

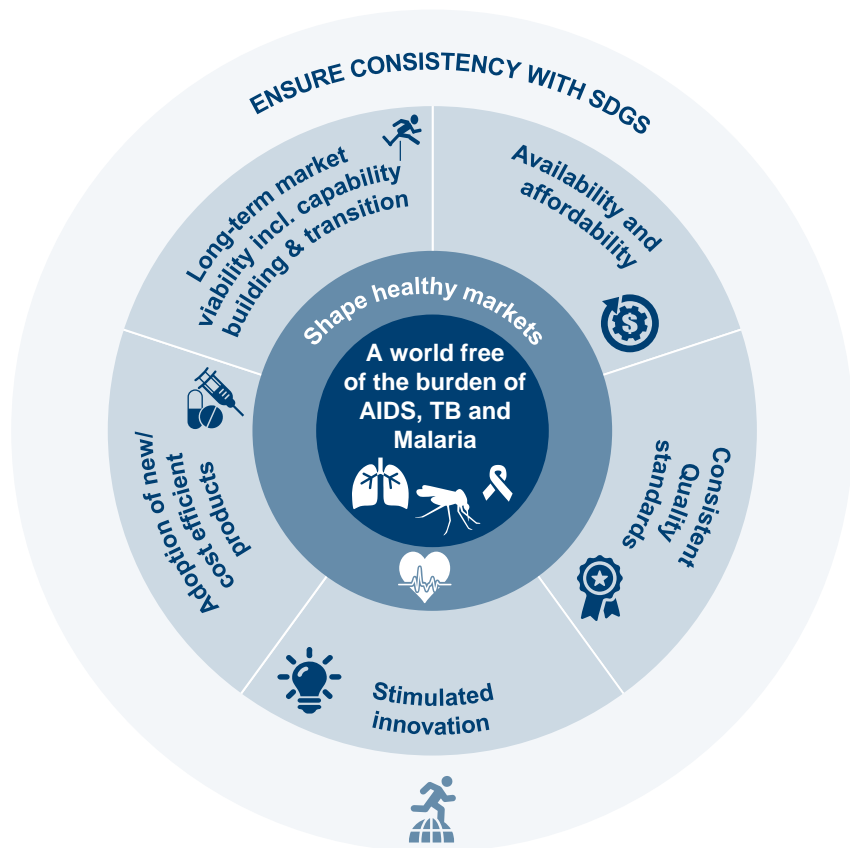
Draft Roadmap for the 2nd phase of implementation of the Market Shaping Strategy

Global Fund Secretariat reflections November 2017

Contents

- **What has happened?**
- Where are we going?
- How will we proceed?

The MSS is a key component of The Global Fund's mission









Mission of MSS: Leverage our position to facilitate healthier global markets for health products – today and in the future



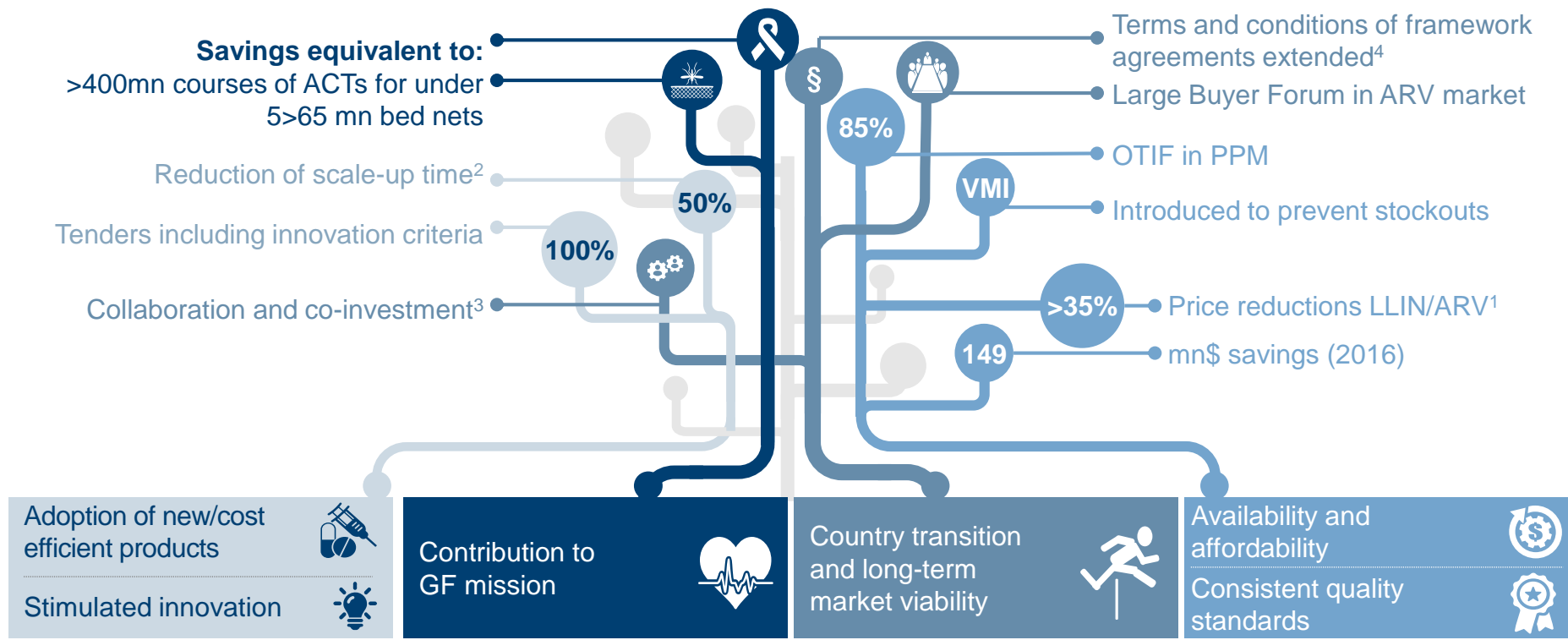
Source: Team analysis

Healthy markets have 6 characteristics

| Dimensions | Description |
|--|--|
| Innovation  | There is a robust pipeline of new products , regimens or formulations intended to improve clinical efficacy, reduce cost, or better meet the needs of end users, providers or supply chain managers |
| Availability  | New and/or superior evidence-supported, quality-assured products are rapidly introduced in the market and made available to those in low- and middle-income countries. Adequate and sustainable supply exists to meet global needs |
| Demand and adoption  | Countries, programs, providers (e.g., healthcare providers, retailers), and end users rapidly introduce and adopt the most cost-effective products (within their local context) |
| Quality  | Medicines and technologies are available at an internationally-recognized standard of quality , and there is reliable information on the quality of the product. This includes not only the quality of the final, finished product, but also the quality of starting and intermediary materials used to manufacture the final product |
| Affordability  | Medicines and technologies are offered at the lowest possible price that is sustainable for suppliers and does not impose an unreasonable financial burden on governments, donors, individuals, or other payers |
| Delivery  | Supply chain systems (including quantification, procurement, storage, and distribution) function effectively to ensure that products reach end users in a reliable and timely way |

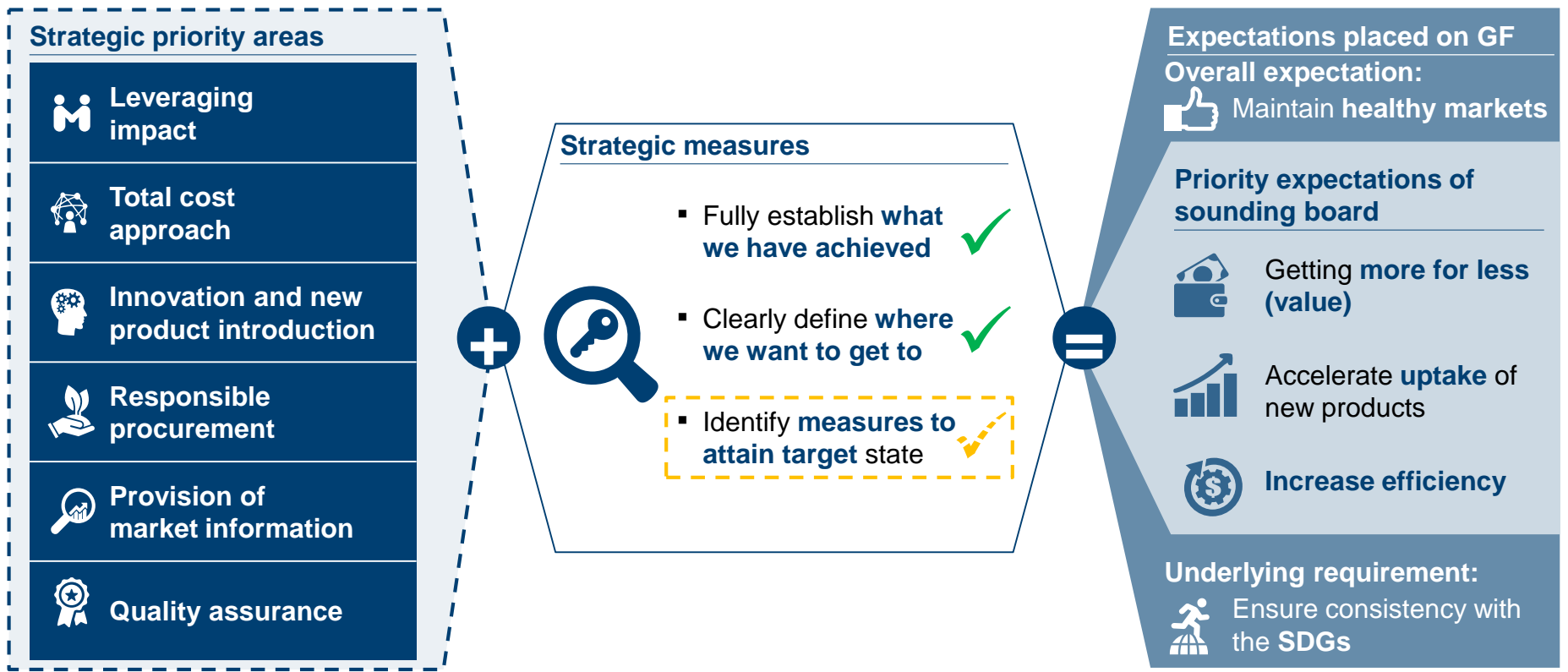
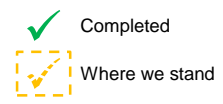
Source: Market Shaping Strategy, Annex 1 to GF/B4/17- Revision 1

The 1st phase of implementation of the Market Shaping Strategy has borne fruit



Source: Team analysis

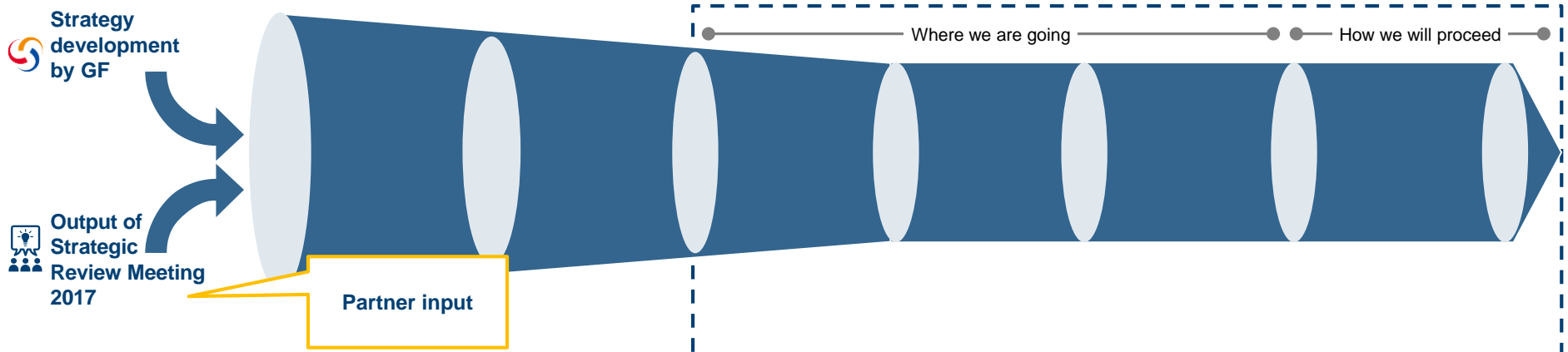
To deliver on the 2nd phase of implementation of the Market Shaping Strategy, we have identified 6 strategic priority areas going forward



Source: GF; Team analysis

We are in the process of seizing prioritized opportunities in each strategic area

Stage-gate Deliverables
 Focus of this document



Process of seizing strategic opportunities

| | Ideation | Selection | Preparation | | | Implementation |
|-------------|--|--|--|---|--|--|
| | | | Prioritize | Identify enablers | Develop roadmap | |
| Description | <ul style="list-style-type: none"> Define strategic priority areas Identify opportunities and pain points in status quo Generate ideas, both consultatively and pro-actively | <ul style="list-style-type: none"> Translate ideas and inputs into initiatives Long-list initiatives and gain initial understanding of links and connections | <ul style="list-style-type: none"> Conduct high-level assessment of initiatives Prioritize a limited set of initiatives per strategic areas | <ul style="list-style-type: none"> Identify what is needed to realize initiatives in terms of contributions by different stakeholders | <ul style="list-style-type: none"> Develop key milestones to realize prioritized initiatives Get high-level understanding of timeline | <ul style="list-style-type: none"> Assess initiatives and identify next steps to progress Detail-out granular activities Engage with partners as needed/possible |

Source: McKinsey team analysis

Contents

- What has happened?
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We identified 6 strategic priorities for which we wish to improve collaboration with partner organizations

x Deep dive in the following

Strategic priority areas

What we have achieved



What we want to attain

1 Leveraging impact



- Greatly improved **affordability and availability**
- Strong partner relationships**, incl. co-investments and benefit sharing

- Define **ways of SMART¹ collaboration**
- Sustain and extend impact** achieved through, e.g., framework agreements, potential joint procurement solutions

2 Total cost approach



- Significant **value unlocked** through unit-price focused efforts

- Unlock **additional benefits beyond unit price reductions** through holistic cost approach

3 Innovation and new product introduction



- Targeted **case-by-case support** leveraging **organically evolving collaboration**

- Leverage **synergetic end-to-end support** based on each partner's **unique value proposition**

4 Responsible procurement



- Societal and environmental concerns addressed through **multiple ad-hoc initiatives**

- Work hand in hand with partners** to comprehensively ensure responsible procurement across 4 dimensions (i.e. **economy, ecology, society, and business practices**)

5 Provision of market information



- Healthier markets** through generous information sharing on case-by-case basis

- Improve impact and mitigate risk** through **principle-based** information sharing

6 Quality assurance



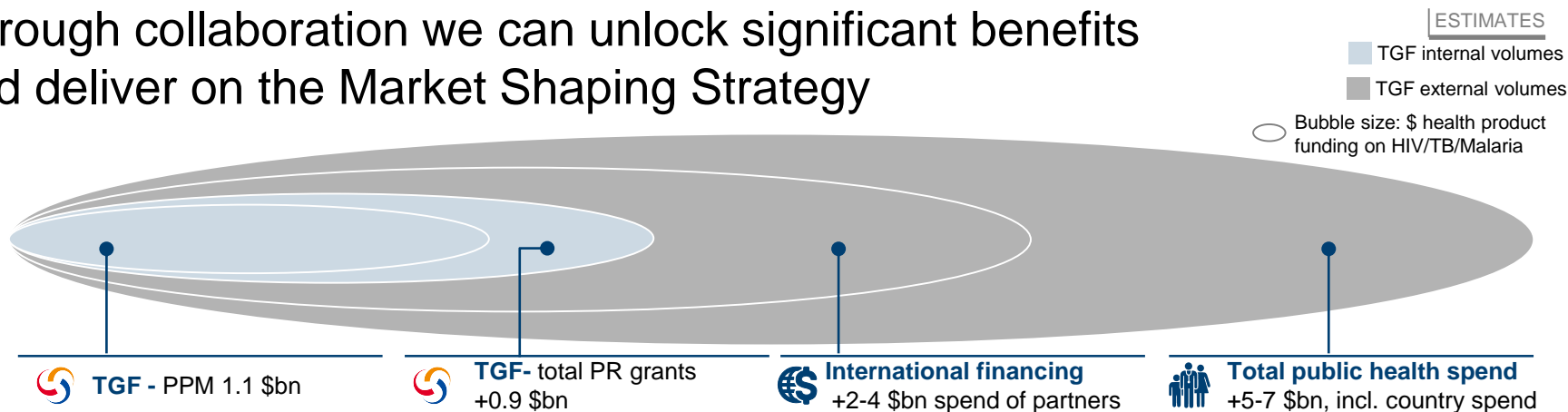
- Averting of critical quality issues/incidences** and improved patient safety

- Play more **pro-active role**, incl., improving of **information flow** and increasing ability to **act upon quality relevant information**

1 Specific Measurable Achievable Realistic Timebound

Source: GF; Team analysis

1 Through collaboration we can unlock significant benefits and deliver on the Market Shaping Strategy



TGF influence

Unleveraged impact

Description

- TGF - PPM 1.1 \$bn**: HIV/TB/Malaria health product expenditure run through PPM
- TGF- total PR grants +0.9 \$bn**: See to the left + grants by TGF for HIV/TB/Malaria health products not run through PPM
- International financing +2-4 \$bn spend of partners**: See to the left + spend of financing partners on HIV/TB/Malaria health products
- Total public health spend +5-7 \$bn, incl. country spend**: See to the left + country and other (e.g., technical partners) spend on HIV/TB/Malaria

Benefits towards MSS

- TGF - PPM 1.1 \$bn**:
 - Increase leverage and buying power through volume
 - Provide access to competitive market prices, eliminate procurement delays, support timely grant expenditure, and ensure quality
- TGF- total PR grants +0.9 \$bn**:
 - Extend benefits through synergies and economies of scale in order to increase impact through collaborative initiatives
 - Build experience and refine tools/processes
 - Gain stakeholder recognition
- International financing +2-4 \$bn spend of partners**:
 - Build market power and capture synergies / economies of scale
 - Attain resource relief by spreading disease burden further
 - Coordinating procurement of low volume ARVs
- Total public health spend +5-7 \$bn, incl. country spend**:
 - Locally embed and enforce impact and align with policies and initiatives
 - Achieve trickle-down effects on overall health system
 - Ensure legitimization and support

Sources: Estimates based on Institute of Health Metrics and Evaluation; UNAIDS report on global AIDS epidemic 2013; Global Tuberculosis Report 2013; World Malaria Report 2013; TGF; extreme scenarios excluded

1 What could we do: Initiate SMART¹ collaboration in 4 areas

NOT EXHAUSTIVE



■ Deep dive on the next page



Prioritized initiatives (deep dive in the following)

Category

Initiatives

Supplier mgmt approach



- Coordinate tender timing across big buyers
- Align QA requirements where feasible
- Promote balanced supply system and align performance management approach/metrics across GF procurement channels and other buyers**
- Coordinate with other buyers (incl. UNITAID) on demand and procurement timing for low volume specialist and new emerging products beyond ARVs**

Leveraging information



- Simplify future exchange and use of information by continuing aligning on nomenclature**
- Share current demand and supply information and procurement practices, incl. assumptions, purpose and methods to decrease the impact of procurement fragmentation**
- Communicate examples of leveraging impact to illustrate potential of collaboration with partners**

Mechanisms and contracts



- Identify procurement / tender approaches to deliver on common strategic objectives across different funders and buyers**
- Simplify the engagement between buyers and manufacturers through existing tools and mechanisms (e.g., aligned terms and conditions, order placement platforms such as wambo.org)

Capability/ Capacity building



- Align and leverage regional/sub-regional procurement mechanisms where applicable and enable countries to access PPM terms and conditions to drive availability and affordability of health products
- Improve information flow to enable better decision making and procurement capabilities at local level
- Build capability to manage data and market information to strengthen procurement capabilities at local level

¹ Specific Measurable Achievable Realistic Timebound

Source: GF; Output of the Strategic Review Meeting; McKinsey team analysis

1 What do we want to do: Strengthen procurement by extending visibility, promoting effective criteria, aligning approaches and increasing coverage

Priority initiatives, simplified Description

A Promote balanced supply system

- **Extend and disseminate benefits** of balanced supply system beyond PPM and to further volumes
- Promote **inclusion of balanced supply system criteria** in tenders and contract implementation of non-PPM countries (i.e., performance, cost competitiveness, sustainability, and risk management)

B Coordinate with other buyers for low volume specialist and new emerging products

- Coordinate with other buyers to **identify demand and align procurement** for low volume specialist/emerging new products
- **Pool volumes across buyers and over time** for products for which **partners individually do not have critical mass**

C Drive visibility into demand and procurement

- **Effectively and SMART¹-ly share** current demand and procurement practices information:
 - Align on **nomenclature** for demand data to simplify future exchange and use of information
 - **Collaborate with other large buyers to share harmonized demand information** for key products, incl. assumptions, purpose and methods (e.g., further extend current sharing practice for 18 months forward funded demand for ARVs)
 - **Intensify dialogue** between manufacturers, buyers and technical partners about forward demand
- Enable **harmonized efforts** on procurement with partners and **unlock value of information-synergies**
- Communicate examples of leveraging impact to **illustrate potential of collaboration with partners**

D Identify procurement / tender approaches to deliver on common strategic objectives

- Align **on all or some procurement objectives and identify a range of complementary procurement models**
- Utilize complementary procurement models to **seize upon synergies and remove friction**
- Enable partnership to **systematically, efficiently and effectively deliver on collective strategic objectives**
- Ensure availability of **global mechanism as an option for procurement for transitioning countries**, e.g., PPM, GDF; PAHO

¹ Specific Measurable Achievable Realistic Timebound

Source: GF; Output of the Strategic Review Meeting; McKinsey team analysis



2 GF runs 2 waves of Total Cost initiatives to first seize the low hanging fruit and sufficiently prepare the big leaps in the long run

- Not in focus of this document
- Deep-dive in the following

First Total Cost wave

- Objectives**
- **Take-stock and identify levers** to optimize Total Cost
 - Prioritize **low hanging fruit of high impact initiatives that are fairly easy** to implement
 - Unlock full value of **current value chain**
-
- Scope**
- Focus on initiatives where **GF has strong leverage**
 - Employ **targeted approach** to tweak existing value chain and identify opportunities, e.g.,
 - On internal processes (e.g., procurement)
 - On external operations (e.g., supplier operations)

Second Total Cost wave

- **Define target state** of Total Cost
 - **Identify big leaps** necessary to move towards target
 - Deliver on **target value chain**
-
- Focus on initiatives where **partners and GF collectively and SMART¹-ly can build critical leverage**
 - **Increase depth of approach** and identify opportunities to re-shape the value chain

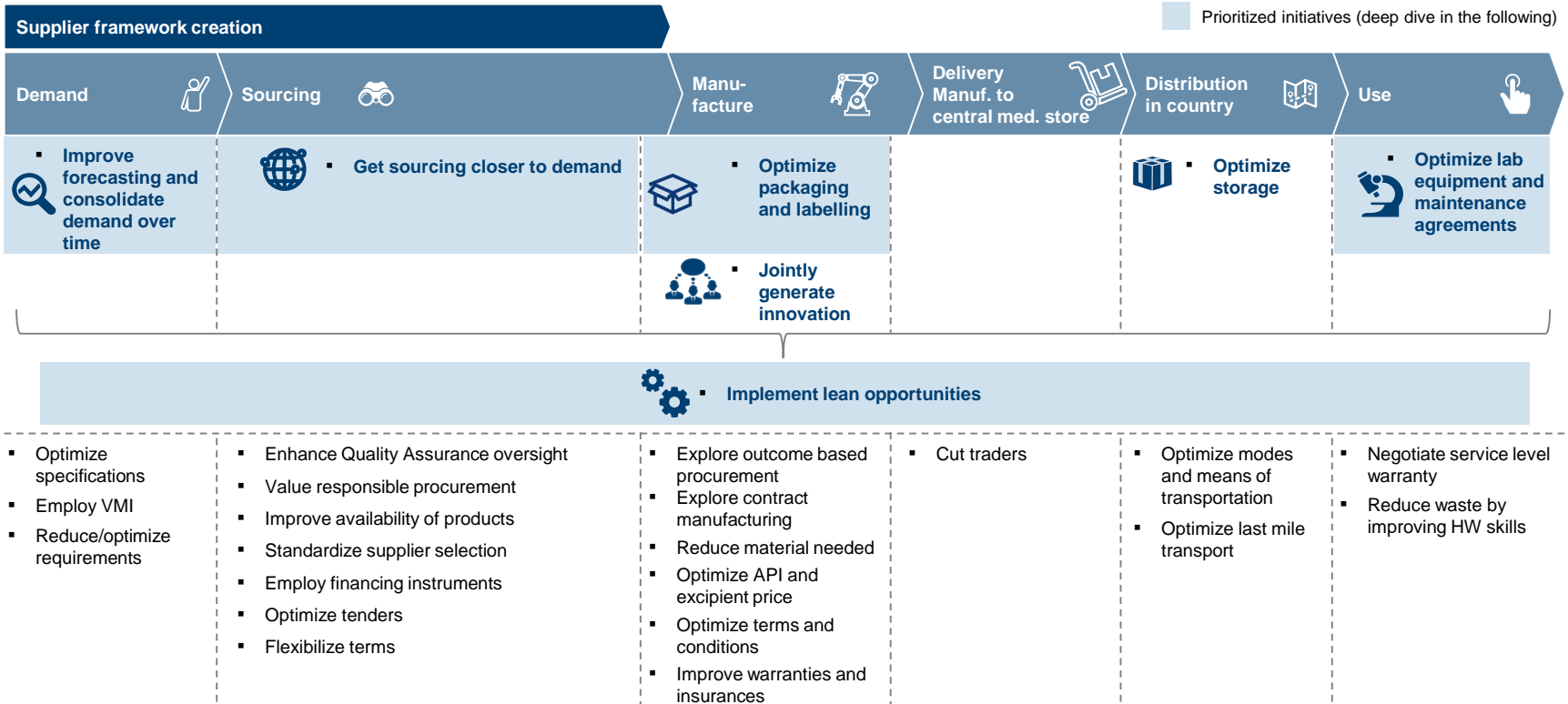
Ease of implementation

Collaboration intensity

¹ Specific Measurable Achievable Realistic Timebound
Source: GF; McKinsey Team Analysis



2 What we could do: To unlock the value of the supply chain, a holistic approach identifies end-to-end levers to optimize Total Cost








1 First degree: Unnecessary orders; Second degree: necessary orders not made

Source: team analysis

2 What do we want to do: Pull different levers that support visibility on and optimization of Total Cost of products funded by GF



Role of Sourcing


| | Initiative | Description |
|---------|---|--|
| Drive | A Implement lean opportunities  | <ul style="list-style-type: none"> Progress realization of lean opportunities across sourcing in a systematic and targeted way Increase efficiency of sourcing and procurement processes and external supply chain operations Unlock value in the face of uncertain demand as well as complex processes; both internally and externally |
| | B Optimize packaging and labelling  | <ul style="list-style-type: none"> Introduce bar-coding for tracking and tracing of products to enable next-level management of products, e.g., data generation and support, supply chain optimization, traceability (QA, pharmacovigilance, fraud) Reduce SKUs, customization and packaging (volume, environmental) to enable greater demand consolidation, volume reductions and unlocking of further efficiency gains |
| | C Source closer to demand  | <ul style="list-style-type: none"> Boost efficiency, responsiveness, supply security, as well as country transition potential Build on existing Global Fund workstream to engage African manufacturers |
| Support | D Improve forecasting and consolidate demand over time  | <ul style="list-style-type: none"> Unlock cost savings in the upstream supply chain, reduce lead times, and improve supply security through demand planning by improving forecasting of volume, specification and time of demand Contribute to and support GF Supply Chain Implementation Plan to develop robust forecasts Clearly articulate methods and definitions to better facilitate SMART¹ partner collaboration (e.g., coordinate with other buyers for low volume specialist and new emerging products) |
| | E Optimize lab equipment & maintenance agreement  | <ul style="list-style-type: none"> With partners and lab advisor, unlock value by further optimizing lab equipment and maintenance agreements by establishing technical needs and developing procurement solutions |

1 Specific Measurable Achievable Realistic Timebound

Source: GF; Output of the Strategic Review Meeting; McKinsey team analysis

3 What we could do: End-to-end support innovation together with partners



 Prioritized initiatives
(deep dive in the following)

Key objectives

Incentivize and facilitate re-
search and development



Develop,
sustain,
and secure
supply




Initiatives

- **Disentangle, clarify and communicate simply presented route to scale in the LMIC market (with partners)**
- Counsel Product Development Partnerships (PDP) and other partners (what GF can/cannot do)
- Continue to value innovation through tenders (as appropriate depending on category)
- Consider valuing participation in regional / WHO collaborative registration in tenders
- Determine value of any role for GF in engaging in negotiating global access agreements
- Intensify dialogue to identify complementary levers with partners, especially close to scale-up in order to sustain support post-donors and before demand scales
- **Fully leverage strong downstream position of GF to sustain needed products to smoothen exit and stabilize supply structures**
- Engage with partners to include supplier performance considerations when they select industry partners (if willing and able)
- Help manufacturers forecast sales erosion and foresee market development
- Share information/forecasting/scenario perspective

Source: GF; Output of the Strategic Review Meeting; Team analysis



3 What we could do: End-to-end support innovation together with partners

 Prioritized initiatives
(deep dive in the following)

Key objectives

Initiatives

Ensure rapid scaling of new health technologies with improved efficacy and/or cost effectiveness



- **Deliberately assess inclusion of opportunities of new products with step-change innovation**
- Convene structured focused periodic engagements to pool resources/information, leverage stakeholder relationships, perform ongoing pipeline analysis and product roadmaps as well as to ensure “needs” for scale are incorporated early on
- Ensure policy coherence to reduce any unintended consequences impeding new product uptake
- Encourage an increase in user and program acceptance to improve successful uptake
- Evolve and prioritize the product scope of Global Fund Expert Review Panel (QA)
- Propose assessment of intent for uptake after UNITAID country adoption activities
- Leverage relationships with partners and PRs to support pick-up of demand

Facilitate transition/switching



- **Introduce cross-secretariat/partner biannual (focused) stock-take of new product uptake**
- Establish the two-way “needs” at each stage of the lifecycle to prepare for scale; identification and filling of gaps

Overarching



- **Articulate end-to-end value propositions of partnership, incl. what Global Fund can and cannot do**

Source: GF; Output of the Strategic Review Meeting; McKinsey team analysis



3 What do we want to do: Selected priority initiatives aim to take collaboration to the next level and leverage each partner's value proposition

Priority initiatives, shortened

| |
|---|
| <p>A Biannual joint stock take of uptake progress and reduce bottlenecks</p> |
| <p>B Disentangle, clarify and communicate simply presented route to scale in LMIC market</p> |
| <p>C Articulate end-to-end value proportions of partnership</p> |
| <p>D Fully leverage strong downstream position of GF</p> |
| <p>E More deliberately evaluate inclusion of new products with step-change innovation</p> |

Description

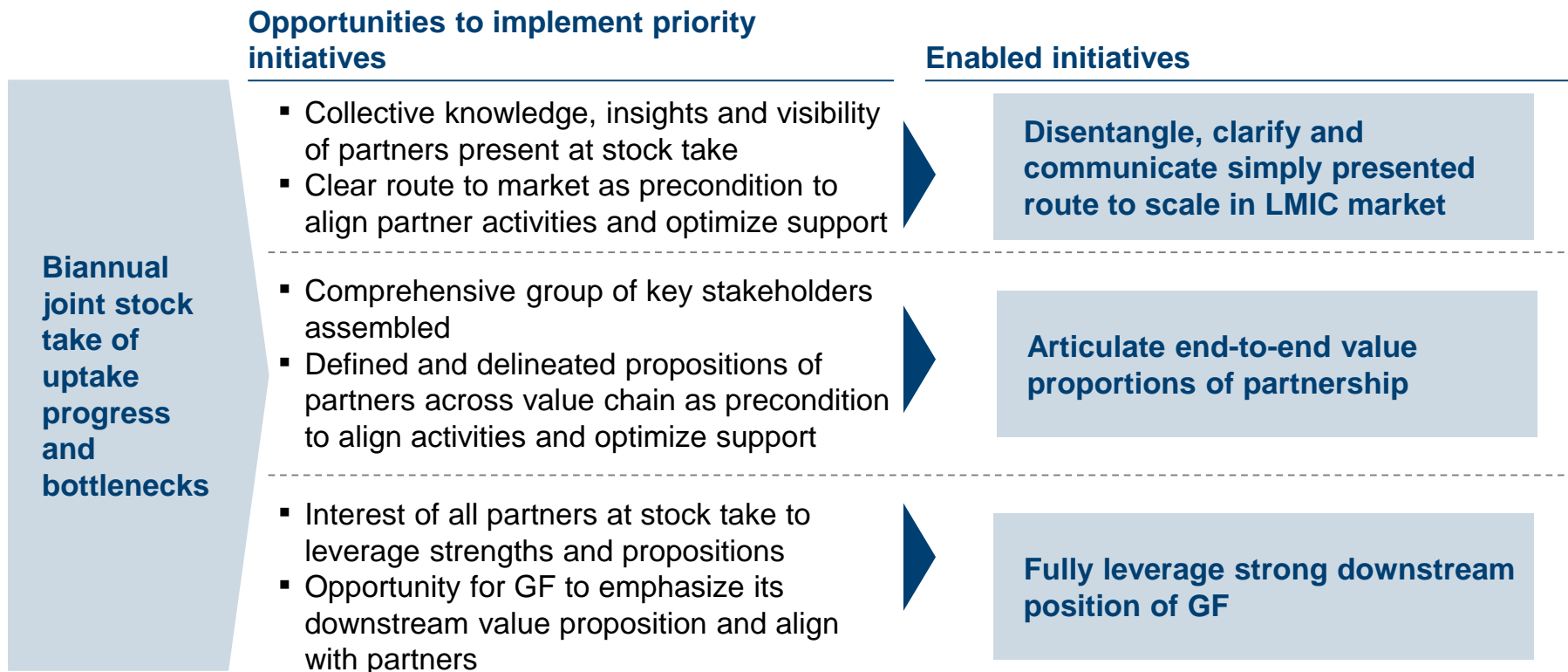
- Establish TOR¹ internally and with key partners
 - Invite **key group of partners** along the innovation value chain (variable, depending on product(s) in focus)
 - Provide **forum for regular exchange and alignment** on uptake progress and reduce bottlenecks for new products meeting criteria for success
 - Ensure end-to-end support** by jointly assessing innovation landscape, removing roadblocks, as well as joining and aligning benefits
-
- Provide simple clear picture to developers how to smoothly navigate introduction/scale up
 - Optimize chances of success for new products by reducing risk
 - Communicate broad position statement on Global Fund to value new products
-
- Map **value proposition of each partner**, including capabilities, capacity and constraints
 - Drive **visibility and simplification of route to market** and identify **whitespots and opportunities** to further leverage partnership to introduce and accelerate uptake
-
- Identify **products facing potential supply shortage** and evaluate measures to ensure continuity of supply until products and countries are ready
 - Leverage downstream-position of GF** to facilitate smooth transition/switching
-
- Define **role and responsibility** within GF to ability of advise on **landscape of** new products
 - Foster proactivity and ensure timely inclusion** of new, promising products during grant approval, making and implementation

¹ Terms of Reference

Source: GF; Output of the Strategic Review Meeting; McKinsey team analysis



3 The bi-annual stock take is an enabler initiative, since it allows to tackle multiple priority initiatives at once










Source: GF; McKinsey team analysis



4 What do we want to do: Embark on a journey to build a holistic responsible procurement approach



Deliverable

| Initiatives | Description | Deliverables | Nature of initiative |
|--|--|--|---|
| <p>Engage with partners and donors</p>  | <ul style="list-style-type: none"> Gather and address inputs as well as understand requirements and expectations from key stakeholders (e.g., partners/donors) Regularly engage in development of framework to ensure alignment Screen landscape and identify complementary partner initiatives to build on and align with |  Framework | <p>React to outside-in expectations</p> <p>Proactively shape responsible procurement inside-out</p> |
| <p>Establish a responsible procurement framework</p>  | <ul style="list-style-type: none"> Develop a holistic responsible procurement framework Address GF's end-to-end value chain along 4 dimensions: economy, ecology, society and business practices Define scope of responsible procurement in 4 dimension and build on best practices | | |
| <p>Provide effective guidance</p>  | <ul style="list-style-type: none"> Ensure principle-based and timely effectuation of responsible procurement across GF and its suppliers Detail-out guidance to ensure actionability <ul style="list-style-type: none"> Create responsible procurement implementation plan to steer implementation of the responsible procurement framework Revise the supplier code of conduct against the responsible procurement framework to clearly communicate GF's expectations and requirements Develop comprehensive responsible procurement guidelines to ensure compliance with policies/regulations, promote best business practices and build resilience against lobbying |  Implementation plan  Updated supplier code of conduct  Guidelines | |

Source: GF; Output of the Strategic Review Meeting; McKinsey team analysis

5 What do we want to do: Develop a principle-based approach to information sharing, evolve our tools and contribute to partners' efforts

x Implementation deep dive in the following



| Category | Initiatives | Description | Role of GF |
|---|---|--|---|
| A Overarching | Define information sharing framework | <ul style="list-style-type: none"> Move towards principle-based information sharing by establishing an information sharing framework Detail out when and how to share information, incl. constraints (i.e., credibility, ethics, legal, and resources) | <div style="border-left: 2px solid black; padding-left: 10px;"> <div style="background-color: #666; color: white; text-align: center; padding: 5px; margin-bottom: 10px;">Lead</div> <div style="background-color: #666; color: white; text-align: center; padding: 5px;">Contribute</div> </div> |
| B Tools <div style="display: flex; flex-direction: column; align-items: center; justify-content: center; gap: 10px;"> <div style="background-color: #ccc; padding: 5px;">PQR</div> <div style="background-color: #ccc; padding: 5px;">Standard market intelligence</div> <div style="background-color: #ccc; padding: 5px;">On demand</div> </div> | Assess ability of PQR to meet today's needs as a source of market intelligence and use PQR more to shape markets | <ul style="list-style-type: none"> Assess ability of tool to answer transaction level information needs for market intelligence purposes by partners and industry – incl., enabling of self-analysis for on-demand requests Identify scale and scope of potential necessary changes Enhance tool to tap its market shaping potential | |
| | Evolve standard market intelligence to increase usability | <ul style="list-style-type: none"> Empower countries and partners to enrich their procurement strategies Structure, organize and refine information in a way that promotes usability | |
| | Enhance management of on-demand requests | <ul style="list-style-type: none"> Answer on demand requests in accordance with information sharing framework Optimize answering of on-demand requests to be more targeted and resource-effective Enhance PQR to enable self-service queries to answer most on-demand requests | |
| C Forecasting | Contribute information to collective partner forecasting efforts | <ul style="list-style-type: none"> Clarify forecasting purpose, assumptions and methods to enable assessment of ability and feasibility effective GF inputs Promote alignment of forecasting approach across different category efforts (where appropriate) Share data where available and in accordance with information sharing framework criteria | |

Source: GF; Output of the Strategic Review Meeting; McKinsey team analysis



6 What we could do: GF strives to evolve to further promote consistent quality standards

Quality related interaction
 Prioritized initiatives
 (deep dive in the following)

Quality assurance ecosystem



Initiatives

Foster in-country capacity to ensure generation of quality-relevant data/information

- Leverage external resource partners**
- Structure GF financing for increased coherence

Systemize and structure information sharing mechanisms to accelerate and increase actionability

Extend rigorous information loop to all national authorities and facilitate information flow

Refine policies to enable application of own risk assessments and appetite

- Clarify GF's position to employ own risk appetite**
- Formalize process for decision making**

Pool and leverage resources, knowledge, and data of GF and other organizations by sharing of regulatory data with key stakeholders (e.g., PRs)

Source: GF; McKinsey Team Analysis



6 What do we want to do: Support and systematize information sharing and enable GF to play a more pro-active role in quality assurance

Focus of initiative

Priority initiatives, simplified

Foster in-country capacity to generate quality-relevant data/information by leveraging external resource partners

Description

- Tackle limited capacities of countries to generate adequate information in a timely manner by **building country quality assurance ability**, e.g., through support on procurement, standard setting, and governance structures
- Leverage **capacity and capabilities of partners where they are more efficient / more able** to enhance country capabilities than GF
- Use **strategic initiative funding to support WHO** for building capabilities of selected countries for health product quality assurance

Role of GF

Systemize and structure information sharing mechanisms

- Mitigate insufficient information quantity and quality from the field for RRA¹ authorities by **fostering adequate availability, processing, and sharing** of quality-relevant information
- **Strengthen in-house quality information system** as first step; observe international standards and align/collaborate as far as possible to ensure compatibility and build interfaces
- **Engage in information sharing with partners and countries and pro-actively shape information flows** in the quality assurance ecosystem

Catalyze

Refine policies to enable application of own risk assessments

- Clarify GF's position to employ own risk appetite
- Formalize process for decision making

- Strengthen **GF's position to play a more pro-active role** in quality assurance
- Establish a principle-based **risk appetite for quality of health products**
- Refine **risk assessments** to ensure full fact base for application of risk appetite
- Enable application of GF's risk appetite on outcomes of risk assessment by
 - Refining **QA policies** (ex-ante mitigation)
 - Establishing a **risk committee with clear and sufficient mandate** to act on ad-hoc quality issues observed (ex-post mitigation)

Own

External

Internal

¹ Robust regulatory authority Source: GF; McKinsey team analysis

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Phasing-in implementation, we continue to welcome engagements

How we will proceed

Implementation

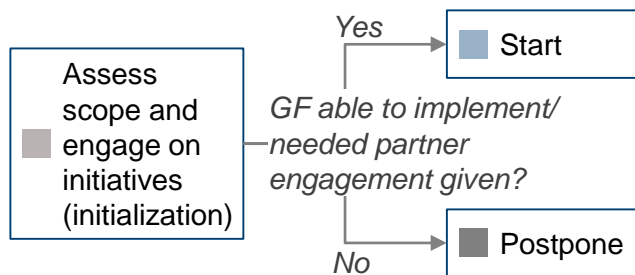
Define next steps and progress initiatives

- **Assess initial implementation readiness** of initiatives, including scoping and identification of necessary engagement with partners
- Conduct **internal prioritization and resource allocation**
- Progress initiatives if **GF is able / engagement for necessary collaboration is initiated, otherwise postpone**

Review and sustain impact

- **Review impact achieved and adjust** (as necessary)
- Establish **lessons learnt**
- **Sustain impact**
- Re-start process for next level of strategic initiatives

GF prioritizes initiatives that fulfill internal/ external requirements for implementation ...



... to achieve a continuous and efficient progression of initiatives

% of priority initiatives, indicative

