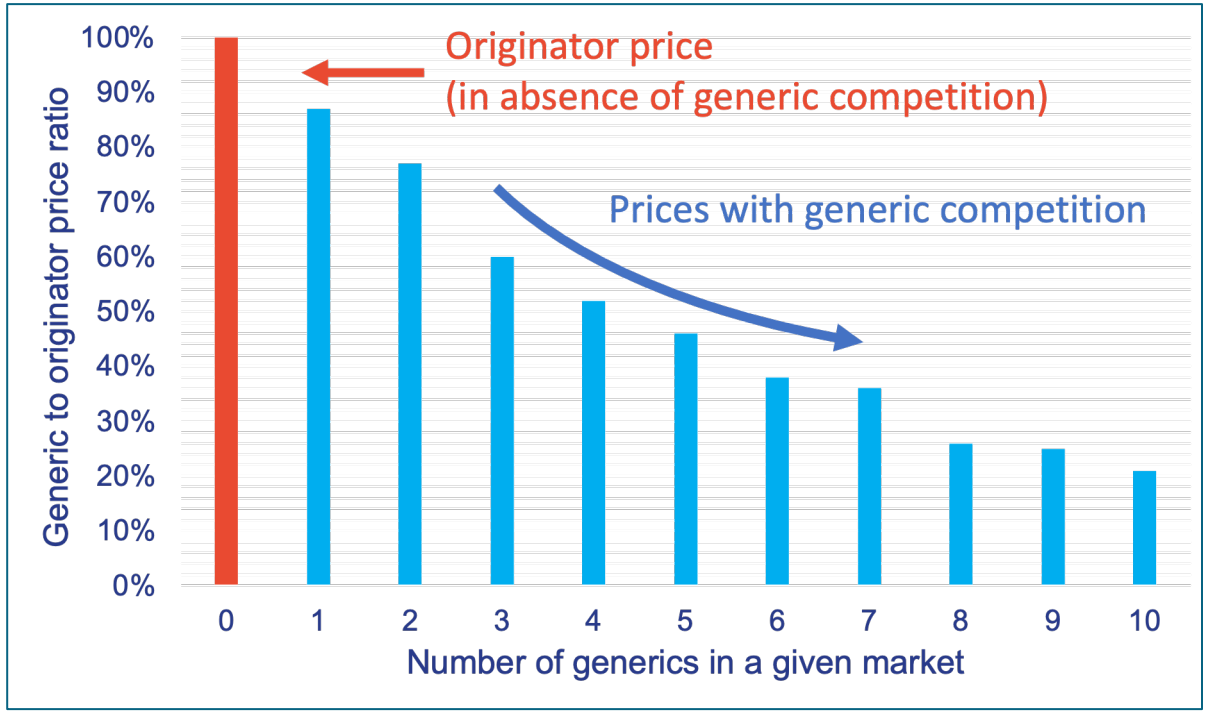
- The work of the Medicines Patent Pool in HIV is made possible by the financial support of Unitaid.
- We thank them, as well as our other current public and philanthropic funders.

MPP's model to accelerate access & improve health

Overview of the voluntary licensing model

- Driving prices down through generic competition
- Accelerating timelines for generic product availability



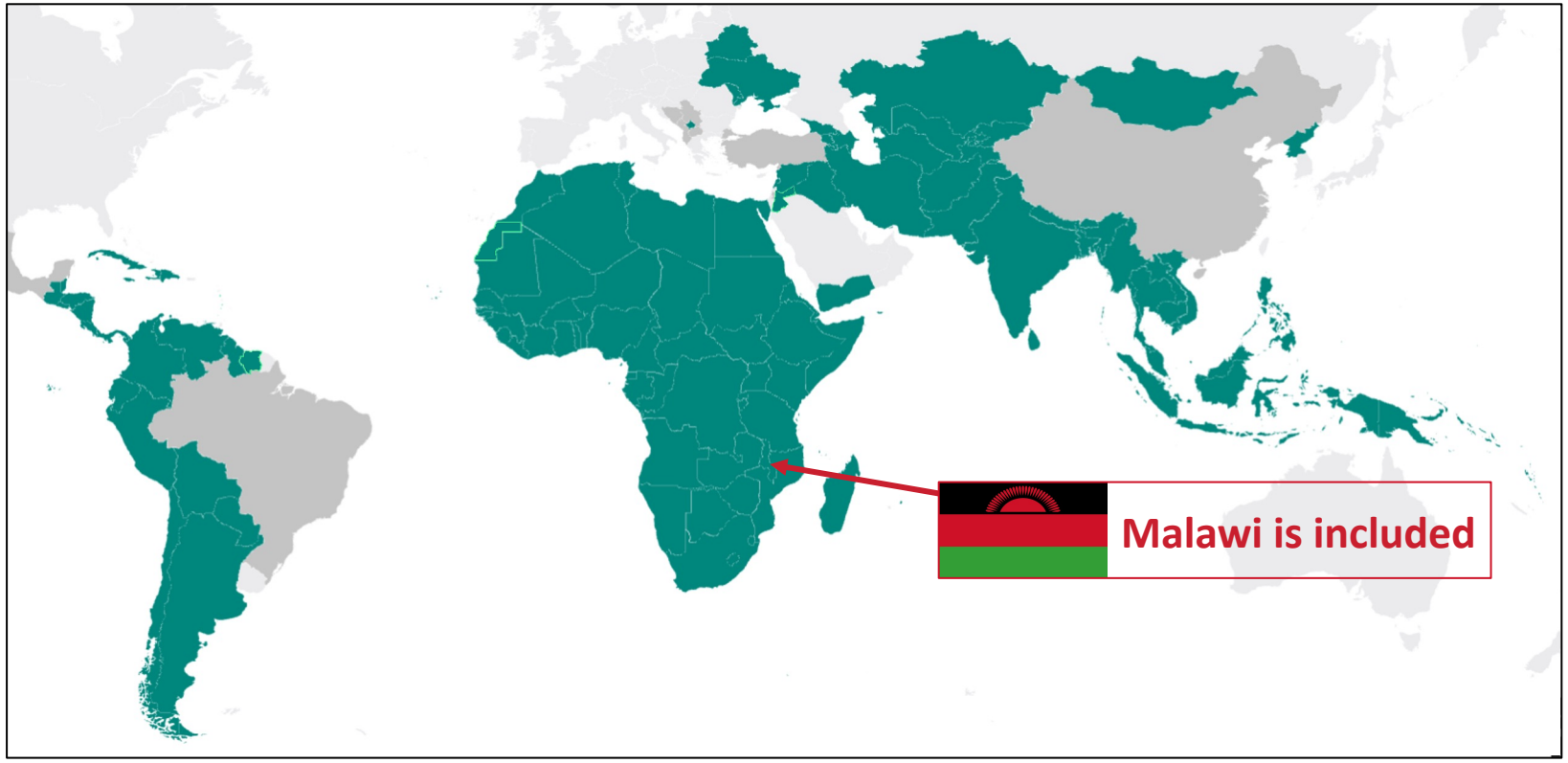


MPP's work in HIV is funded by Unitaid

Enabling access to DTG-based paediatric HIV treatment

1. Generic competition through partnership: Licensing

>130 countries able to access paediatric generic DTG products



More at: https://medicinespatentpool.org/licence-post/dolutegravir-paediatrics-dtg & https://accesspal.org

Enabling access to DTG-based paediatric HIV treatment

2. Generic development through partnership: Tech support

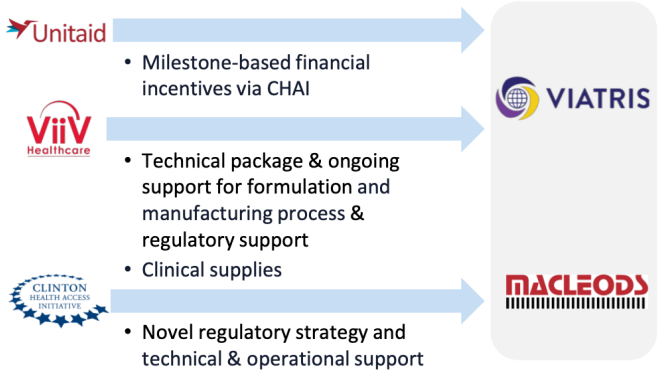
The paediatric DTG single tablet was developed with incentives, extensive technical support, and an innovative regulatory approval strategy…

Project Approach

1. Development Incentive Program

Generic manufacturers Mylan (a Viatris company) and Macleods were selected via competitive request for proposal (RfP) as partners to develop DTG 10mg dispersible and scored tablets in parallel with ViiV's development of a 5mg dispersible product.

ViiV conducted clinical trials to demonstrate safety, tolerability, and efficacy of DTG in children >3kg and >4 weeks old.



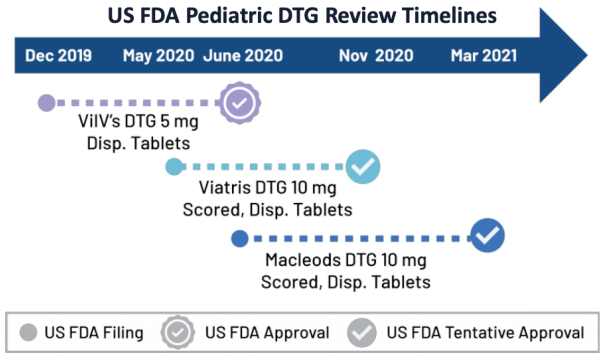
Negotiating an *affordable and sustainable* price in advance of product launch (**US $4.50 per 90-count bottle**) was a critical component of the incentive program. This resulted in a 75% price reduction from the existing lopinavir/ritonavir-based standard of care, which could generate **US $60-260 million in savings over five years.**

2. Innovative Regulatory Strategy

CHAI, with the support of ViiV, established an innovative regulatory approach enabling *concurrent* US FDA review of the generic products during innovator product review.

This pathway took advantage of the US FDA's PEPFAR review program, and the difference in strengths between the 5mg and 10mg products allowed the generic suppliers to submit their dossiers as 505(b)(2) new drug applications (NDAs) and priority review was obtained.

Advance agreement on this novel pathway with the US FDA improved confidence in filing success.



At the time of publication, 18 countries have approved DTG 10mg disp. and scored for use, with more registrations pending.

12X Faster than average generic pediatric HIV treatment approval SINCE PEPFAR was established

25X Faster than average generic pediatric HIV treatment approval EVER

2018 Project initiated

2019 Product developed

2020 Product approved

2021 Product launched

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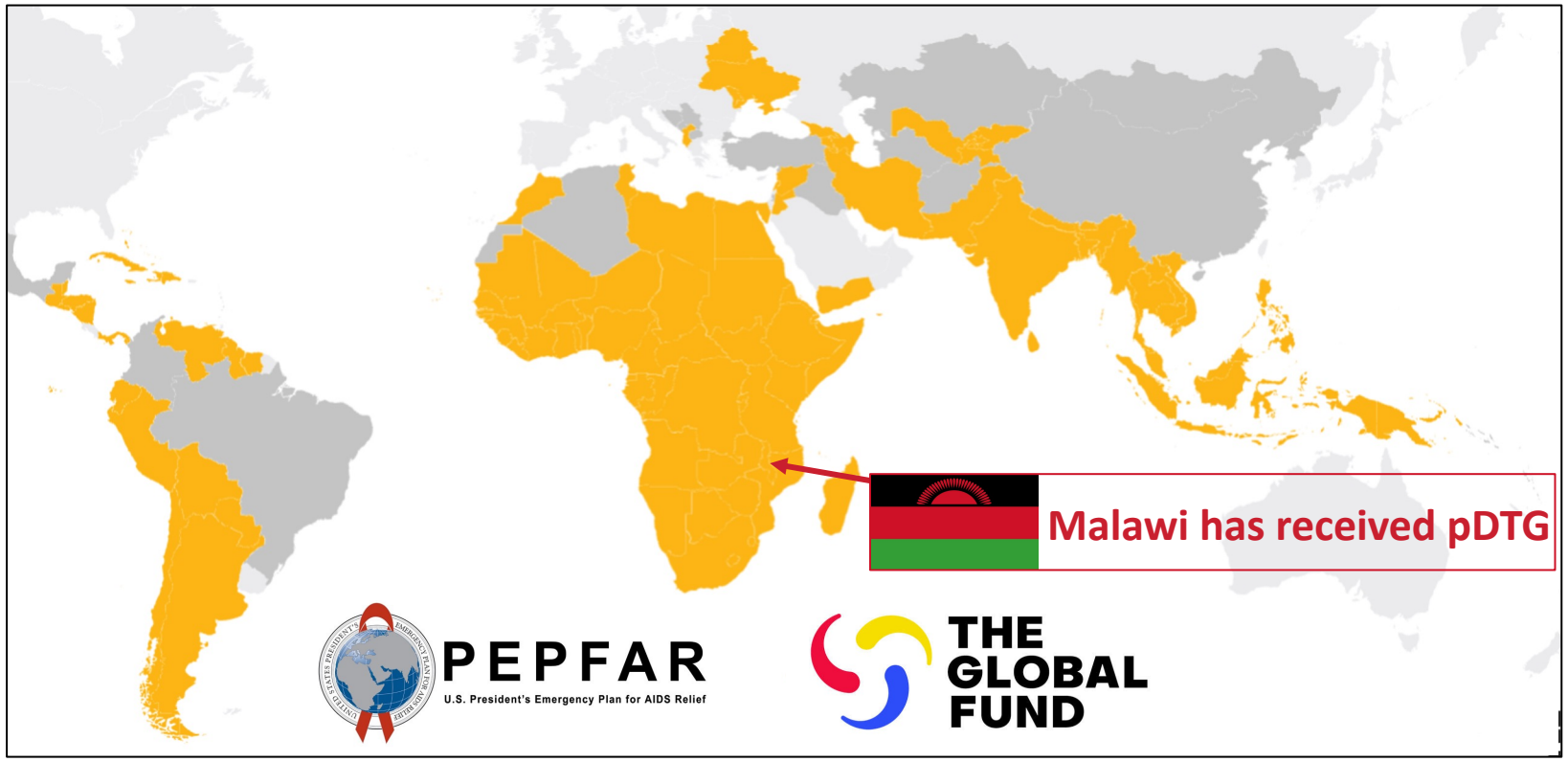
3. Generic rollout through partnership: Coordination

106 countries supplied pDTG 10mg scored dispersible tablets





GAP·f Global Accelerator for Paediatric formulations WHO Hosted Network

PAEDIATRIC DTG IMPLEMENTATION CONSIDERATIONS FOR NATIONAL PROGRAMMES

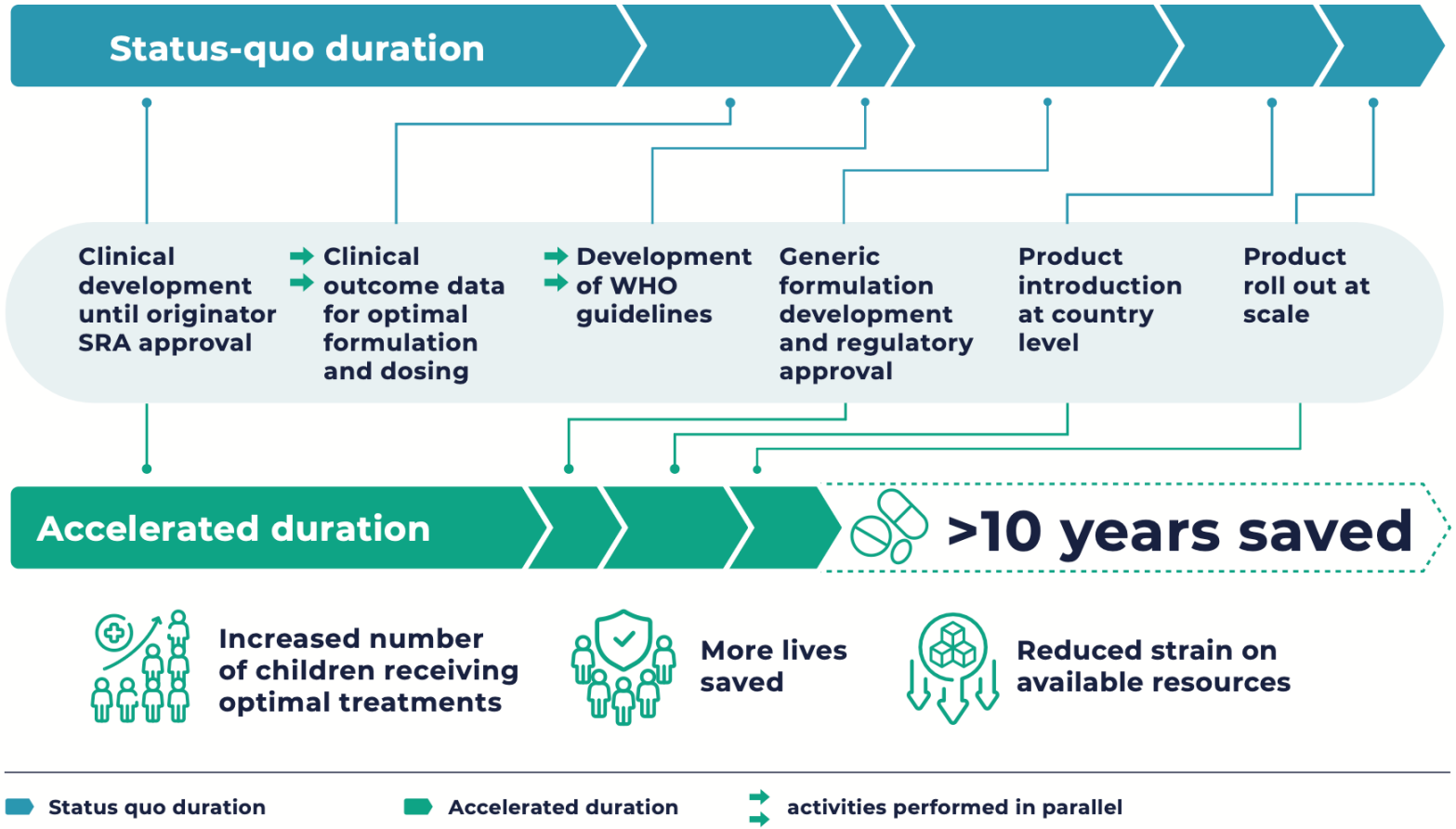
APRIL 2022

CDC · Clinton Health Access Initiative · Elizabeth Glaser Pediatric AIDS Foundation · medicines patent pool · Access Campaign · PATA · PEPFAR · USAID · World Health Organization

More at: https://medicinespatentpool.org/what-we-do/addressing-childrens-needs & https://accesspal.org (data by end Q2-2026)

Enabling access to DTG-based paediatric HIV treatment

4. Optimal formulation success story



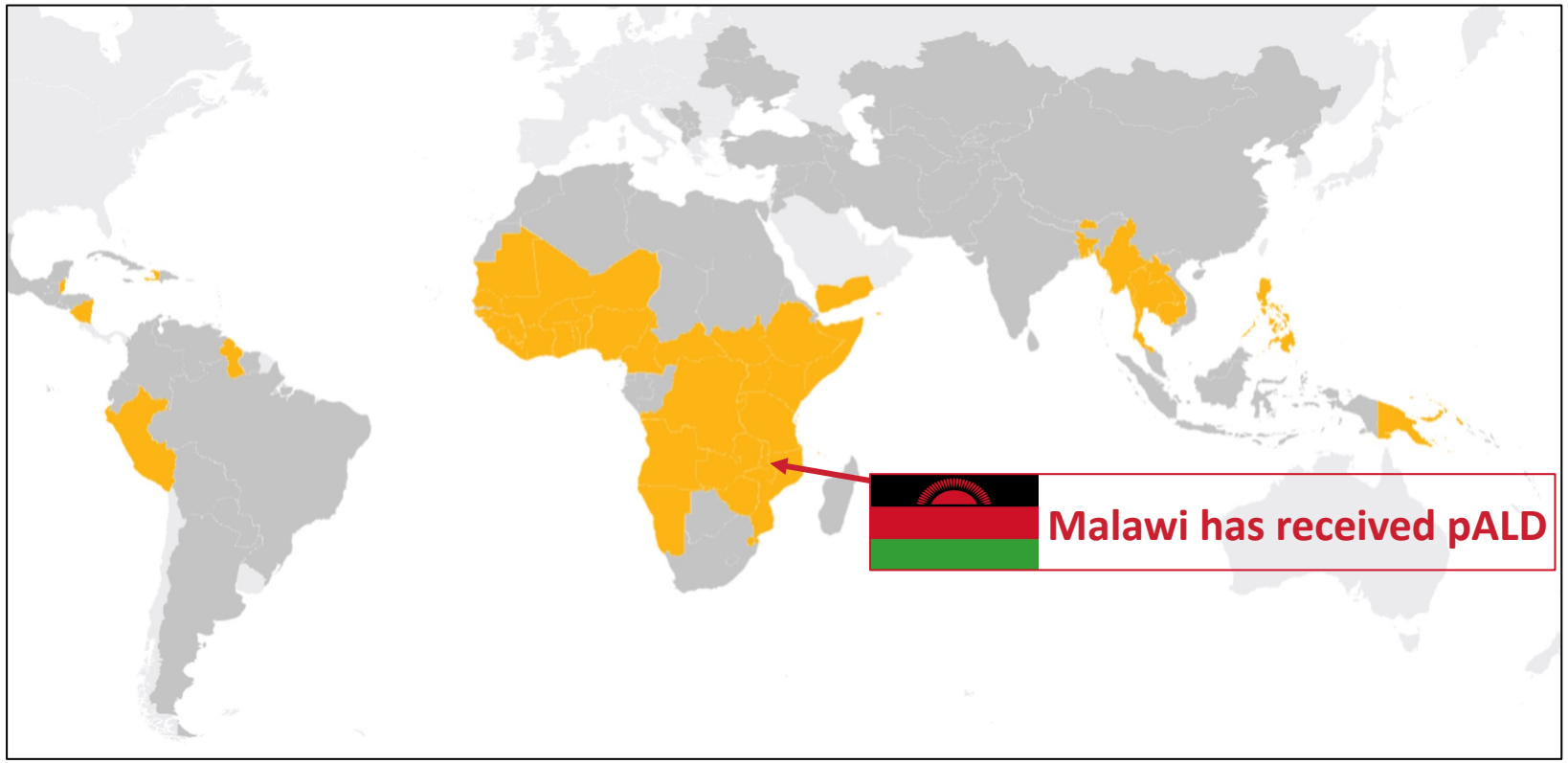
GAP-f Global Accelerator for Paediatric formulations WHO Hosted Network

*GAP-f, a WHO network created to **respond to the persistent paediatric treatment gap**, aims to replicate this success*

More coming soon as this story is being written for publication in a peer-reviewed journal…

Enabling access to DTG-based paediatric HIV treatment
5. Developing and rolling out a fixed dose combination

50 countries supplied pALD 60/30/5mg dispersible tablets





More at: https://medicinespatentpool.org/what-we-do/addressing-childrens-needs & https://accesspal.org (data by end Q2-2026)

In summary

Globally

- **The pDTG → pALD transition has advanced well since 2025**
- **pALD is now the most used paediatric DTG formulation**
- **By end of Q2-2026, pALD had been:**
  - Filed in 19 countries
  - Approved in 21 countries
  - Supplied in 50 countries
- **Many countries have not transitioned yet (including several in Africa)**

Malawi



- **pDTG rollout proceeded from Q1-2021 until Q4-2024**
  - During that period, 504,000 bottles of 90 tablets have been supplied
- **The transition to pALD started in Q4-2024**
  - To date, 250,000 bottles of 180 tablets have been supplied
- **Malawi can encourage other countries to transition to pALD by sharing its experience**

Some recommendations…
Advocating for children's access to optimal treatment

1. **Continue rolling out pALD** as the central pillar of HIV treatment in children <20 kg

2. **Document the Malawi experience with pALD** to date and share it with countries planning their transition

3. **Prioritize pALD for the smallest kids**, and transition those >20 kg to standard ALD tablets, and later to TLD



Thanks for your attention!

Thanks to our funders!

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And thanks for your collective dedication to HIV care for all

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