THE GLOBAL FUND

Joint Pharma Strategy

Supplier consultation: 2022-2025

Disclaimer

The Global Fund Procurement Strategy on pharmaceutical products is currently under development and will be finalized in the forthcoming months.

This document presents the Global Fund's current intention which is subject to change.

The data and information herein are provided for illustrative purposes and derive from a limited and preliminary analysis of the Global Fund.

The present document shall not be considered as the Global Fund's representation or commitment of any kind.

Some housekeeping rules

The audience will all be on Mute, only presenters will have access to the mic while presenting

The **chat function will be disabled** due to the time restrictions & the number of participants

During the QA session **please raise your hand** if you would like to share

Try to keep your comments and questions to 1 min during the Q&A session

Agenda

1. **Update of GF strategy (2023-2028) & NextGen Market Shaping** (12:05-12:15 pm)
2. **Disease Updates**
   - 2.1 WHO
     - 2.1.1 ARV (12:30-12:45)
     - 2.1.2 ANTM (12:15-12:30)
   - 2.2 Global Fund TAP Team
     - 2.2.1 ARV (12:45-12:55)
     - 2.2.2 ANTM (12:55-13:05)
     - 2.2.3 TB (13:05-13:15)
3. **Quality and Compliance**
   - 3.1 Global Fund QA Team (13:15--13:25)
   - 3.2 Ethics (13:25-13:35)

Break: 10 minutes (13:35-13:45)

4. **Market observations and evolution** (13:45-14:00)
   - 4.1 Current Market dynamic context
   - 4.2 Lessons learned from previous strategy implementation
   - 4.3 **Supplier** feedback on new strategy considerations
   - 4.4 **Partner** feedback on new strategy considerations
5. **Category insight and outlook** (14:00-14:15)
   - 5.1 Anti-Malaria Medicine(ANTM) Portfolio
   - 5.2 Antiretroviral medicine (ARV) Portfolio
6. **Joint Pharma Strategy & approach Principles** (14:15-14:25)
7. **Request for Proposal (RFP) outlines & Timelines** (14:25-14:35)

Q&A: (14:35-15:00)

Note: Follow-up meeting slots are available for potential bidders on Feb 16th & 17th and can be booked using the link

(https://outlook.office365.com/owa/calendar/DEMOBOOKINGS@tgf.onmicrosoft.com/bookings/)

Who are here today from Global Fund & Partners*

The Global Fund

Supply Operations

Hui Yang
Head of Supply Operations

Strategic Sourcing

Lin (Roger) Li
Senior Manager, Strategic Sourcing

Cathal Meere
Manager, Global Sourcing Pharmaceutical

Anne-Sophie Briand
Strategic Sourcing Category Lead: ANTM

Uranchimeg Badarch
Strategic Sourcing Category Lead: ARVs

Marlene Coffy
Strategic Sourcing Associate Specialist

Wanlin Ren
Strategic Sourcing Associate Specialist

Quality Assurance

Stephen Kimatu
Quality Assurance Specialist

Andrew Wingate
Strategic Sourcing Specialist

Technical Advice & Partnership (TAP)

Roopal Patel
Senior Diseases Advisor Malaria

Vindi Singh
Senior Diseases Advisor HIV/Aids

Grania Brigden
Senior Disease Advisor, TB

Legal Department

Tulin Adiyaman
Principle Legal Counsel

Ethics Office

Artem Lazurenko
Specialist, Integrity Due Diligence Ethics Office

WHO

Boniface Dongo Nguimfack
Technical Lead,
Access to Medicines and Diagnostics Services in the HIV Aids, Hepatitis and STIs Programme / Strategic Information Analysis & Use Unit

Silvia Schwarte
Technical Officer,
Global Malaria Strategy and Agenda Setting.
Global Malaria Programme

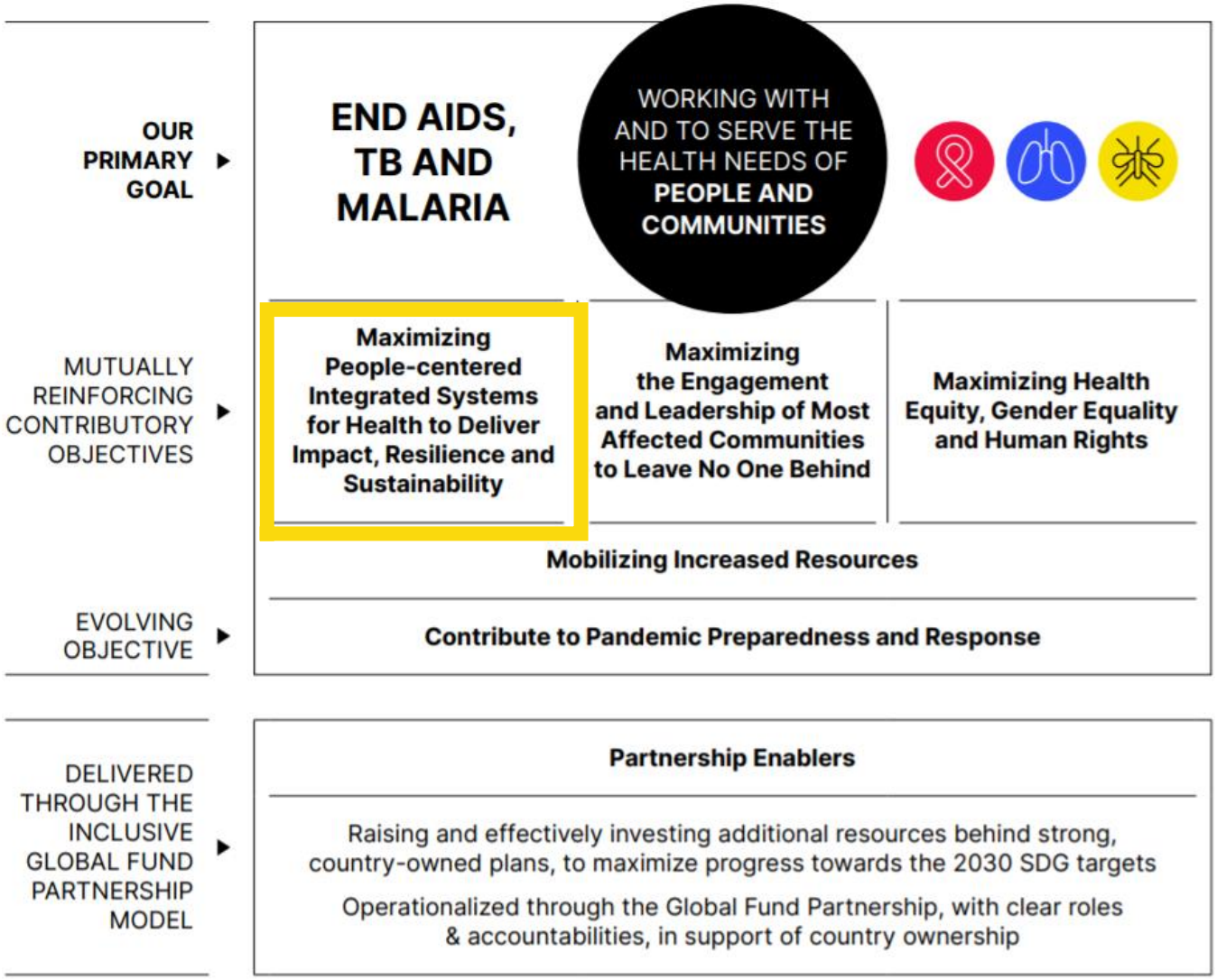
* Other Global Fund Colleagues present today include: Health Product Management, Risk Management, Finance, PR Services

Section 1:

Update of GF Strategy (2023-2028) and NextGen Market Shaping

2023-2028 Global Fund Strategy

NextGen Market Shaping

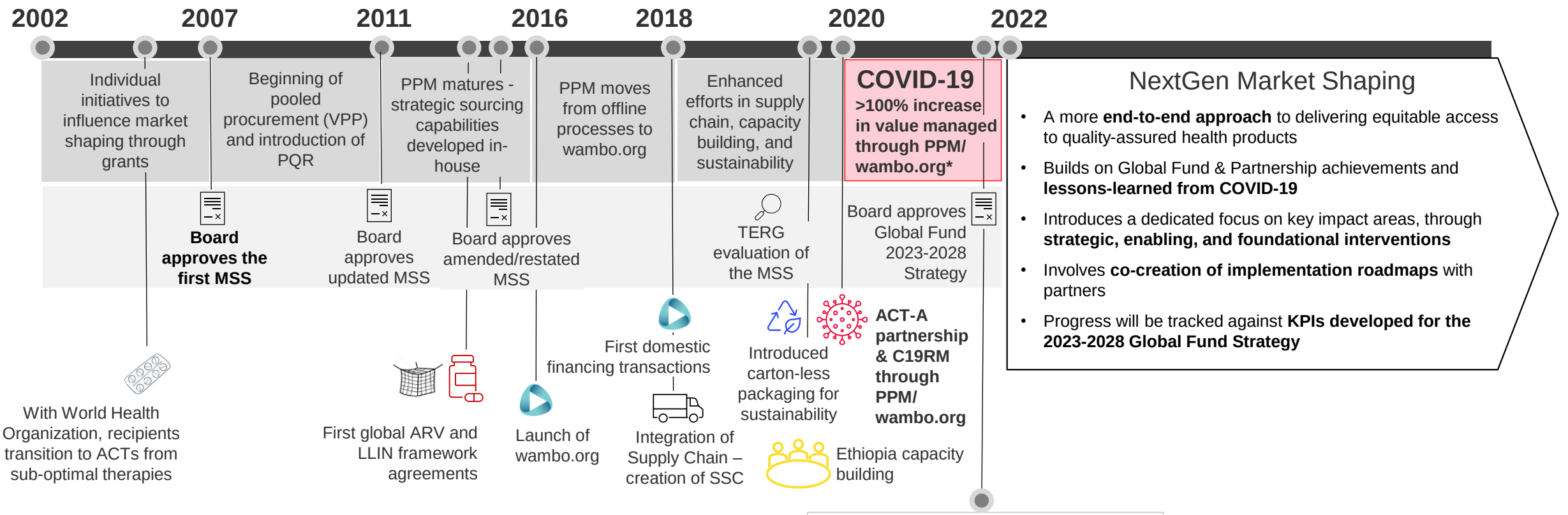


10 Examples of Aspects that Change our Work

1. **Across all three diseases, an intensified focus on prevention.** We have made better progress on saving lives than on reducing infections, but to end the pandemics, we have to cut new infections dramatically, including among key and vulnerable populations.
2. **Much more emphasis on integrated, people-centered services,** rising above disease silos to build RSSH that protect people from multiple pathogens, address their holistic needs and underpin health and well-being for all.
3. **A more systematic approach to supporting the development and integration of community systems for health,** recognizing the vital role they play in combatting the three diseases and reinforcing system resilience and sustainability.
4. **A stronger role and voice for communities living with and affected by the diseases,** reinforcing this unique strength of the Global Fund partnership and tackling barriers to effective participation and leadership, to put the most affected communities at the center of everything we do.
5. **Intensified action to address inequities, human rights and gender-related barriers,** scaling up and strengthening current activities, building on our experience, and raising our level of ambition.
6. **Greater emphasis on programmatic and financial sustainability,** to ensure the progress we achieve can withstand shocks and reversals, and that the momentum can be sustained.
7. **Greater focus on accelerating the equitable deployment of and access to innovations,** working with partners to take an end-to-end view to rapidly address bottlenecks to deployment to those most in need.
8. **Much greater emphasis on data-driven decision-making,** by investing in systems and capabilities to enable the rapid generation, analysis and use of high-quality, disaggregated data.
9. **Explicit recognition of the role the Global Fund partnership can and should play in pandemic preparedness and response,** given the knock-on impact of pandemics on HIV, TB and malaria, the unique positioning of the Global Fund in this arena, and acknowledging the need to define roles and responsibilities in collaboration with our partners.
10. **Clarity on the roles and accountabilities of Global Fund partners across every aspect of the Strategy** to ensure we hold each other mutually accountable in delivering this Strategy.

Evolution of the Global Fund's Market Shaping partnership efforts

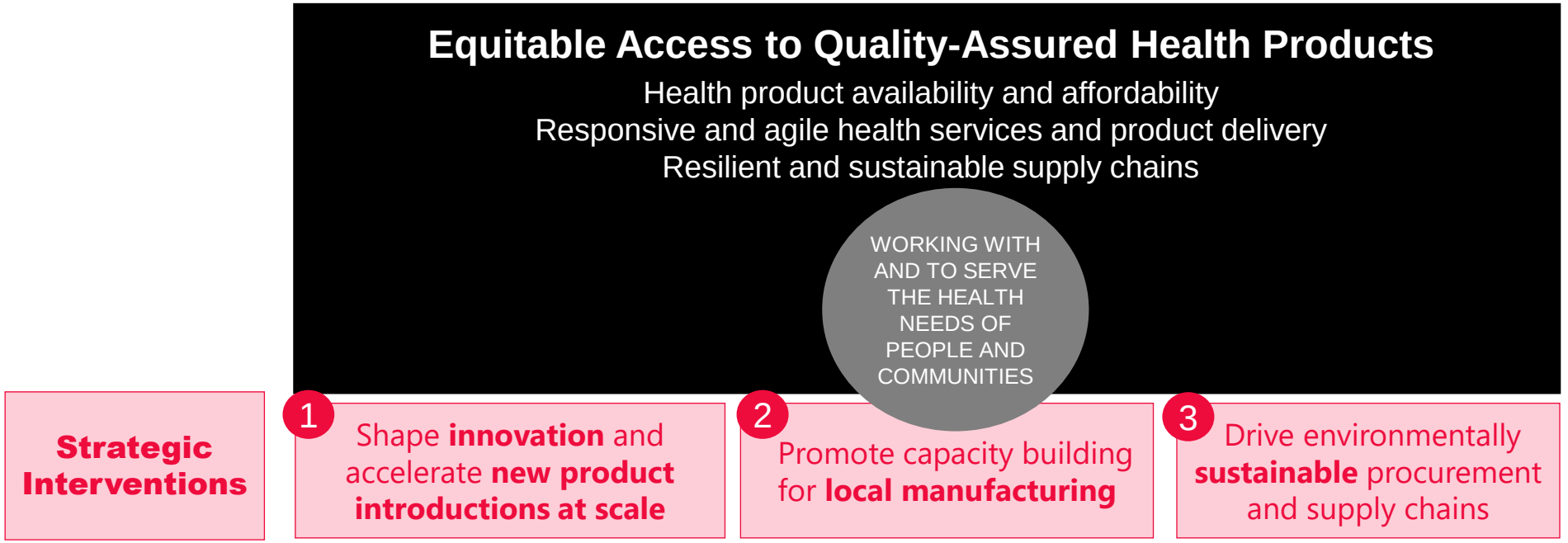
To date, our partnership's Market Shaping interventions have focused on leveraging pooled procurement and centralized sourcing to drive availability, affordability, and quality of health products. Now, with lessons learned from COVID-19, we have a platform to expand on our partnership's achievements, leveraging our increased scale to drive more comprehensive Market Shaping interventions.



THE GLOBAL FUND

ARVs = Antiretrovirals
LLINs = Long-lasting Insecticidal Nets
ACTs = Artemisinin combination therapies
MSS = Market Shaping Strategy
PPM = Pooled Procurement Mechanism
SSC = Sourcing and Supply Chain
*US$ 958M in 2019 versus US$ 2.2 billion in 2021
PQR = Price and Quality Reporting
VPP = Voluntary Pooled Procurement

NextGen Market Shaping Framework

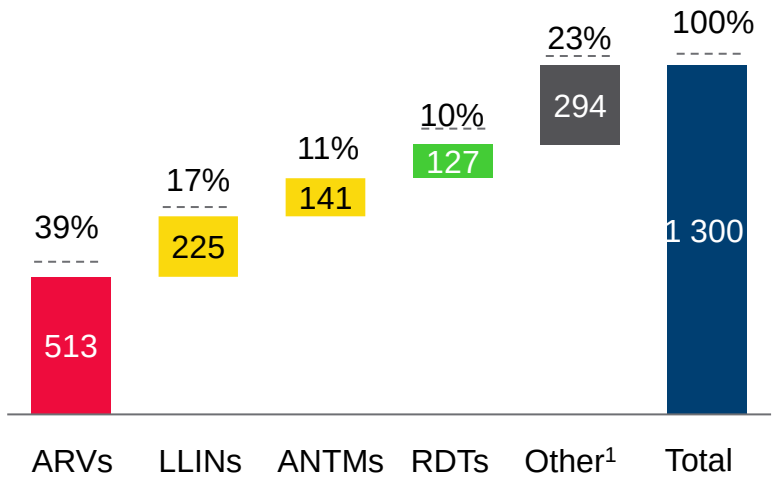


- Finalize Market Shaping Outline and initiate working groups to co-create implementation roadmaps through thematic consultations with partners (Q3 2022)
- Integrate outputs and finalize the complete market shaping framework (Q4 2022)
- Implement NextGen Market Shaping, including through operationalization of Joint Pharma Strategy

We will continue to leverage our scale to drive value through Market shaping interventions

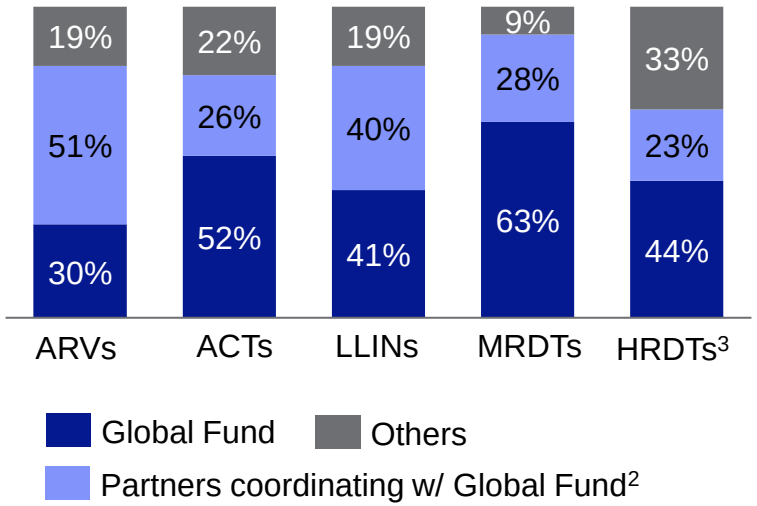
Total PPM spend ~$1.3B in 2020, with ~40% on ARVs

2020 GF PPM spend on each product category ($M)

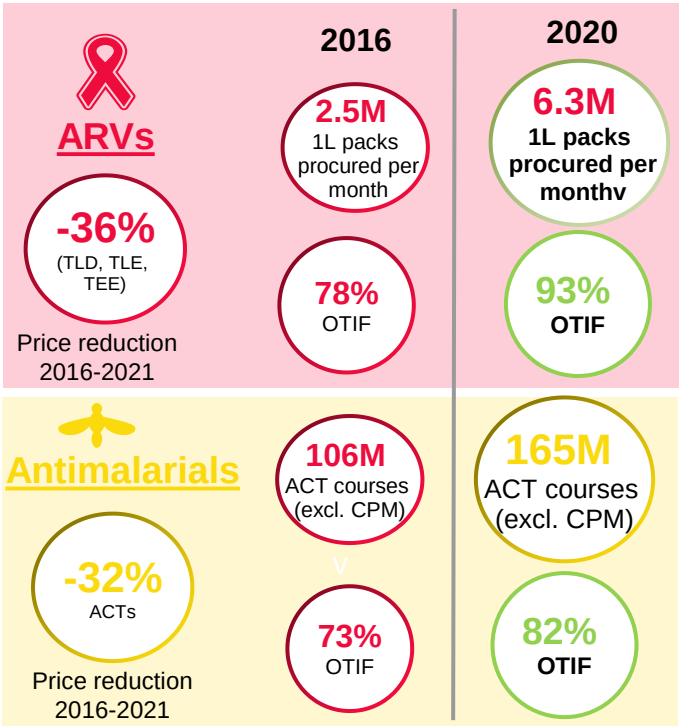


Global Fund market share between 30%-63% across key commodities

2020 Spend share for each product category (%)



PPM pharma 2016 versus 2021



1. Diagnostics, IRS, Laboratory and medical supplies, Condoms, Other essential medicines 2. ARVs, HRDTs : PEPFAR, RSA, ANTMs-LLINs-MRDTs : PMI 3. 2017 data
Source : 2020 Global Fund Annual Financial Reports, 2021 PFSCM Transaction Files, 2021 ARV Risk assessment and allocation memo, ANTMs Risk Assessment allocation 2021, 2021 LLINs Allocation Memo, 2021 Malaria RDT Supplier Allocation. OTIF = Supplier OTIF

Section 2:

Disease Updates*

- **WHO ARV & ANTM teams**
- **Global Fund TAP teams**

*Slides 12 to 37 have been provided by WHO

WHO HIV forecasts

Boniface Dongmo N.
WHO/UCN/HHS

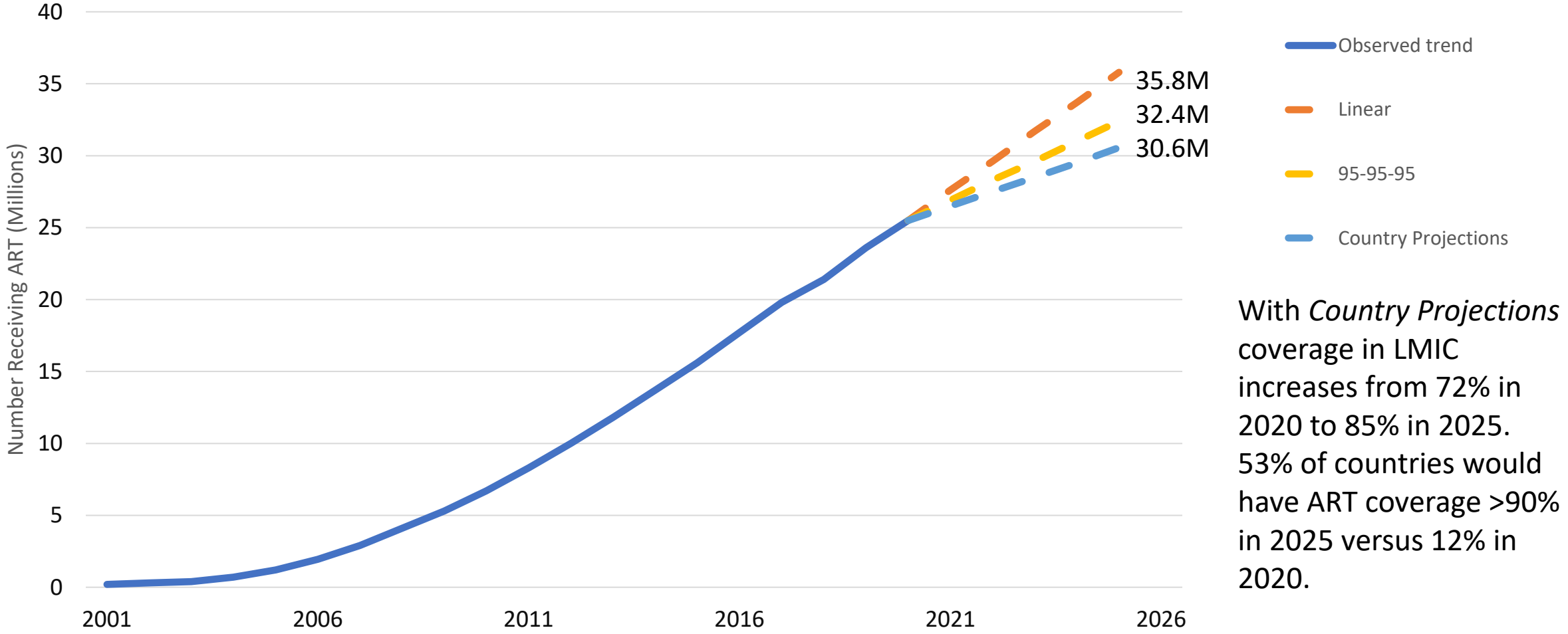
Consolidated Forecast of Global ARV Demand: Scenarios, Data and Forecasts 2020 – 2025

Global forecasts of antiretroviral demand for 2021 – 2025

6 October 2021

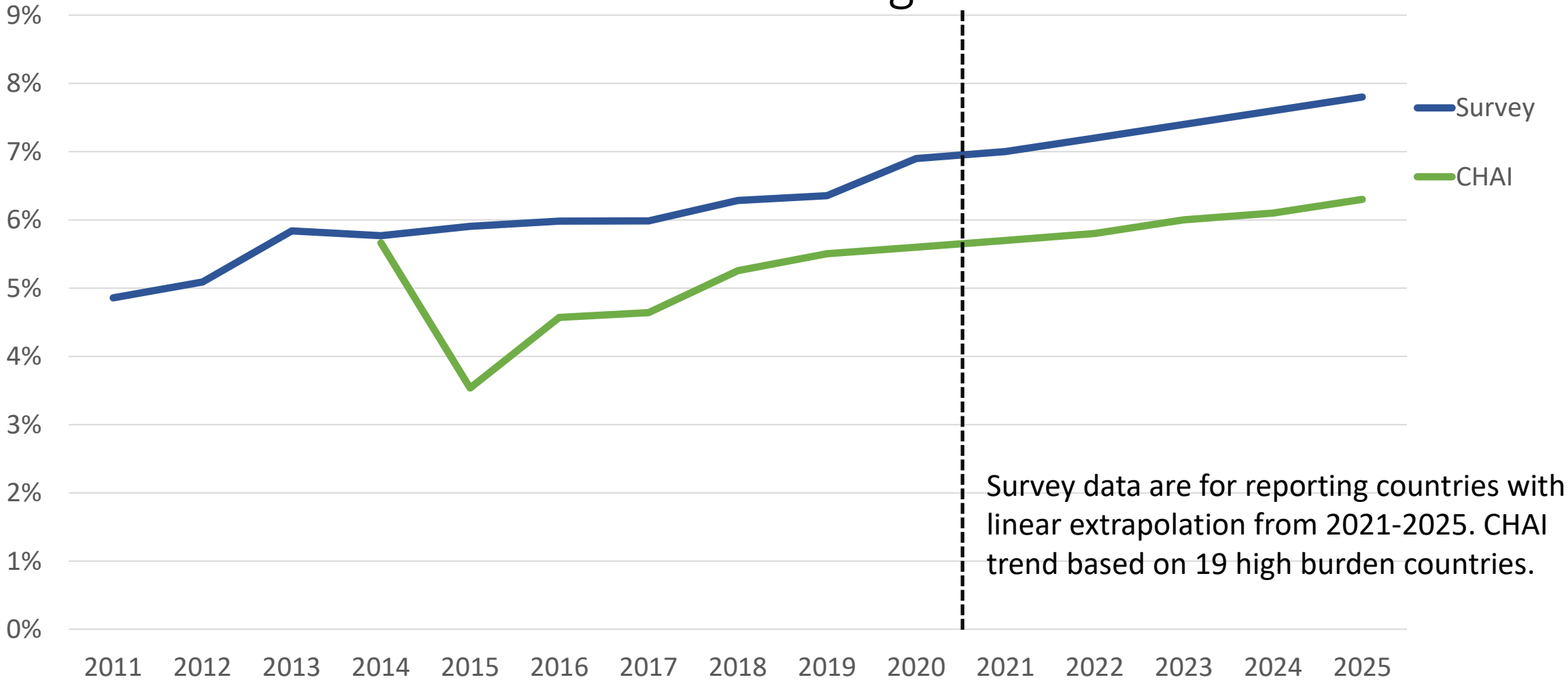
Forecasting Technical Working Group: WHO, UNICEF, CDC, CHAI, USAID-GHSC, Global Fund, UNAIDS, USAID, UNITAID, MPP, Avenir Health

Number of Adults and Children on ART in LMIC

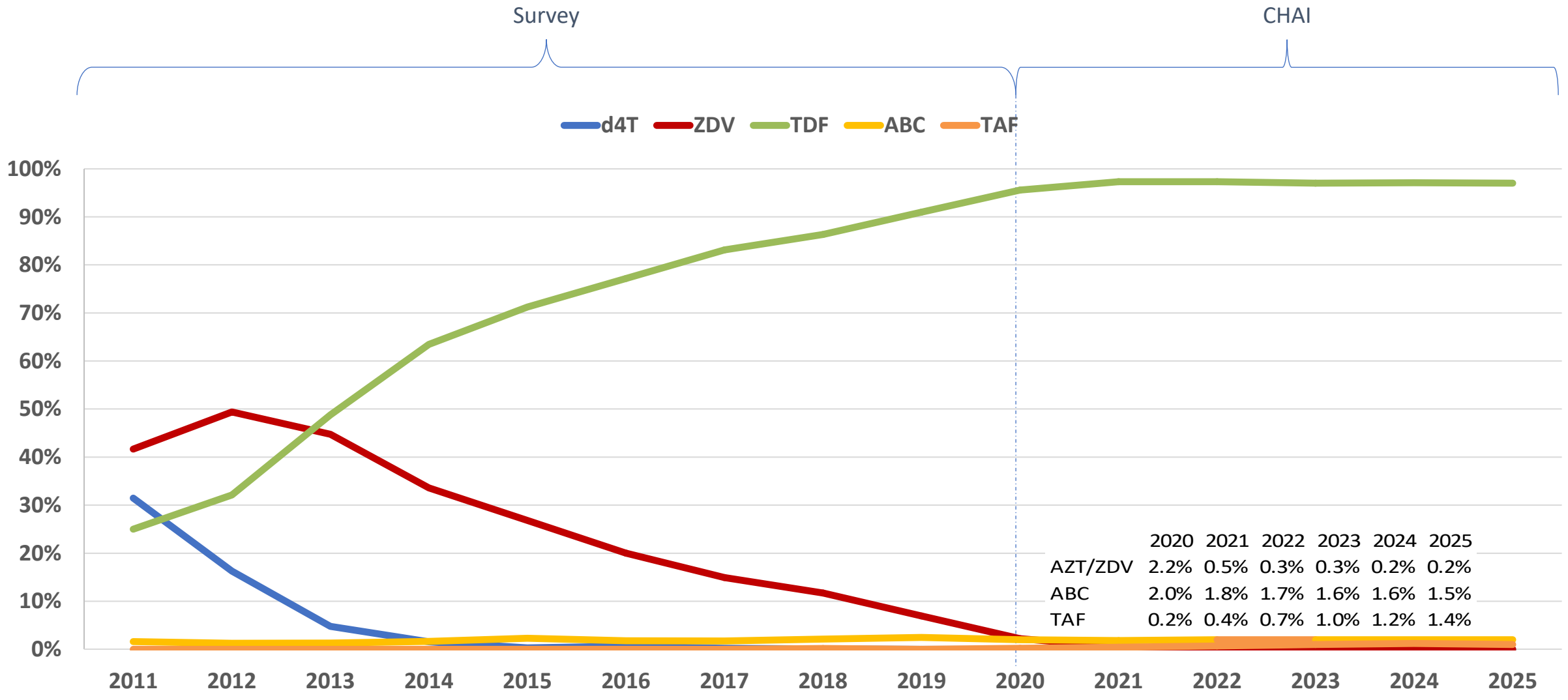


With *Country Projections* coverage in LMIC increases from 72% in 2020 to 85% in 2025. 53% of countries would have ART coverage >90% in 2025 versus 12% in 2020.

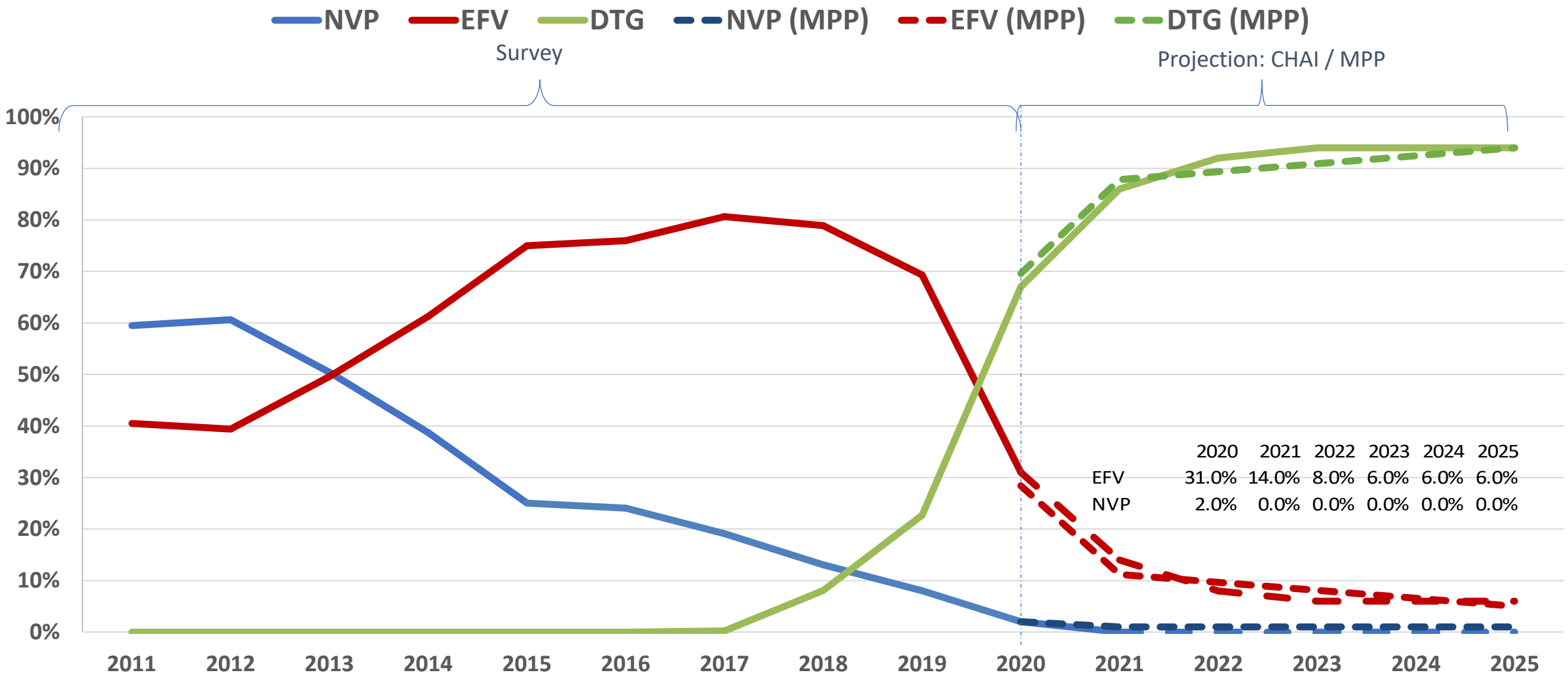
Percent of Adults on Second Line Regimens



Adult First-line Primary NRTIs (d4T, ZDV, TDF, ABC and TAF)

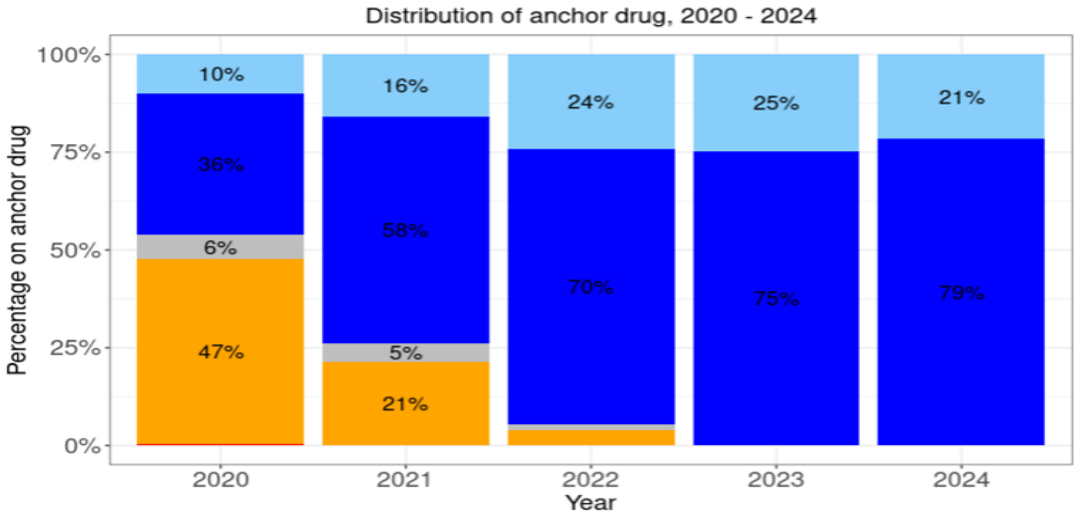


NNRTI and DTG Share of Adult First-line Market

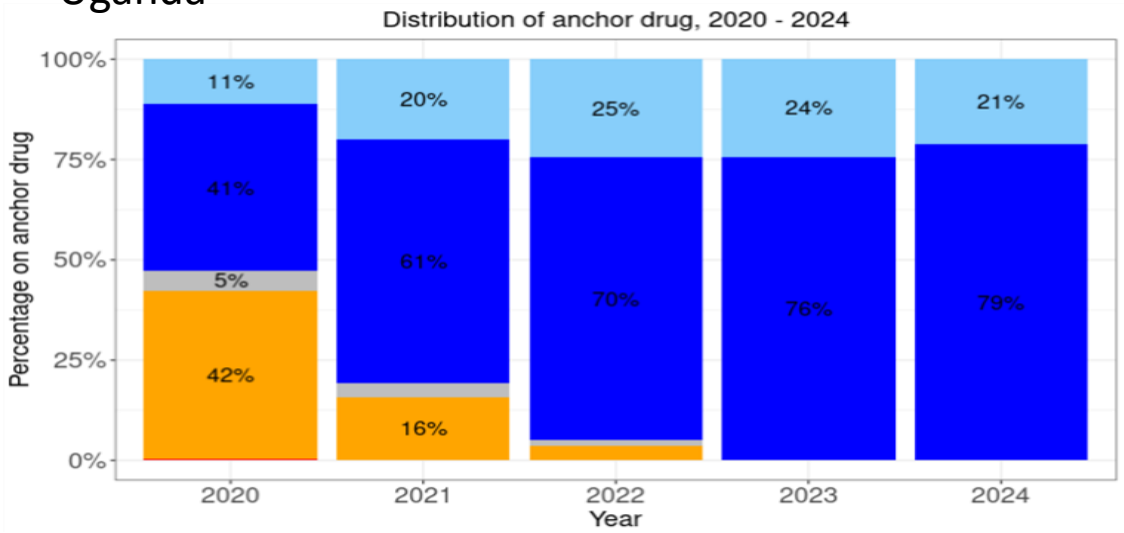


Distribution of anchor drug for Paediatrics, 2020-2024

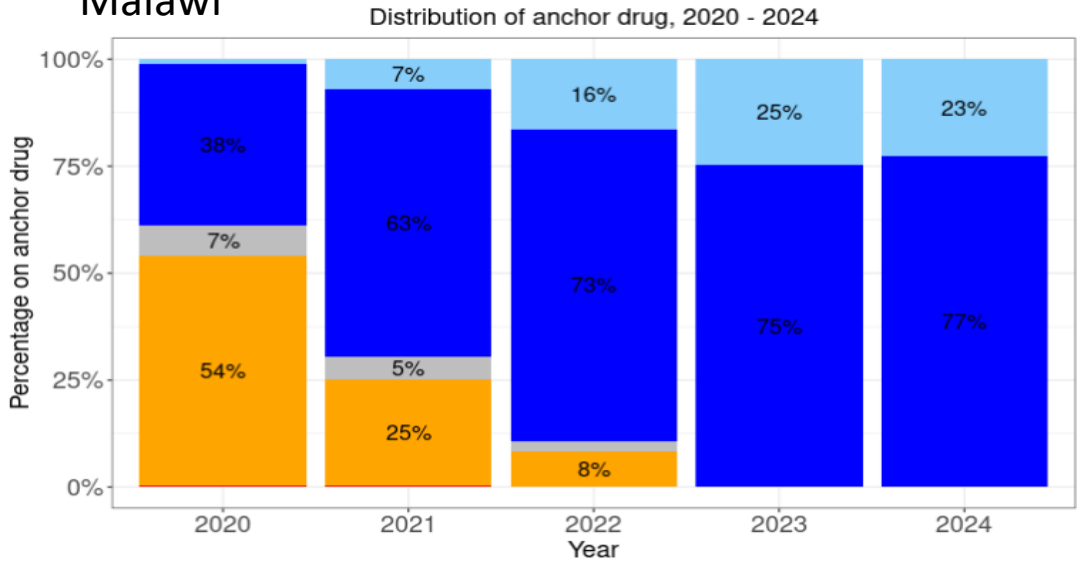
Zambia



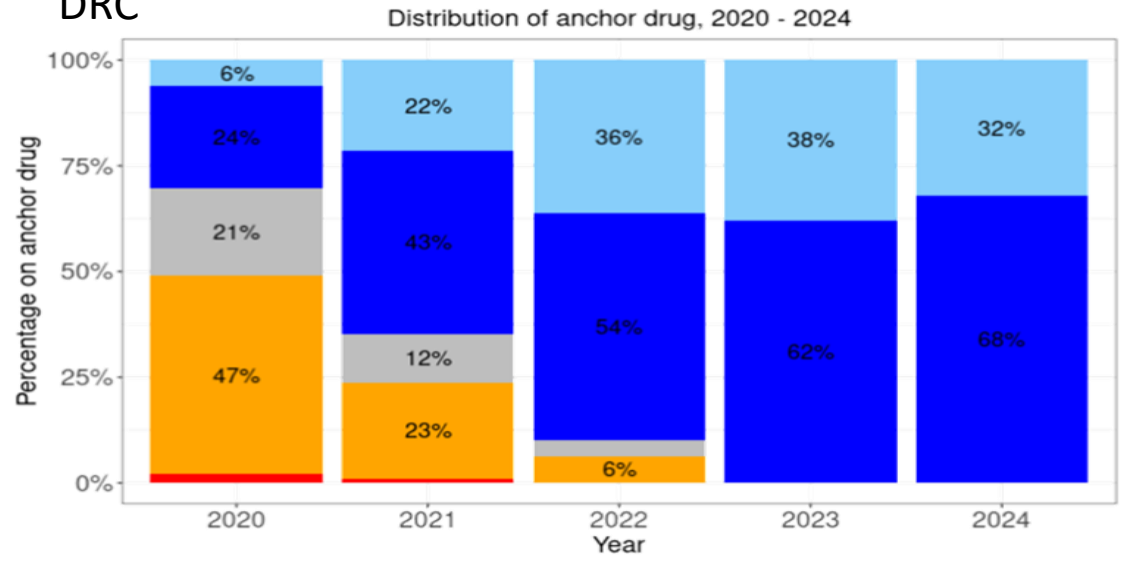
Uganda



Malawi



DRC



Anchor drug
LPV
EFV
RAL
DTG 10mg
DTG 50mg

Key Insights:

- Continued growth in numbers of people on ART. The number on ART in 2025 is projected to be 1/3 larger than 2020
- Slow increases in the proportion of adults on second line plus growth in numbers of patients means that patients on second line regimens will grow by 50% from 2020 to 2025.
- NVP and EFV market share largely replaced largely by DTG
- Challenges in projecting for 2L market given expected uptake and impact of DTG on adult transition to 2L and adults currently on 2L
- Reduction in growth of pediatric patient taking effect as more adults are on treatment and more children transition to adult treatment.
- Nevertheless, limited visibility in pediatric market with anticipated impact of DTG and greater effort in index testing.

WHO-recommended antimalarial medicines

Global Fund Supplier Consultation

15 February 2022

Virtual meeting

Silvia Schwarte

e-mail: schwartes@who.int

Global **Malaria** Programme

World Health Organization

What is in this presentation...

- Global Technical Strategy (GTS) 2016 – 2030, 2021 update
- World Malaria Report (WMR) 2021
- WHO Guidelines for malaria (July 2021) – MAGICapp – Recommendations for chemoprevention and case management
- WHO Prequalification

Global technical strategy for malaria 2016-2030, **2021 update**

VISION – A WORLD FREE OF MALARIA

GOALS	MILESTONES		TARGETS
	2020	2025	2030
1. Reduce malaria mortality rates globally compared with 2015	At least 40%	At least 75%	At least 90%
2. Reduce malaria case incidence globally compared with 2015	At least 40%	At least 75%	At least 90%
3. Eliminate malaria from countries in which malaria was transmitted in 2015	At least 10 countries	At least 20 countries	At least 35 countries
4. Prevent re-establishment of malaria in all countries that are malaria-free	Re-establishment prevented	Re-establishment prevented	Re-establishment prevented

STRATEGIC FRAMEWORK

– comprising three major pillars, with two supporting elements: (1) innovation and research, and (2) a strong enabling environment

Maximize impact of today's life-saving interventions

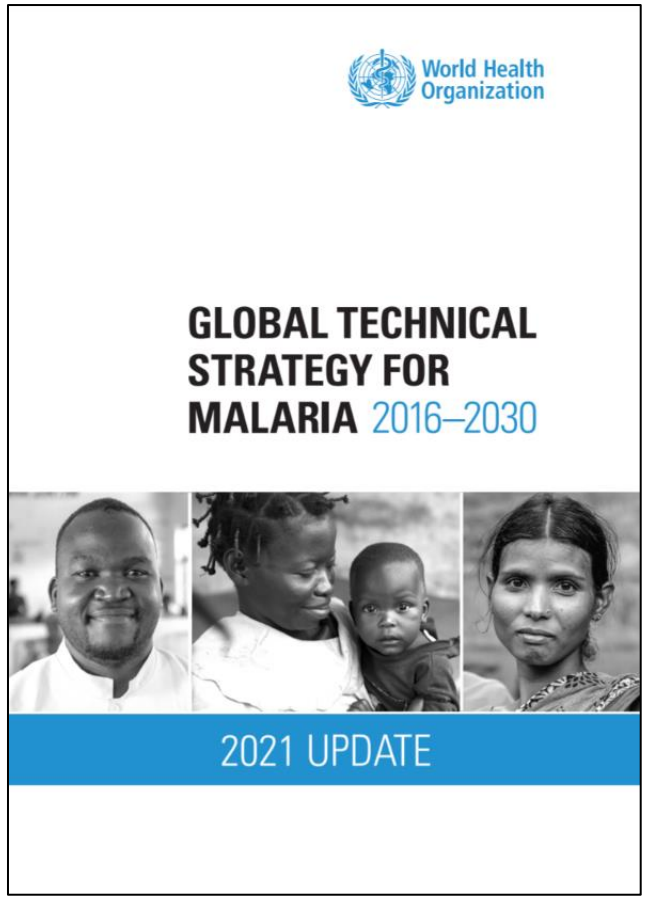
- **Pillar 1.** Ensure access to malaria prevention, diagnosis and treatment as part of universal health coverage
- **Pillar 2.** Accelerate efforts towards elimination and attainment of malaria-free status
- **Pillar 3.** Transform malaria surveillance into a key intervention

Supporting element 1. Harnessing innovation and expanding research

- Basic research to foster innovation and the development of new and improved interventions
- Implementation research to optimize impact and cost–effectiveness of existing interventions
- Action to facilitate rapid uptake of new interventions

Supporting element 2. Strengthening the enabling environment

- Strong political and financial commitments
- Multisectoral approaches, and cross-border and regional collaborations
- Stewardship of entire heath system including the private sector, with strong regulatory support
- Capacity development for both effective programme management and research



https://www.who.int/publications/i/item/9789240031357

WHO World Malaria Report 2021

https://www.who.int/teams/global-malaria-programme/reports/world-malaria-report-2021

2020 global estimates:

241 million malaria cases

627 000 malaria deaths

Key antimalarial interventions and strategies

Prevention

- Insecticide-treated mosquito nets (LLINs)
- Indoor Residual Spraying (IRS)

In areas of high and stable transmission

- **IPT in pregnancy (IPTp)**
- **IPT in infancy (IPTi)**

  Sulfadoxine-pyrimethamine (SP)

In areas of high seasonal transmission

- **Seasonal Malaria Chemoprevention (SMC)**

  SP-amodiaquine (SP+AQ)

Diagnosis and Treatment

- Parasite-based diagnosis: Microscopy or Rapid Diagnostic Tests (RDTs)
- **Artemisinin-based combination therapies** (ACTs)
- **Severe Malaria**: Artesunate (AS)
- **Transmission interruption (Pf), radical cure (Pv, Po):** Primaquine (PQ)

Case management service delivery areas:

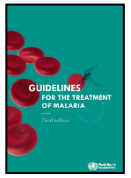
- Health facilities
- Community Case Management
- Private sector

Surveillance, M&E

- Routine Health Management Information System (HMIS)
- Malaria surveillance and response systems
- Household surveys
- Health Facility Surveys

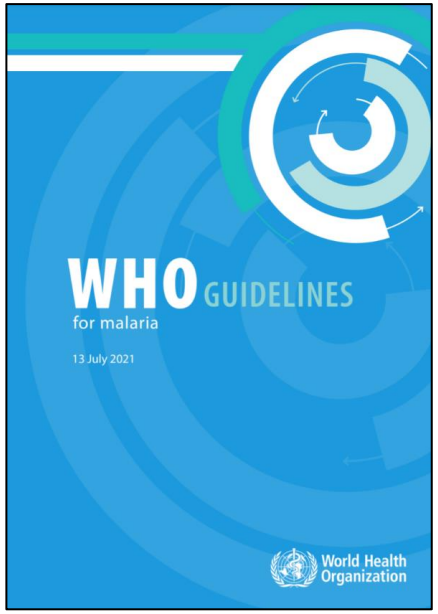
Strengthening health systems in endemic countries

WHO Guidelines for malaria



- The *WHO Guidelines for malaria* supersedes 2 previous WHO publications:
  the *Guidelines for the treatment of malaria*, 3rd *edition,* and the *Guidelines for malaria vector control.*

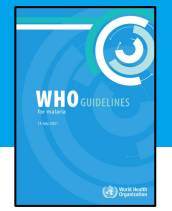
  Consolidated guidelines accessible on WHO website:
  https://www.who.int/publications/i/item/guidelines-for-malaria



- Most up-to-date recommendations for malaria in one user-friendly and easy-to-navigate place – MAGICapp online platform: https://app.magicapp.org/#/guideline/5700

Recommendations on malaria will continue to be reviewed and, where appropriate, updated based on the latest available evidence. Any updated recommendations will always display the date of the most recent revision in the **MAGICapp** platform. With each update, a new PDF version of the consolidated guidelines will also be available for download on the **WHO website**.

The second version of the Guidelines (**13 July 2021**) includes updates to the vector control guidance in the malaria prevention section and replaces the version published in February 2021.



4.2.1 Intermittent preventive treatment of malaria in pregnancy (IPTp)

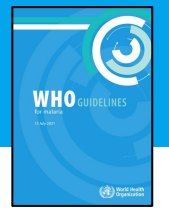
In malaria-endemic areas in Africa, provide intermittent preventive treatment with **SP** to all women in their first or second **pregnancy** (SP-IPTp) as part of antenatal care. Dosing should start in the second trimester and doses should be given at least 1 month apart, with the objective of ensuring that at least three doses are received.

4.2.2 Intermittent preventive treatment of malaria in infants (IPTi)

In areas of moderate-to-high malaria transmission of Africa, where SP is still effective, provide intermittent preventive treatment with **SP** to **infants (< 12 months** of age) (SP-IPTi) at the time of the second and third rounds of vaccination against diphtheria, tetanus and pertussis (DTP) and vaccination against measles.

4.2.3 Seasonal malaria chemoprevention (SMC)

In areas with highly seasonal malaria transmission in the Sahel subregion of Africa, provide seasonal malaria chemoprevention (SMC) with monthly **amodiaquine + SP** for all **children aged < 6 years** during each transmission season.



5.1 Diagnosing malaria (2015)

All cases of suspected malaria should have a **parasitological test** (microscopy or RDT) to confirm the diagnosis. Both microscopy and RDTs should be supported by a quality assurance programme.

5.2 Treating uncomplicated malaria

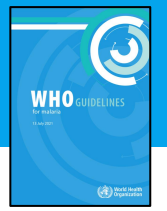
5.2.1 Artemisinin-based combination therapy

Treat children and adults with uncomplicated P. falciparum malaria (except pregnant women in their first trimester) with one of the following ACTs:

- artemether + lumefantrine
- artesunate + amodiaquine
- artesunate + mefloquine
- dihydroartemisinin + piperaquine
- artesunate + sulfadoxine–pyrimethamine

- artesunate + pyronaridine

  The use of artesunate-pyronaridine for the treatment of uncomplicated malaria https://www.who.int/publications/i/item/WHO-HTM-GMP-2019.13



5.2.2 Duration of treatment

Treating uncomplicated *P. falciparum* malaria (2015): ACT regimens should provide **3 days**' treatment with an artemisinin derivative.

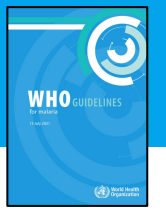
5.2.5 Reducing the transmissibility of treated *P. falciparum* infections in areas of low-intensity transmission

Reducing the transmissibility of treated *P. falciparum* infections: In low-transmission areas, give a **single dose of 0.25 mg/kg bw primaquine with ACT** to patients with *P. falciparum* malaria (**except** pregnant women, infants aged < 6 months and women breastfeeding infants aged < 6 months) to reduce transmission. G6PD testing is **not** required.

5.3 Treating special risk groups

5.3.1 Pregnant and lactating women

Treat pregnant women with uncomplicated *P. falciparum* malaria during the first trimester with **7 days of quinine + clindamycin**.



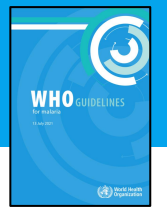
5.4 Treating uncomplicated malaria caused by *P. vivax, P. ovale, P. malariae* or *P. knowlesi*

(a.) Blood stage infection (2015)

In areas with chloroquine-susceptible infections, treat adults and children with uncomplicated *P. vivax, P. ovale, P. malariae* or *P. knowlesi* malaria with either **ACT** (except pregnant women in their first trimester) **or chloroquine**.

In areas with chloroquine-resistant infections, treat adults and children with uncomplicated *P. vivax, P. ovale, P. malariae* or *P. knowlesi* malaria (except pregnant women in their first trimester) with **ACT**.

Treat pregnant women in their first trimester who have chloroquine-resistant *P. vivax* malaria with **quinine**.



5.4 continued

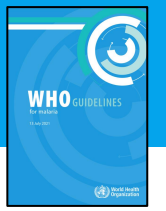
(b.) Relapse prevention

The **G6PD status** of patients should be used to guide administration of primaquine for **preventing relapse**.

- To prevent relapse, treat *P. vivax* or *P. ovale* malaria in children and adults (except pregnant women, infants aged < 6 months, women breastfeeding infants aged < 6 months, women breastfeeding older infants unless they are known not to be G6PD deficient, and people with G6PD deficiency) with a **14-day course of primaquine** in all transmission settings.
- In people with G6PD deficiency, consider preventing relapse by giving **primaquine** base at **0.75 mg/kg bw once a week for 8 weeks**, with close medical supervision for potential primaquine-induced haemolysis.

When G6PD status is unknown and G6PD testing is not available, a decision to prescribe primaquine must be based on an **assessment of the risks and benefits** of adding primaquine.

Pregnant and breastfeeding women: In women who are pregnant or breastfeeding, consider **weekly** chemoprophylaxis with **chloroquine** until delivery and breastfeeding are completed, then, on the basis of G6PD status, treat with **primaquine** to prevent future relapse.



5.5 Treating severe malaria

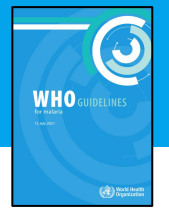
5.5.1 Artesunate

Treat adults and children with severe malaria (including infants, pregnant women in all trimesters and lactating women) with **intravenous or intramuscular artesunate** for at least 24 h and until they can tolerate oral medication. Once a patient has received at least 24 h of parenteral therapy and can tolerate oral therapy, complete treatment with **3 days of ACT.**

Children weighing < 20 kg should receive a **higher dose** of artesunate (3 mg/kg bw per dose) than larger children and adults (2.4 mg/kg bw per dose) to ensure equivalent exposure to the drug.

5.5.2 Parenteral alternatives when artesunate is not available

If artesunate is not available, use **artemether in preference to quinine** for treating children and adults with severe malaria.



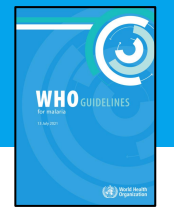
5.5.3 Pre-referral treatment options

Where complete treatment of severe malaria is not possible, but injections are available, give adults and children **a single intramuscular dose of artesunate**, *and refer* to an appropriate facility for further care.

Where intramuscular artesunate is not available use **intramuscular artemether** or, if that is not available, use **intramuscular quinine**.

Where intramuscular injection of artesunate is not available, treat children < 6 years with a **single rectal dose (10mg/kg bw) of artesunate**, and *refer* immediately to an appropriate facility for further care. Do **not** use rectal artesunate in older children and adults.

WHO Information Note: The use of rectal artesunate as a pre-referral treatment for severe *P. falciparum* malaria. https://www.who.int/publications/i/item/9789240042513



5.7.2 Quality of antimalarial drugs Antimalarial drug quality (2015)

National drug and regulatory authorities should ensure that the antimalarial medicines provided in both the public and the private sectors are of acceptable **quality**, through regulation, inspection and law enforcement.

5.7.3 Monitoring efficacy and safety of antimalarial drugs and resistance

All malaria programmes should regularly **monitor the therapeutic efficacy** of antimalarial drugs using the standard WHO protocols.

5.8 National adaptation and implementation

The **choice of ACTs** in a country or region should be based on optimal efficacy, safety and adherence.

Medicines used in IPTp, SMC and IPTi should **not** be used as a component of first-line treatments in the same country or region.

When possible, use:

- **fixed-dose combinations** rather than co-blistered or loose, single-agent formulations; and
- for young children and infants, **paediatric formulations**, with a **preference for solid formulations (e.g. dispersible tablets)** rather than liquid formulations.

Summary of required recommended medicines

Prevention

Intermittent preventive treatment (pregnancy and infants – IPTp, IPTi):

- sulfadoxine-pyrimethamine (SP)

Seasonal malaria chemoprevention (SMC):

- sulfadoxine-pyrimethamine + amodiaquine (SP + AQ)

Treatment

P. falciparum treatment – ACTs:

- Artemether + lumefantrine (AL)
- Artesunate + amodiaquine (AS+AQ)
- Artesunate + mefloquine (AS+MQ)
- Dihydroartemisinin + piperaquine (DHA+PPQ)
- Artesunate + sulfadoxine–pyrimethamine (AS+SP)
- Artesunate + pyronaridine (*see slide 8)

Treatment and pre-referral treatment of severe malaria

- Injectable artesunate (AS inj)
- Rectal artesunate (AS supp)

P. vivax treatment

- Chloroquine

P. falciparum transmission interruption, *P. vivax* radical cure

- Primaquine (PQ)

Summary of WHO-prequalified medicines (last updated 14 Feb 2022)

ACT fixed-dose combinations (FDCs)	
- AL 20/120mg	Ajanta, Cipla, **Guilin**, Ipca, **Laboratorios Basi**, Macleods, Mylan, Novartis, Strides
- AL 20/120mg dispersibles	Ajanta, **Cipla, Ipca, Guilin, Macleods, Strides**, Novartis
- AL 40/240mg	**Ajanta, Cipla, Macleods**, Mylan
- AL 40/ 240mg dispersible	**Guilin**
- AL 60/ 360mg	**Ajanta, Cipla**
- AL 60/ 360mg dispersible	**Guilin**
- AL 80/480mg	**Ajanta, Cipla, Ipca, Guilin, Macleods, Strides,** Novartis
- ASAQ	Ajanta, Cipla, Guilin, Ipca, **Macleods, Microlabs**, Sanofi
- ASMQ	Cipla
- DHA-PPQ (20/160mg, 40/320mg)	Sigma-Tau
- DHA-PPQ (40/320mg, 60/480mg, 80/640mg)	**Guilin**
- DHA-PPQ (20/160mg, 30/240mg, 40/320mg), disp	**Guilin**
ACT co-Blisters (Co-B)	
- AS + AQ	Cipla, Guilin, Ipca, Strides
- AS + SP	Guilin
Injectables	
- AS (30/60/120mg)powder for inj	Guilin
- AS 60 mg	**Macleods, Ipca**
- Artemether (80mg/ml)	**Sanofi**
Rectal artesunate (RAS)	
- RAS 100 mg	**Cipla, Strides**
Preventive medicines	
- SP 500/25mg	**Guilin**
- SP 250/12,5mg, dispersible	**Skant, Macleods**
- SP 500/25mg, dispersible	**Skant, Macleods**
- SP + AQ (76.5+250/12.5mg, 153+500/25mg)	Guilin
- SP + AQ (76.5+250/12.5mg, 153+500/25mg), disp	**Guilin**
- SP + AQ (75+250/12.5mg, 150+500/25mg), disp	**SKant**
AS + pyronaridine (20/60mg, 60/180mg)	Shin Poong / EMA Article 58

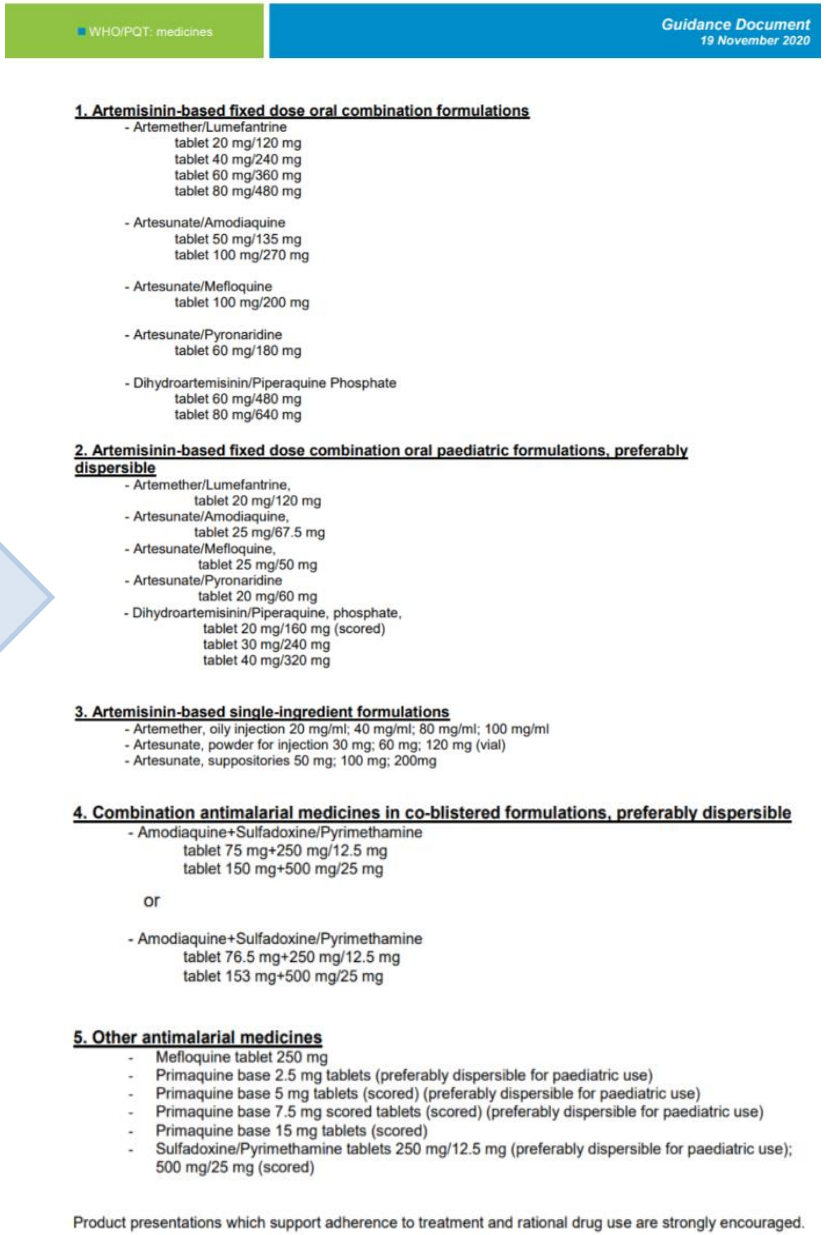
WHO-prequalified medicines since last presentation in 2016

WHO Prequalification Programme

List of WHO prequalified medicines / Finished Pharmaceutical Products
https://extranet.who.int/pqweb/medicines/prequalified-lists/finished-pharmaceutical-products

19th **Invitation to Manufacturers of Anti-malarial Medicines** to Submit an **Expression of Interest (EOI)** for Product Evaluation to the WHO Prequalification Unit (PQT), 19 Nov 2020
https://extranet.who.int/pqweb/sites/default/files/documents/EOI-MalariaV19.pdf

General information on the Prequalification Programme for medicines
https://extranet.who.int/pqweb/medicines



WHO/PQT: medicines — Guidance Document 19 November 2020

1. Artemisinin-based fixed dose oral combination formulations
- Artemether/Lumefantrine
  tablet 20 mg/120 mg
  tablet 40 mg/240 mg
  tablet 60 mg/360 mg
  tablet 80 mg/480 mg
- Artesunate/Amodiaquine
  tablet 50 mg/135 mg
  tablet 100 mg/270 mg
- Artesunate/Mefloquine
  tablet 100 mg/200 mg
- Artesunate/Pyronaridine
  tablet 60 mg/180 mg
- Dihydroartemisinin/Piperaquine Phosphate
  tablet 60 mg/480 mg
  tablet 80 mg/640 mg

2. Artemisinin-based fixed dose combination oral paediatric formulations, preferably dispersible
- Artemether/Lumefantrine,
  tablet 20 mg/120 mg
- Artesunate/Amodiaquine,
  tablet 25 mg/67.5 mg
- Artesunate/Mefloquine,
  tablet 25 mg/50 mg
- Artesunate/Pyronaridine
  tablet 20 mg/60 mg
- Dihydroartemisinin/Piperaquine, phosphate,
  tablet 20 mg/160 mg (scored)
  tablet 30 mg/240 mg
  tablet 40 mg/320 mg

3. Artemisinin-based single-ingredient formulations
- Artemether, oily injection 20 mg/ml; 40 mg/ml; 80 mg/ml; 100 mg/ml
- Artesunate, powder for injection 30 mg; 60 mg; 120 mg (vial)
- Artesunate, suppositories 50 mg; 100 mg; 200mg

4. Combination antimalarial medicines in co-blistered formulations, preferably dispersible
- Amodiaquine+Sulfadoxine/Pyrimethamine
  tablet 75 mg+250 mg/12.5 mg
  tablet 150 mg+500 mg/25 mg

or

- Amodiaquine+Sulfadoxine/Pyrimethamine
  tablet 76.5 mg+250 mg/12.5 mg
  tablet 153 mg+500 mg/25 mg

5. Other antimalarial medicines
- Mefloquine tablet 250 mg
- Primaquine base 2.5 mg tablets (preferably dispersible for paediatric use)
- Primaquine base 5 mg tablets (scored) (preferably dispersible for paediatric use)
- Primaquine base 7.5 mg scored tablets (scored) (preferably dispersible for paediatric use)
- Primaquine base 15 mg tablets (scored)
- Sulfadoxine/Pyrimethamine tablets 250 mg/12.5 mg (preferably dispersible for paediatric use); 500 mg/25 mg (scored)

Product presentations which support adherence to treatment and rational drug use are strongly encouraged.

Thank you

Suppliers Consultation

Global Fund ANTM Team Presentation

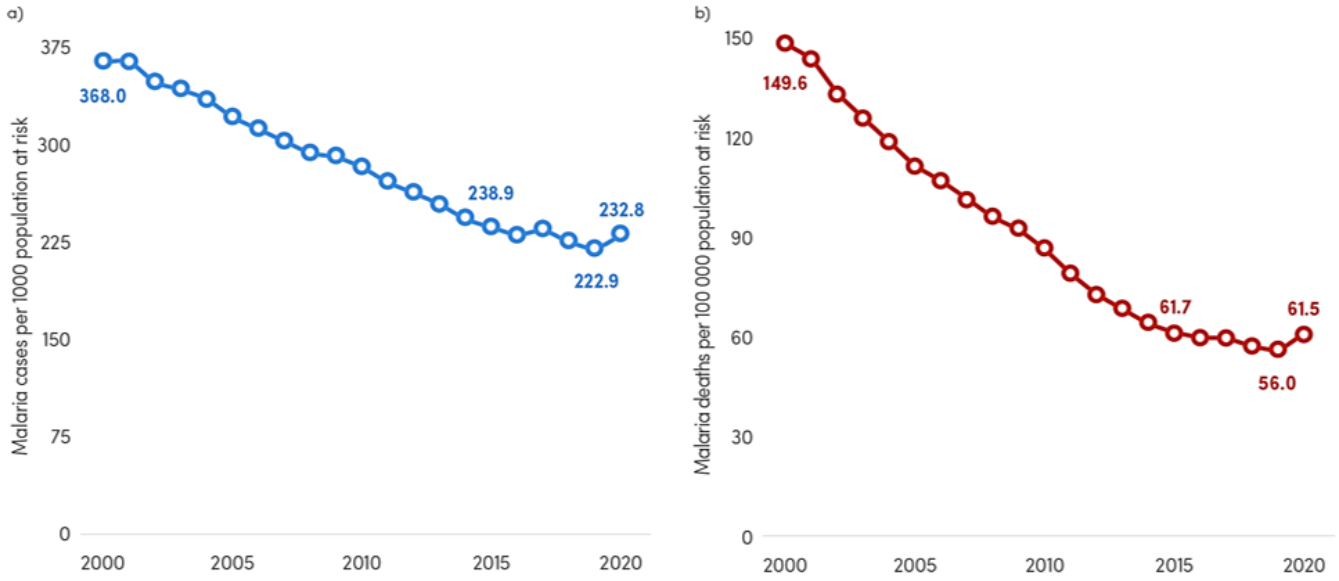
Feb 15, 2022

Malaria strategy objectives 2023-2028

1. Ensure optimal effective vector control coverage
2. Expand equitable access to quality early diagnosis and treatment of malaria, through health facilities, at the community level and in the private sector, with accurate reporting
3. Implement malaria interventions, tailored to sub-national level, using granular data, and capacitating decision-making and action
4. Drive towards elimination and facilitate prevention of reestablishment of malaria
5. Accelerate reductions in malaria in high burden areas and achieve sub-regional elimination in (a) select area(s) of sub-Saharan Africa to demonstrate the path to eradication

FIG. 3.3.

Trends in a) malaria case incidence (cases per 1000 population at risk) and b) mortality rate (deaths per 100 000 population at risk), 2000–2020; and c) malaria cases by country in the WHO African Region, 2020 *Source: WHO estimates.*



WHO: World Health Organization.

WMR 2021: Observed reduction in overall cases and deaths between 2000 and 2017, stagnated through 2019 and increasing in the context of the COVID-19 pandemic and disruption in malaria services.

Priorities for Malaria Case Management and Chemoprevention

Malaria case management	• Improving access and quality in public sector, community and private sector. • Continued focus on adherence, ease of use, formulations, tolerability and affordability. • Addressing *P. vivax* including radical cure. • Severe malaria and the continuum of care.
Addressing biologic threats	• Improved surveillance and mapping of drug resistance. • Prevention and mitigation of resistance – strategies to reduce selection pressure of current ACTs including diversifying 1st line treatment based on the context and support innovation for newer drugs.
Prevention	• Continued and expanded availability of ANTMs for expanding strategic areas in chemoprevention--- IPTi, SMC, MDA. • Portfolio of ANTMs to balance optimal delivery and impact of IPTp, SMC and IPTi and maintain effectiveness of first- line treatments in the same country.

Suppliers Consultation

Global Fund HIV Team Presentation

Feb 15, 2022

Global Fund Strategy 2023-2028: END AIDS sub-objectives

1. Accelerate access to and effective use of precision combination prevention, with behavioral, biomedical, and structural components tailored to the needs of populations at high risk of HIV infection, especially KVP
    - Close gaps in HIV prevention coverage
    - **Accelerate access to and use of new HIV prevention options**
    - Evolve and expand the range of platforms for access to and delivery of people-centered HIV prevention

2. Provide quality, people-centered diagnosis, treatment and care, to improve well-being for PLHIV, prevent premature mortality and eliminate HIV transmission
    - Optimize diagnostic pathways
    - Differentiate and scale up quality HIV treatment services
    - Integrate services to prevent, identify, and treat advanced HIV disease, comorbidities, and coinfections
    - Evolve care pathways to strengthen therapeutic alliances between the people in care and the health and community systems
    - **Accelerate the introduction of diagnostics, therapeutics, technologies, and service delivery innovations**

3. Advocate for and promote legislative, practice, program and policy changes to reduce HIV-related stigma, discrimination, criminalization, other barriers and inequities and uphold the rights of PLHIV and KVP

End AIDS sub-objectives aligned with global goals

Objectives

Objective 1: Accelerate access to and effective use of precision combination prevention, with behavioral, biomedical and structural components tailored to the needs of populations at high risk of HIV infection, especially key and vulnerable populations (KVP).

Objective 2: Provide quality, people-centered diagnosis, treatment and care, to improve wellbeing for people living with HIV (PLHIV), prevent premature mortality and eliminate HIV transmission.

Objective 3: Advocate for and promote legislative, practice, program and policy changes to reduce HIV-related stigma, discrimination, criminalization, other barriers and inequities and uphold the rights of PLHIV and KVPs

Outcome

- 95% of people at risk of HIV infection use appropriate, prioritized, person-centered and effective combination prevention options.

- 95% of HIV is diagnosed (early) –in all populations – including HIV exposed children
- 95% of PLHIV (all subpopulations, age including children living with HIV) get effective combination therapy
- 95% of PLHIV achieve and sustain viral suppression (all subpopulations, including pregnant and breastfeeding women & children)
- 90% of PLHIV receive preventive treatment for TB & comorbidities/coinfection

- Less than 10% of countries have punitive legal and policy environments that lead to the denial or limitation of access to services.
- Less than 10%of people living with HIV and key populations experience stigma and discrimination.
- Less than 10% of women, girls, people living with HIV and key populations experience gender-based inequalities and all forms of gender-based violence.

Impact

- 90% reduction in annual new HIV infections by 2030 (baseline of 2010).
- Elimination of vertical transmission
- 90% reduction in new infections and AIDS-related deaths (2010 baseline).
- Less than 10% of people living with HIV (& key populations) experience stigma and discrimination.

Vision

Zero new infections, Zero AIDS related deaths, Zero discrimination

Health Products for HIV diagnosis, prevention and treatment

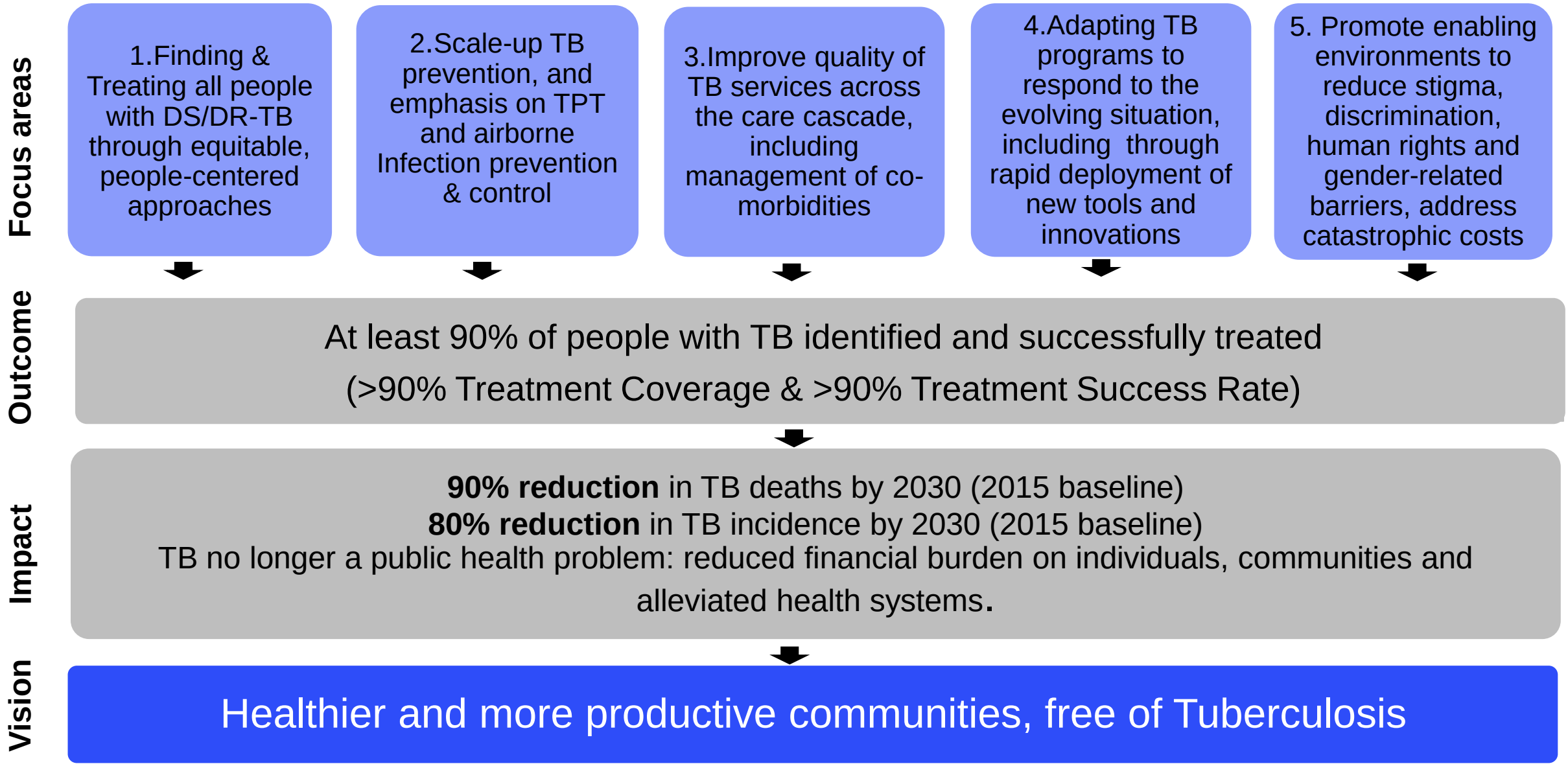
Diagnostics/screening	HIV Prevention	HIV Treatment	Devices/technology
Improve HIV case finding, accelerate self-care and prevention (esp for men, adolescent girls and young women, key populations)	Expand choice, enable self-care, people centered approach (esp for men, AGYW, and KPs)	Achieve **early and sustained viral suppression and reduce mortality** (esp. for men, pregnant/BF women, children and adolescents, key populations)	Accelerate digital and virtual service delivery; and use of point of care devices
• HIV self-testing • Rapid diagnostic tests -multi-disease options (STIS/HIV/Hepatitis) • Diagnostics for advanced disease (esp Fungal/TB LAM) • HPV/Cervical Ca screening • Infant testing (EID)	• Pre-exposure prophylaxis options (daily oral meds, injectables, vaginal ring, etc)	• ARV formulations (pediatric – DTG 10mg) • New ARV drugs (in line with WHO recommendations) • New ARV delivery systems (injectables etc) as approved and recommended • TB preventive treatment (3HP, 1HP etc) • Treatment options for co-infections (AHD)	• Viral load testing devices, esp. POC VL/EID • POC CD4 • Multi disease molecular testing

Suppliers Consultation

Global Fund TB Team Presentation

Feb 15, 2022

TB priority areas of focus and expected results



Section 3:

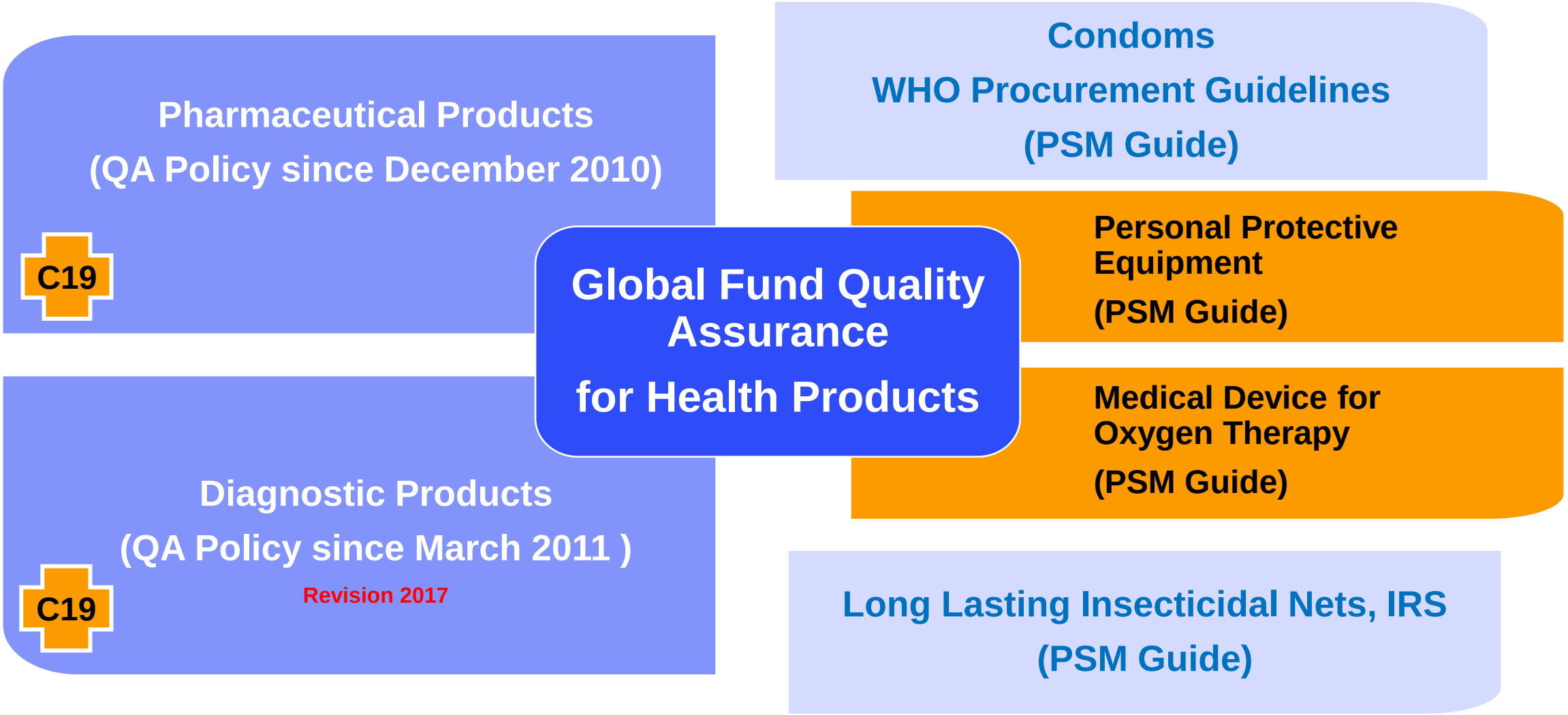
Quality and Compliance

Implementing Global Fund Quality Assurance Policy for Pharmaceuticals

Stephen Kimatu, Quality Assurance Specialist, QA Team

Sandrine Cloëz : (sandrine.cloez@theglobalfund.org)

Overview of QA Requirements



QA Policy for Pharmaceutical Products

Selection

1. Clinical Criteria

• Medicines listed in WHO or national or institutional **Standard Treatment Guidelines**

• Require applicants/ recipients to provide justification for selection **of unlisted products** in one of the STGs

+

Procurement

2.a. Quality Criteria

For all products:
Authorization for use in the recipient countries

2.b. Quality Criteria

For TB, Malaria, HIV and Covid-19 :
Specific Requirements

+

In-County Management

3. Monitoring Quality

• Monitoring quality of products all along the supply chain

4. Implementing Pharmacovigilance

• Monitoring ADRs of pharmaceutical products

Quality Criteria for Pharmaceutical Products

For All Products:

- Marketing Authorization for use in the recipient countries

+

For ARVs, anti-TB & anti-Malarial Products:

- WHO-prequalified (WHO PQ),

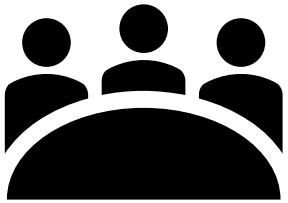
Or

- Authorized by a **Stringent Regulatory Authority** (SRA),

Or

- Found eligible for use by the **Expert Review Panel.**

Quality Criteria for Pharmaceutical Products: Expert Review Panel (ERP)



- Expression of Interest following extensive consultation.
- A panel of experts hosted by WHO.
- Assesses the potential risks/benefits associated with the use of FPPs that are not yet WHO-prequalified or SRA-authorized.
- Eligibility criteria for dossier submission:
  - product manufactured in GMP site **and**
  - dossier already submitted to and accepted for review by WHO PQ program or by a SRA
- Assesses abbreviated product dossiers submitted by manufacturers (questionnaire + annexes)
- Makes time limited recommendations to GF: validity maximum 12 months

COVID-19 Pharmaceutical Products

For COVID-19 pharmaceutical products to be eligible for Global Fund funding, they must meet these two minimum criteria:

1 Clinical Standards

All pharmaceutical products procured with Global Fund resources are to be compliant with the following clinical standards:

National / Institutional

- Country Standard Treatment Guidelines (c.STG)

or

- National Essential Medicines List (c.EML)

or

WHO

- Standard Treatment guidelines (STG) or Essential Medicines List (EML)

2 Quality standards

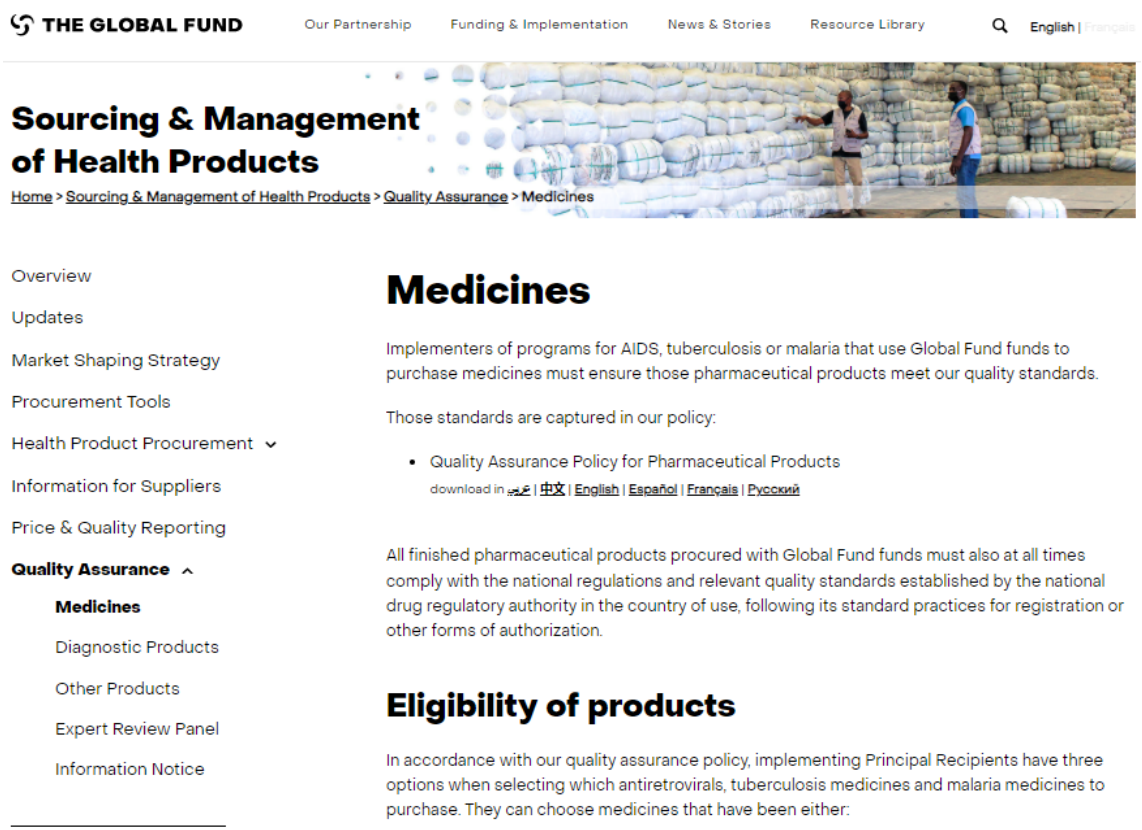
"**COVID-19 Pharmaceutical Products**" were defined as products used for the curative treatment and prevention of Coronavirus disease (COVID-19).

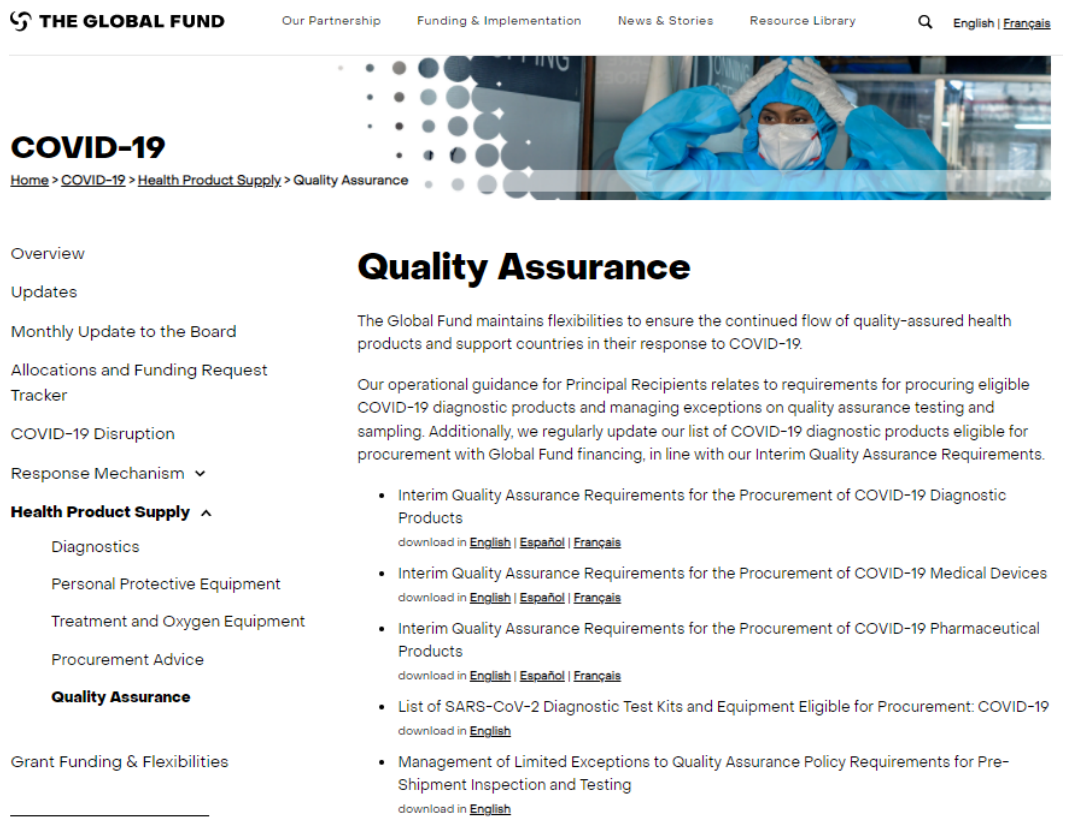
This definition was stated as exclusive of essential medicines used for the management of patients with suspected or confirmed COVID-19.

		Approval required	
		Stringent-type authority*	NRA
Curative Treatment & Prevention	***COVID-19 Pharmaceuticals*** • Casirivimab, Imdevimab • Molnupiravir	Yes	Yes
Disease Management & Symptom Alleviation	***Essential Medicines*** • Dexamethasone • sarilumab, tocilizumab	No	Yes

**This includes SRAs (as defined in the QA Policy for Pharmaceutical Products), or WHO PQ, or ERP, or WHO EUL, or SRA Emergency Use Authorization*

More information is available on Global Fund website





Suppliers Consultation

Ethics & Responsible Procurement

Feb 15, 2022

Ethics, Sustainability and the Environment - a renewed focus.

The Global Fund is dedicated to pursuing, promoting and achieving the highest ethical, responsible and sustainable procurement standards at the Secretariat and amongst our supply base. The Global Fund Strategy (2023-2028) draws attention to the challenges posed by climate change; inviting GF, partners and stakeholders to address and mitigate its impact. These values, principles and objectives are subsequently embodied in the following initiatives;

New Supplier Code of Conduct (CoC)

- The current CoC (as amended 11 Feb 2021) aims to observe the highest standard of ethics in Global Fund-funded activities regarding supply of goods and/or services.
- The Global Fund recognizes that the historically prevalent focus of the Code on compliance, records and financial crime created challenges for putting the Code at the centre of a robust and comprehensive ethics programme.
- Consequently, the Global Fund intends to replace the current CoC with a revised CoC for Suppliers (currently in draft form), systematically aligned with the core values of the Global Fund and presenting both requirements and expectations of suppliers' conduct to proactively manage the total cost of their activities to society and the environment.

Climate Change and Environmental Sustainability

- COP26 has injected a greater sense of urgency into global efforts to address climate change.
- The new GF Strategy acknowledges the importance of addressing the threat and impact of climate change on the three diseases and the vulnerability of at-risk populations.
- The Secretariat is undertaking a number actions to address and mitigate environmental risks and promote sustainability at the Secretariat and in the procurement of Health Products.
- Please find our published statement by following this hyperlink.

The Responsible Procurement Framework - realising our ambitions and achieving our goals.

To date, the Global Fund's Supply Operations Department has put many of these principles into action through the adoption of a responsible procurement approach, yielding significant results:

- **LLIN Waste Packaging:** The Global Fund continues to recommend the distribution of LLINs without individual bags. This led to an estimated plastic waste reduction of 720 metric tons in 2019 and 1,110 metric tons in 2020.

- **LLIN Standards:** Global Fund LTAs require suppliers to comply with international environment, health & safety standards. The number of manufacturers whose systems meet ISO standards for environmental management (14001:2015) and occupational health & safety (ISO 45001:2018) has increased by 19% since 2020

- **Artemisinin EHS Compliance:** The Global Fund mitigated EHS risks and incentivized best practices by leveraging 3 year volume allocations.

Nevertheless, sustainable principles and impact monitoring have been applied in a targeted manner. A more systematic approach is needed to realize the Global Fund's sustainability ambitions

The Global Fund intends to build on our successes to date by developing a "Responsible Procurement Framework" (RPF), based on the triple-bottom-line framework.

Operationally, the RPF will:

- Be a Secretariat-level operational guide for Global Fund buyers.
- Enable the buyer to systematically identify relevant Environment, Social, and Economic risks;
- Provide the appropriate tools and metrics to address, mitigate and monitor risk.

The RPF aims to:

- Capture, build upon, and enhance current practice.
- Enshrine sustainable principles in the Global Fund's sourcing and SRM approaches.
- Allow the Global Fund to monitor and minimize its impact across environmental, social and economic sustainability dimensions.
- Support the Global Fund's sustainability ambitions, also linking with the UN Sustainable Development Goals.
- Encourage the broad adoption of sustainable practices.
- Complement existing frameworks; such as the Integrity Due Diligence and Code of Conduct.

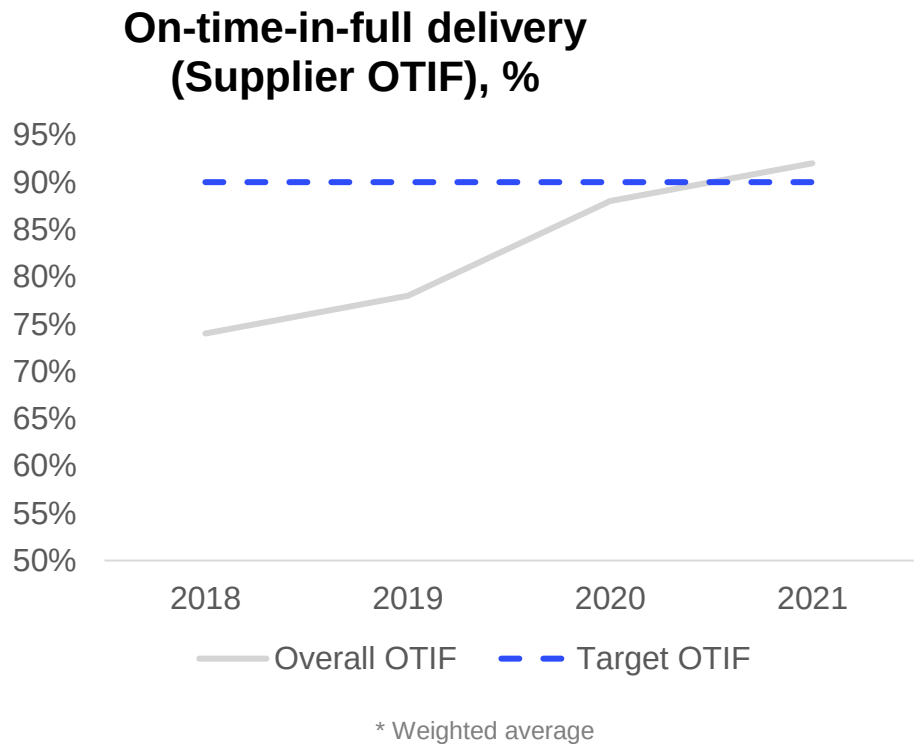
Section 4:

Market observations and evolution

Marked improvement in Supply Performance

<u>Supplier OTIF</u> has shown consistent improvement since 2018. Despite the global and sectoral challenges observed in 2020-21, the 90% target was surpassed in 2021.

- **Supplier delivery performance** (OTIF) has improved from 74% (2018) to 92% (2021)
- **Price decreases are not negatively impacting manufacturer performance.**
- **Continued delivery improvement in 2020 & 2021** despite COVID 19 impact.
- Supplier with **better forward planning** perform better and can adapt to fluctuating demand.
- Upstream KSM & API **make or buy decisions are decisive.**
- **Procurement partner alignment** is key in crisis management .

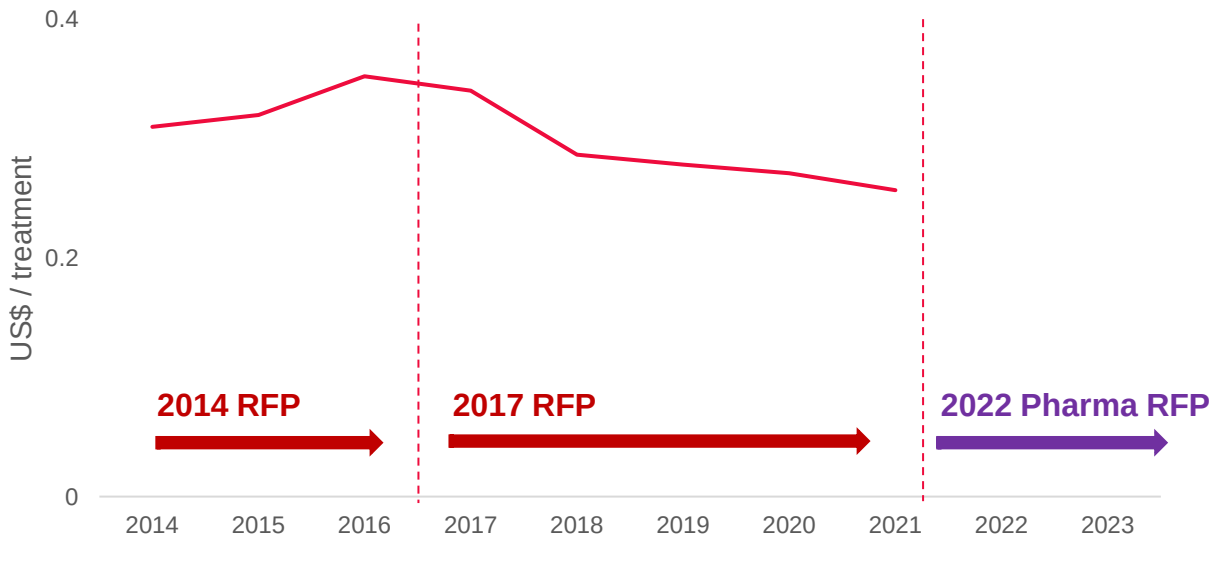


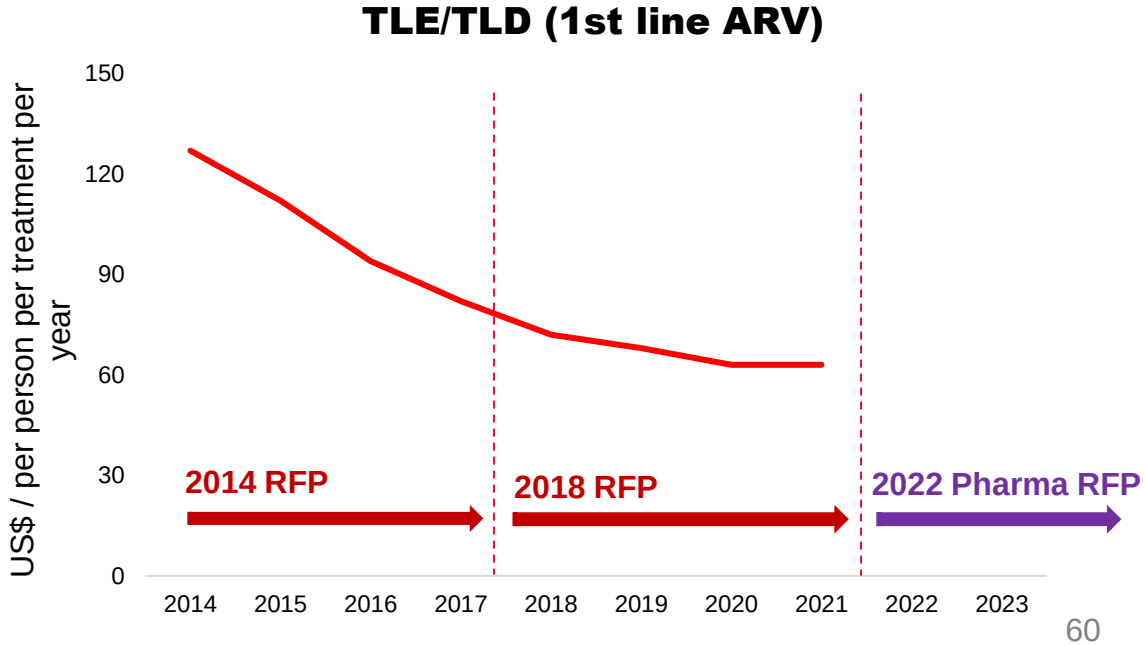
Data Source: From the Global Fund's Procurement Service Agencies

ARV and ACT price evolution & projection

Product pricing has continually decreased through previous RFP cycles for larger volume and 1st line regimen ARV products

- Pricing for ARV's & ACT's have consistently decreased since 2016.
- Prices have not decreased at the expense of performance.
- We expect future cost reductions to continue however key drivers are expected to be mainly non price factors.
- In 2020 1st line ARVs representing 80% of ARV spend with artemether/lumefantrine representing 70% ANTM spend.





THE GLOBAL FUND

Note: Weight Average Price (WAP); 2014-2021 prices are indicative based on our current analysis and market intelligence;

Market Observations - Global

The Global Fund has identified several developments affecting global markets which impact the Pharma strategy

- The **security of supply is closely linked to supply chain complexity & geography**. This has proven to be especially true in an emergency.
- **Greater world-wide focus on climate change and minimizing carbon footprints** have significant potential to affect shipping, packaging, supply chain and EHS policies.
- **Government intervention, in times of crisis, can severely impact supply availability**, create uncertainty in markets and lead to short term supply bottlenecks and price increases
- **Freight issues, inflation, raw material price increases and local energy shortages** remain key challenges.

Key Message

Global dynamics impacting supply security remains fast-changing. The Global Fund seeks to strengthen supplier engagement to achieve resilient, robust and sustainable supply chains and prices.

Market Observations – Pharma Sector

The Global Fund has identified several developments within the Pharma sector which directly impact the Pharma strategy.

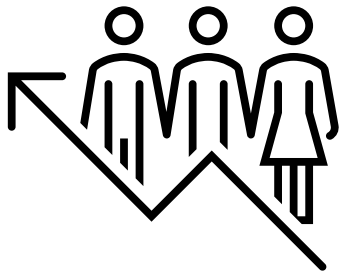
- Both pharma categories continue to be highly competitive but with different dynamics.
- Demand shifting over a 6-year cycle with WHO recommendations a key driver.
- National implementation requires technical assistance and proper change management for product transitioning.
- API make or buy decisions are fundamental to determining cost competitiveness, supply security and long term FPP strategy.
- Complex regulatory frameworks & regulations leading to delays in country registrations & additional cost.
- The COVID crisis saw the pharmaceutical industry stepping up on social responsibility.
    - Generic manufacturing plays an essential role to ensure broad and equitable access.
    - Originator product development & innovation continues to be a key factor in portfolio optimization.

Key Message

The Global Fund seeks to encourage and leverage any positive market developments in alignment with WHO guidelines. Innovation and new product introduction are key to optimal portfolio alignment

Partner & Supplier Consultation Feedback

Feedback from Partner & Supplier consultations supports the strategic direction, building on previous RFP cycles.



- **Positive feedback on strategy direction** during previous RFP cycle.
- **EHS aspects continue to be important with changing country guidelines** and importance of local manufacturing.
- **Importance of clarity on demand forecasting** highlighted.
- Regular **supplier reviews and partner engagement supporting KPI adherence**.
- **Portfolio rationalisation, product transition planning and new product introduction** planning are essential.
- **Backward integration and a strong supply base** are key to supply security.

Key Takeaway

The GF strategic sourcing strategy has evolved over previous cycles based on supplier and partner feedback

Pharma strategy is evolving along with Global Fund priorities building on lessons learned & Partner observations

- **Clear OTIF improvement for ARV & ANTM** from previous RFP cycles
- **Procurement evolving to include more non-price factors** and performance-based implementation.
- **Artemisinin strategy** driving uptake of semi synthetic API, promoting best practice & strengthening supply base
- **Product transitioning and ARV portfolio rationalization** resulting in a skew toward 1st line regimen
- Pricing clauses (e.g., MFN) seen to be effective, **but more rigor required in the implementation.**
- **Rapid Supply Mechanism (RSM) usage declining** but will remain a key emergency supply tool.
- **New product introduction requires** increased project management focus & partner alignment.

Key Takeaway

Lessons-learned will inform Sourcing's strategies going forward to accelerate the creation of stronger markets & more robust supply chains

Despite COVID-19, GF & its partners have continued to drive value through strategic sourcing

The consultation process has concluded but collaboration will continue through strategy implementation

Section 5:

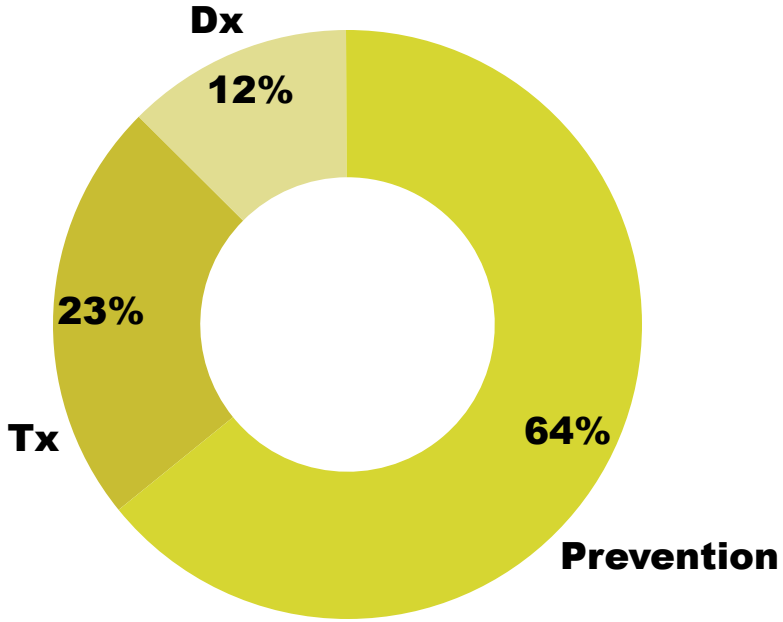
Category insight & outlook

Malaria Portfolio: Key Messages

Category focus expected to continue toward prevention and diagnostics with SMC campaign playing a key role

- **The ANTM portfolio represented over 11% of the GF 2020 PPM spend** of $1.3 billion.
- **The product portfolio is more mature driven by a less dynamic market however** ensuring continued access to all required products remains essential
- **The malaria strategy focuses on Prevention and Diagnostics** representing ~ 76% of the overall Malaria Portfolio spend.
- **Seasonal Malaria Chemoprevention (SMC) is considered a breakthrough intervention** & a key element of the Global Funds prevention strategy

PPM Malaria Portfolio Overview 2020 (Spend $)



ANTM Product Segmentation

The ANTM portfolio covers several product segments however Global Fund sourcing will continue to provide access to all needed ANTM products

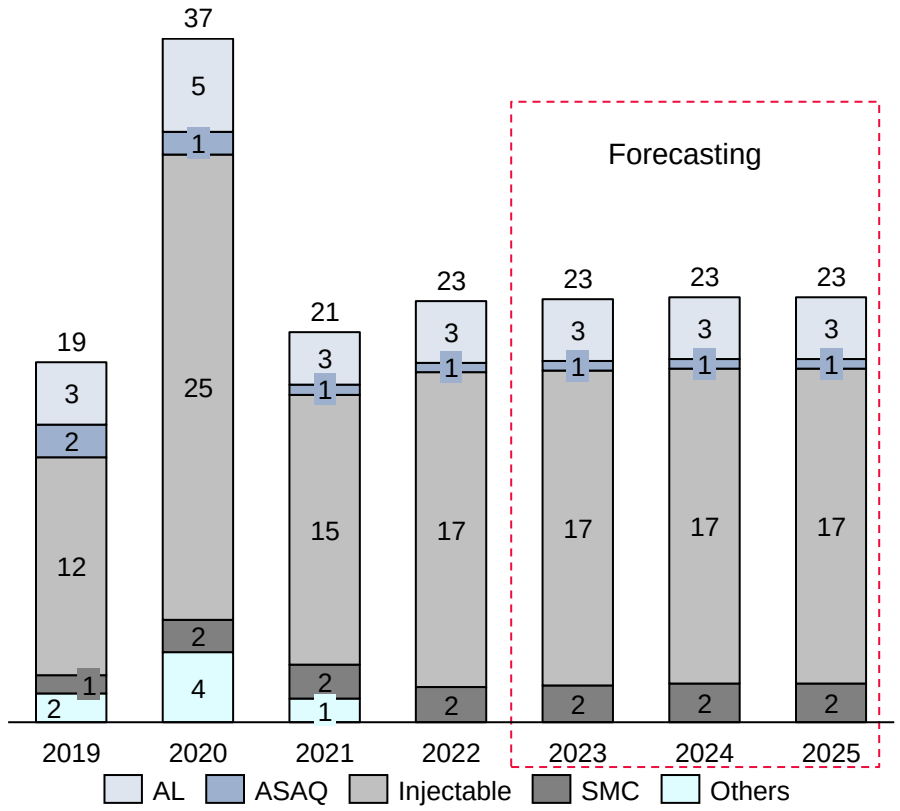
Product set	Focus	Notes
1. ACTs: high/low volumes	Full scope and leverage of strategy objectives	▪ Mainstream products, maintain a strong supplier base in relation to the demand
2. Severe Malaria	Full scope and leverage of strategy objectives	▪ Steady or increasing market ▪ Maintain a strong supplier base of eligible manufacturers
3. Chemoprophylaxis for special risk groups (IPTp, IPTi, SMC)	Access and affordable pricing	▪ Growing market ▪ Increase number of eligible manufacturers for SMC products
4. Low-transmission areas & to prevent P. vivax relapse) 5. Uncomplicated chloroquine-sensitive infections	Access and affordable price	▪ Maintain a limited eligible manufacturer base

ANTM Demand Trend & Forecasts

AL market continues to be stable with volume growth expected for SMC

- **AL main ACT in use** with a stable market. ASAQ volumes declining & new regimen introduction as DHA/PPQ and Artesunate/Pyronaridine may increase in coming years.
- **SMC continuous growth expected** in Sahel sub-region. WHO do not recommend use of ASAQ for treatment during SMC period. SMC feasibility/impact on-going in Eastern and Southern Africa
- **The forward-looking forecast is an average estimation of demand for PPM & shows the minimum expected volumes** in the next tender cycle. Overall volumes are expected to remain flat although product segment fluctuation is expected
- **Global Fund grant replenishment** planned in H2 2022. We therefore expect some demand peaks in 2022/2023 toward the end of the current grant cycle

PPM Procurement Demand 2019–2022
Outlook 2023 – 2025*
(million packs)



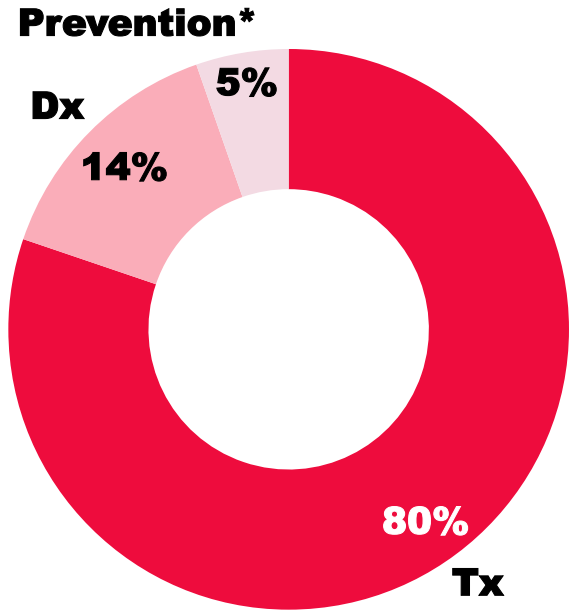
* CPM included

ARV Portfolio: Key messages

Therapeutics are the main element of the HIV disease approach, and this is expected to continue. New product introduction and an increased focus on prevention products are an essential part of the pharma strategy

- **Global Fund accounted for ~30 % of the Global ARV market share** in 2020
- **GF procurement portfolio is expanding to include new prevention products,** but focus expected to continue toward therapeutics
- **Product portfolio consolidation progressing in ARV's** with the number of products required to run adult and paediatric programs moving from > 15 to ~ 10 in 2022
- **Global Fund** encourages suppliers to continue **to ensure equitable access** to needed products

PPM HIV Portfolio Overview 2020 (Spend $)



* HIV prevention is currently driven mainly by non-pharm products

ARV product portfolio segmentation

The ARV portfolio covers several product segments however Global Fund sourcing will continue to provide access to all needed ARV products

Product set	Focus	Notes
1. WHO preferred and alternative regimens	Full scope and leverage of strategy objectives	▪ Heavy product skew toward 1st & 2nd line regimen ▪ ~ 10 mainstream adult and paediatric 1st and 2nd line products ▪ “Strategic” ARVs include TLD; ALD; DRV/r; DTG 10mg dispersible
2. WHO limited use/ specialist products	Availability across multiple procurement channels	▪ Panel of suppliers ▪ Utilize the multiagency ARV procurement working group to inform allocation ▪ Communicate longer lead-times ▪ Disaggregate in OTIF measurement and performance management

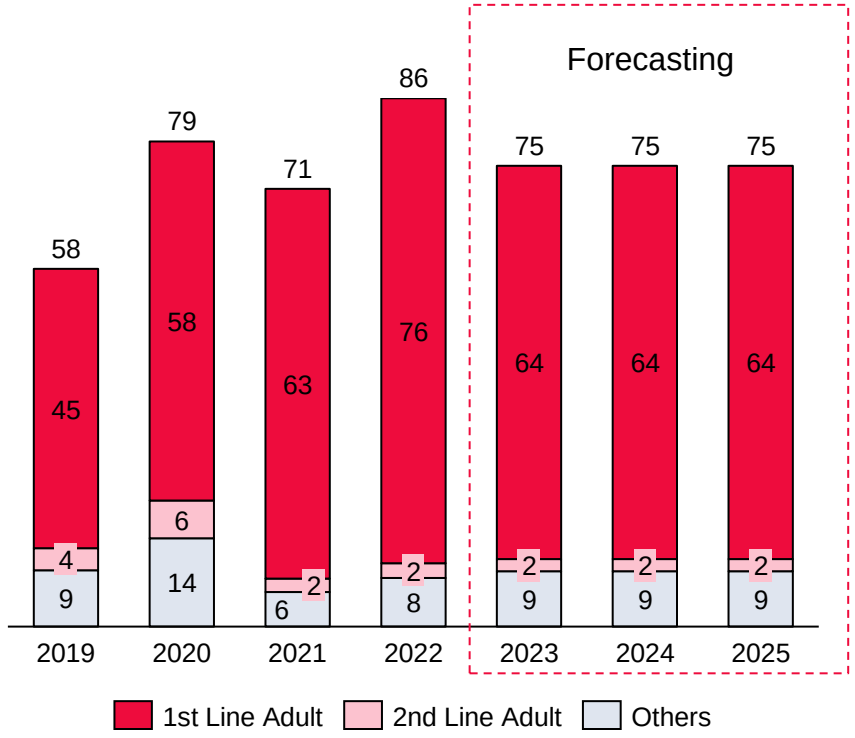
3. Related products used in HIV programs	Access and affordable pricing to Global Fund & other buyers	▪ Hepatitis B & C
		▪ Preventative therapies
		  ▪ Isoniazid
		  ▪ cotrimoxazole/isoniazid/B6
		▪ Advanced HIV disease
		  ▪ flucytosine
		  ▪ amphotericin B: deoxycholate/liposomal
		  ▪ pegylated liposomal doxorubicin

ARV Demand Trend & Forecast

WHO recommended ARV 1st line regimen will continue to drive volumes. Overall demand to remain relatively constant however YoY growth is expected for key segments

- Global Fund sourcing will continue to **ensure that all needed ARV products are available**
- The ARV portfolio is **heavily skewed toward large volume WHO 1st line regimen,** driven mainly by TLD, which currently accounts for 84% of annual demand
- **Overall forecasted ARV demand expected to remain constant in the coming tender cycle, however some fluctuation is anticipated** in the final grant year 2023
- **Product transitioning will continue with paediatric patients moving** from LPVr to paed DTG expected to accelerate in 2022

Procurement Demand 2019–2022
Outlook 2023 – 2025
(million packs)



Section 6:

Joint Pharma Strategy & Approach Principles

Note

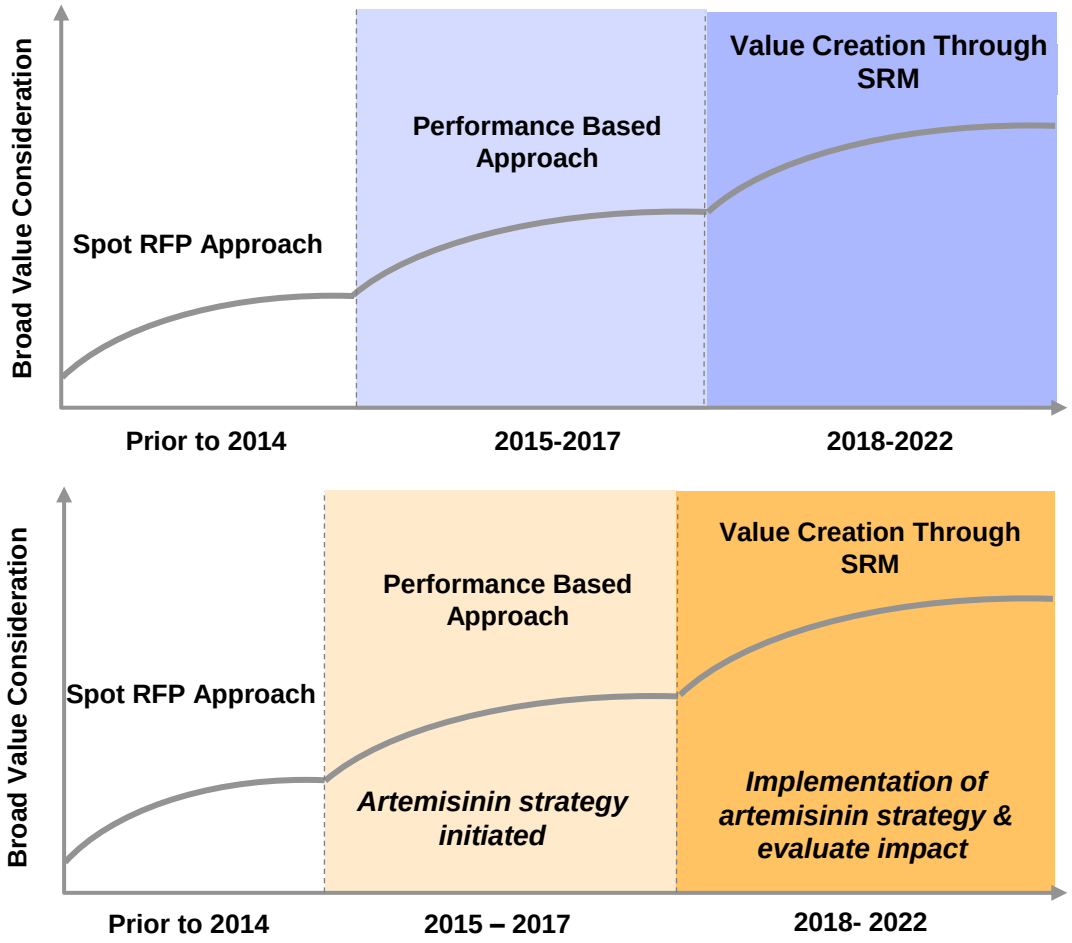
- The Combined Pharma Tender includes both ARV and ANTM products. Covid-19 Therapeutical products are covered in a separate Tender (RPF: TGF-D-00008) published under “business opportunities” on the Global Fund’s website;
- The partnership with PAHO will continue regarding ARVs products. As done in the past, PAHO will be one of the potential buyers under the Global Fund Framework Agreement and PAHO will be associated with the Combined Pharma Tender process

ARV & ANTM Strategy Development 2014-2022

Recap

The ARV & ANTM strategies have evolved in cycles, building on learnings as well as disease specific dynamics.

ARV & ANTM Strategy Evolution



Spot RFP Approach (-2014)

- Cost based pricing approach
- Performance management matrix set up

Performance Based Approach (2015-2017)

- **Long-Term Agreements** implemented
- **Rigorous supplier performance** management initiated
- RFIs launched & consultations held to **better understand Artemisinin supply base market dynamics**

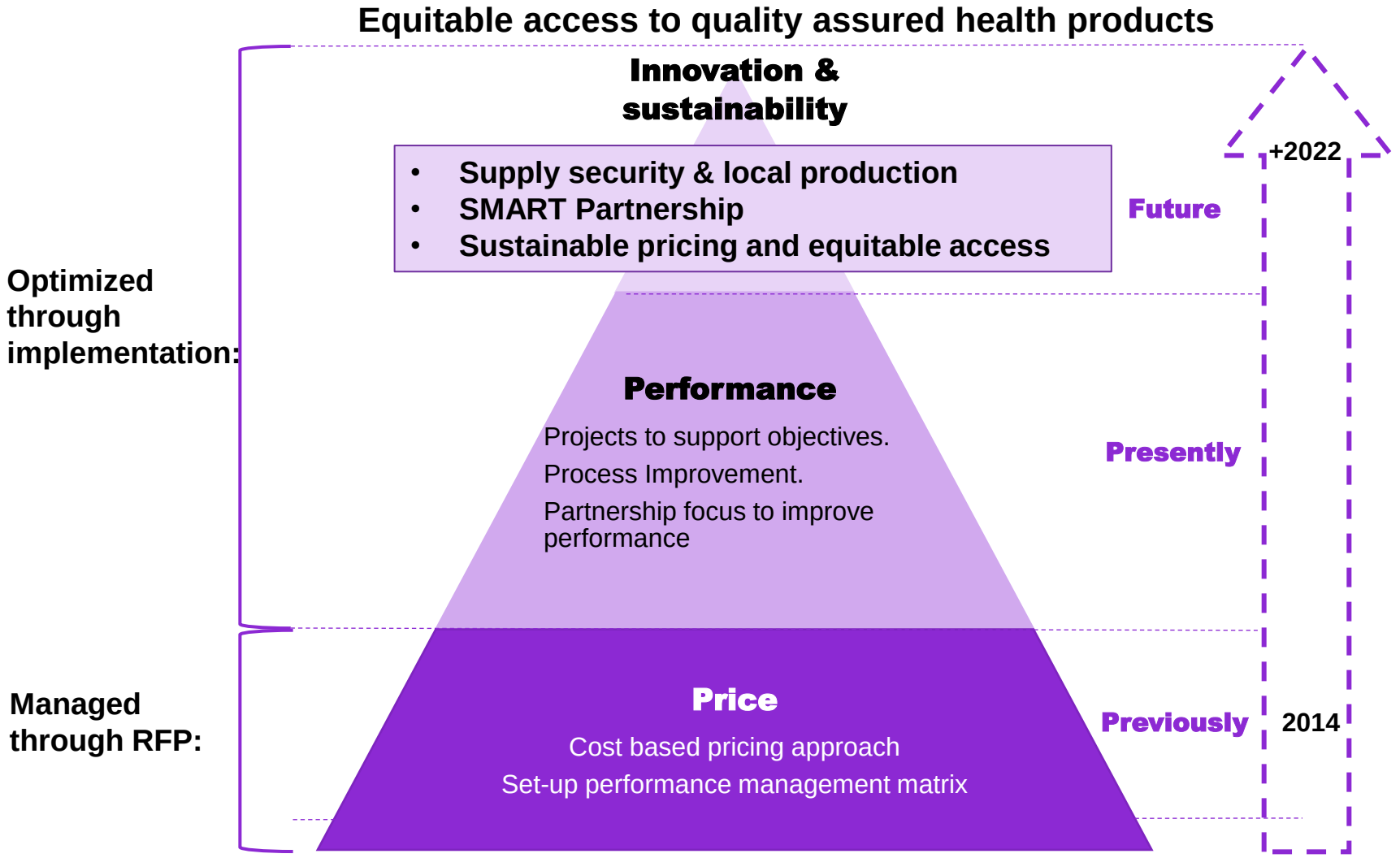
Value Creation through SRM (2018-22)

- **Key principles of supplier relationship management** (SRM) applied
- **Performance management matrix enhanced** to enable decision-making
- More direct **supplier engagement with originators**
- Artemisinin **manufacturers panel created,** focus on EHS & **encouraging best practices** with Artemisinin manufacturers
- **Uptake of SSA encouraged** to mitigate price volatility

Global Fund Sourcing Strategy Shift

The 2022 RFP strategy is a further evolution, building on the momentum created from previous strategies with an enhanced approach.

- **Leveraging supply and cross-disease synergies** through one joint pharma strategy
- The **pharma strategy has evolved** over time, adapting to market and demand requirements
- Next steps will **focus on innovations & sustainability through a set of objectives** (to be articulated in the following slides)



Objective 1: Competitive & Sustainable Pricing to deliver Health Product Availability and Affordability

Enhancing the sourcing strategy to creating value beyond product pricing

- GF will **continue to support and maintain competitive and sustainable markets.**
- **Cost will remain a key element** of the sourcing strategy to ensure an optimal use of resources.
- Broadening the **definition of "Value" beyond pricing** and looking for saving opportunities beyond product costs.
- **Continue with multi-year agreements** in line with strategic objectives.
- **Continuation of RSM process** to further reduce supplier lead times.
- **Increasing supplier accountability** including MFN implementation.

Note

- Building on artemisinin strategy successes, securing access & strengthening the uptake of semi-synthetic artemisinin will remain a key element of the next pharma strategy
- Broadening artemisinin access, allowing the introduction of new suppliers but with increased supplier accountability for ensuring EHS compliance & conformity
- All suppliers will be required to have a semi synthetic artemisinin (SSA) supplier approved
- A reward system will be introduced for suppliers who have a minimum update of SSA annually

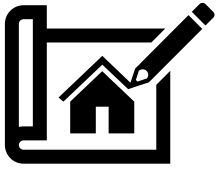
Objective 2: Supply Chain Security for responsive and agile health services and product delivery

Adapt learnings from previous tender cycles & the pandemic with a stronger focus on supplier accountability & supply chain robustness

- Strategy will **continue to ensure the reliable supply** of all required ARV and ANTM medicines.
- **Increased focus on supplier accountability** to ensure upstream supply security & robustness
- **Resilient supplier base** to ensure sufficient and reliable supply
- Continue to **promote geographic diversification & promote local manufacturing and capability building**
- **Improving product traceability through market surveillance for quality and access**; tracking product and quality incidents throughout supply chain, implementing GS1
- **Moving toward a make to stock model** to mitigate supply fluctuations
- **Deepen partnership with suppliers** to proactively understand and address challenges.

Objective 3: Innovation to accelerate new product introduction at scale and drive environmentally sustainable procurement and supply chains

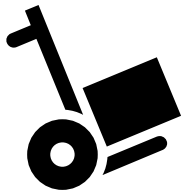
Accelerating the equitable introduction of new products and innovations is key to ensuring patient access to optimal formulations, cost reduction and reducing environmental impact



- **Support a robust pipeline of new products** intended to improve efficacy, reduce cost, & better meet the needs of end users in line with disease guidelines
- **Continue to stimulate innovation** through agreed supplier-driven projects.
- **Improve on new product uptake & accelerate transition** to more optimal health products.
- Leverage innovations to **reduce packaging and shipping costs.**
- **Reduce environmental & carbon footprint** through better planning, adapting transport routes, reduce packaging etc.

Objective 4: Supplier relationship management (SRM) aligned with SMART Partnership

Building on supplier relationships with an increased focus on accountability & adherence



- **Continue to strengthen performance management** through quarterly reviews with increased emphasis on accountability & continuous improvement
- **Revaluation of KPI effectiveness** to reflect 360^0 performance.
- **Portfolio rationalization**, long tail of specialist adult and pediatric treatments with fragmented demand for small quantities
- **Continue to promote the expansion of equitable access** to all LMIC's.
- **Initiate pilot projects to reduce product lead times** in line with end-to-end supply initiatives
- Building on partnerships to **openly address issues and actively look for common solutions**

Objective 5: Quality Assurance

Quality assurance is a key element of the pharma strategy promoting equitable access to quality assured health products:

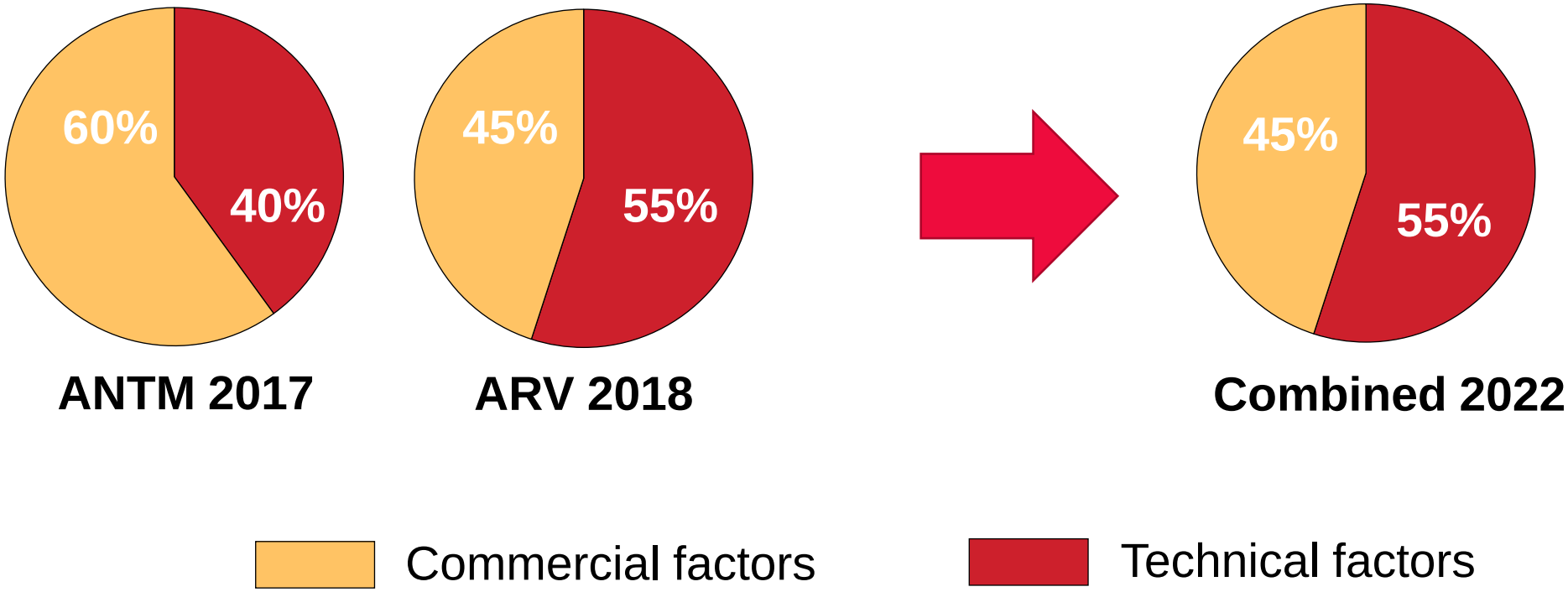
- **Quality Assurance will become an integral part of our supplier review process** going forward where quality updates and topics impacting supply will be covered
- **Product Quality remains a key element** in ensuring supply security for all required products
- **QA will continue to ensure** that medicines and health technologies are available at an **internationally-recognized quality standards**

Section 7:

RFP Approach & Timeline

The Approach in Current Practice

The combined evaluation weighting during the RFP evaluation aims to reduce complexity and reflect the market situation



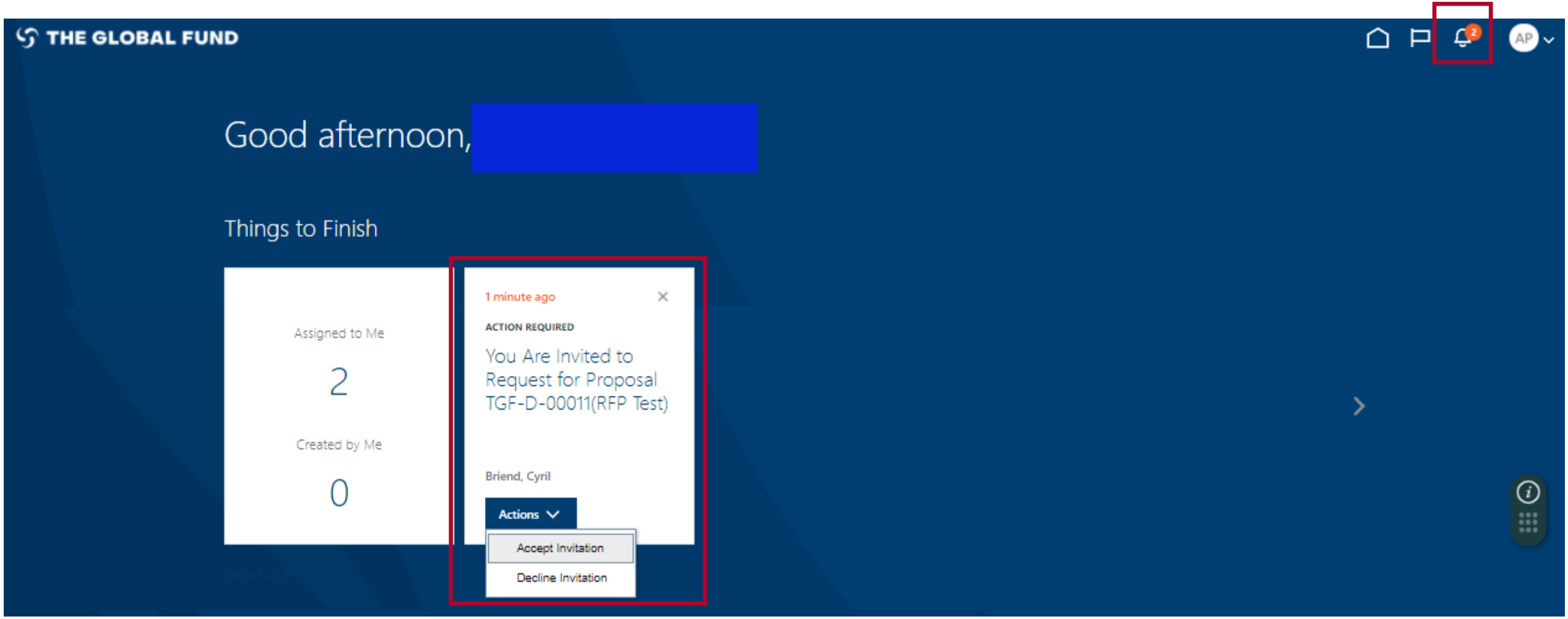
RFP process and timelines

Indicative timing

Phase I: RFP Launch (March 2022)	Phase II: Submissions and Evaluations (end May-July 2022)	Phase III: Evaluations (August-September 2022)	Phase IV: Contracting (September-October 2022)
▪ RFP documents are uploaded on the RFP Platform ▪ Two rounds of questions/answers on the RFP documents and process	▪ Round 1: Bid submissions and initial evaluation ▪ Round 2: Evaluation Workshop, including negotiations (pricing & strategic projects)	▪ Final Evaluations ▪ Internal Approvals ▪ Award	▪ Contract finalizations and signature

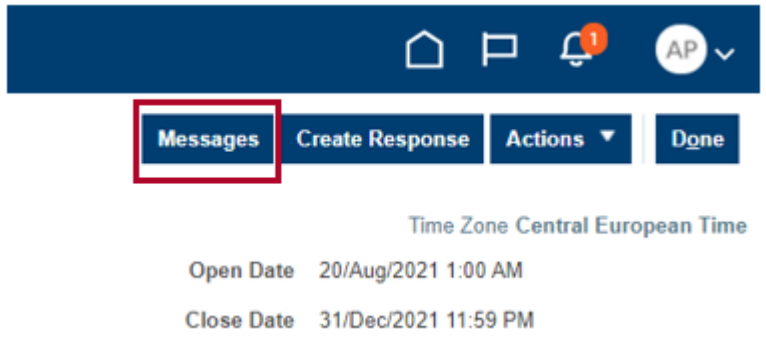
Platform used for RFP

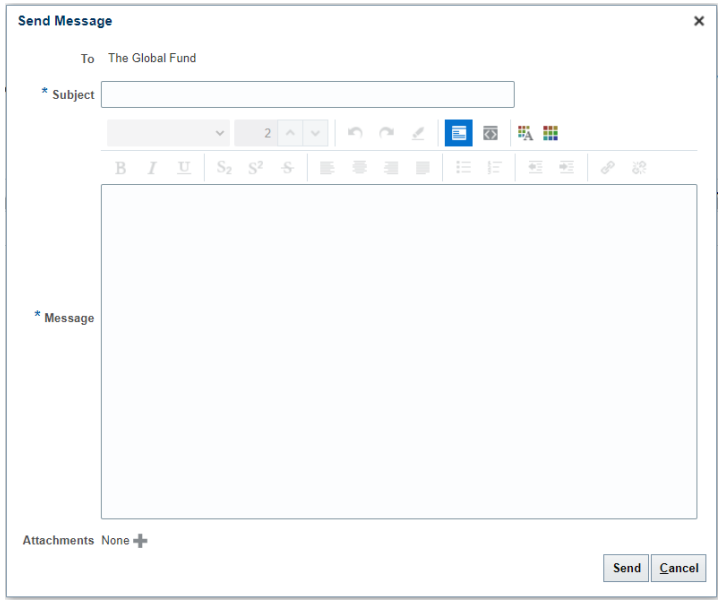
welcome page & notifications



Contact detail of support related to access

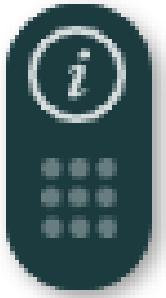
- All communications with regards to this RFP, including clarification questions, shall be in writing and sent through the TGF Sourcing Application using the online discussion.
- Should the Global Fund deem it necessary to revise the RFP as a result of a clarification, it shall do so as an amendment to the RFP available on the Global Fund's website.
- Any communication from a Respondent to the Global Fund regarding this RFP, which is not through the designated channel (https://fa-enmo-saasfaprod1.fa.ocs.oraclecloud.com/), are not permitted and will not be answered to.

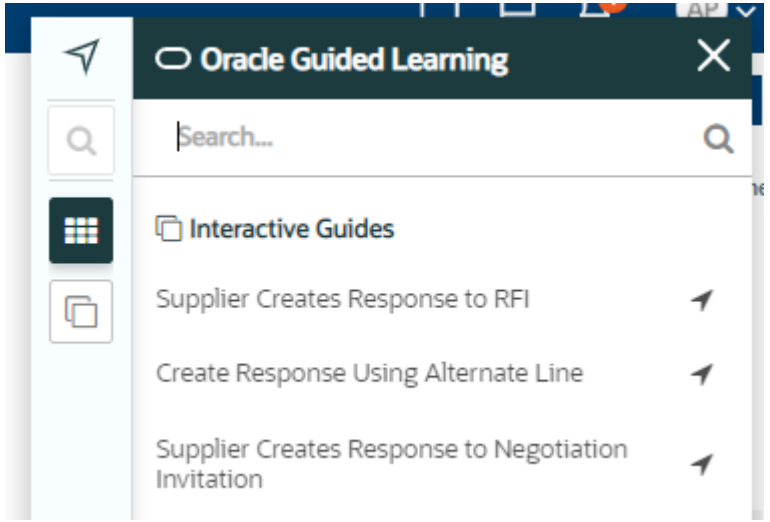




Other specificities

- **Oracle Guided Learning (OGL)**
  - Feature which provides step-by-step and personalized guides in the negotiation module. We will design an OGL which will be tailored for the Pharmaceuticals Request for Proposal
  - Access to the OGL: Click on the “I” icon and select the appropriate Guide





Q&A Session

Thank you

The Global Fund to Fight
AIDS, Tuberculosis and Malaria

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